WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE
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Model System for Computer-Assisted Drug Registration

SIAMED

USER MANUAL

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ABOUT THIS MANUAL

This manual is designed to serve as a training guide and a reference manual for anyone using SIAMED, the WHO Model System for Computer-assisted Drug Registration. For the learner, the basic commands and procedures for each option are explained step by step. For the experienced user, the manual has bold headings for referencing the SIAMED procedures or commands discussed within each section. Answers to specific questions or steps for a particular procedure can easily be located by looking up the key word in the index. Concepts unique to SIAMED and instructions on data interpretation are presented throughout the manual, and can also be found in the Glossary.

Important SIAMED features are covered in summary sections:

1. key SIAMED concepts and design in Chapter 1,
2. command keys in Chapter 3,
3. a step-by-step quick start tutorial in Chapter 4.

In each chapter on SIAMED options, all data entry information is described in detail.

Throughout the manual, arrow brackets are used to indicate computer keystrokes. For example, **<Enter>** means you should press the Return or **<Enter>** key on your keyboard. **<PgDn>** refers to the Page Down key. The key names that are used correspond to those printed on your keyboard. To activate some SIAMED functions or options, you may:

- ♦ if using a mouse, click on the function,
- ♦ highlight the function and press **<Enter>**, or,
- ♦ type the letter that corresponds to the desired function.

Since any one of these actions can be used to access the function, the term ***select*** will be used throughout the manual to indicate that any one of the above actions may be performed. Whenever possible, the manual has used SIAMED notations, so that what you see in the manual corresponds to what you see on your screen. See Chapter 3 for more details on key commands.

SYSTEM REQUIREMENTS

Recommended Hardware

- 486 or Pentium personal computer.
- 4 MB of RAM - DOS (8 MB required if changes to the source code are to be made). 32 MB if using Windows 95 or Windows NT
- 100 MB Hard Disk space.
- Colour monitor
- Mouse

Network Support

- LANtastic 6.0
- Windows NT 4.0
- Novell DOS 7
- Novell NetWare 3.11.

Memory requirements are much higher if using a Windows-based operating system. For specific instructions and assistance when performing a network installation, contact the World Health Organization

Chapter 1

INTRODUCTION TO SIAMED

1. INTRODUCTION TO SIAMED

1.1 Background

The recommendations of the Conference of Experts on the Rational Use of Drugs held in Nairobi, Kenya in November 1985 are the basis of the WHO Revised Drug Strategy as endorsed by different subsequent resolutions of the World Health Assembly. Within the context of these resolutions, WHO is requested to prepare guidelines for a simple drug regulatory authority, and to support governments in setting up, or strengthening drug regulatory authorities.

In response to this, WHO has developed Guiding Principles for Small Drug Regulatory Authorities which have been endorsed by the WHO Expert Committees on Specifications for Pharmaceutical Preparations and on the Use of Essential Drugs. In addition, WHO has updated the Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

To complement these administrative instruments, WHO has developed a **Model System for Computer-Assisted Drug Registration** which is now available after consultation and field testing in several countries. **The acronym for the WHO model system is *SIAMED*.**

The **main objective** of the model system is to improve the efficiency of drug regulatory authorities enabling them to assure that marketing authorizations are consistent with their national drug policy. This is to be achieved through the provision of technical advice, a specifically designed, locally adaptable computer system, and assistance to make effective use of the system.

SIAMED has been developed by the World Health Organization and the Pan American Health Organization with technical and financial support from GTZ and DSE, both international cooperation agencies of Germany, and Direzione Generale per la Cooperazione allo Sviluppo, the official development agency of Italy. Further technical input has been provided by the Institut Universitaire de Médecine Sociale et Préventive of the University of Lausanne, Switzerland, by the State Institute for Drug Control of Prague, Czech Republic, by CHD, Amsterdam, the Netherlands, and by HS Programar, Medellin, Colombia.

However, the development of this software package has been made possible only by the invaluable support and technical inputs provided by the officials of the Drug Regulatory Authorities of all the countries where field tests and development work have been carried out. Software and guidelines will be continually field tested, and where necessary and feasible, adapted to meet specific national requirements.

The development of SIAMED has been undertaken with the realization that the introduction of desktop computers and ad hoc software alone are not enough to ensure efficient drug registration. The provision of this software package and its guidelines are therefore intended

as a component of a broader national programme aimed at efficient drug registration and encompassing legislation, regulations, human resources, and appropriate facilities. Thus, the implementation of the WHO model software requires:

- a feasibility study to define local specifications;
- the establishment of an appropriate organizational structure;
- the establishment of reliable working procedures;
- the appointment of competent staff;
- allocation of resources;
- the adaptation of the software to meet local needs; and
- data entry and validation.

Support, if required, can be provided by WHO for these activities.

System Design

SIAMED has been developed in FoxPro 2.6 (DOS). It is a user-friendly system that provides for entering, updating, retrieving, and printing information which is stored in a relational database. A relational database can be schematically defined as a system of files linked to each other by means of key words. This permits the user to access several different files at the same time, making use only of selected information from each. However, users do not need to know which programme or which file is active at any given moment to be able to use the system. A system of menus, messages and instructions leads users through all the options of the package.

In order to standardize information in a way that assures meaningful retrieval of information, several abbreviations and codes should be used. All abbreviations and codes are entered, updated and printed using specific menu entries. The definition and compilation of these abbreviations and codes are key activities which demands careful preparatory work by professional staff within each regulatory authority. As is the case with any computer application, the efficiency of the system depends on the accuracy with which this work is undertaken.

The main files within this system are:

Catalogue Files A set of files containing codes used throughout the SIAMED system. These codes are used for dosage forms, primary containers, country names, drug classification (the ATC Classification is included, but a different one can be accepted), sale/dispensing modalities, etc. The information in these files is linked to a number of related screens requiring information stored in the catalogue files.

Company File

These files contain information on companies that participate in the Drug Registration program. Information includes the company's name, addresses, contacts, activity profile, history of inspections, and relation with other companies.

Main Register File

Information on each application and licensed product is stored within these consolidated files. This includes information on approved indications, dosage and administration, precautions, contraindications, adverse effects, use in pregnancy and lactation, interactions, treatment of over-dosage, and storage conditions. This main file is linked to related files holding information on ingredients, manufacturers, regulatory status in other countries, distributors, prices, fees, etc. Any variations to licensed products are also recorded here.

1.2 The System

1.2.1 Overview of Use

The system is intended to improve management of information on companies and drug items at a Drug Regulatory authority. This is to be achieved through five different types of operations:

- prepare and keep the catalogues up-to-date (i.e. tables of abbreviations, substance names, application processing steps, correspondence formats);
- develop and maintain company file (information on company data, activity profile, history of inspections);
- develop and maintain drug item file (detailed information on item data, application/ authorization status, history of variations);
- use system options to issue correspondence with applicants and product certificates;
- generate and make use of retrieval and reporting functions to make decisions, present work done, and check quality and consistency of data.

1.2.2 Security

A few basic rules must be respected to ensure that data are stored securely:

- install the computer(s) in an appropriate place where it is protected from excess heat, direct sunlight, and unnecessary access;
- back-up data on a regular basis, and store back-ups in a secure, place separate from the system;
- allocate individual passwords to those authorized to use the system. These passwords imply a specified level of authority allowing activities ranging from reading, to entering data, to validating and/or changing data, to allocating passwords and levels of authority to potential users.

1.2.3 Factors for Successful Program Implementation

Availability of the required hardware and software is not enough to achieve efficient drug registration. The success of a computer-based drug registration system also depends on:

- **legal and regulatory framework to clearly define policy.** Each country needs legislative measures to assign responsibility for establishing and enforcing drug control to a central Drug Regulatory authority. This must have a structure that is appropriate to the various responsibilities involved in drug registration — including control of labelling, information and advertising — and for inspection and control of manufacture, import, export, distribution (including promotion, prescription and dispensation) and, in some cases, pricing. This central body should also have access to an independent quality control laboratory, either in the country or by arrangement with

a foreign partner.

- **availability of adequate resources** for the efficient functioning of the drug regulatory authority. In several countries, the imposition of application, licence, and annual/ retention fees provides a practical way to help meet the running costs of the drug regulatory authority, of inspections and other regulation enforcement activities, and to filter out superfluous and irrelevant applications. If a decision is made in favour of establishing fees, consideration should be given to the following points:

    - fees should be high enough to contribute significantly to the efficient and effective functioning of the national drug regulatory system (i.e. registration, inspectorate and quality control), in relation to its market size.

    - appropriate mechanisms need to exist within the government administration to ensure that funds collected as fees are made available to the drug regulatory authority for use in ensuring that pharmaceuticals on the market are acceptable in terms of quality, safety, efficacy, and are rationally used.

    - provisions for fee reduction or exemption should be made in order to ensure that vital drugs with a limited market are reliably available. Such provisions may also be needed for other purposes (e.g. to privilege nationally-manufactured drugs). On the other hand, fees may be higher for very popular drugs with a sizeable market, if these can be identified.

    - the risk that the collection of fees may induce approval of a greater number of applications can be contained by appropriate mechanisms such as transparency of the evaluation process, setting no relation between fees and evaluation results, and the involvement of institutions external to the drug regulatory authority in decision-making.

- **adequate staff and technical support from national experts.** Initially, the introduction of computer-based drug registration will put an additional burden on staff, especially when existing information needs to be revised, and for validating data entry. This phase can take more than one year in countries where three to five thousand drug products are marketed. However, once the system is operational, staff will face less routine and clerical work, and will have more time available for technical and professional work. None the less, staff will need technical support from other institutions and individuals. In several countries, a Technical Advisory Group (TAG) or committee has been established to provide technical advice to the drug regulatory authority.

  A TAG may consist of national experts in clinical pharmacology, pharmacology, pharmacy, pharmaceutical sciences and clinical medicine. The group or theme-specific subgroups could meet once or twice a month to provide advice on specific issues. The group could also define a list of basic criteria, e.g. which fixed-dose combinations are acceptable, a common basic data sheet for drugs of the same profile (as in the WHO Model Prescribing Information, the British National Formulary, the Guide National de Prescription, the American Medical Association's

Drug Evaluations, and other publications), labelling criteria, a "positive" list of active principles (e.g. all accepted benzodiazepines, systemic corticosteroids etc.), or acceptable excipients. On the basis of these documents, the regulatory authority will be able to process registration applications for widely used drugs more expeditiously without submitting them to the TAG.

- **effective and meaningful communication with other regulatory authorities.** Regulatory Authorities with limited resources (both human and material) may wish to proceed cautiously in licensing drugs containing active ingredients that have not been widely used. When facilities or resources do not allow for analysing a large amount of technical documentation, or for conducting appropriate studies (e.g. sufficiently large clinical trials and post marketing surveillance), ad hoc connections with more advanced regulatory authorities in other countries could be established in order to learn from each other's experience and to give as solid a basis as possible to a decision about licensing active ingredients for which there is limited experience of use. A simplified approach which regulatory authorities with limited resources may adopt is to establish continuous working relations with two or three highly-evolved drug regulatory authorities of countries with a sizeable pharmaceutical market, and to exclude from registration all active ingredients not registered in at least one of the reference countries unless exceptional circumstances demonstrate a need.

  In addition, the evaluation of manufacturers based abroad, for registration purposes, is not an easy task for many regulatory authorities. Foreign manufacturers premises can be visited only sporadically (if at all), and such visits may not be enough to express sound judgement nor have any legal significance. The most practical approach seems to be to establish connections with the regulatory authorities of the countries where manufacturers are based. This would ascertain whether a regulatory authority is in place, what task it performs, and on the basis of which criteria it grants manufacturing licences and monitors production meant for national use and for export. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce is an administrative tool for the exchange of information among regulatory authorities. Its regular and proper utilization may contribute to reduce significantly the risk of being confronted with substandard or spurious drugs.

- **simplified and meaningful procedures** and documentation analysis may significantly contribute to the efficiency and the reliability of the evaluation of licence applications. In all cases where the safety and efficacy profile of the active ingredient, strength and dosage form of a drug submitted for registration is well established and the licencing authority is satisfied with the available information showing that this item is relevant to meet recognized therapeutic needs, quality becomes the most important concern in evaluating an application. If regulatory authorities counting on limited human and material resources limit most of their licensing activities to well established drugs, they will be in a better position to concentrate on evaluating those parts of the applications that describe the manufacturing process and its controls, the specifications of the proposed product and its regulatory status in other countries, and the GMP profile of the manufacturer. WHO has developed guidelines on assessing bio-equivalence and stability data. A simplified model application form based on

these considerations is under development.

- **adaptation and use of the software.** The present software package is provided by WHO free of charge, and of copyright to all interested drug regulatory authorities. Subject to availability of funds, installation of the package and training in its use, as well as its adaptation - when necessary - to meet national requirements, will be undertaken by WHO. National authorities will also receive a separate set of instructions giving full details of the software structure in order to enable local professionals familiar with database management systems to correct any inaccuracies that may become evident after several months of use or to introduce additional functions or options. Whenever feasible, a short period of training for local programmers will be organized to make the manipulation of the software easier. WHO is ready in all circumstances to provide further assistance as well as updated versions of the software as need arises.

  Commercially-available database management systems necessary to introduce changes into or to run the un-compiled version of the WHO model software cost less than US$500. The computer equipment of the suggested configuration is generally available for less than US$3,000 (costs vary considerably in different parts of the world). Consumables and running costs (paper, diskettes, ribbons, power, etc.) depend on use and can be estimated at no more than US$1,500 per year. The cost of professional programmer assistance for local maintenance or adaptation of software varies considerably in different parts of the world. In fact, in some countries the Ministry of Health or another governmental body may employ such professionals regularly, while elsewhere it may be difficult for the drug regulatory authority to obtain the services of programmers. Therefore, this matter will need to be tackled case by case.

- **staff commitment.** The package has been conceived to be used directly by professionals. Data entry has been limited as much as possible. Most information can be selected from lists with a simple click of a mouse button to eliminate tedious retyping of data and permit standardization of terms. In addition, generation of correspondence and certificates is by simple selection of items, the computer automatically places the specific variable information in the right place. This reduces the clerical work to a minimum. Thus, it is vital that professionals be willing to work directly with a computer and receive ad hoc training (2-3 days) for this.

  In addition, the introduction of computer-assisted drug licensing is a **major undertaking** for any drug regulatory authority. It often entails revision of the existing working procedures and habits, and the establishment of new ones. It also entails reviewing existing files and information to assure completeness and consistency. For these reasons staff at the decision-making level needs to be substantially involved in all the activities which will eventually lead to a fully functioning computer-assisted drug licensing programme.

1.3 Key Concepts

In the design of computer applications a number of assumptions and choices, need to be made with regard to terminology and format of information. The following definitions are those that have been used in this model system, and this manual. The choice of terms is to a large extent arbitrary and should not be seen as a recommendation to adopt them. These concepts are presented only for the sake of clarity and with the understanding that terms routinely used by national regulatory authorities have considerably different meanings in different parts of the world.

1.3.1 Authorization

In this system the term ***authorization*** is used in the following different situations.

Marketing Authorization

This refers to an authorization for a product to be marketed. In some countries it is called ***product licence***. Each marketing authorization is characterized by a number called registration number, licence number, or marketing authorization number.

It is also characterized by the following elements: a company responsible before the authorities for all the implications that can arise from product marketing (marketing authorization holder, or licence holder), a product name (be it a generic name or a trade mark), a dosage form, a strength, and a primary container. A change in one of these elements implies a different registration number.

In this system, the registration number can be automatically generated by the computer or can be entered by a user having the appropriate type of password. The maximum length of the registration number is twenty (20) digits, characters, or a mixture of the two. To make it fit in screens, the term most commonly used in this system is ***licence***.

Company Operating Authorization

This refers to an authorization given to company to exert a given activity falling under the control of the drug regulatory authority. It is also known as an ***operating licence*** or ***permit***. If a company carries out more than one activity, it may have a separate operating licence for each individual activity. The maximum length of the operating licence number is ten (10) digits, characters, or a mixture of the two.

Other Types of Company-related Authorization

In several countries the regulatory authority needs to store information linking companies with other institutions, e.g. Ministry of Industry, Ministry of Finance, Customs. In these situations, this form of authorization is used. These pieces of information are called in several different ways - e.g. Ministry of Industry Number, Customs Number, etc. - when they are used. The present system permits you to store up to five (5) different items of this type with user-defined field labels.

1.3.2 Application

In this system the term ***application*** is used in the following different situations.

Application for Marketing Authorization

This refers to an application for a new marketing authorization. Each application for marketing authorization is characterized by a number called application number. It is also characterized by the following elements: a company responsible before the authorities for all the implications that can arise from product marketing (marketing authorization holder, or licence holder), a product name (be it a generic name or a trade mark), a dosage form, a strength, and a primary container. A change in one of these elements implies a different application number.

In this system the application number can be automatically generated by the computer or can be entered by a user having the appropriate type of password. The maximum length of the application number is fifteen (15) digits, characters, or a mixture of the two.

Application for Revalidation/ Renewal of Marketing Authorization

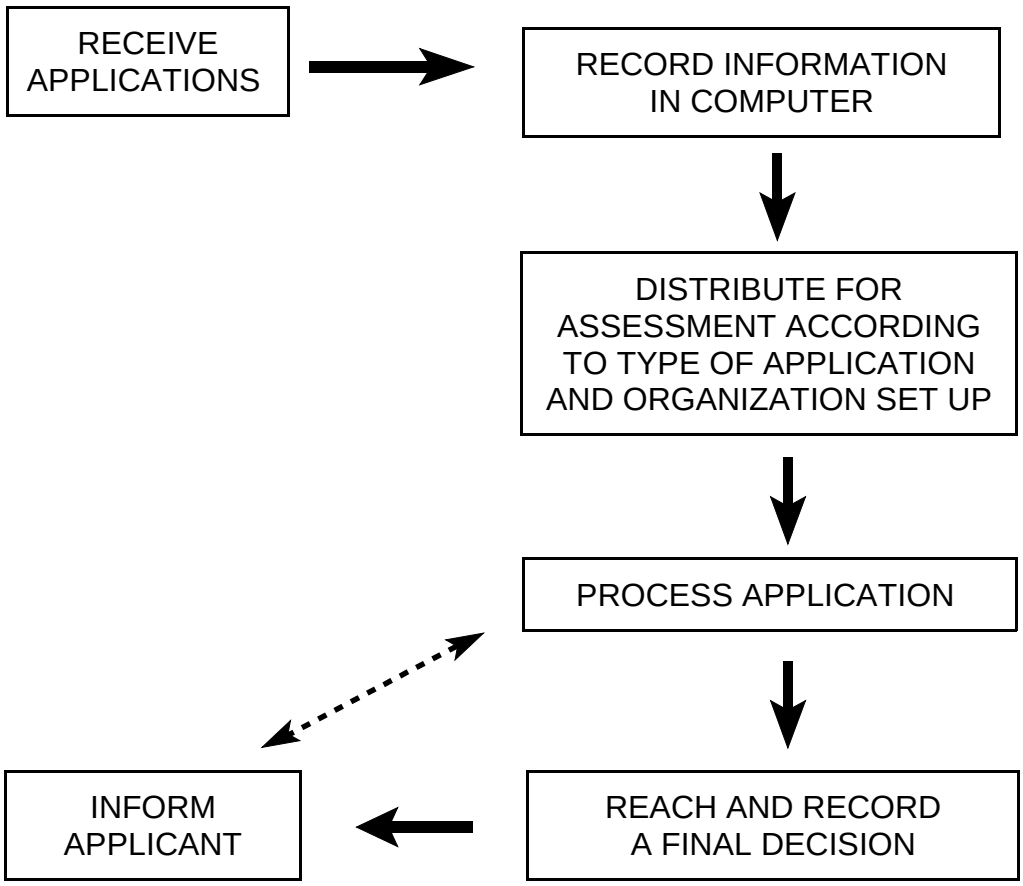
This refers to an application for extending the period of validity of an existing marketing authorization. Application numbers for this type of applications can *only* be computer-generated.

Application for Variation to Marketing Authorizations

This refers to an application for changing selected information related to an existing, valid marketing authorization. Application numbers for this type of applications can *only* be computer-generated. Depending on established regulations, the type and extent of variations permitted vary from country to country. Variations admitted in some countries, entail, elsewhere, issue of a new marketing authorization and cancellation of the previous one. To accommodate such a variety of requirements, the system permits you to record variation of all marketing authorization data except number and validity. In all cases, the history of variations is recorded.

1.3.3 Application Processing Steps

This system is based on the assumption that applications are treated as follows:



The above diagram makes two basic assumptions.

1. It is assumed that as soon as applications are received they are entered into the computer system. In the case of applications for:

   - ♦ new marketing authorizations, this operation entails at least the following: numbering the application, and entering number, applicant name, drug item name, strength, dosage form, and primary container.
   - ♦ revalidation and variation applications, this operation entails: retrieving the marketing authorization to which the application refers, and reading the application number that the computer generates.

   At this point, with three key strokes, the computer can issue a receipt stating basic application information, and reception date and number. We shall call the reception of an application, a ***processing step***.

2. It is assumed that a coordinating person or group assigns the application, or parts of it, to those in charge of its assessment. These assignments should also be entered into the computer system. This distribution of work is a second processing step.

   The third box on the left side of the diagram indicates that the conclusions reached assessing each individual part of the application can also be entered in the computer. Each of these assessment operations are a different processing step. This set of operations leads to a final decision about an application. This decision should be entered into the computer system. This is the last step in the processing of applications.

On the basis of the above schematic presentation, a processing step is defined as any event in the processing of an application characterized by a date on which the event starts, or is expected to start, a technical or operational decision, and a date on which such decision is taken. The system is designed to permit users to define as many different steps and sub-steps as required. By making proper use of this feature, users will be able to trace applications and know their status at any given moment during processing. They will also be able to produce statistics on duration of assessment as a whole or by step. However, the use of this feature **is not** obligatory. Regulatory authorities with very limited staff do not usually have difficulty in tracing pending applications. They can use the system disregarding this option.

1.3.4 Generic Name

In this system, the names of the individual ingredients constituting the formula of a drug are called ***substance names***. The term generic name is used as follows:

Drug Products with Only One Active Ingredient

The generic name is the name of the base that constitutes the active ingredient, regardless of the form used in the formulation - unless a specific salt has unique therapeutic uses unrelated to those of the base.

For example, the generic name “ampicillin” applies to all drugs containing either ampicillin trihydrate, ampicillin sodium, ampicillin hydrochloride, etc. In this way, a search based on the generic name ampicillin would permit the user to retrieve all products containing any form of ampicillin irrespective of the dosage form.

This simplification applies only to the generic name field of an application. It does not limit the possibility for users to record the full name and quantity of the active substance(s) in the ingredient fields. Thus, searches can be based on either the generic name of the drug product or the individual full substance names of the ingredients.

Drug Products with Two Active Ingredients

The generic name reflects the name of the base that constitutes the two active ingredients regardless of the molecular form used in the formulation, unless a specific salt has unique therapeutic uses unrelated to those of the base. These two names are entered in the same field. It is recommended that, to avoid repetitions, a fixed format is used to enter them. For example, one could use a plus sign to separate the two names and enter them only in alphabetical order such as amoxycillin+clavulanic acid instead of clavulanic acid+amoxycillin.

Drug Products with More Than Two Active Ingredients

Building a generic name by adding those of the individual components is not practical. In addition, it is infrequent that a rational drug has three or more active ingredients. The proposed approaches are these: **a**) enter in the generic name field, the same predefined term for all drugs e.g. combination, See formula/composition, or **b**) enter an arbitrary term to indicate a loosely homogeneous group, and use a predefined term for those drugs, as in example "a" for those drugs for which an homogeneous group is not easily identified e.g. multivitamin, minerals, minerals+multivitamin, electrolytes, electrolytes+ glucose, cold preparation, combination, See formula.

The use of these arbitrary generic names does not limit search on the basis of an individual ingredient name. On the other hand, it contributes to establishing searching criteria that permit users to group together drugs that have the unusually large number of active ingredients in common.

1.3.5 Types of Companies

Four types of company entries can be made in application fields. These are labelled: Applicant / Licence Holder, Representative, Manufacturer, and Distributor. A brief description is given here below of their use in the system.

Applicant/ Licence Holder

Refers to the company submitting the application. Usually it is the owner of the trade mark, where applicable. If the application results in a marketing authorization, this company becomes the holder of such authorization. As explained previously, to make it fit in screens, we have used the term ***licence*** rather than marketing authorization. Thus, **licence holder and marketing authorization holder are synonyms in this system**. Only one company can be entered as applicant/licence holder.

Representative

This field is meant to accommodate the name of a company that either represents the licence holder for selected issues, or is related to the product or the licence holder in some other way. This is a specific requirement of a limited number of countries.

Manufacturer

Refers to a company that in some way participates in the manufacturing of a drug product. The system can accept up to fifty (50) different manufacturers for the same drug product, permitting users to specify for each of them which role they play - e.g. source of starting materials, preparation of semifinished product, formulation, labelling, repackaging, etc.

Distributor

This field accommodates the requirement of some countries, which have regulations to establish that importation or wholesale of a given drug product can be done only by selected companies. Up to fifty (50) different distributors can be related to each individual drug product.

1.4 What This Software Package Does

SIAMED is designed to aid users in the process of collecting and tracking all data related to the drug registration process. This software package organizes all required data into structured databases, and produces the required reports and licences.

SIAMED is intended to improve the registration and licencing process by allowing the user to properly record, keep up-to-date, and retrieve:

- **information on companies** including name, mailing address, premises address, phone, fax, telex/e-mail numbers, contact/responsible officials, activity(ies), operating licences and their validity, authorization to act as applicant/licence holder for drug licensing purposes, authorization to handle psychotropic/narcotic drugs,

- **summary information on inspections** carried out at company premises, keeping separate records for each individual activity that a company is or has been carrying out (manufacturer, wholesaler, importer, QC lab, etc.),

- **information on drug items for which an application and/or a licence has been received/issued**. This includes data on application number, generic name, dosage strength, dosage form, linkage code with social security or other system, prices, distributors/importers, regulatory situation in other countries, etc.

- **information on status and decisions made at the different steps of the evaluation process.** Up to twelve different paths of evaluation can be used:

Drug licence application for:	A new human drug / A new veterinary drug A new biological drug
Drug licence renewal for:	A new human drug / A new veterinary drug A new biological drug
Minor Variation for:	A human drug / A veterinary drug
Major Variation for:	A human drug / A veterinary drug
Variation for:	A biological drug
Special Procedures	

  at each step any number of sub-steps, or responsible officials/experts, can be indicated to help keep track of the documentation under evaluation,

- **information on decisions** like rejecting applications, recovering rejected applications, issuing licences, canceling licences, and revalidating licences,

- **information on variations to valid licences**, which automatically keeps history of all variations made to a licence,
- **information to automatically issue correspondence and certificates** based on user-defined standard models, and keep record of the issued documentation,
- **record of application/licence/retention fees,**
- **information to carry out data searches** and produce reports on the basis of multiple searching criteria encompassing all the pieces of information mentioned above,
- **information on national databases** to create, expand, keep up-to-date, and make automatic or on-line use of stored information on substances whose use is restricted, and excipients (admitted uses, limitations, etc.)
- **export reports and correspondence** to user-selected external word processors in order to issue printouts in any format.

INSTALLATION

Chapter 2

2. INSTALLATION

This chapter outlines the requirements for installing and configuring SIAMED.

Your computer uses a system configuration file (CONFIG.SYS) to load any necessary system configuration parameters. This file can be viewed or changed using a simple text editor programme such as MS-DOS EDIT, or Windows Notepad. For SIAMED to run properly, make sure that in the root directory of your computer there is a CONFIG.SYS file containing the following statement:

FILES=160

The parameter entered in the CONFIG.SYS file controls how many files SIAMED (and other programmes) can have open at one time. SIAMED uses many database files and needs to have enough room available to open all necessary files. If the settings are incorrect, the programme may halt.

After making any changes to the CONFIG.SYS file, reboot the computer (turn if off and back on again) before continuing the installation process, so that your changes will be effective. Repeat this for all workstations if you are installing on a network.

2.1 Installation Procedures

To install or update the system:

1. If it is a first installation, create a directory called SIAMED.
2. Copy disks 1 and 2 to the directory SIAMED.
3. Go to the directory to which you copied the diskettes, type INSTALL and press **<Enter>**.
4. Choose the appropriate option from the installation menu. Disregard any File not found messages that may appear on the screen during installation. The system will expand the necessary program files.
5. From the directory which contains the file REGX.EXE type REGX and press **<Enter>**. Use REG as both name and password to start using the system. Wait about five minutes until the system completes the creation of its indexes.

2.2 Updating Procedures

To update the system:

1. Make a back-up copy of the existing data.
2. Make sure that you begin at the DOS prompt (C:\>) on the hard drive of your computer. For simplicity, the following discussion assumes that the C:\ drive is being used and that the system was installed in a directory called SIAMED.
3. At C:\>, type CD\SIAMED and press **<Enter>**. The computer will give you a prompt, C:\SIAMED.
4. Place the SIAMED Disk 1 into your floppy drive.
5. Copy disks 1 and 2 to the SIAMED directory.
6. If the computer will ask for confirmation for overwriting any existing file, answer YES to overwriting.
7. Go to the directory to which you copied the diskettes, type INSTALL and press **<Enter>**.
8. Choose the appropriate option from the installation menu. Disregard any File not found messages that may appear on the screen during installation. The system will unpack in a minute or two.
9. From the SIAMED directory type REGX and press **<Enter>**. Use REG as both name and password to start using the system. Wait about five minutes until the system completes the creation of its indexes.

IMPORTANT: If you are upgrading from a previous installation, remember that all established passwords should be revalidated through the Password Assignment menu option before they can be used to their full extent with the new menu.

2.3 Starting SIAMED

The first time you run SIAMED, the system will create its own indexes. This process may take up to 10 minutes depending on the computer being used. When indexing has been completed, the system will display the login screen (See Figure 2-1).

This login screen requires that you enter your user name and password. If this is the first time logging into the system (if this is after first installation of update), type REG for the name and press the <**Tab**> key. Next, enter REG as your password. The system will not display your password, but instead will display an asterisk in place of each character typed. Press <**Enter**> after typing in your password.

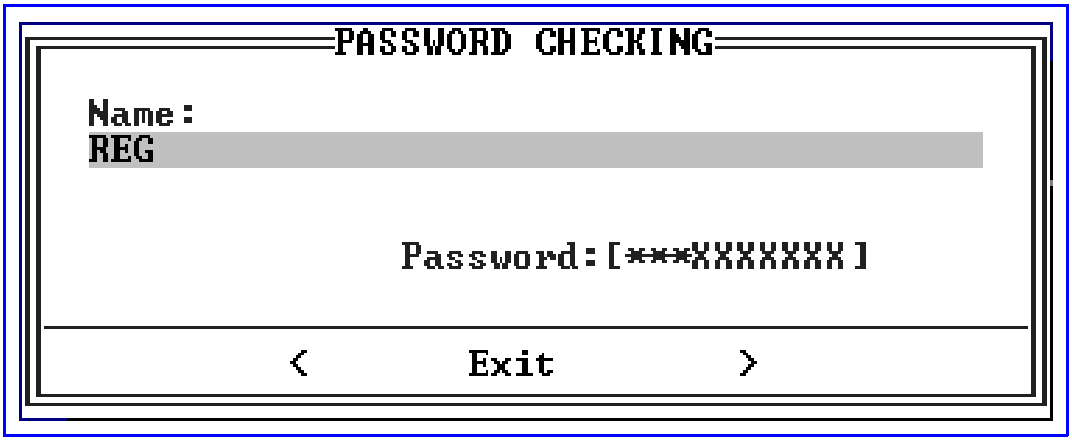


Figure 2-1: Initial Password screen

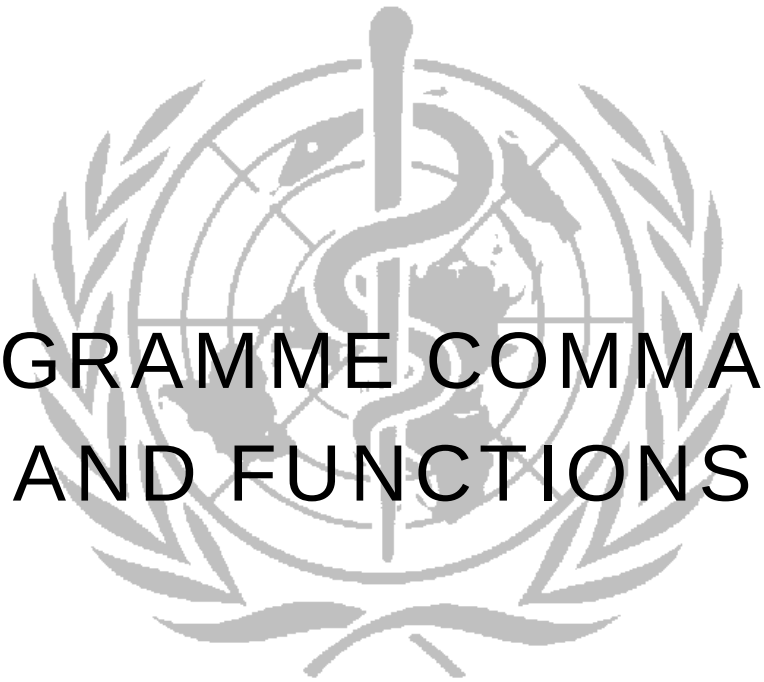
If the system displays a message that says, data not found, this indicated that the name entered is not in the system. Be sure to type REG. If you get a message that displays Wrong password, this indicates that you have mistyped your password. In either case, press the <**Esc**> key and retype your name and password correctly. After pressing <**Enter**>, the main menu will be displayed.

After password checking, you are shown the MAIN MENU. Before discussing the features of the Main Menu, please read the sections in Chapter 3 on Mouse & Keyboard use. After reviewing the necessary sections, see Chapter 4 for an overview of the features of the Main Menu. Then choose Configuration and attune the system to your requirements.

2.4 Troubleshooting Steps

For any Notes fields displayed, if the entry indicates “MEMO” in upper case letters, this means that the system contains information that can be viewed by pressing either <**Ctrl**>+<**Page Down**>, or double clicking on the memo field. To return to the list, simply press <**Esc**>. You may also continuously press <**Esc**> until you are returned to the main processing duration screen. At that point you must select <**Exit**> to return to the main menu.

Chapter 3



PROGRAMME COMMANDS AND FUNCTIONS

3. COMMANDS AND FUNCTIONS

3.1 SIAMED Main Menu

To start the SIAMED programme in DOS, change the root directory by typing *CD\SIAMED*. At the prompt (C:\ SIAMED) type *REG*. The Password Checking window will appear. Type your name and press the **<Enter>** key. Next, enter your password and press **<Enter>**. ***If this is the first time starting the programme, enter REG for both the Name and Password entries.*** The SIAMED Main Menu will appear. The SIAMED software system has five primary labels that are displayed on the Main Menu when you activate the program. These options cover all the principal SIAMED functions needed to conduct drug registration procedures.

This is the Main Menu of SIAMED. It consists of five primary labels as described below:

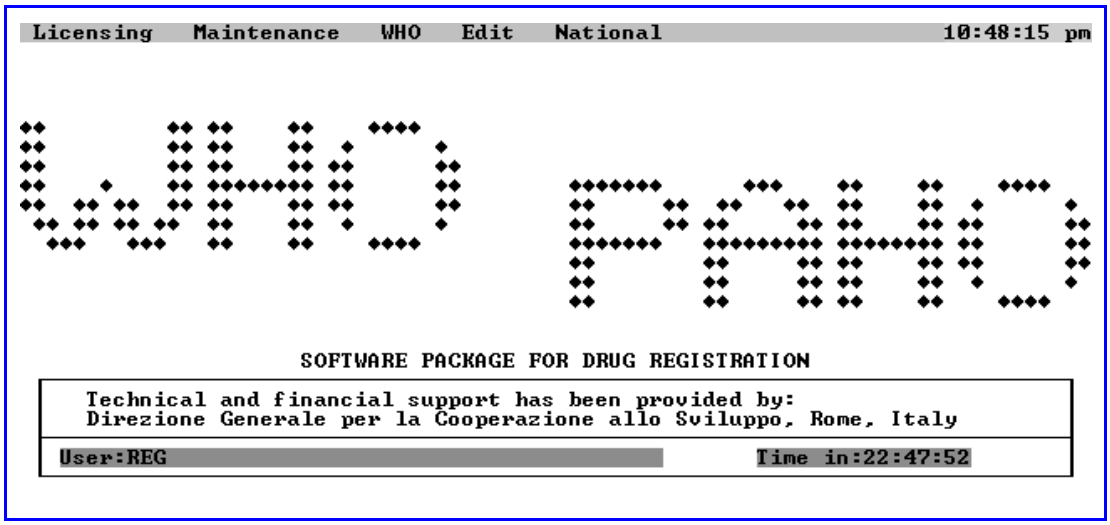


Figure 3-1: SIAMED Main Menu

LICENSING

The Licensing label gives access to management of abbreviations, company information, inspections, fees, and all operations related to drug licensing. This is the primary area for constructing and maintaining databases regarding various catalogues, companies, drugs, inspections and fees associated with the effective operation of SIAMED Chapters 5-9 describes all the information necessary to properly use this feature of the programme.

MAINTENANCE

The Maintenance label is used to access all operations related to maintenance of the system. This option establishes defaults for the entire system, and allows you to Exit the programme. Chapter 10 describes all the information necessary to properly configure and maintain the system.

WHO

The WHO label permits the user to print product certificates, access selected WHO documents, and consult the UN Consolidated of Products Whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted, or Not Approved by Governments. Chapter 11 describes all the information necessary to properly use this feature of the program

NATIONAL

The National label outlines specific national requirements which need to be developed at the time of installation.

To activate a label on the Main Menu, you may perform either of the following actions:

- Point and click the left mouse button on the label to pull down the menu lists.
- Press the **<F10>** or **<Alt>** key and then the highlighted letter of the menu title you want to select.

A faded menu label means that either your password does not allow access to that operation or, in that specific occasion, that operation cannot be carried out (e.g., trying to open the company's file while already working on it, trying to use the editing functions when the cursor is not in a text field). Some menu entries are faded because the related software needs to be finalized after the first installation.

EDIT

The Edit label is used to access text editing options. The options listed under this label are available when entering data in other label screens. Chapter 12 describes all the information necessary to properly edit data using the Edit label.

3.2 SIAMED Window Objects

This system is operated successfully by activating various window objects. The window system is easy to use and instructions about each window are clearly indicated on each screen. However, if this type of system is new to you, the following is a description of the various window objects that are used in this system.

Standard Form Windows

A form window is a screen version of a form containing the information that you need to manage such as data on companies, drug applications and inspections. There are various type of data fields on a form window.

In some data fields, information is entered by you the user, while in others the programme automatically enters data based on information gathered from other data fields.

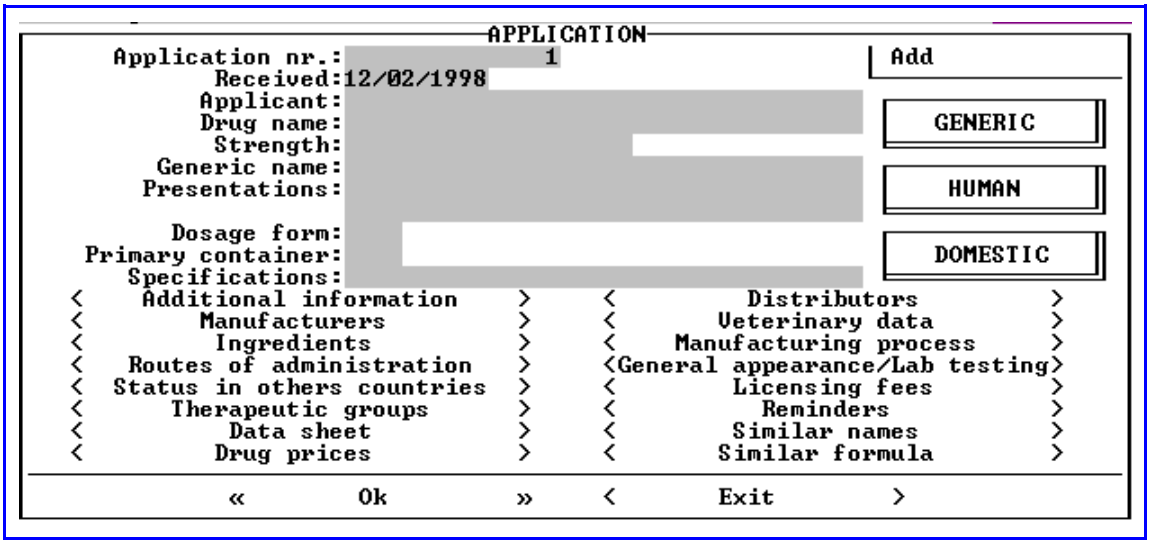


Figure 3-2: Sample of a Standard Form Window

Pop-Up Windows

Pop-up windows provide you with a list of specific data to be selected. For example, in the Geographical Codes menu option (Licensing menu), selecting Country displays the Countries screen. The Continent option is a Pop-up field. If you click the right mouse button, or press the **<Enter>** key, a list of continents will appear. You need only to highlight the desired continent to continue with your data entry. In certain occasions, some of the listed items are faded. Faded items cannot be selected. The screen below is an example of a pop-up screen.

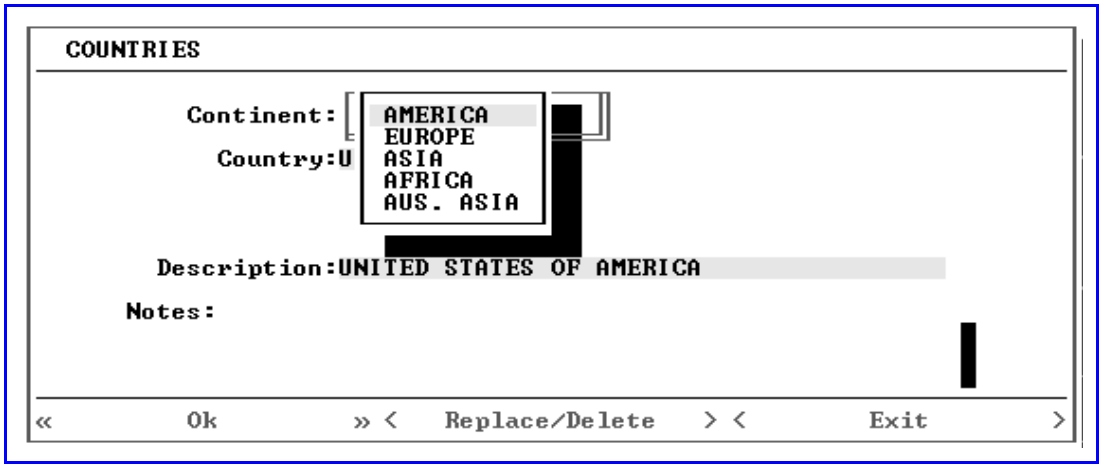


Figure 3-3: Sample of Pop-up Window

Push Buttons

The three "buttons" labeled <<Ok>>, <Replace/Delete>, <Exit> at the bottom of most form windows should be 'pressed' by either clicking the left mouse button or pressing <**Enter**> when they are highlighted (to highlight them, press <**Tab**> as many times as required to position the cursor on them). The fields are highlighted when they change colour or shade.

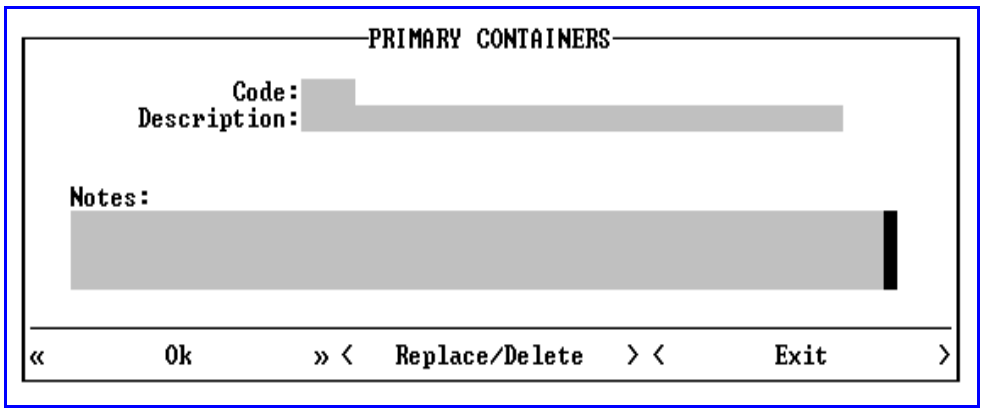


Figure 3-4: Illustrates the position of Push Buttons

The following is a description of each button, and how they should be used.

<<Ok>> This button is used to complete entries, write them to disk, and clear the screen fields.

<Replace/ Delete> This button is used to remove the entry shown on the screen from the database. After pressing this button, a new window appears indicating the entry to be replaced or deleted. If you press the <Delete> button, the system will search all your data to check whether the entry you want to delete is in use. If so, it will not

allow you to delete it until you have replaced it with another one.

If you wish to Replace the data with new values, **you must first enter the new data that shall replace the old one**. After pressing the <Replace> button, the system will go through all your data and replace all occurrences of the old entry with the new one. *Example:* You realize that your catalogue has a double abbreviation for the same item, say US and USA for United States of America. You decide you want to use only USA and want to "clean" your data assuring that only USA is present. You do the following: access the country catalogue and select US, press <Replace/Delete>, enter USA as new entry and press Replace, then press Delete to remove from the catalogue the entry US. Now all your data will contain USA where there was US before.

<Exit> This button is used to leave the screen and return to the main menu. When the Exit button is pressed, any information shown on the screen is ignored. This means that you can use the Exit button as an escape button when you do not want to write to disk an entry you are creating or the changes you made to an existing entry (i.e., the existing entry remains recorded as it was before).

Push buttons that have double delimiters, like << Ok >>, can be activated regardless of the position of the cursor in the screen by pressing <**Ctrl**>+< **Enter**> keys.

Check Box

Check boxes are screen objects used for data that can have only two values, like YES, NO, or very specific choices. Leaving the check box untouched means you do not wish to select or choose the option. Checking the box means YES, you do mean to select that specific option. To check the box, click on it with the mouse or press <**Enter**> when the cursor is on it (i.e. when it is highlighted). Multiple boxes can be checked at the same time. To *"uncheck"* a box, just click on it again.

[ ] Manufacturer
[**X**] Distributor
[ ] Pharmacy
[**X**] Other

Radio Buttons

Radio Buttons are used to indicate reciprocally excluding options. To check the button, click on it with the mouse or press **<Enter>** when the cursor is on it (i.e. when it is highlighted). Unlike check boxes, only one radio button can be selected of a list. **NOTE:** One button **must** be selected.

(!) With limit
( ) Without limit

Working With Multiple Windows

When entering data, users type information in *fields* that are placed in windows (like when filling rectangular boxes drawn on paper forms). In many cases, while working on one window, the system may need you to enter information into fields that are placed in other windows. When this happens, the new window will appear automatically on top of the former one. To return to the previous window, you must complete the entry in the current window.

If you click on a window placed in the background before completing your data entry, the background window will become the foremost window, but the other one is still open, active, and waiting for your entry. If you have not closed it and you try to type information on the foremost window, you will get the impression that the system is "frozen," i.e., you type or click the mouse but nothing happens. If you look at the extreme right or left of the foremost window you may see a small part of the one that has disappeared behind it. If you see it, just click on it and the hidden window will return to the front of the screen.

If you cannot see the background window, use the *Change foremost window* option on the Maintenance label or press **<Ctrl>+<F1>.** The hidden window will come to the front and you will be able to continue working.

Alphabetical Search Window

At different stages in the SIAMED system, you will need to enter information from your Catalogue files such as Geographical Codes or Companies (just to name a few). The alphabetical search window lists file contents contained in your database file inn alphabetical order. This window is activated by clicking the right mouse button, or pressing **<F2>** when your cursor is in a field that requires data from a catalogue file. As you type each letter of the item name, the system will automatically search the list for that item.

Figure 3-5: Alphabetical Search Window

The purpose of this window is to help you in locating an item in the file or to make sure that it is not there. When searching names written with special characters (e.g. Bogotá, Mérida, μg) you may experience some imprecisions in the appearance of the alphabetical order.

When using an alphabetical search window, the following actions may be performed:

To locate and point to an item:

- Regardless of the position of the cursor, type any number of characters. An alphabetical search will start automatically, positioning the light bar on the first item whose description matches the entered string of characters, if one exists, or on the item that immediately follows the one closest to the entered string.
- Move the bar through the existing codes using **<PgUp>**, **<PgDn>**, or the arrow keys.
- Move the mouse pointer to the item and click the left mouse button.

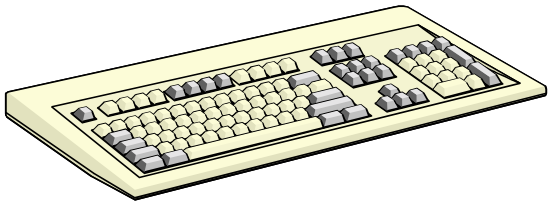
To select an item:

- Press **<Enter>** or click the right mouse button when the light bar is on the item.

To exit without selecting an item:

- Press **<Esc>** (escape) or click the left mouse button on the little square box that appears in the upper left corner of the window.

3.3 Standard Keyboard Commands



Moving From Field to Field

The easiest way to move within menus and screens is using a mouse. The best way to move without the mouse is the <**Tab**> key. To move using the mouse it is sufficient to move the pointer to the desired location and then click the left mouse button. Unless otherwise specified, to click the mouse should be understood as to click the left button of a two-button mouse set for right-handed use. Pressing the <**Tab**> key moves the cursor from field to field; to move backward, hold down the shift key and press <**Tab**>.

SPECIAL KEYS

<F1> Gives access to context-sensitive help. This means that if you press the <**F1**> key while in the catalogue "country" option, you will see help information regarding that option.

<F2> Gives access to a window displaying a list of selectable items. This is active only when the cursor is in a field where the user should enter an item drawn from an existing file (e.g., a company name, an application number for an existing application, an abbreviation or code). See the subsection *Alphabetical search* earlier in this section for further information.

<F3> Used to carry out special actions. These key functions are available only under special circumstances, all indicated by a specific message appearing at the bottom of the screen.

<F7> Used to quit the program.

<F10> Activates the menu bar at the top of the screen.

<F12> Pulls down a calculator.

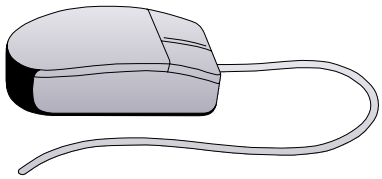
<Alt>+<D> Used to select a printer.

<Alt>+<I > Activates the ASCII chart

<Alt>+<S> Activates the Special Characters screen.

<Alt>+<U>	Used to switch control to another password/user.
<Alt>+<X>	This key combination can also be used to quit the system.
<Tab>	Used to move forward from one field to another.
<Shift>+<Tab>	Used to move backward from one field to another.
<Enter>	Used to execute a command entered from the keyboard.

3.4 Mouse Functions



Click

Quickly press and release the mouse button.

Left

Clicking the left mouse button:

- In any field of a record in the form window will select that field for editing.
- Anywhere in the title line of the form window will allow you to adjust the position of the window on your screen.
- On the tiny triangle in the upper or lower right side of the Alphabetical search window will allow you to scroll through the list of items in the window.
- On the tiny triangle in the lower left or right corner of the Alphabetical search window will allow you to scroll from left to right to view more information about a particular item.

Right

Clicking the right mouse button:

- On an item in the Alphabetical search window will cause the item to be selected and entered in the original field on the form window. The Alphabetical search window will automatically close.
- On a pop-up field will cause the field to display all options for that field.

QUICK START

Chapter 4

4. QUICK START

The Quick Start chapter is designed to provide the beginner with a schematic overview for configuring and using the SIAMED system.

If you have just received the diskettes and no one is assisting you with the installation, or introduction on how to the use of the system, follow the primary steps shown here:

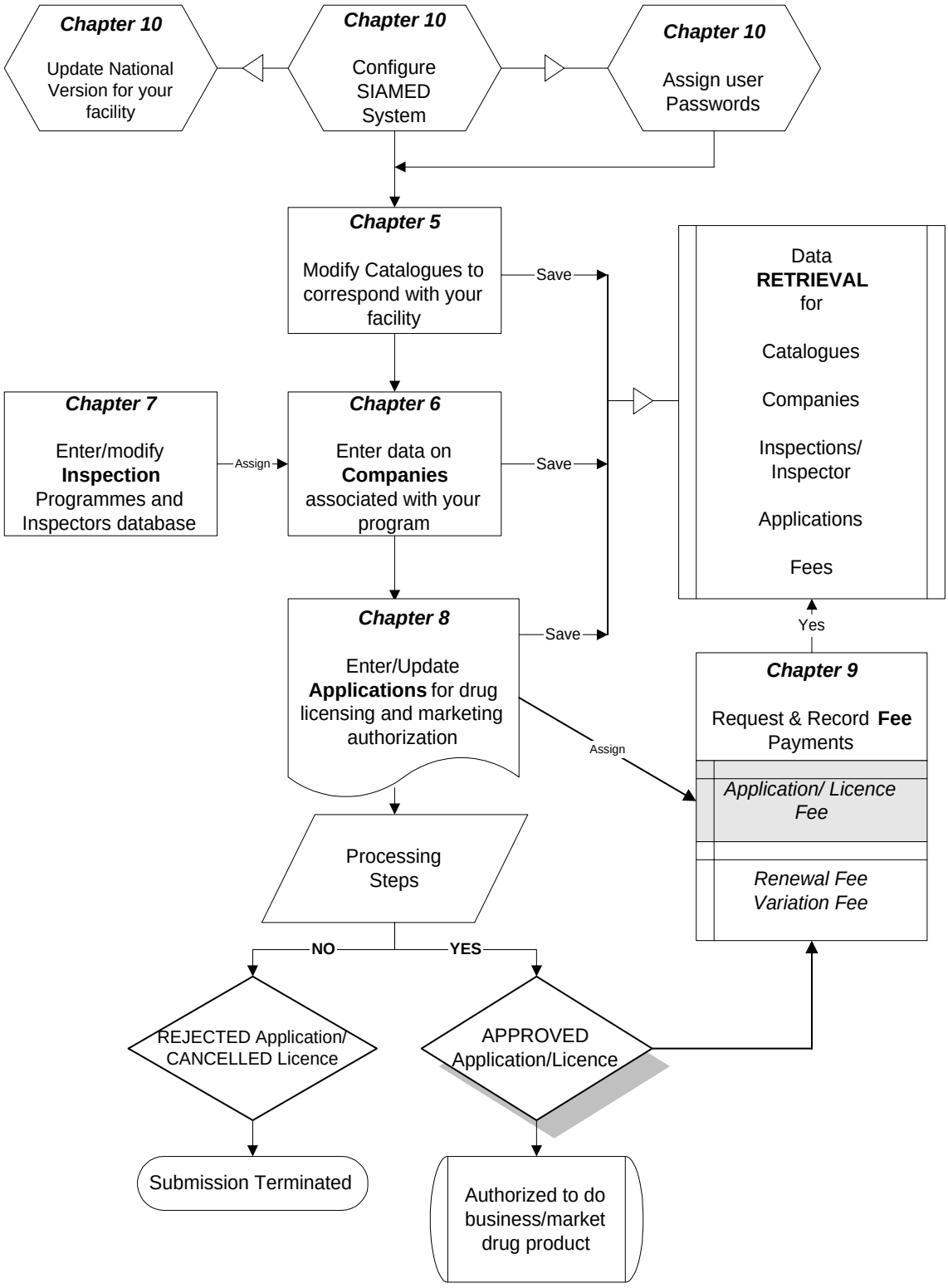
- Configuration
- Password Assignment
- Catalogues
- Companies
- Fees
- Application for Marketing Authorization
- National Version

Each step will refer you to a section in the remainder of this manual that contains detailed instructions for editing or adding data to the specific menu option. (See diagram).

You should also make use of the **<F1>** key to access the Help database which provides additional information on the function of each feature under the various menu options of the SIAMED system.

See also the Flowcharts appendix at the end of this manual for a simple graphical presentation of the menu options permitting to implement the different operations of the drug registration process.

Overview of SIAMED Process



Step 1: Configuration

The first step in setting up the SIAMED program is to configure the system, and edit the preset options to meet the specifications of your SIAMED facility. See Section **10.1.3** for detailed information on configuring your system.

Step 2: Assign User Passwords

Passwords are assigned to users by accessing Maintenance Tools under the Maintenance menu tab, and then selecting Password Assignment from the list. Passwords are used to determine the level of access - limited access and unlimited access - that a user has to menu entries. Any entry in the SIAMED program can be assigned a password access in the Maintenance-Password Assignment option. See **Section 10.1.1** for details on assigning passwords.

Step 3: Catalogues

Catalogues are any files that contain an abbreviation (or code) and its description. For example, there is a catalogue of countries where all country codes and their descriptions are stored (for example, AFG is the code for Afghanistan and ZIM is the code for Zimbabwe).

This step requires that you begin to create or modify any catalogue files so that they apply to the needs of your system and/or facility. To assure consistency and avoid redundancy, it is important that the definition of codes be completed during your initial setup. There are 21 different types of catalogues ranging from Geographical Codes to Types of Price. Many catalogues have already been filled with examples to make familiarization with the system easier. See **Chapter 5** for more details on Catalogues.

Step 4: Companies

This step requires that you begin to create or modify any company files so that they apply to the needs of your system and/or facility. The Companies database permits you to enter detailed information about a company that your facility utilizes/associates with in connection with the drug registration process. To assure consistency and avoid redundancy, it is important that the bulk of this information be updated during your initial setup. See **Chapter 6** for detailed information on Companies.

Step 5: Inspections

The Inspections step of the SIAMED Quick Start process requires that you begin to create or modify data regarding your facility's inspection criteria and programmes, and the inspectors who will conduct the inspections. Once you begin to conduct actual inspections, you will begin to utilize the Inspections component which allows you to enter detailed information about the individual inspections. To assure consistency, it is important that the definition of codes be completed during your initial setup. See **Chapter 7** for detailed information on

Inspections.

Step 6: Fees

This step creates and/or modifies the Fee database which established the standard prices to be charged to applicants for different activities (application, renewal, etc.) within the drug licensing and marketing authorization process. To assure consistency and avoid redundancy, it is important that the bulk of this information be entered during your initial setup, if available. See **Chapter 9** for detailed information on Fees.

Step 7: Applications for Marketing Authorization

The step gives access to all operations related to drug licensing including management of abbreviations (catalogues), company information, inspections, and fees. Once data has been entered using Steps 3 to 6, the preparatory work has been completed. Now, you can begin to enter information regarding the drugs to be registered. See **Chapter 8 - Drugs** for detailed information on Applications for Marketing Authorization.

Step 8: National Version

This step, National Version, allows each facility to accommodate alternative expressions which they as users can define at set-up or when the need arises. This option allows you to locate the text you want to change and permits you to edit it, regardless of caps status (i.e. whether text is lower or upper case lettering or both), and the position of the word in the string. In this way you may replace any text string thus producing screens and printouts which are more meaningful to your specific context, while reflecting the language and/or spoken of your facility and the country in which it operates. See **Section 10.1.4** for details on customizing the system using the option National Version.

Retrieval

Although is not a formal step in the quick start process, the ability to retrieve information is a pivotal component of the entire system. The SIAMED system allows you to retrieve and print information through the Retrieval option associated with the primary operations (Catalogue/Company, Drug, Inspections, etc.) under the Licensing module.

Selecting the retrieval feature under any operation displays a list of choices from which you can select the report that best meets your need. If needed and requested, the printouts can be adapted to the local needs. **See the Retrieval section of each licensing option, Chapters 5 through 9**, for details on using the retrieval system.

Chapter 5

5. CATALOGUES

5.1 Licensing Menu Option

The Licensing menu option gives access to all operations related to drug licensing. This menu is divided into four distinct function areas, catalogues and company, inspections, drugs, and fees.

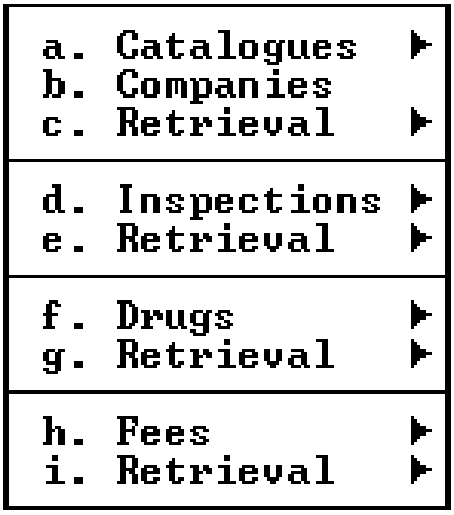


Figure 5-1: Licensing Menu

The following is a brief description of the primary operations under the Licensing menu.

Catalogues These are the files where all the abbreviations used in the system are stored. Abbreviations must be stored in catalogues for the system to work properly. Entry of abbreviations in catalogues is done directly using the catalogue menu option which is accessible - to those with the appropriate password even while performing other operations such as entering company or drug data. See help screens and manual entries of individual Catalogues for more details.

Companies Gives access to the file holding information on company name, address, activities and operating licence status.

Retrieval Opens a submenu which allows you to generate reports on catalogues and companies. This information can be shown on the screen or printed.

Inspections Gives access to files where users can store information on inspectors, prepare inspection programmes, and enter summary information about company inspection results.

Retrieval	Opens a submenu which allows you to generate reports on inspections. This information can be shown on the screen or printed.
Drugs	This option opens a submenu permitting access to operations on applications and marketing authorizations/licences.
Retrieval	Opens a submenu which allows you to generate reports on applications and marketing authorizations/licences. This information can be shown on the screen or printed.
Fees	Gives access to management of fees related to applications and marketing authorizations/licences.
Retrieval	Opens a submenu which allows you to generate reports and print information on payment and validity of fees.

In this chapter, we shall present details on the information that can be entered under the Catalogues menu options and specify where additional information may be found within the manual.

5.2 Catalogues

The Catalogues menu option gives access to all the files containing descriptive data that will be used throughout the system. This option allows you to build standard abbreviations (or codes), to ensure that all staff members use the same terms when entering data in the system.

There are 21 different types of catalogues ranging from Geographical Code to Type of Price. To access the Catalogue menu options, select Catalogue on the Licensing main menu and then select the desired option.

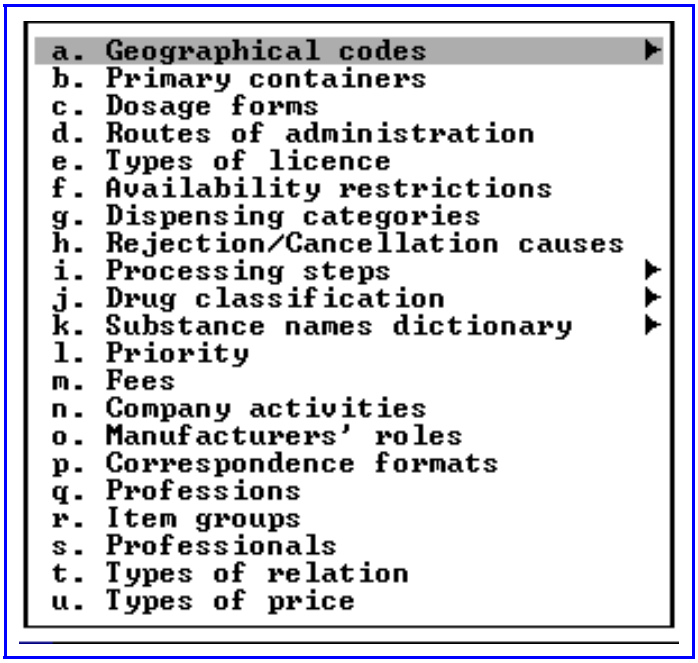


Figure 5-2 Catalogue Menu

Abbreviations must be stored in catalogues for the system to work properly. Entry of abbreviations in catalogues is done directly using the Catalogue menu options, which are accessible even while performing other operations such as entering company or drug data. Some catalogues are already filled with examples to make familiarization with the system easier, others must be completed by the SIAMED user based on their working procedures.

This section is designed to act as a reference guide. The following is a discussion that presents all catalogue options and their uses. This discussion is followed by detailed information on each option.

Geographical Codes	The Geographical Codes catalogue contains a database listing of codes assigned to define countries, regions, districts, and/or towns in your country, and make them more easily identifiable. See Section 5.3 for more details.
Primary Containers	Identifies the type of container that is in direct contact with the dosage form.
Dosage Forms	Used to build a database that defines the form in which the products are dispensed, such as tablets, capsule, or liquid.
Routes of Administration	Used to build a database that defines the various ways a drug or product may be administered, e.g. orally.
Types of Licence	In this context, licence means marketing authorization. The menu label and the screens use *Licence* only to make it fit in the available space. In some countries it is a requirement to specify whether a marketing authorization is to import and sell, to manufacture and sell, to import, complete manufacture and sell, etc. This catalogue is there for those countries that may require it.
Availability Restrictions	This option builds a database that is used to indicate whether a druf product enters the general distribution system or is available only at special sites or through special mechanisms. Restrictions are based on decisions of the drug regulatory authorities to prevent a particular drug from entering the general distribution system.
Dispensing Categories	This option will be used to build a list of dispensing categories which will be used to determine how the item can be dispensed, i.e. OTC for over-the-counter preparations, POM for prescription only preparations, etc. These distribution categories are normally provided for in the statutes of each country and are part of the conditions of issue of a product licence.
Rejection/ Cancellation Causes	This option is used to build a database listing the various reasons for which an application could be rejected or a licence cancelled.
Processing Steps	This is an optional catalogue which is used to define processing steps for applications, and indicate how long an application could be in a particular phase of process.
Drug Classification	This option is used to build a database that defines levels drug classification.

Substance Names Dictionary	Gives access to the file holding information on over 80,000 different non-proprietary names of pharmaceutical substances, including their cross-related synonyms and A.T.C. codes.
Priority	The priority levels that are built in this database can be used to determine in what priority applications will be processed.
Fees	This option is used to build a database that defines the different types of fees used within the system.
Company Activities	This database is designed to contain the various types of company activities. Users must NOT create codes here for the following activities: manufacturer, distributor, or pharmacy. These have preset codes within the system.
Manufacturers' Roles	This option is used to build a database containing the different roles that manufacturers may play in the production process.
Correspondence Formats	This option is used to prepare standard formats of letters and certificates, which can be automatically filled and printed automatically by the computer system.
Professions	Used in conjunction with the Professionals catalogue to allow more flexibility and consistency in defining professions relating to the management of inspections.
Item Groups	Used to further specify the activities of a given company.
Professionals	Used to build and maintain a database of responsible professionals within manufacturing units or other activities requiring exclusive engagement of professionals.
Types of Relation	Used to build a database of abbreviations for the various relationships that can be established between companies.
Types of Price	Used to build a database of abbreviations for the various types of prices applied to medicinal products.

5.3 Geographical Codes

These are the codes assigned to countries, regions, districts and/or towns in your country. The level(s) you have access to will depend on which levels have been selected during configuration of the system. The screen below shows an example in which only country and town have been selected at the time of setting the configuration.

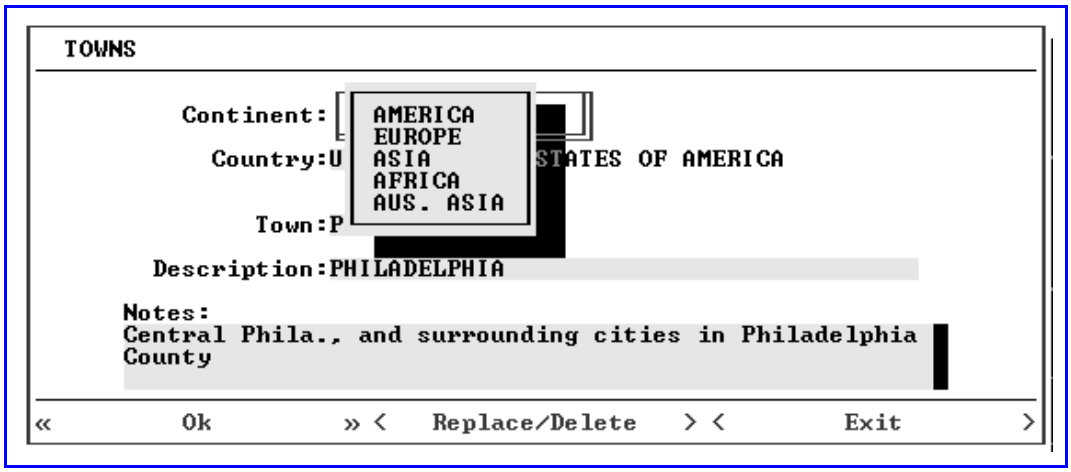


Figure 5-3: Geographical Code screen

For each option, you must define an abbreviation and a description for the abbreviation. After entering the desired data, select <<Ok>> to save your data. You may begin entering more data, or select <Exit> to leave the current screen.

Continent — This is a pop-up field that allows you to select the continent on which your country resides. Press <**Enter**> or click the right mouse button to view the list of continents.

Country — This field contains the abbreviation for your country. A predefined list of countries is available by pressing <**F2**>. This list is based on the continent you selected. If the country you wish to enter is not on the list, you may add the desired abbreviation.

Region — This field should contain the abbreviation for a defined region in the above country. A list of regions is available by pressing <**F2**>. This list is based on the country you selected. If the region you wish to enter is not on the list, you may add the desired abbreviation.

District — This field should contain the abbreviation for a district in the above region. Pressing **<F2>** will display a list of available districts for the region. This list will only show districts that have been defined specifically for the selected region. If you wish to add a new district, enter the abbreviation here.

Town Use this field to define a specific town in a district. Keep in mind that each town you add is specific to a district. If there are multiple districts, then you must specify the towns in each district.

Description This field displays the full name of the country/region/district or town for which you entered an abbreviation.

Notes Use this text field to add any additional descriptive information or notes about the country.

5.3.1 Currencies

Currencies and exchange rates can be entered here to permit comparison between prices when these are not expressed in the national currency. Currencies take the same code as the country to which they belong.

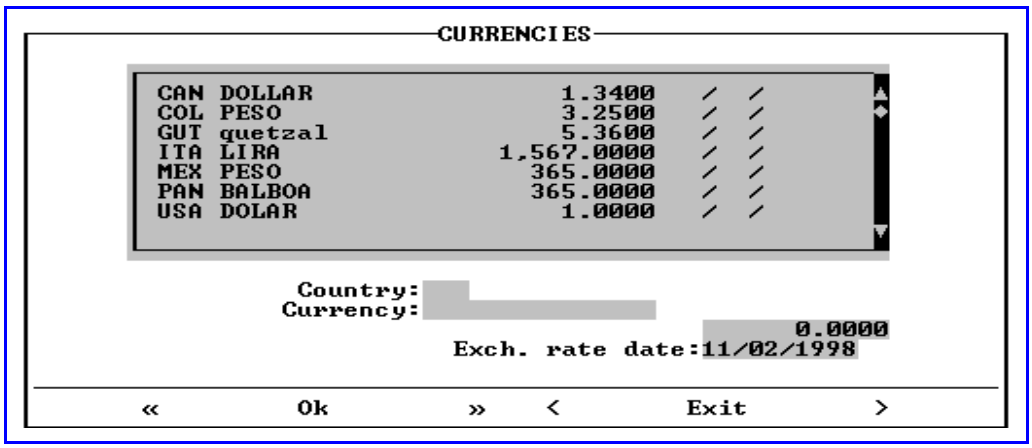


Figure 5-4: Sample of Currencies screen

Country Select the country for which you wish to enter currency exchange information. A selection list is provided by pressing **<F2>** or the right mouse button.

Currency Enter the name of the currency used in the selected country. For example, the United States uses the *dollar* as currency, and Switzerland uses the *franc* as currency.

Exchange Rate Date Enter or edit the date on which the exhange rate was established.

Click <<OK>> to add the entry to the catalogue. Additional entries can be added by inputting information into the data fields provided on the screen.

NOTE: Do not forget that several countries use the same name and/or symbol for their currency, try to avoid confusion.

5.4 Primary Containers

This is the container in direct contact with the drug product.

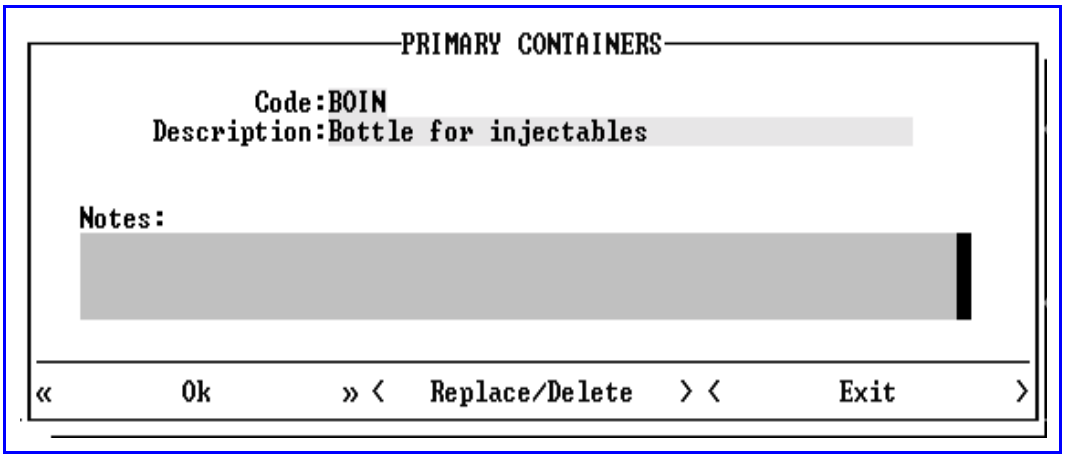


Figure 5-5: Primary Containers screen

Code This option is used to build a database of the various containers that are in direct contact with the drug.

Description This field displays the meaning of the code selected under the Code field. For example: Code: BLIS is described as a 'Blister.'

Notes Use this text field to add any additional information or notes.

5.5 Dosage Forms

This is the presentation form of the product.

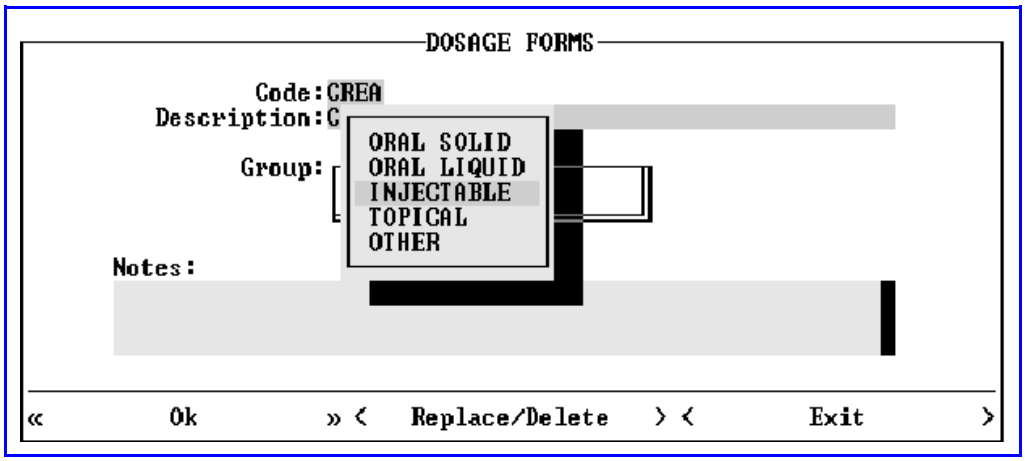


Figure 5-6: Dosage Form screen

Code This is a unique code used to identify the form. For example, if the item is paracetamol and it comes in tablet form, the dosage form could be TAB.

Description This field displays the full description of the code.

Group This field is used to select a group to which the selected form should be assigned from the pop-up window. The following group options are displayed: oral-solid, oral-liquid, injectable, topical or other.

Notes Use this text field to add any additional information regarding the dosage form.

5.6 Routes of Administration

Routes of Administration describe how the drugs are to be administered. A product may have more than one route of administration and the system allows you to specify this selection.

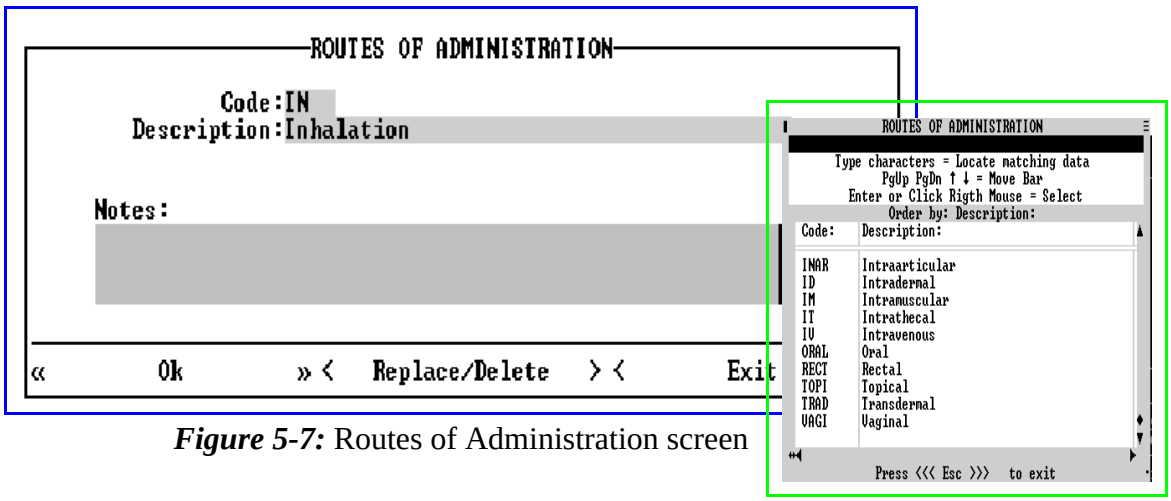


Figure 5-7: Routes of Administration screen

Code This is a unique code used to identify the route of administration.

Description This field displays the full description of the code.

Notes Use this text field to add any additional information.

5.7 Types Of Licence

This catalogue is available for countries that may require the user to specify whether a licence has been granted for importing, selling, studying or manufacturing purposes. Other countries, with only one type of licence will have to enter that one type of licence, or a code to indicate that the type is not specified.

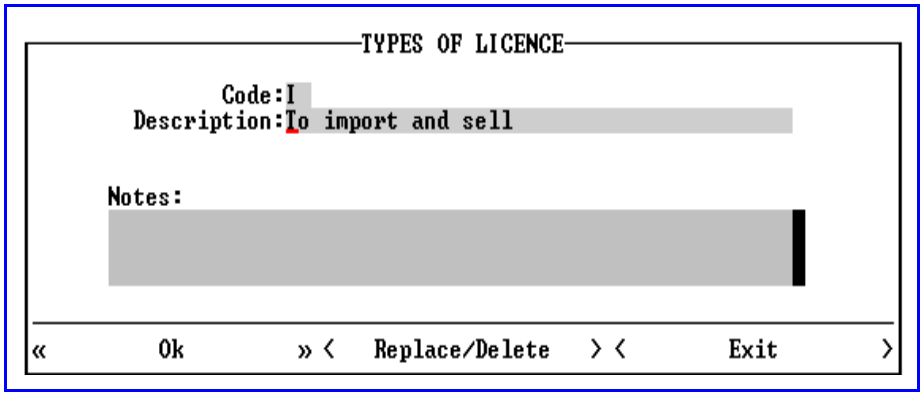


Figure 5-8: Type of Licence screen

Code This is a unique code used to identify how a licence is classified.
For example:
(**I**) - to import and sell,
(**S**) - to import for clinical study only,
(**M**) - to manufacture and sell, or
(**A**) - to import, complete manufacture and sell.

Description This field displays the full meaning of the code.

Notes Use this text field to add any additional information regarding the type of licence.

5.8 Availability Restrictions

This option is used to specify any decisions of the drug regulatory authorities to prevent a particular drug from entering the general distribution system. *For example:* Drugs available only for clinical studies, drug available only at poisoning treatment centres, or drug available only through designated institutions (e.g. for TB drugs).

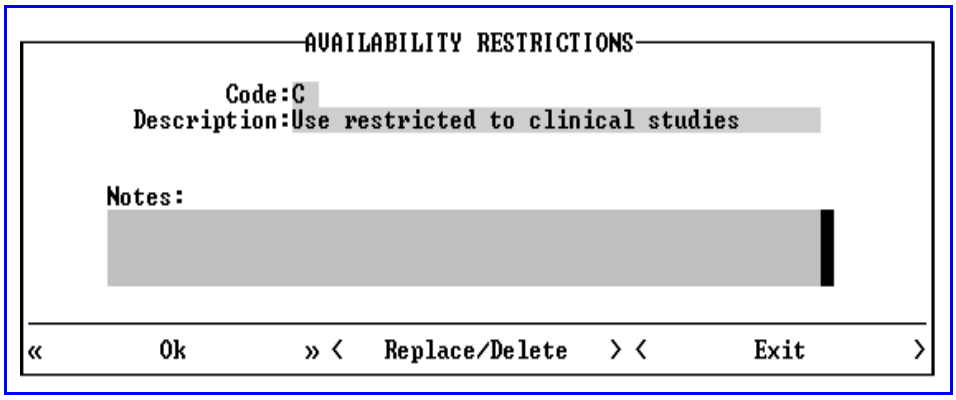


Figure 5-9: Availability Restrictions screen

Code This is a unique code used to identify restrictions of drug availability.

Description This field displays the full meaning of the code.

Notes Use this text field to add any additional information regarding the restriction.

NOTE: Availability Restrictions is a provision over and above the normal statutory dispensing modalities or categories for distribution.

5.9 Dispensing Categories

These distribution categories are normally provided for in the statutes of each country and are part of the conditions for issuing a product licence. Examples of these include OTC for over-the-counter preparations, POM for prescription only preparations, and prescription for narcotic drugs.

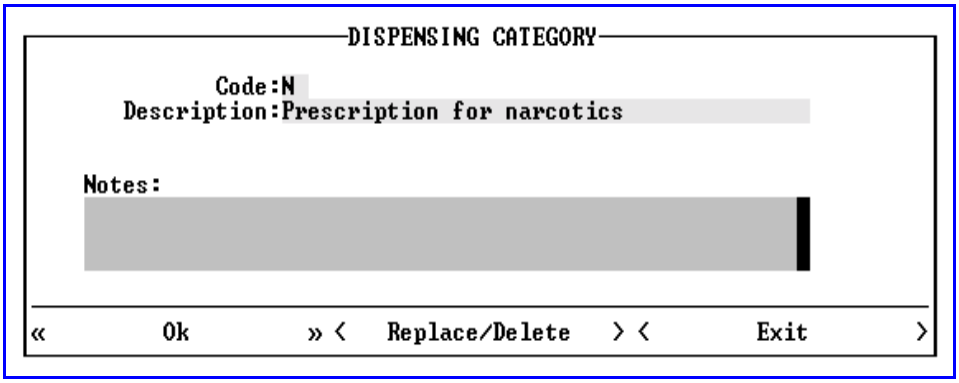


Figure 5-10: Dispensing Categories screen

Code This is a unique code used to identify the dispensing category.

Description This field displays the full meaning of the code.

Notes Use this text field to add any additional information.

5.10 Rejection/Cancellation Causes

Reasons for rejecting applications and for cancelling licences can be predefined. Rejection is reversible through a specific menu option. The voluntary withdrawal of product applications or the abandonment of applications by applicants should be given ad hoc rejection cause codes. Cancellation is reversible and is performed through the Renewal menu option. Suspension of licences is performed through the Cancellation menu option.

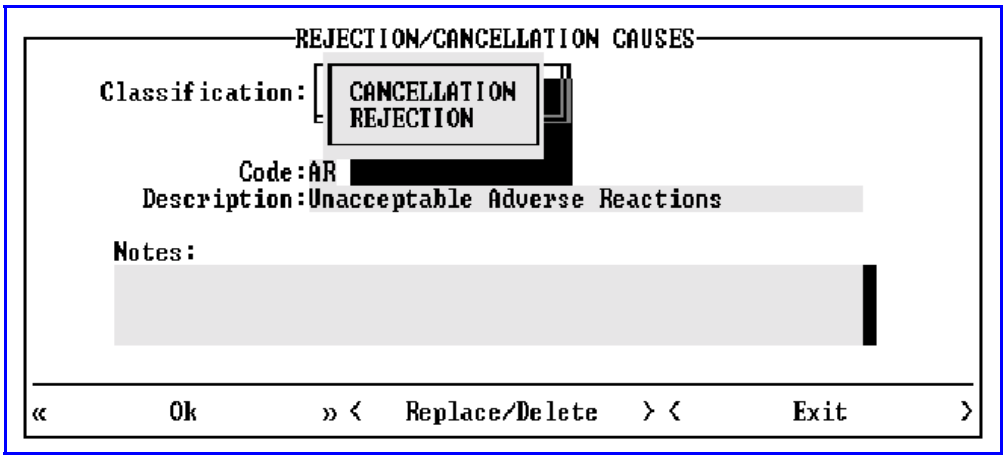


Figure 5-11: Rejection/Cancellation screen

Classification Use this field to specify if the reason for the action being taken is rejection or cancellation.

Code This is a unique code used to identify the cause of the rejection or cancellation. This field can contain up to two characters.

Description This field displays the full meaning of the code.

Notes Use this text field to add any additional information about the reasons for rejection or cancellation.

5.11 Processing Steps

This menu option allows users to define the processing steps for applications, and indicate their expected duration. It is not compulsory that this feature be used, but, once chosen, it has to be complied with otherwise you may not be able to issue marketing authorizations or record revalidations/variations. Making use of the processing steps feature prevents issuing licences with incomplete processing and enables you to trace licences "forgotten" in process.

5.11.1 Defining Processing Steps

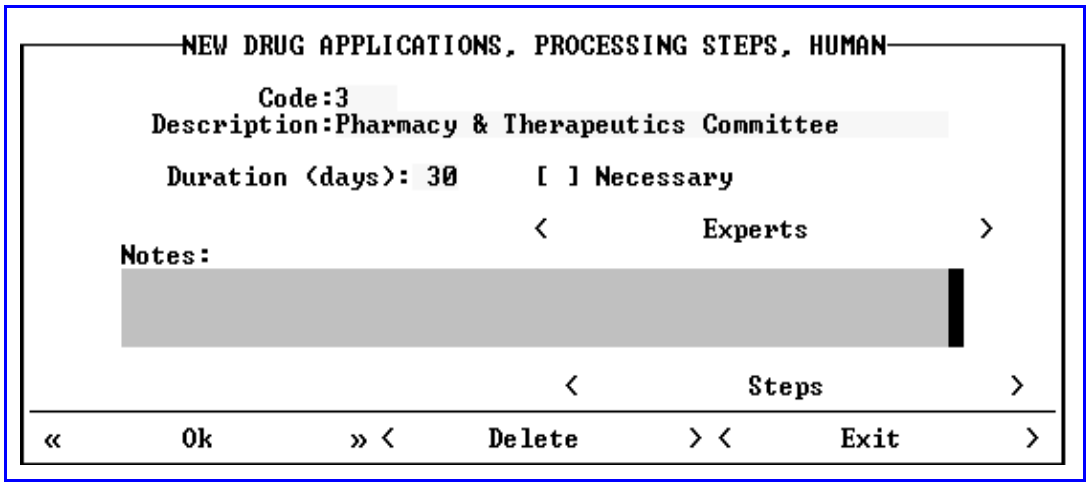


Figure 5-12: Sample of Processing Steps screen

Users can define processing steps for drug licence applications with their expected duration. Up to twelve different paths for processing applications can be defined. These paths are divided into four categories:

Human Drugs	- New, Revalidation, Minor Variation and Major Variation
Veterinary Drugs	- New, Revalidation, Minor Variation and Major Variation
Biological Drugs	- New, Revalidation, and Variation
Special Procedures	

Users that wish to implement this option should enter as many steps as appropriate in the catalogue. When entering steps, users are prompted to decide whether a positive conclusion of a given step is necessary to permit the approval of an application. This distinction becomes useful when you want to enter steps that are only required for selected applications.

Users can change the entries in this catalogue (add new steps, remove steps, edit duration, change between necessary and non-necessary) as required at any moment during the routine use of the system. The system will take care of making the necessary changes to all applications that had been entered prior to the changes made in this catalogue. More precisely:

a.) if you remove a step from the catalogue, all pending applications will disregard any decision made at that step, if any, and will not accept or require entry of data

regarding that step;

b.) if you add a new step, all pending applications will accept entry of decisions made at that step and will require a positive decision if the new step has been marked 'necessary';

c.) if you change the “necessary” mark, all existing applications will require data as appropriate.

Users that prefer not to take this option should simply ensure that the Processing Steps catalogue is empty.

The following is a description of each field displayed on the Processing Steps screen. Since the screens are the same for all twelve paths, this discussion will apply to all paths.

Code The unique code for this step. To simplify the process, you may wish to use sequential numbers which indicate the step level. For example, if this were the first step in the process, you would enter 1 for the code. All additional steps would follow as 2, 3, 4 and so on..

Description The name or description for the processing step. Examples include Reception of application, Pricing Committee, and QCL.

Duration (days) This value represents the number of days that is considered normal for the duration of the step.

Necessary This field indicates whether this specific step is necessary to permit licence approval.

Experts This option, when selected, displays a text box which can be used to enter expert names or sub-steps for the purposes of tracking applications that must be sent for expert opinion or assigned to different members of a panel.

Notes This field displays any additional information relating to the specific processing step.

Steps Selecting this button results in a window displaying all steps entered for the specific processing path. If you wish, you may change the order in which each step appears by pressing the left mouse button on the little double arrow to the left of any step, and moving (while the mouse button is still pressed) the selected step up or down the line. The sequence shown does not impose that users start or complete any given step before entering information on a subsequent one. Click <<Ok>> to save your changes.

Data entry, update and retrieval is identical for all processing steps. You may add as many steps as you wish to each path in this catalogue.

5.12 Drug Classification

This catalogue permits you to enter and update information regarding the classification for all drugs, if national classification, or national classification from the Anatomical Therapeutic Chemical (A.T.C.) classification system has been selected. If the ATC classification system has been chosen at configuration, this option will be faded. The number of levels of the national classification is set using the configuration option.

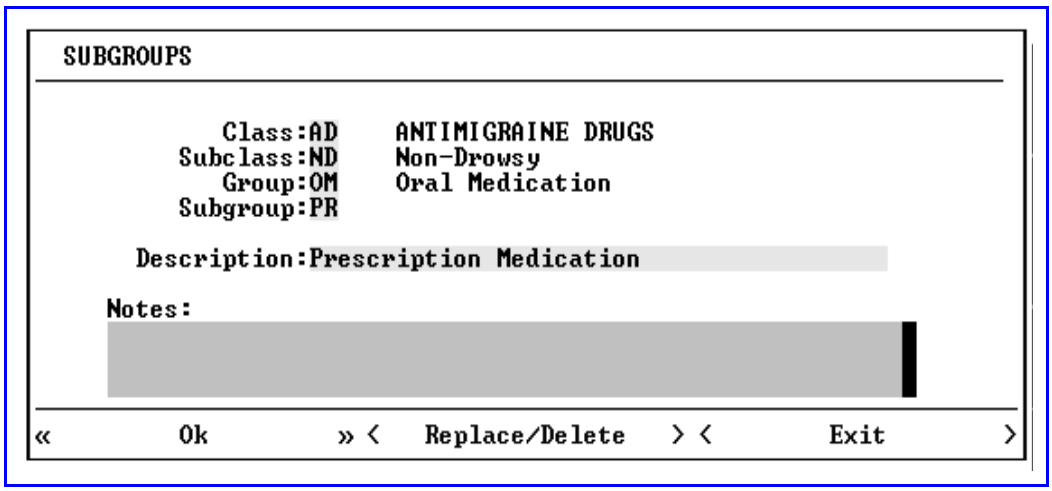


Figure 5-12: Drug Classification screen

Class Code — A two-character field that displays the code and the corresponding description of where this drug should be classified.

Subclass Code — This field displays the code and the corresponding name of the classified drug. This field is linked to the Class code.

Group Code — Defines what group this item should be assigned to. This field is linked to the subclass code.

Subgroup Code — Provides a more specific category to which the item should be assigned. This field is linked to the group code.

Description — This field displays the full name of the classification level.

Notes — Use this field to add any additional information or notes about the classification level.

Each screen (class, subclass, group and subgroup) displays a different level of classification where the user can enter a code with their description and notes. As each successive level is chosen, classification fields from the previous levels will be displayed. Thus at the subgroup level all 3 previous levels are shown.

5.13 Substance Names Dictionary

This is a database with over 80,000 non-proprietary names of active principles and excipients. Users can enter additional names to keep the dictionary up to date and to accommodate specific national names (e.g. traditional remedies).

It is **important** to check, before adding a new entry, whether the file contains any synonym of the name users wish to add. Adding new names without linking them to existing synonyms reduces the efficiency of the dictionary. It increases the probability of licensing drugs with the same ingredient under different names.

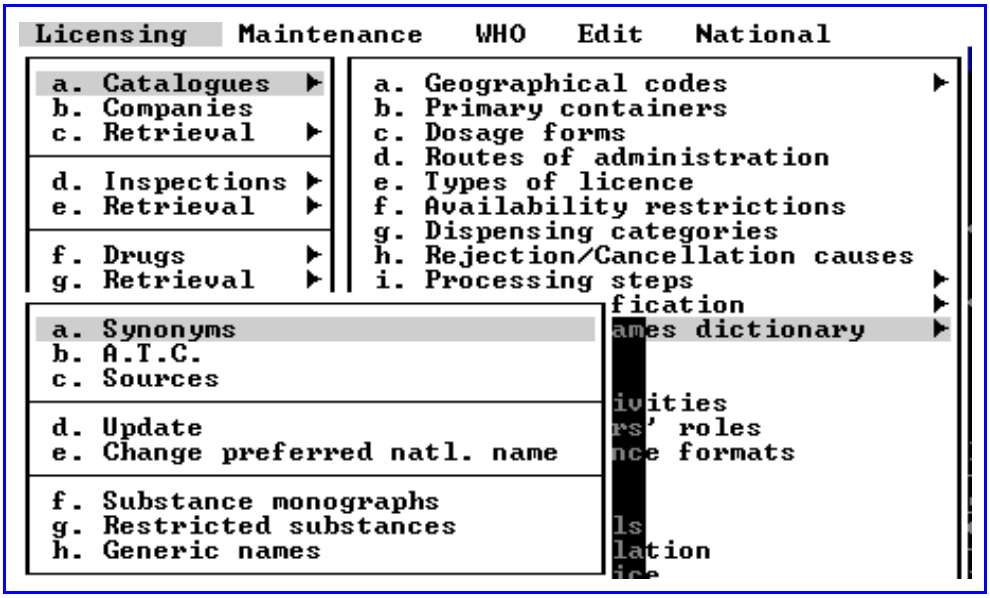


Figure 5-13: Substance Names Dictionary menu options

The first three options of the Substance Names Dictionary submenu permit you to see the list of synonyms, ATC codes, and the literature sources of the listed substance names/synonyms, respectively.

The Update option permits you to add entries to the Substance Names Dictionary. The Change Preferred National Name, Substance Monographs, Restricted Substances, and Generic Names options, are described in further detail below.

5.13.1 Synonyms

Provides a listing of substances, cross-referenced with the possible synonyms associated with each item and their sources. Select a substance name and press **<Enter>** to display a listing of possible synonyms associated with the selected name.

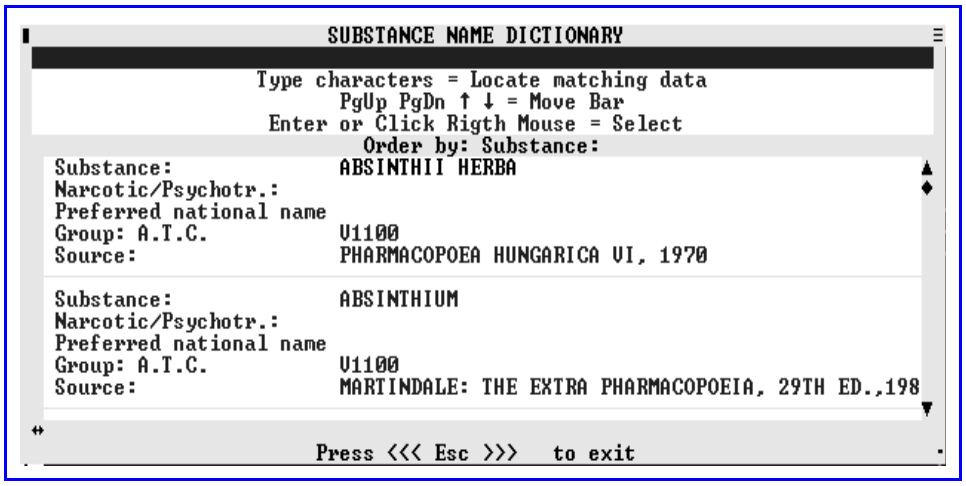


Figure 5-14: Sample of Substance Name Dictionary

Substance — This field displays the name for which a synonym is being sought.

Narcotic/Psychotr. — Displays the narcotic/psychotropic drug code for the substance. A label N1, N2, N3, P1, P2, P3, or P4 has been added to indicate that the substance is listed in tables 1 through 3 of the 1961 Convention on Narcotic Drugs, or in tables 1 through 4 of the 1971 Convention on Psychotropic Drugs. If the substance is **not** under international control, there will be no label displayed.

Preferred National Name — Displays a P if this synonym has been selected as the Preferred National Name of the substance. The preferred national name serves as a system default so that the same item isn't referred to by several different names within the system.

To assure consistency in data display and retrieval, each regulatory authority should select one synonym for each substance, the first time the substance is used to record data in an application. After this is done, every time you select a synonym, the system will automatically convert to the preferred national name. This will prevent licensing drugs with the same ingredients being recorded under different names. To change the preferred national name, see Section 5.13.5.

Group A.T.C. — The A.T.C. code for the substance. See Section 5.13.2 for more details.

Source — Indicates the origin of the information.

5.13.2 A. T. C.

The anatomical Therapeutic Chemical (ATC) classification system is an international coding system provided by the WHO Collaborating Centre for Drug Statistics and Methodology of Oslo, Norway and recommended by the WHO. The ATC provides a common basis for drug classification to facilitate comparative data for drug consumption between different countries. Drugs in this system have been divided into 14 main groups called the first level, with two (2) subdivisions, called second and third levels, which are therapeutic subgroups. There are two additional levels, referred to as fourth and fifth levels, which describe the chemical/therapeutic subgroups and the single chemical substance, respectively. SIAMED comes with the 1993 version of the complete ATC classification list.

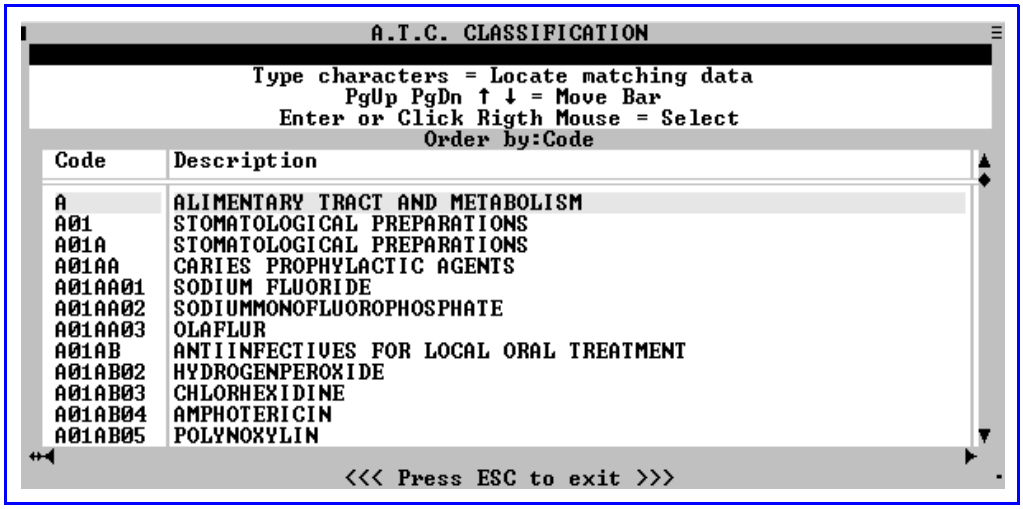


Figure 5-15: Sample of the ATC Classification List

Code This is a unique code used to identify the ATC classification level.

Description This field gives the description.

5.13.3 Source

This option provides pop-up window with an alphabetical search list indicating the literature sources of the listed substance names/synonyms.

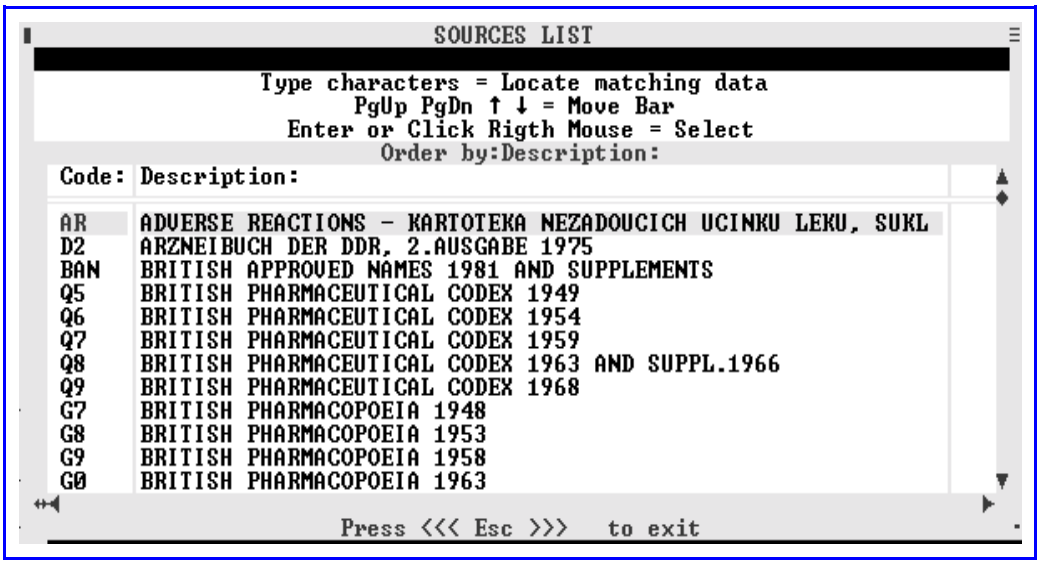


Figure 5-16: Sample of Source List

Code A unique code used to identify the source of the literature

Description This field gives the full name of the literature source.

5.13.4 Update

Allows for the entry of additional substance names with the possibility to relate them to existing synonyms. It is **important** to check, before adding a new entry, whether the file contains any synonym of the name users wish to add. Adding new names without linking them to existing synonyms reduces the efficiency of the dictionary. It increases the probability of licensing drugs with the same ingredient under different names.

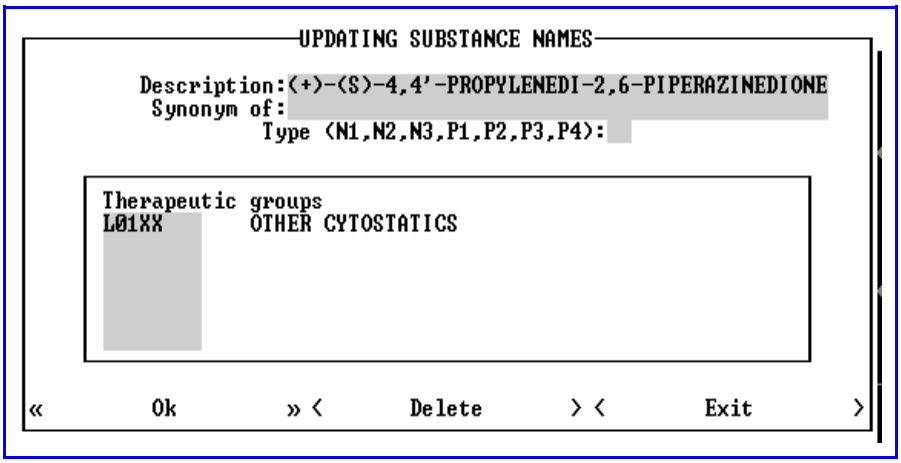


Figure 5-17: Sample of Update screen

Description — Enter the name you wish to add.

Synonym of — Type the name of its synonym or press **<F2>** to select an item from the search window. It is very important that users try as much as they can to identify synonyms in the file.

Type — Enter the type, (N1-N3, P1-P4) for the new name. If you related the new name to an existing synonym this field will be filled automatically with the information belonging to the synonym.

Classification — Select the classification for the new name. Pressing **<F2>** in the classification option will give you a list of items according to their ATC codes. If you related the new name to an existing synonym this field will be filled automatically with the information belonging to the synonym.

5.13.5 Change Preferred National Name

Synonyms in the substance names file are cross-referenced to help ensure consistency in the substance names used. Consistency is made possible by the use of *preferred national name*. Users are prompted to select a preferred national substance name among a number of synonyms. After such a selection is done, the system will convert any synonym entered to the preferred national name, and prevent licensing drugs with the same substance recorded under different names.

The preferred national name status can be changed from one name to another as many times as is necessary. The computer will automatically change a previously selected name to the new preferred name throughout the system.

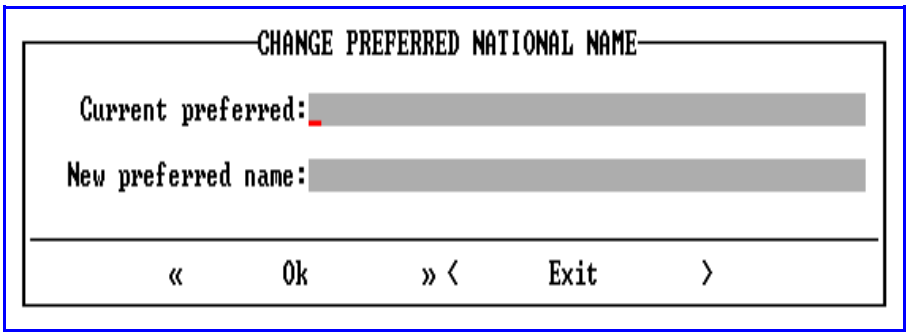


Figure 5-18: Change Preferred National Name screen

Current Preferred

Enter the name currently used as the preferred national name to identify the substance, or press **<F2>** to select it from the list of preferred names.

New Preferred Name

You can now change the preferred national name previously selected, by entering the new preferred name, or by pressing **<F2>** to select it from the list of synonyms.

5.13.6 Substance Monographs

This feature has been developed for those licensing authorities who desire to record specific information on selected substances, particularly excipients and items of natural origin. The information stored in this file is meant to be used to guide decision making by all staff in the licensing process.

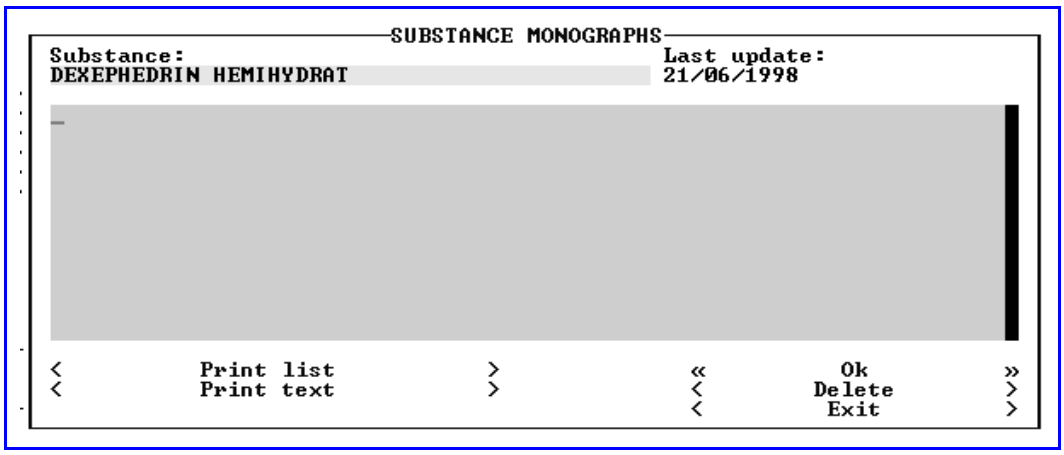


Figure 5-19: Substance Monograph screen

For example: When a technical decision on the admissible levels of an excipient is reached after consulting several sources, it may be desirable to record such a conclusion in order to be able to retrieve it and avoid having to redo all the work next time that the same issue arises. At the same time, this helps to assure consistency of technical decisions among different staff members.

5.13.7 Restricted Substances

The Restricted Substances feature is meant to prepare a national list of substances whose consumption is banned, restricted or not approved in the country of installation.

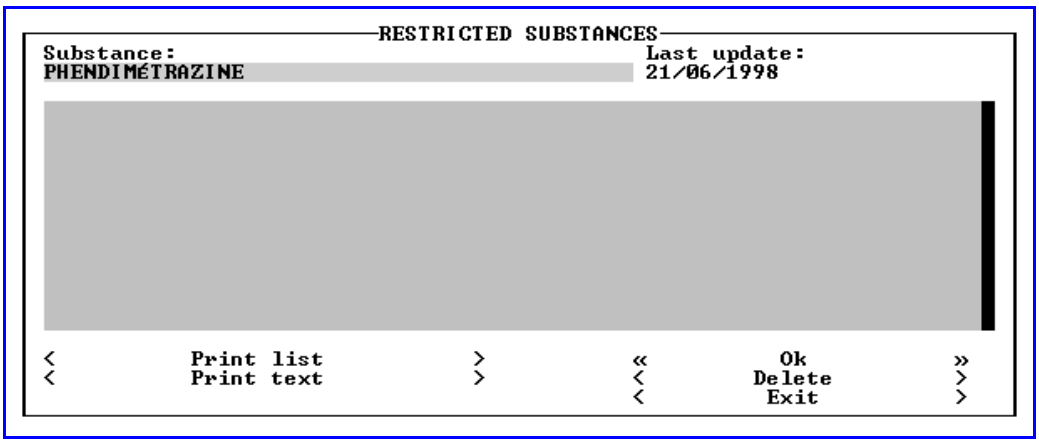


Figure 5-20: Restricted Substance screen

When a substance has been entered here a warning appears automatically to alert the user who is recording information on applications or licences involving such substance. This feature is similar to that used for the substances listed in the UN Consolidated List.

5.13.8 Generic Names

In this system, the names of the individual ingredients constituting the formula of a drug are called ***substance names***. The term ***generic name*** is used with reference to a product. Two drug products may have the same generic name if they contain the same base of an active ingredient, regardless of the dosage form or molecular form used in the formulation.

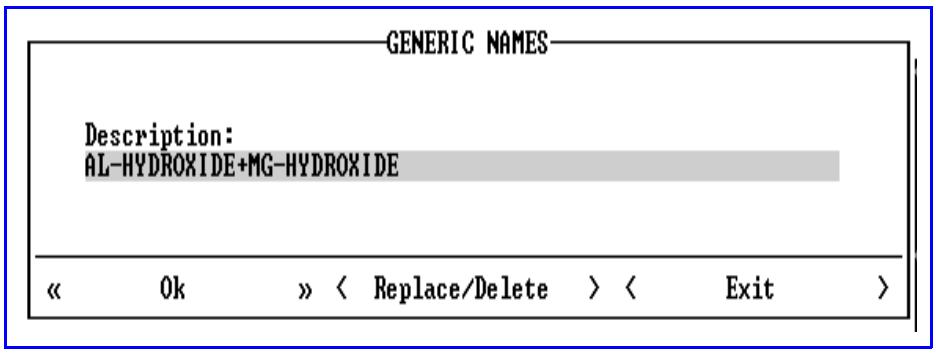


Figure 5-21: Generic Names screen

When determining generic name, it is strongly recommended that the consideration provided below be given careful review.

Drug Products with Only One Active Ingredient

In this case, the generic name is the name of the base that constitutes the active ingredient regardless of the molecular form used in the formulation - unless a specific salt has unique therapeutic uses unrelated to those of the base. For example: The generic name, ampicillin, applies to all drugs containing either ampicillin trihydrate, ampicillin sodium, ampicillin hydrochloride, etc.

In this way, a search based on the generic name ampicillin would permit you to retrieve all products containing any form of ampicillin irrespective of the dosage form. This simplification applies only to the generic name field of an application. It does not limit the possibility for users to record the full name and quantity of the active substance(s) in the ingredient fields. Thus, searches can be based on either the generic name of the drug product or the individual substance names of the ingredients.

Drug Products with Two Active Ingredients

In this case, the generic name is the name of the base that constitutes the two active ingredients regardless of the molecular form used in the formulation - unless a specific salt has unique therapeutic uses unrelated to those of the base.

These two names are entered in the same field. It is recommended that, to avoid repetitions, a fixed format is used to enter them. For example one could use a plus sign to separate the two names and enter them only in alphabetical order: e.g. amoxycillin+clavulanic acid instead of clavulanic acid+amoxycillin.

Drug Products with More Than Two Active Ingredients

Building a generic name by adding those of the individual components is not practical. In addition, it is uncommon that a rational drug has three or more active ingredients. The proposed approaches are these: **a)** enter the same predefined term for all drugs e.g. combination, see formula, or **b)** enter an arbitrary term to indicate a loosely homogeneous group, and use a predefined term for those drugs for which an homogeneous group is not easily identified e.g. multivitamin, minerals, minerals+multivitamin, electrolytes, electrolytes+glucose, cold preparation, combination, see formula.

The use of these arbitrary generic names does not limit search on the basis of an individual ingredient name. On the other hand, it contributes to establishing searching criteria that permit you to group together drugs that have the unusually large number of active ingredients in common.

5.14 Priority

Priority levels can be allocated to drug items or to applications. Examples are drugs listed in the national essential drug list, drugs that are not listed.

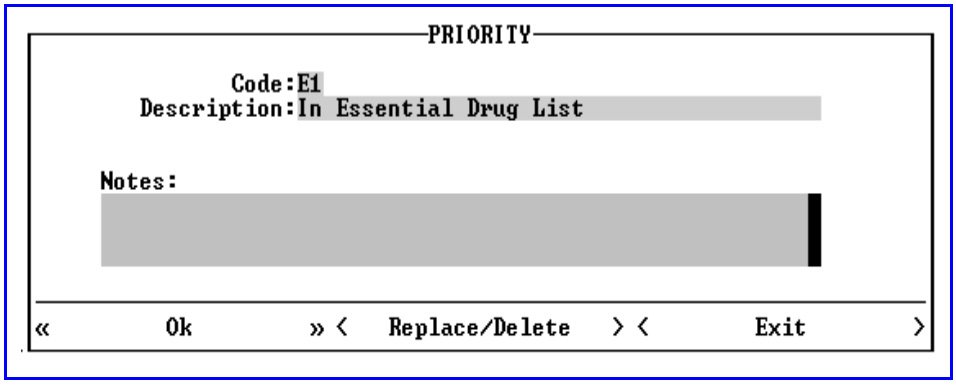


Figure 5-22: Sample of Priority screen

Code This is a unique code used to identify the priority level that can be assigned to an application..

Description This field displays the description of the code.

Notes Use this text field to add any additional information.

5.15 Fees

Different type of fees such as application fee, licence fee for imported products, licence fee for domestic products, QC laboratory fee, and others may need to be used in the company and drug licensing process. This catalogue permits you to define these fees, record payments and to check expiry of payment validity where applicable.

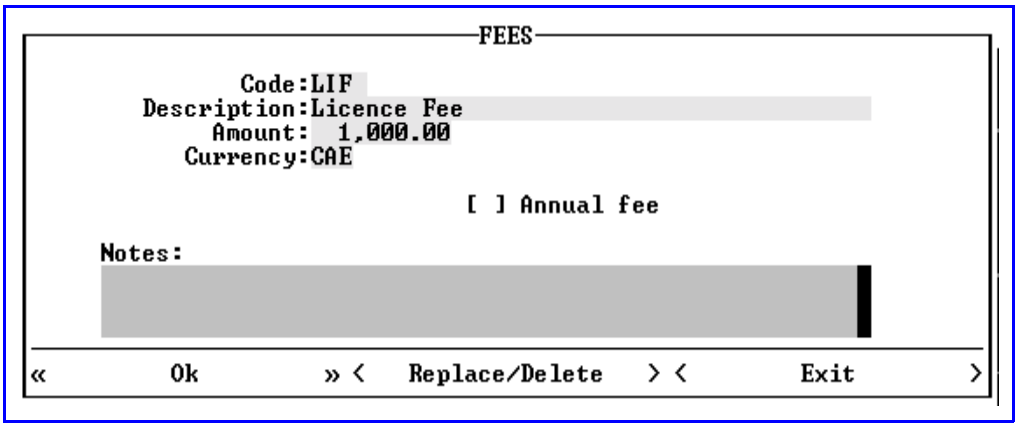


Figure 5-23: Sample of Fees screen

Code This is a unique code used to identify the fee types.

Description This field displays the description of the code.

Amount Used to specify the amount of the fee.

Currency This field is used to specify the currency in which the fee is to be paid.

Annual Fee Check this box to indicate that the fee is to be paid yearly while the marketing authorization remains valid. When a fee with this box checked is related to a marketing authorization, the system will create as many payment deadlines as the number of years of validity of the authorization.

Notes Use this text field to add any additional information.

The process of assigning fees works as follows:

Establishing Fees	Fees are established under the Fee catalogue option.
Relating Applications/ Licences to Fees	The user must set a relationship between fees and the applications/ licences by selecting the relevant fee(s) while entering application data, when issuing a marketing authorization, or from the Fees submenu option.
Issuing Invoices	Users can print invoices to applicants/licence holders to remind them of payments due or simply to issue lists of fees due. This is done through the Fees Retrieval submenu options.
Recording Payments & Issuing Receipts	Users can record payments through the Fees submenu options. After recording a payment, a receipt is automatically printed.

5.16 Company Activities

This catalogue includes definitions of all the various types of possible company activities whether they require licences or permits issued by the authority or not. This catalogue also extends to those companies that may not be involved in the importing or manufacturing of drugs, but may merely be end users such as a dispensing physician, or hospital pharmacy.

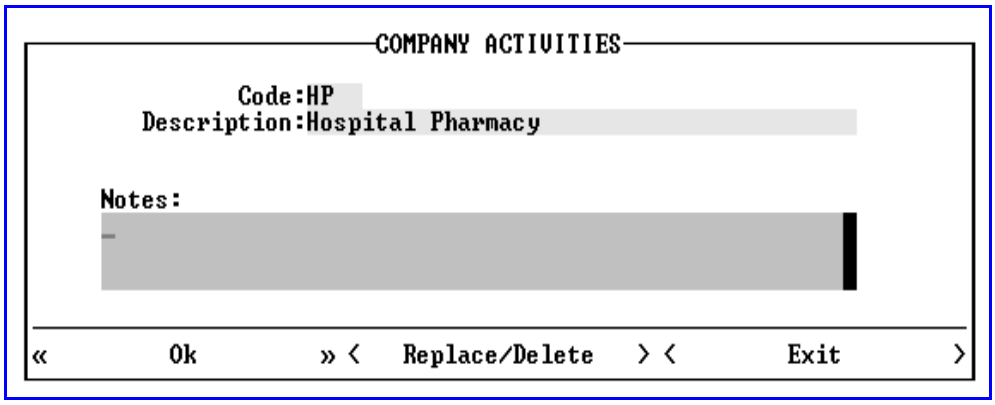


Figure 5-24: Company Activities screen

Code This is a unique code used to identify the various types of company activities.

Description This field displays the description of the code.

Notes Use this text field to add any additional information.

All activities involving a specific licence can be listed here as well as those that do not require it. To ensure proper functioning of the system, Manufacturers, Distributors, and Community /Street pharmacies have preset internal codes and should not be entered here.

5.17 Manufacturer's Roles

This catalogue allows the user to specify the roles of the different manufacturers that intervene in the production process of each individual drug such as production of raw materials, formulation, packaging, etc.

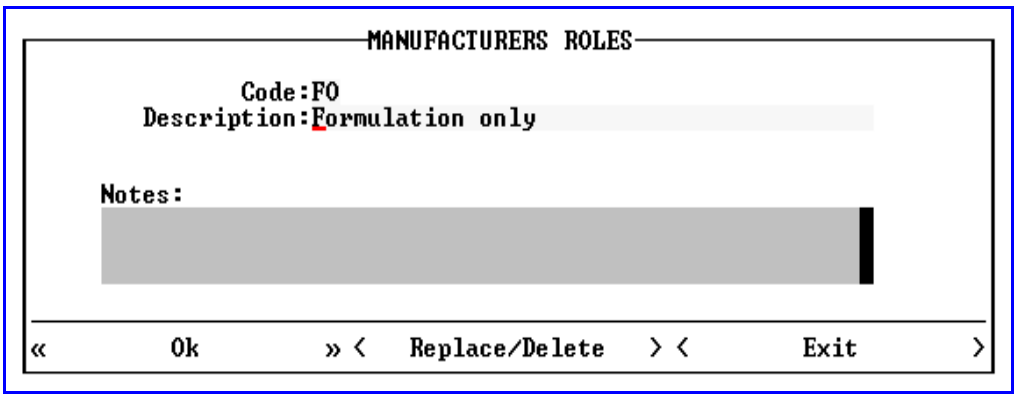


Figure 5-25: Sample of Manufacturer's Roles screen

Code This is a unique code used to identify the various manufacturers' roles.

Description This field displays the description of the code.

Notes Use this text field to add any additional information.

5.18 Correspondence Formats

Correspondence Format is used to prepare the standard format of letters or certificates to be filled automatically by the system when the need arises. On the screens you will see the word "Letter", but this is to be understood as any type of pre-formatted print out. To utilize this menu option, simply enter the Letter Title, and click you mouse in the gray portion of the screen to be able to access the list of variables (**<Ctrl>+<L>**) and edit the appearance of the document's text (**<Ctrl>+<O>**).

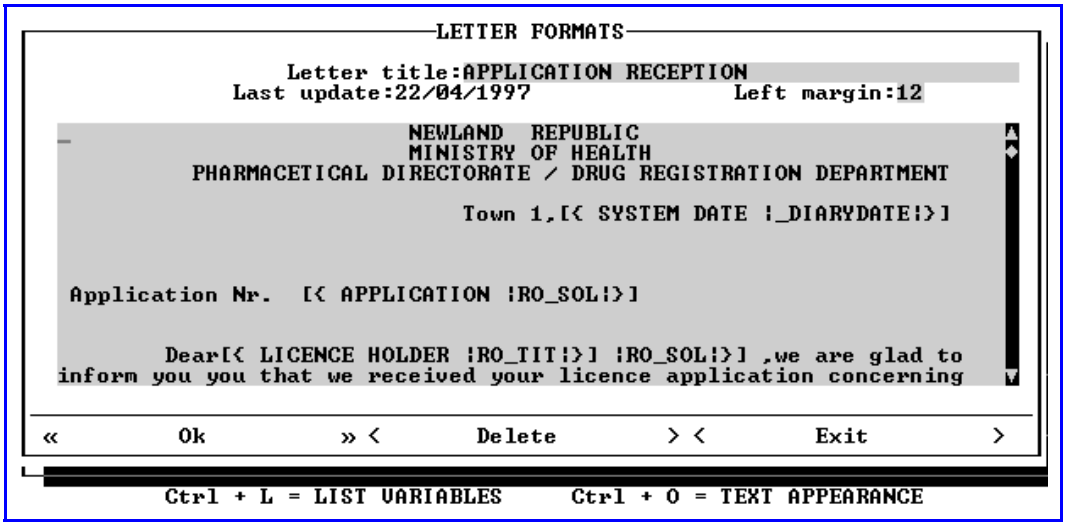


Figure 5-26: Sample of Correspondence Format screen

Letter Title — Specifies the title of the letter. The title can be selected by pressing **<F2>**, or clicking the right mouse button to select from the available list of options.

Last Update — Indicates when this letter format was last updated.

Left Margin — Use this field to specify the distance from the left margin where the letter is to begin.

A standard format serves as a mask which contains both text and variables. The text will be printed as it has been written in the format while the variables, indicated by "[{ }]"will be replaced by their actual value. The value of each variable depends on the context, application or licence, where the user has requested that this information be retrieved from. The user determines which variable to use by clicking **<Ctrl>+<L>** and selecting from the pop-up list.

The following format is prepared as an example of the correspondence format.

> Dear Mr [{ LICENCE HOLDER'S CONTACT |CP_BOS|}]
> I wish to refer to your application [{ APPLICATION NUMBER |RO_SOL|}] .....etc..

When this format is retrieved while entering data of application number 1234567890 submitted by COMPANY ABC whose contact person is Mr REDWHITE, the screen will show the following:

> Dear Mr REDWHITE
> I wish to refer to your application 1234567890..... etc...

If that format is retrieved from another application or licence, the appropriate data reflecting that application or licence will appear. To enter special marks, or set text appearance click **<Ctrl>+<O>** and chose the desired text option (such as system date, new page, bold type) from the pop-up list.

NOTE: All correspondence formats must end with a new-page mark. The text may appear to be out of alignment, but you will be able to edit this appearance once the variables have been replaced by real data, and before sending the letter to the printer.

5.19 Professions

This catalogue works in conjunction with the Professionals catalogue option, and permits greater flexibility in the definition of professions. Its use is related to the management of inspections.

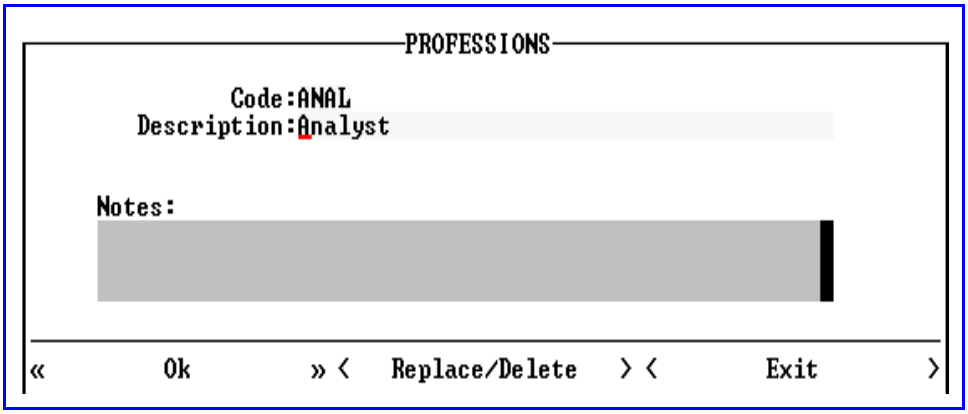


Figure 5-27: Sample of Professions screen

Code This is a unique code used to identify a profession.

Description This field displays the description of the code.

Notes Use this text field to add any additional information.

5.20 Item Groups

The Item Group catalogue is utilized to provide additional specifications of the activities of a given company. For example, a manufacturer can deal with oral forms, injectables, external liquid forms, disinfectants, cosmetics, etc; each of these has been called an item group. This additional specification can be used as a searching criterion for retrieval as well as a planning criterion when programming inspections.

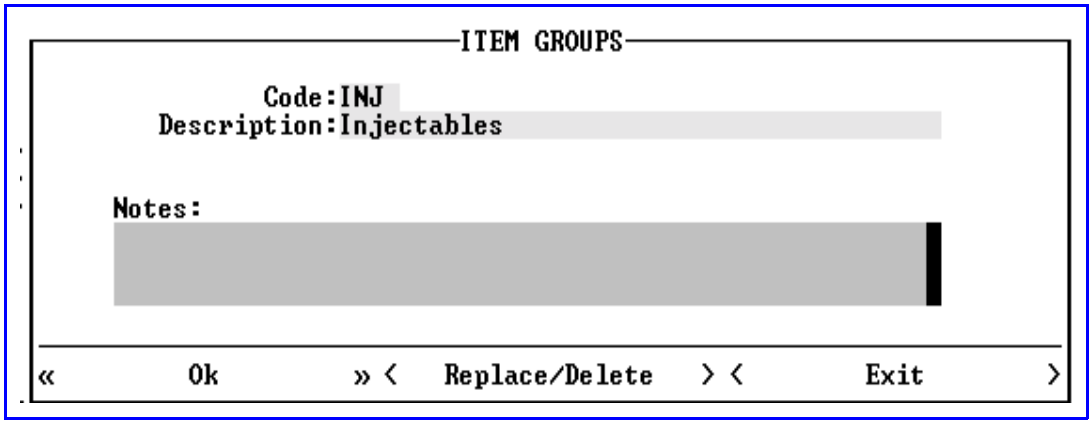


Figure 5-28: Sample of Item Groups screen

Code A unique code used to identify the item group for the activities of a given company.

Description This field displays the description of the code.

Notes Use this text field to add any additional information.

5.21 Professionals

The Professionals catalogue permits you to store information on professionals associated with the SIAMED process. Responsible professionals of manufacturing units need to be entered here before you can enter them in the company file. This permits you to have control on who is engaged where and avoid, if required, double assignments.

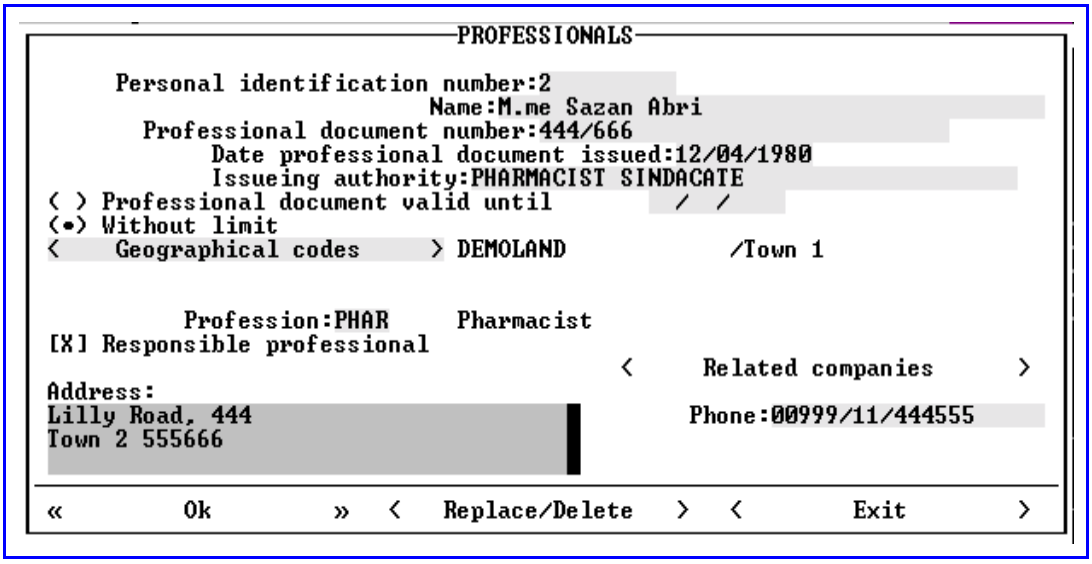


Figure 5-29: Sample of Professionals screen

Personal Identification Number — This is a unique identifying number which is given to each professional.

Name — Enter the name of the professional.

Professional Document Number — This field indicates the unique number assigned to each professional document.

Date Professional Document Issued — Indicates the date the professional document was issued.

Issuing Authority — This field specifies who issued the professional documents.

Professional Document Valid Until — This push button, if selected, specifies that the current professional documents have an expiration date.

Without Limit — This push button, if selected, indicates that the current professional documents have no expiration date.

Geographical Codes This field identifies the primary geographical area (i.e. country, region district, or town) where this professional conducts business.

Profession This field specifies what this individual's profession is.

Responsible Professional This field indicates whether or not this professional is a primary contact within their organization/company.

Related Companies This field indicates other related companies with which this professional might be associated.

Address Indicates the address where the professional can be contacted.

Phone Indicates the telephone number where the professional can be contacted.

5.22 Type of Relation

The Type of Relation catalogue is for storing abbreviations of the relations that can be established between companies, such as holding company, subsidiary, packaging unit, QC lab, exclusive distributor, or marketing agent.

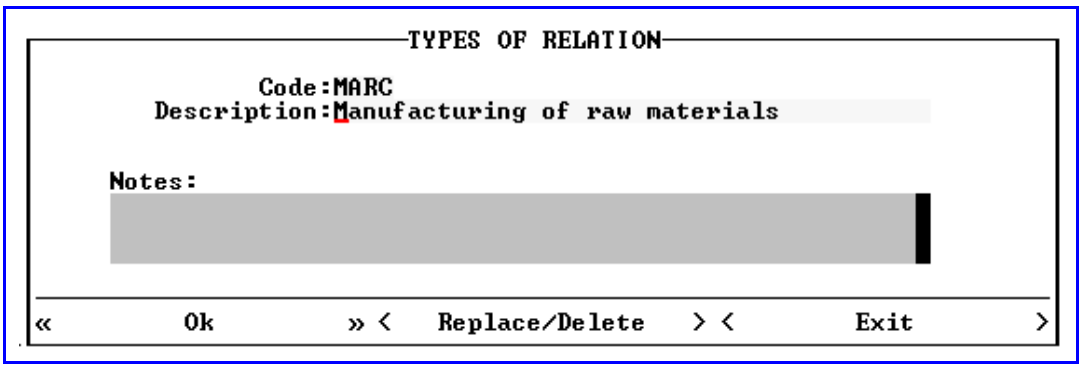


Figure 5-30: Sample of Types of Relation screen

Code This is a unique code used to identify the type of relation..

Description This field displays the description of the code.

Notes Use this text field to add any additional information.

5.23 Type of Price

The Type of Price catalogue permits you to establish abbreviations for the different types of prices that may be applied to medicinal products.

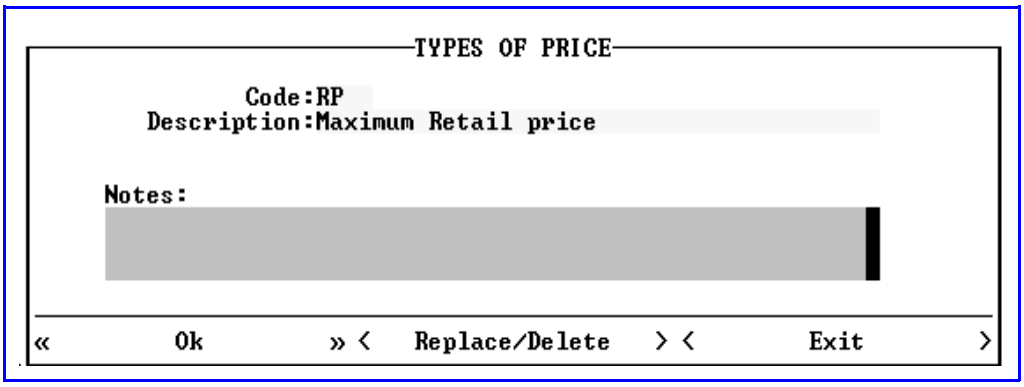


Figure 5-31: Sample of Types of Price screen

Code This is a unique code used to identify the type of price applied to a product.

Description This field displays the description of the code.

Notes Use this text field to add any additional information.

5.24 Retrieval: Catalogues

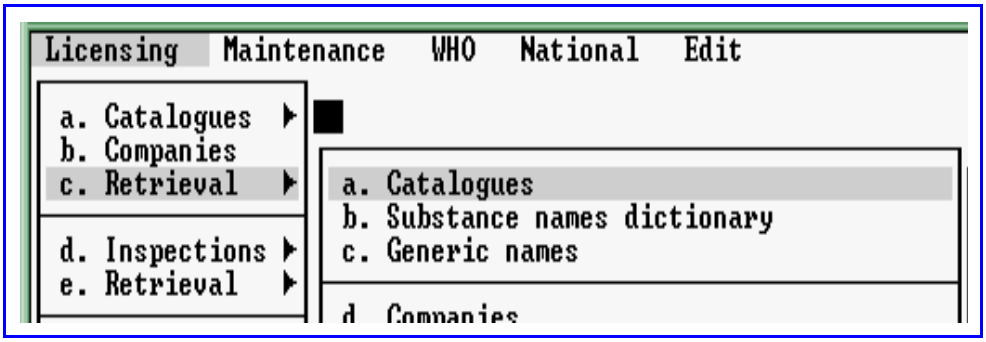


Figure 5-32: Catalogues Retrieval main menu

This options allows you to print or view on the screen, the contents of the catalogues, ordered either by code or description.

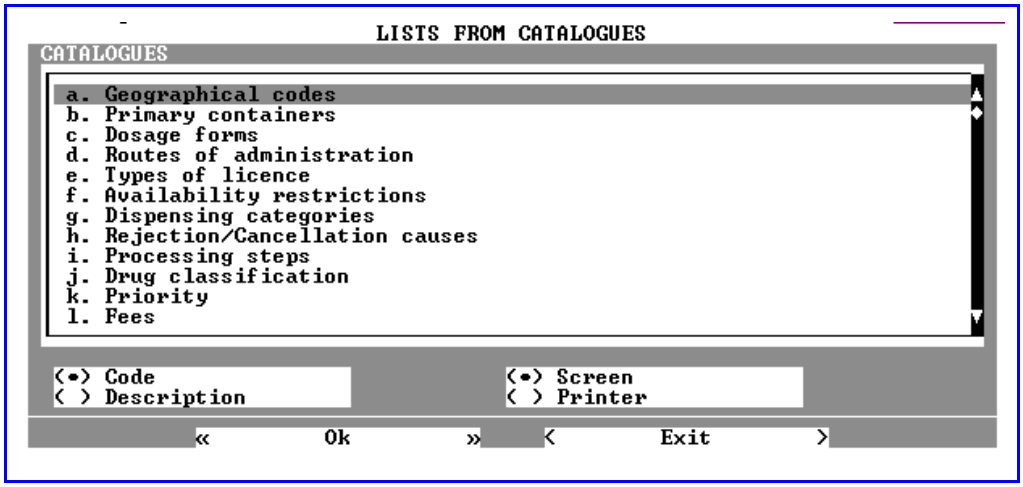


Figure 5-33: Retrieval: Catalogues screen

Catalogues Displays a list of all available catalogue options. Select the catalogue for which you wish to retrieve a report.

Code Selecting this radio button will sort the output by order of code.

Description Selecting this radio button will sort the output by alphabetical order of description.

Screen/Printer Specifies where you want the output sent. As a default, all output goes to the screen.

5.24.1 Substance Name Dictionary

This option permits you to print all the content of the substance names file or to print the synonyms of any selected name, in alphabetical order.

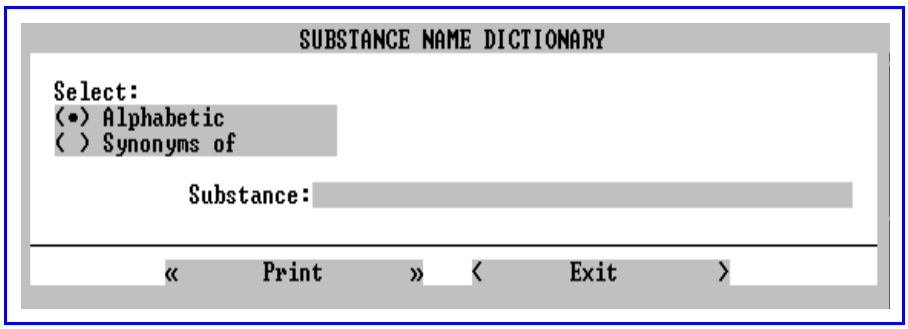


Figure 5-34: Substance Name Dictionary screen

WARNING: The substance names files is hundreds of pages. Think carefully before you try to print it!!

Select: Alphabetic/ Synonyms of — Specifies if you want the data printed in alphabetical order, or if you only want the synonyms of a selected name printed.

Substance — This field is only available if Synonyms of is selected first. Once selection is made, clicking **<F2>** here, reveals a pop-window listing all substance names available in the SIAMED programme. Simply select the desired substance name.

5.24.2 Generic Names

This option allows you to retrieve the generic names of the drug products contained in both application and in marketing authorization.

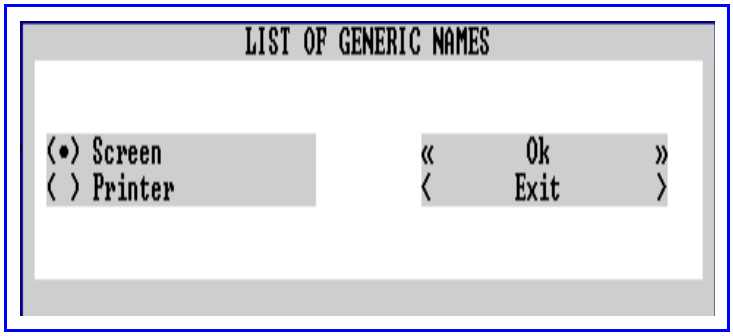


Figure 5-35: Generic Names

Screen/Printer — Select whether you want the report to be displayed on the screen or to be sent directly to the printer.

COMPANIES

Chapter 6

6. COMPANIES

6.1 Companies

The Companies database is intended for storing information about all companies, institutions and any other entity having relevance for the work of the drug regulatory authority.

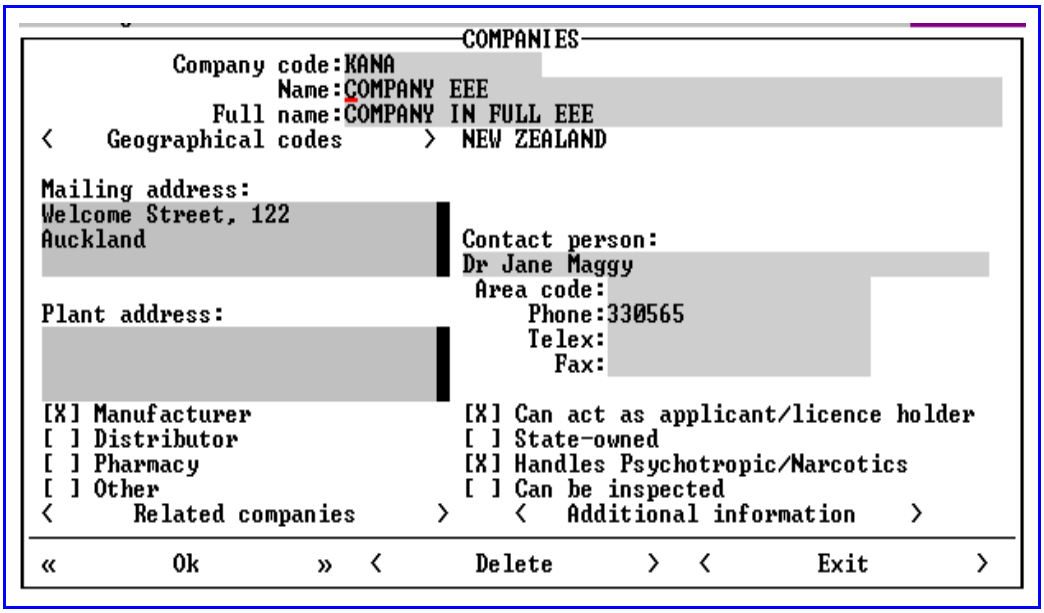


Figure 6-1: Companies primary screen

Users are expected to enter pertinent information regarding manufacturers (both domestic and based abroad), importers, distributors, wholesalers, government institutions, pharmacies, etc. This database is similar to a catalogue in that it is not possible to use a company or institution that does not exist here while doing drug registration data entry. However, this database is intended to be used for storing summary information related to the management of licences issued for various domestic premises and the monitoring of the activities of companies based abroad.

Code — A 15-character code that is uniquely assigned to each entity associated with the drug regulatory authority.

Name — The name by which the company is commonly referred, i.e. Roche

Full Name — Displays the full name of the company, institution, or entity to which the code has been assigned, i.e. Hoffman La Roche Pharmaceuticals, Inc. When issuing correspondence, users can select which name (short or full) shall appear on printed material.

Geographical Codes	Codes assigned to define countries, regions, districts, and/or towns in your country, and make them more easily identifiable. This option is used to indicate what those code assignments are. See Section 5.3 for more details.
Mailing Address	The location of the company/ institution, such as street number, street name, city, and country as you would want it to appear on an envelope.
Plant Address	The physical location of the organization's operating plant. If a company has several plants in the same country, separate company entries should be made to enable inspection to be referred to each specific unit.
Contact Person	The name of the person primarily responsible for managing all company activities.
Area Code	The numerical prefix for the organisation's telephone number(s).
Phone	The organization's telephone number.
Telex	Telex communication number.
Fax	Telephone number used to send a facsimile (fax transmission) to the organization.
Check Boxes	Used to provide additional information on the company's activities. Click the check box next to each activity that the company has been authorized to perform. For manufacturer, distributor, pharmacy, and other, additional screens will appear requesting more information (see below). The other options are simple check boxes and do not require any additional information.
Related Companies	Used to specify a company name and its relationship to the company for which you are entering this data. See below for more details.
Additional Information	This field is used to enter any additional information about a company. These fields are established during the configuration process. See Chapter 10 for additional information on Configuration.

Selecting the check boxes for manufacturer, distributor or pharmacy reveals the following screen.

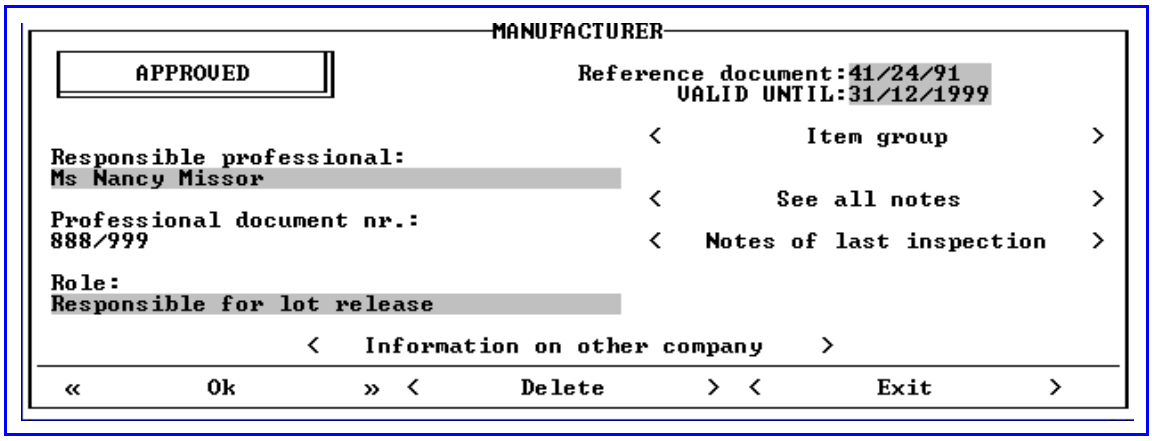


Figure 6-2: Screen displayed when the Check Boxes for Manufacturer, Distributor, Pharmacy or Other are selected

Approved/ Cancelled/ Term to Comply

Select the appropriate option to indicate the status of the company as Approved, Cancelled or given a Term to Comply with inspector's recommendations.

Reference Document

Enter a reference number i.e. licence number, file number, etc., that is unique to document related to the above mentioned status, and a date as appropriate.

Responsible Professional

Press **<F2>** to reveal the list of responsible professionals, and select the contact person who is associated with this activity.

Professional Document Number

This is a read-only field that displays a unique licence number that identifies the professional.

Role

Specify what the professional's responsibility or title is for this activity.

Item Group

The button reveals an additional screen which allows you to select the item groups to be associated with this activity, such as Controlled Substances, Injectables, Semisolid, etc. Simply click the left mouse button on the appropriate item group. You are also given the option to "Select All" or "Deselect All" activities listed on this screen.

See All Notes — Selecting this button reveals a text screen of notes previously entered when using this option or when entering summary information. You may enter additional noted on this screen any time. These free notes will be accessible when entering summary inspection results.

Notes of Last Inspection — This button allows you to view the inspectors notes on the last inspection of the referenced company.

Information on Other Company — Selecting this button will permit you to select another company and view its information. By double clicking on the activities for which the other company has been authorized, reveals fields that indicate if the company has been approved/cancelled or given a term to comply, and corresponding dates, the reference document number, and notes relating to the document.

If you select the check box Other, another window is revealed where you must indicate an activity drawn from the company activities catalogue. This window is similar to the screen shown above with the exception of two additional fields:

Activity — Select an activity from the list by pressing <**F2**> and double clicking on your choice.

If the item you need is not in the catalogue you can add it now. To add a new entry you simply pull down the Licensing menu from the menu bar at the top of the screen. Then you select catalogues and the company activity. Enter the necessary data and then click <Ok> to save and on < Exit > to return to the operation you where performing.

Date/ Reference/ Activity — This text field displays notes as to the date, reference and activity associated with the referenced document as described above for manufacturers, distributors, and pharmacies.

After completing the entry of information related to an activity, you press the <<Ok> > button and summary information about your entry will appear in the large window placed in the lower part of the screen. Clicking on any line of this latter window will give access to the entry for editing.

Selecting the button, <Related Companies> reveals a window which allows you to relate one company to another. When entering related companies it must be remembered that these must be companies already existing in the computer for it to accept them. In other words

when you start using the system and you enter the first company, you will not click the < Related companies > button even if you know that you want to enter one. You will then enter the second company as the second entry and relate it to the first company, the change will automatically take effect in both company's entries.

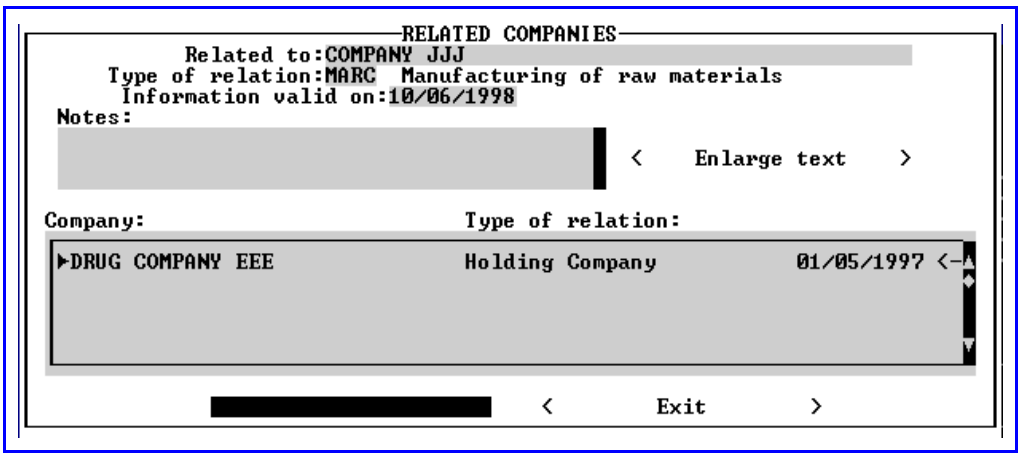


Figure 6-3: Related Companies screen

Related to

Selecting **<F2>** in this field allows you to select the name of a company you want to indicate as related to the company for which you are entering data.

Note: Both companies must exist or be created in the system before they can be related. Once the data has been entered to specify the relationship, the change will automatically take effect in both companies' entries.

Type of Relation

Selecting **<F2>** in this field allows you to specify what type of relationship exists between both companies. These options are available based on information entered in the Types of Relation catalogue.

Information Valid on

Indicates the date on which this information was valid

Notes

Free text field to enter information the better explain the relationship between the companies.

Company/ Type of Relation

This part of the screen, displays which relationships of the company for which you are entering data, have already been recorded. An arrow on one line indicates that the information displayed in the upper part of the screen is referred to that specific relation.

When all entries are completed and saved by pressing <<Ok>>, you can return to the main entry window by pressing <Exit>.

6.2 Retrieval: Companies

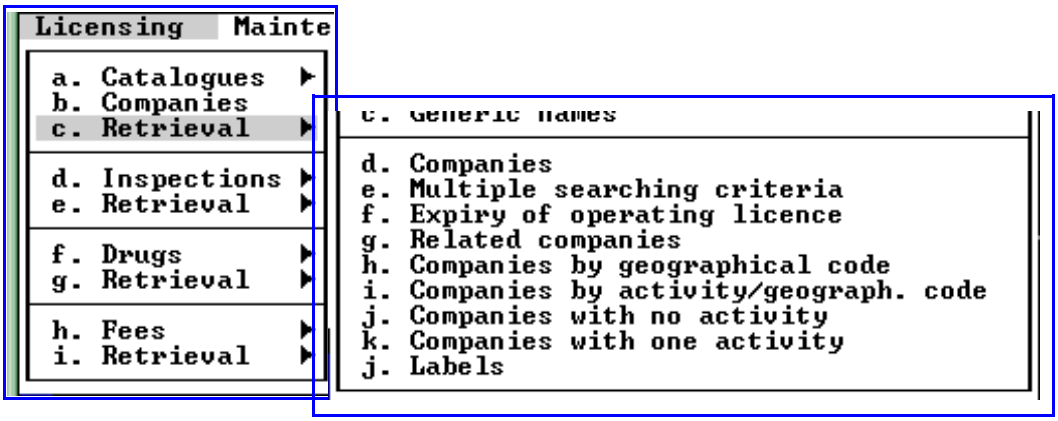


Figure 6-4: Companies Retrieval main menu

This Retrieval Companies option permits retrieval of information from the Company file.

6.2.1 Companies

The screen for the retrieval option Companies, reveals a series of radio buttons. By selecting the radio button options that best suit your needs, you specify how the data is to be formatted and displayed.

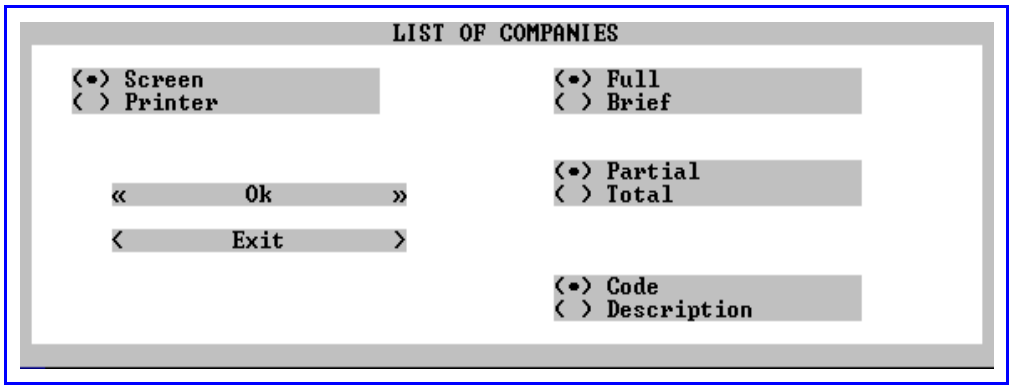


Figure 6-5: Retrieval: Company screen

Screen/Printer Specifies where you want the data sent.

Full/Brief

Selecting "Full" will include ALL data entered into the system about your selected company. "Brief" will provide a synopsis of the company such as code, name, address and licenced activities.

Partial/Total

Selecting "Total" means that all companies will be printed. "Partial" means that you are shown on the screen the list of all companies in file. Pressing <**Enter**> or clicking left mouse when the bar is on a company name results the data being printed for that specific company. You can repeat this as many times as is necessary. You can leave this selection mode by pressing <**Esc**>.

Ordered by: Code/ Description

This feature, in the case of a "Total" printout, allows you to select whether, companies should be listed by code or by name. Once selections have been made, press << Ok >> to execute the selected action, or < Exit > to return to the main menu.

6.2.2 Multiple Searching Criteria

The multiple searching criteria feature under the Retrieval option permits you to select groups of companies rather than the entire file.

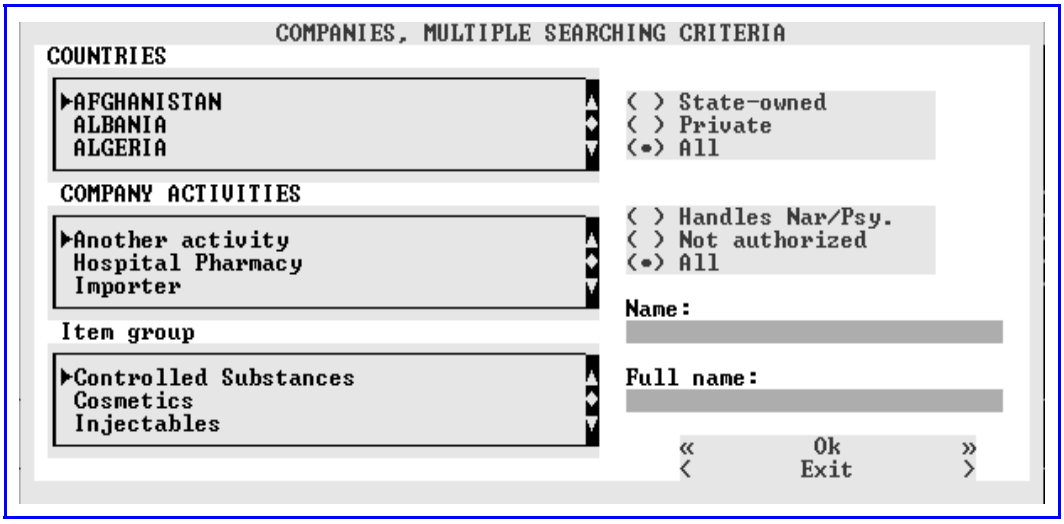


Figure 6-6: Multiple Searching Criteria screen

Countries

Select any number of countries, ranging from one country to all countries within the database. If you do not select anything the system includes *all* countries in the search. If you select country A, B and C, the system lists companies from country A, companies from country B as well as companies from country C.

Company Activities

You can select any number of company activities such as manufacturer, pharmaceutical, or distributor. If you do not select anything, the system disregards this selection criterion and lists companies regardless of their licenced activity(ies).

If you select activities A, B and C, the system lists companies that are licenced for ALL three activities. If a company is not listed for all three activities, it will not be included.

Item Group

You can select any number of item groups. If you do not select anything, the system disregards this selection criterion and lists companies regardless of their licenced item group(s).

If you select item groups A, B and C, the system lists companies that are licenced for ALL three item groups. If a company is not listed for all three groups, it will not be included.

State-owned/ Private/ All

The radio buttons permit you to select whether you want to list private or state-owned companies or either. If you do not select anything the system assumes you selected all.

Handles Psychotropic/ Narcotic Drugs, Not Authorized, or All

Select whether you want to list companies authorized to handle psychotropic and narcotic drugs, or not authorized, or either. If you do not select anything the system assumes you selected all.

Name/Full Name

Use these fields to limit the search range to companies whose name or full name starts with a string of characters. Enter the appropriate characters in the proper field. For example: If you want to limit your search to companies with the name ‘Roche’, simply enter Roche in the name field. If you want to limit your search to that particular company, enter ‘Hoffman La Roche...’.

Press << Ok >> to execute. If at least one company matches the selection criteria, you are shown an additional window to select display options as described in Section 6.2 Retrieval: Companies.

6.2.3 Expiry of Operating Licence

This option permits you to see or print company operating licence expiry dates.

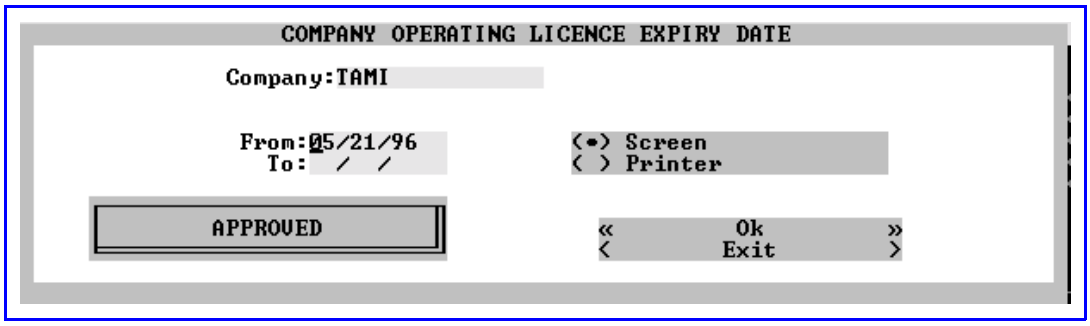


Figure 6-7: Expiry of Operating Licence screen

Company — Use this to retrieve information on a given company simply by typing its name, or selecting a name from the pop-up window list provided when you press <**F2**>, or click the left mouse button. If you want to list all companies, just leave this field blank.

From/To — Use this field to specify the range of dates from which you want to retrieve data regarding expiring licences . If you leave blank the 'From' date the system assumes 11th November 1111 (i.e. much before you started your licensing activities). If you leave blank the 'To' date, the system assumes 31st December 9999 (i.e. much beyond the scope of your licensing activities). Although leaving dates blank does not result in any error message, it may give meaningless output. For example: From 01/01/1994 To [blank] lists all licences expiring anytime after 01/01/1994, which practically means that all company licence will be shown as expired.

Approved/ Cancelled/Term to Comply/ All — Use this field to determine if you want the search to be restricted to companies currently operational, cancelled or with term to comply with inspection recommendations.

Screen/Printer — Select where output should go.

Press << Ok >> to execute, < Exit > to return to main menu. The output lists all activities of each company with the indication of the operating licence expiry date.

6.2.4 Related Companies

This option enables you to retrieve information on the types of relationships exist between companies. To relate companies to each other, you must press the < Related companies > button of the company data entry screen.

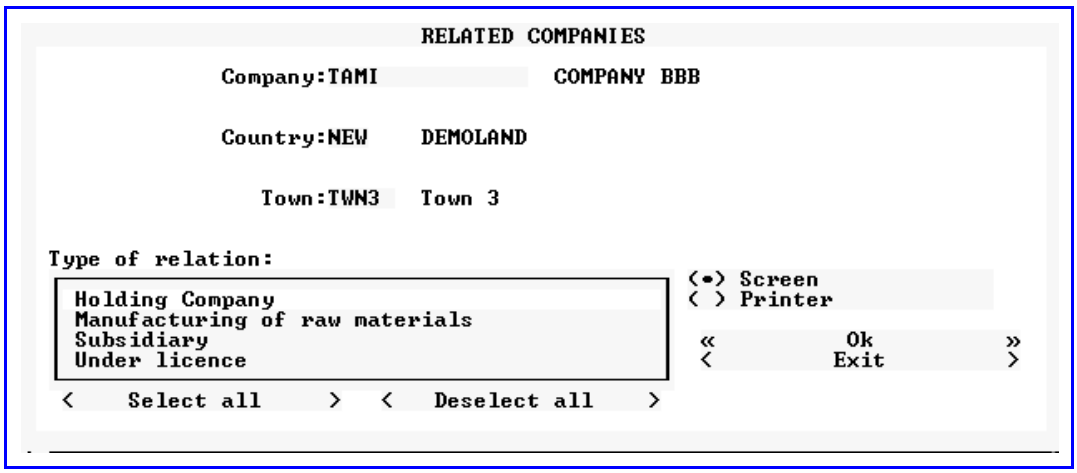


Figure 6-8: Used to establish relationship between companies

Company — Indicate the name of the company you want for which you want to retrieve information.

Country/ Region/ District/ Town — Displays information about the selected company as determined above.

Type of Relation — Specify the type of relation for which you want to retrieve information.

Screen/Printer — Select where output should go.

6.2.5 Companies by Geographical Code

This screen permits you retrieve information on companies by geographical code, i.e country, region, district or town.

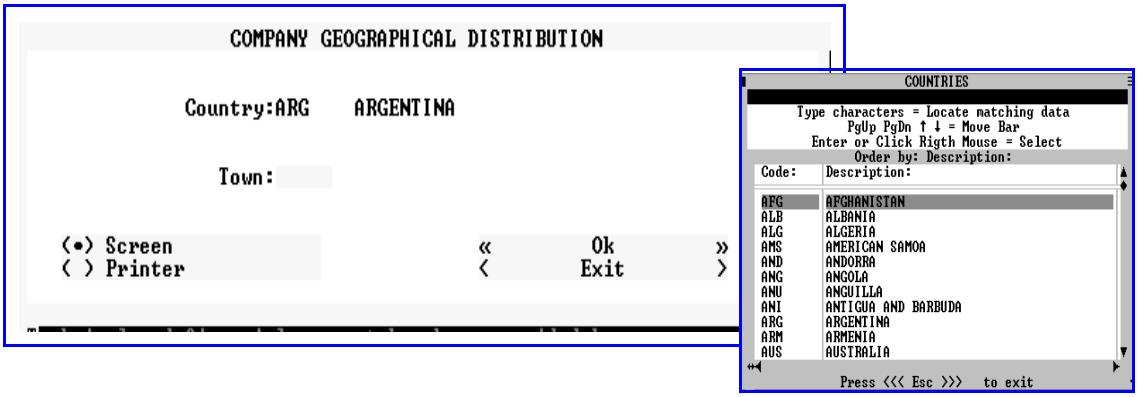


Figure 6-9: Retrieve Companies by Geographical Code

In order to retrieve data under this option, the levels of geographical codes must have been established at configuration. If you are unsure of the code, press **<F2>** or click right mouse to get a list. Press <<Ok>> when done.

6.2.6 Companies by Activities and Geographical Distribution

This feature retrieves information on companies by activity and geographical distribution.

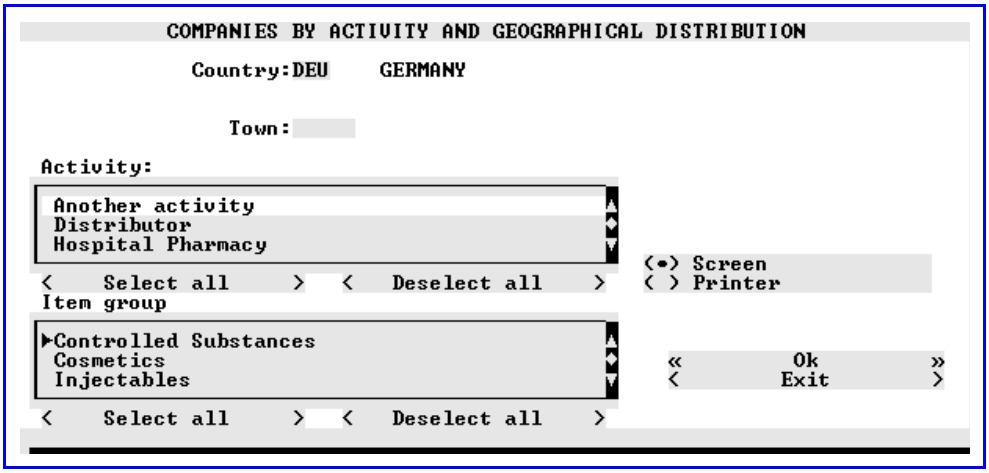


Figure 6-10: Retrieval of Companies by Activity and Geographical Code

Country/ Region/ District/ Town Specify the country, region, district or town that serve as the primary criteria for sorting companies

Activity Specify the activities with which the companies are involved

Item Group Specify which item groups the companies are involved with.

Select All/ Deselect All Choosing “Select All” or “Deselect All” either selects all activities or item groups listed in the respective boxes, or deselects them.

6.2.7 Companies with No Activities

This retrieval option identifies companies by geographical code for which no activity has been recorded in the computer system.

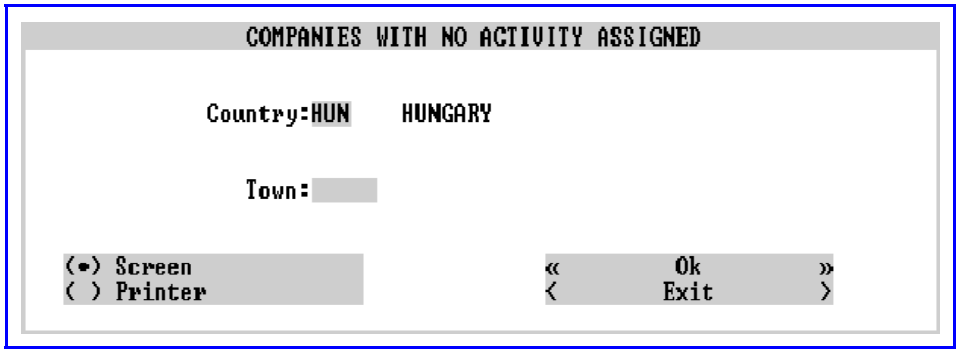


Figure 6-11: Companies with No Activities retrieval screen

6.2.8 Companies with One Activity

This retrieval option will list companies for which no other activity than the one selected has been recorded.

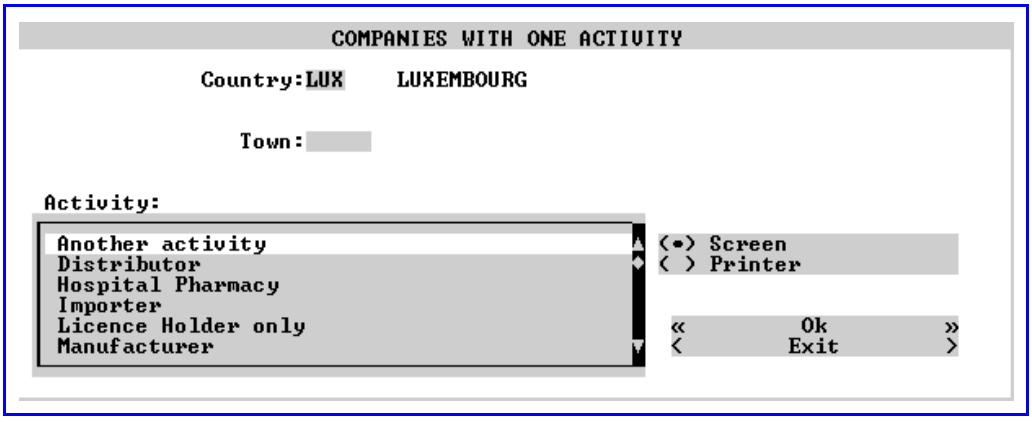


Figure 6-12: Companies with No Activities retrieval screen

6.2.9 Labels

The ability to retrieve labels from the system must be developed at the time of installation.

INSPECTIONS

Chapter 7

7. INSPECTIONS

The purpose of this menu option is to allow you to record the key outcome of inspections, which can be important for drug licensing work. The Inspections menu option consists of four components: Inspectors, Inspection Programmes, Inspection, and Retrieval.

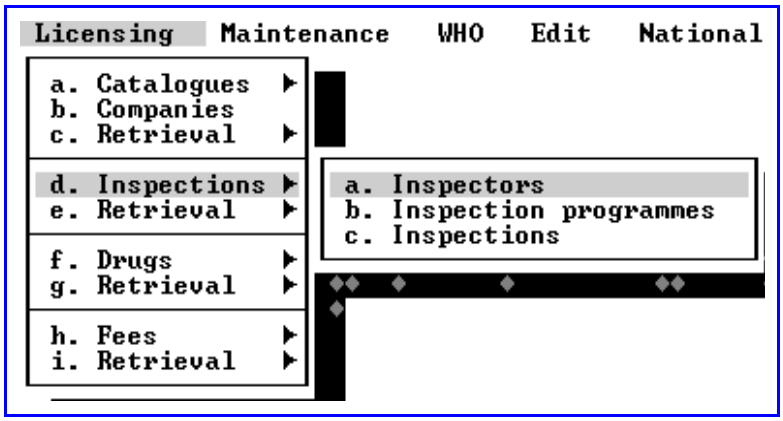


Figure 7-1: Inspections main menu

7.1 Inspectors

This relates to the inspectors and the type of activities and item groups they can inspect. In order to effectively utilize this feature to programme inspections, relevant data must first be entered into the system using the following screen.

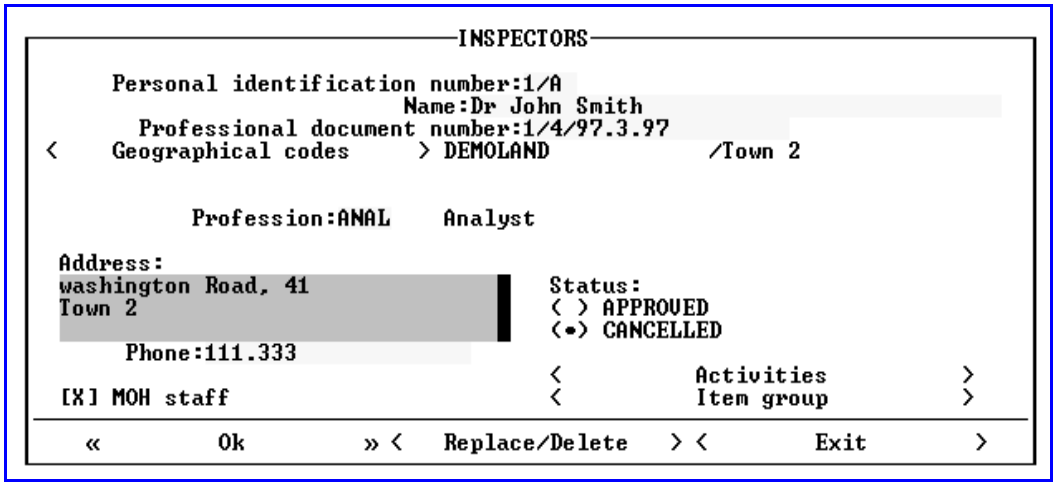


Figure 7-2: Inspectors sample screen

Below is a description of this screen:

Personal Identification Number	This is a unique identifying number which is given to each inspector.
Name	Enter the name of the inspector. By pressing **<F2>** you can also make a selection using the professionals file. ***Please note:*** There is no compulsory relation between the inspectors file and the professionals file, i.e. an inspector may or may not be included in the professionals file. If the inspector's name does not appear, continue to enter data into the fields indicated below.
Professional Document Number	This field indicates the unique licence number assigned to each inspector.
Geographical Codes	This field identifies the primary geographical area (i.e. country, region, district, or town) where the inspector is authorized to conduct business.
Profession	Select the profession for the inspector you are entering, using the list of options provided when you press **<F2>**.
Address	Type in the mailing address as it will appear on envelope labels.
Phone	The telephone number of the inspector.
Status	This field is used to indicate the status of the inspector. **Approved** means that he/she will be considered in computer- generated inspection programmes. **Cancelled**, means he/she will not be considered.
Activities	Selecting this button enables you to select the company activities (e.g. manufacturer, warehouse, distributor, etc.) that this inspector is qualified to inspect. You have the option of selecting all or deselecting all activities
Item Group	Selecting this button enables you to select the item groups (e.g. biologicals, injectable, etc.) that this inspector is qualified to inspect.
MOH Staff	Checking the MOH staff box indicates that this individual is a central level inspector. A non-checked box indicates that the inspector is a peripheral administration inspector. Check the box as appropriate.

Press the <<Ok>> button to add this entry to the catalogue. To enter additional inspectors,

repeat the data entry process, or press <Exit> to return to the main menu.

7.2 Inspection Programmes

This option permits you to generate a list of companies to be inspected. You also have the option of generating a list of proposed inspectors to conduct the inspection.

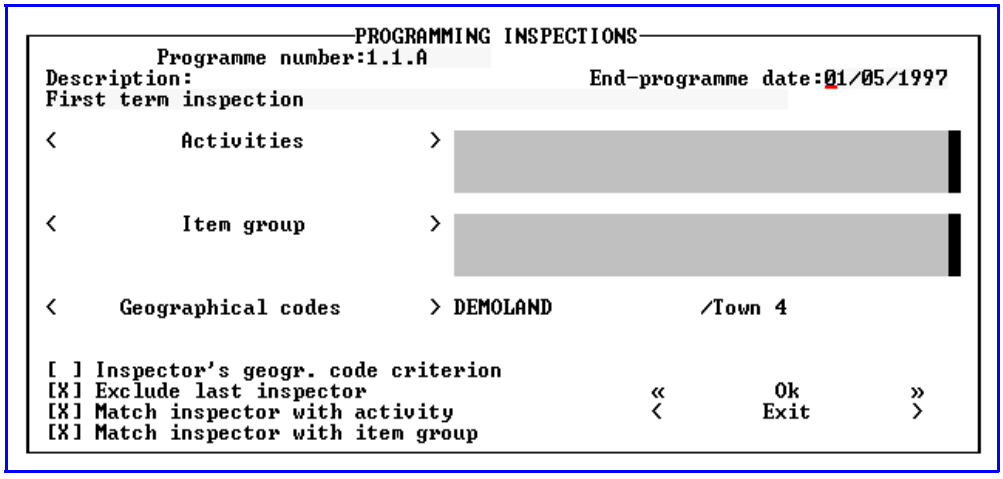


Figure 7-3: Programming Inspections screen

When you select Inspection Programmes, the screen Programming Inspections appears requesting the following data:

Programme Number

A unique number used to identify each programme. If creating a brand new program, enter the program number. If reviewing a predefined inspection program, press **<F2>** to select the programme.

In this latter case, an additional option box will be displayed giving you the following 3 choices:
<See Data> - If you wish to see existing data relating to this programme that was previously defined.
<Delete> - If you wish to delete the option.
<Go Back> - functions like the **<Esc>** (escape) key.

Description

A descriptive name for the inspection programme e.g. Insp. manufacturers of injectables, 1st quarter 1997.

End-programme Date

Enter the date on which the programme will end. The computer will use "today" as the starting date.

Activities

This option is linked to the Company Activities database. Selecting the <Activities> button, allows you to limit the selection of companies to one or more specific activity(ies).

Item Group

Selecting the <Item Group> button, allows you to limit the selection of companies to one or more specific item group(s).

Geographical Codes

Selecting the <Geographical codes> button, will allow you to limit the selection of companies to one specific geographical area. If no selection is made, all companies based in the country of installation will be included if they match the other criteria established under activities and item group.

Check Boxes

These fields are used to further narrow the search criteria. Checking any or all of the following boxes results in the following:

Inspector's Geographical Code Criterion - limit the selection of inspectors only to those of the geographical area selected;

Exclude Last Inspector - excludes those who last visited the company from the list of proposed inspectors;

Match Inspector with Activity - limits the selection of inspectors only to those qualified for the activity(ies) selected; and

Match Inspector with Item Group - to limit the selection of inspectors to only those qualified for the item group(s) selected.

Press << Ok >> for the computer to generate the list of companies and proposed inspectors.

In generating the list of companies and proposed inspectors based on the criteria you have entered, the computer considers the following elements:

- date proposed for next inspection at the time of last inspection,
- date of last inspection,
- degree of risk assigned to each company.

These three elements are taken into account as follows:

- for each company, the computer seeks the last inspection information
- if this is found, it checks whether a date was proposed for the next inspection. If one was proposed, and falls before the end of the programming period, the company is included in the list. If no date was proposed, the computer checks what degree of risk is assigned to this company. If the company has been assigned "Low risk," the computer checks whether date of last inspection plus 720 days falls before the end of the programming period, if so the company is included. The other degrees of risk are treated the same way substituting 540, 360 or 180 days for 720 as appropriate.
- if no information on a previous inspection is found, the company is included.

7.3 Inspections

The purpose of this catalogue option is to allow you to record the key outcome of inspections, which can be important for drug licensing work. The system allows you to enter notes that may arise from inspections or any particular decisions made during discussions following inspections.

Data entry involves selecting first the company and then the activity for which you wish to enter data. To guide in selecting, the activities for which the company is licensed are listed in the lower portion of the screen. Selecting a valid activity results in the appearance of a subsequent window where data can be entered.

SIAMED also permits the inspection results of the different company roles or activities to be entered separately. A situation can therefore arise where a company is permitted to continue with one activity e.g. wholesale dealing, but not permitted to manufacture as a result of an inspection.

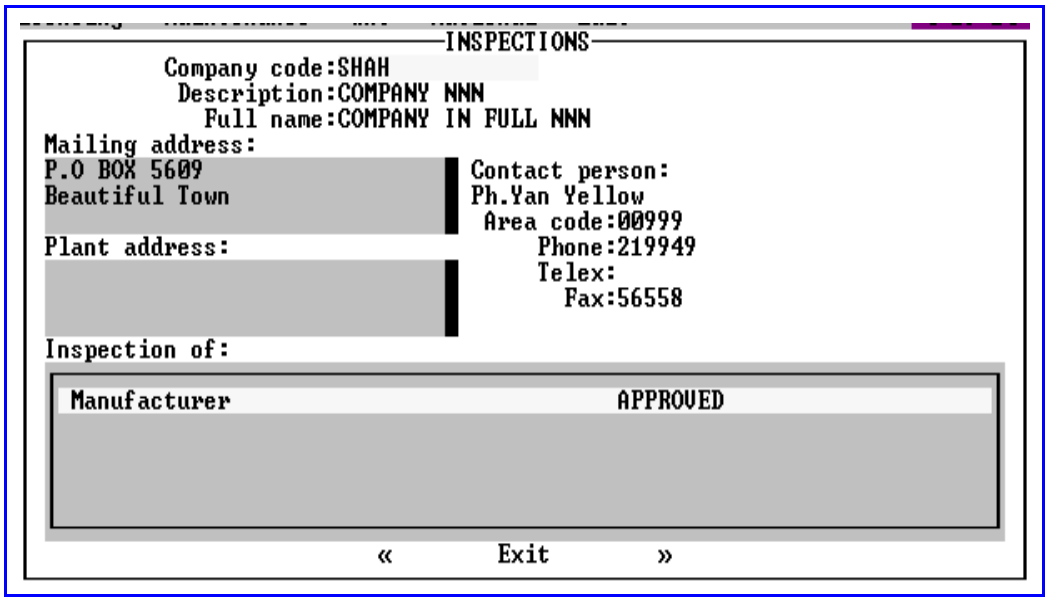


Figure 7-4: Inspections screen

The primary Inspections screen consists of the following data entry fields:

Company Code — A code that is uniquely assigned to each entity associated with the drug regulatory authority.

Name — Gives the name by which the company is referred, e.g., Roche

Full Name — Displays the full name of the company, institution, or entity to which the code has been assigned, e.g., Hoffman La Roche Pharmaceuticals, Inc.

Mailing Address Pertinent information regarding the location of the company/ institution, such as street number, street name, city, country, etc., as you would want it to appear on an envelope.

Plant Address Pertinent data regarding the physical location of the organisation's operating plant.

Contact Person Name of the person primarily responsible for managing all company activities.

Phone The organization's telephone number.

Telex Number utilized to send a telex communication to the organization.

Fax Telephone number used to send a facsimile (fax transmission) to the organization.

Inspection of This screen displays the current status of each activity defined for the selected company. Selecting the desired activity, displays a new window which allows you to retrieve or record information on inspections. See Section 7.3.1 for more details.

7.3.1 Inspection Details

Through this option, you can enter data concerning inspections for each given company activity. The criterion to distinguish between different inspections for the same activity is the date of inspection.

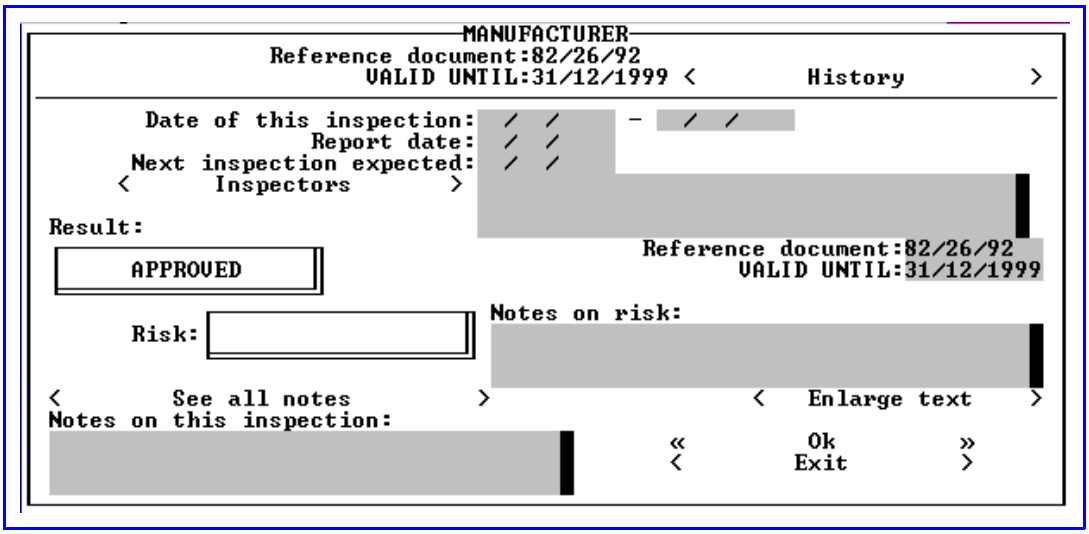


Figure 7-5: Inspection Details sample screen

The following is a discussion of all data entry fields in this screen.

Reference Document

This field displays the reference document number which was entered when creating the company entry. This field is **display only**, and cannot be edited here.

Valid Until

This field displays the date of validity of the authorization given for the activity you are working on (see Company data entry screen for more details). This field is **display only**, and cannot be edited here.

History

This button provides access to information on dates and results of all previous inspections ordered by the inspection date.

Date Of This Inspection

The date or dates of the current inspection. Enter valid dates for which the current inspection has been carried out.

Report Date

This date indicates the date on which the report is being completed.

Next Inspection Expected

The date on which the next inspection should occur.

Inspectors

This button provides access to the list of authorized inspectors and can be used to assign inspectors for this inspection. You may select one or all inspectors. After making your selection, press <Exit>, and the selected inspector(s) will be displayed in the adjacent text field.

Result

This pop-up field provides three choices for a summary result.

Approved - This result indicates the company has a valid operating licence, or if based abroad is accepted by implication.

Cancelled - This result indicates the company does not have a valid operating licence or, if based abroad, is not or no longer accepted for carrying out business in your country.

Term To Comply - This result indicates that following the results of an inspection, a delay has been given to comply with recommendations. If this result is selected, the *Valid Until* field becomes *Must Comply Before*: and requires that you enter a deadline date for the company to comply.

Reference Document

Each Result displays a reference document number to assist in retrieving information about the result. This field allows you to edit the number of the reference document.

Below the reference document field is a numerical date field whose title changes based on the status indicated in the Results pop-up window.

If the inspection concludes that the activity for which it was carried out IS performed consistent to the established requirements, then the summary result will be indicated as **Approved** and the date field title will display **'Valid Until'** to indicate the date of validity.

If the inspected activity IS NOT consistent with the established requirements, then the summary result will be indicated as **Cancelled** and the date field title will display **'On'** to indicate the date on which cancellation is effective.

If the inspected activity IS NOT consistent with the established requirements, but can be met within a certain time, then the summary result will be indicated as **'Term to Comply'** and the date field title will display **'Must Comply By'** to indicate the date limit for complying with the recommendations issued by the inspector(s).

Risk

Select a risk level that may be associated with the inspection. Your options are *Very Low Risk*, *Low Risk*, *Moderate Risk*, *High Risk*, and a blank field to indicate no risk. Use the Notes on risk field to provide any details on the risks associated with conduction the inspection. **For example:**, if the inspection includes a high-risk of exposure to a carcinogen, select the High Risk level, and enter any notes and precautions necessary in the text box to the right.

See All Notes

This button provides access to a text window that displays all related inspection information pertaining to the selected company. All notes are stored in the same text file so that it is easy to make reference to results of previous inspections, and to notes written while entering company data in the company file.

Notes on this Inspection

This text box may be used to type in any free notes to give more details of the results of the inspection.

Select <<Ok>> to save your data and return to the previous Inspections screen. <Exit> will return you to the Inspections screen without saving any changes.

7.4 RETRIEVAL: Inspections

The Retrieval feature under the Inspections menu option gives access to submenu entries permitting you to produce a list of inspectors, retrieve inspection information, and to produce a list of companies that have never been inspected.

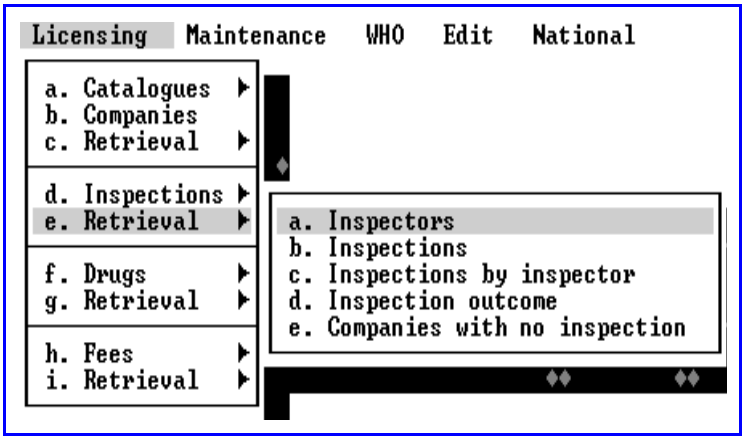


Figure 7-6: Retrieval: Inspections menu

7.4.1 Inspectors

This retrieval option permits you to produce a list of inspectors. It also allows you to limit the search to a given geographical area (i.e. country, region, district, or town).

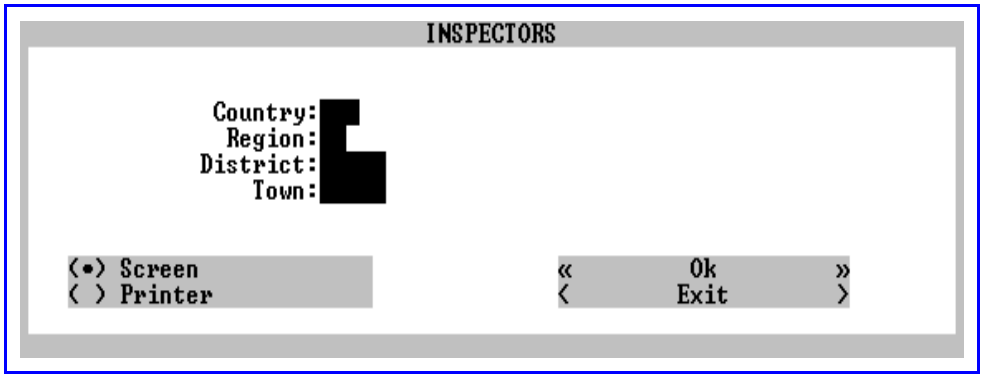


Figure 7-7: Retrieval by Inspectors

Country/Region/ District/Town — Specify the geographical area to be included in the retrieval process. Pressing **<F2>** or clicking the right mouse button will reveal a pop-up window from which you can select a country.

Once the search criteria is established, you can determine if you want to display the output on screen or send it to the printer.

7.4.2 Inspections

This retrieval option permits you to retrieve information on various inspections. This process can be carried out through different grouping criteria. The search criteria options are as follows:

- the search can be related to one company, or to ALL companies by simply leaving the company field blank,
- the search can be limited to one or more specific activity or open to all
- the search can be limited to companies based in one specific country or region,
- the search can be limited to companies having a given status (approved, cancelled, term to comply), or
- the search can be carried out within a given range of inspection dates.

The criteria are set based on the information you input on the screen.

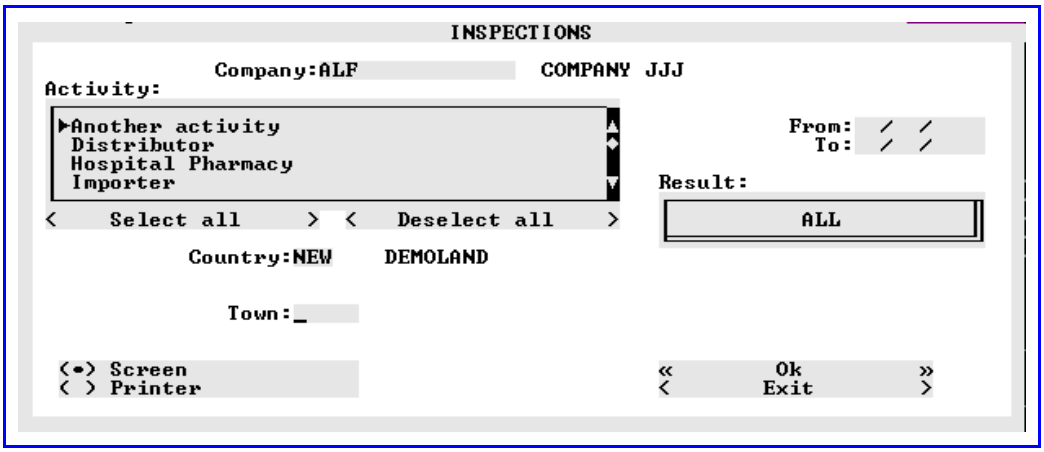


Figure 7-8: Retrieval by Inspections screen

Company — The name of the company to be included in this search. Leaving the company field blank includes ALL companies in the search.

Activity — Specify what activity(ies) should be included i.e. manufacturer, distribution, etc. If you wish to include all activities, click the **<Select All>** button below the activity window.

Country/Region/ District/Town — Specify the geographical area to be included in the retrieval process. Pressing **<F2>** or clicking the right mouse button will reveal a pop-up window from which you can select.

From/To (date) — Specifies the date range in which the inspections were performed.

Result

Allows you to retrieve information only for companies that have a specific status:
Approved - This result indicates the company has a valid operating licence, or if based abroad is accepted by implication.

Cancelled - This result indicates the company does not have a valid operating licence or, if based abroad, is not or no longer accepted for carrying out business in your country.

Term To Comply - This result indicates that following the results of an inspection, a delay has been given to comply with recommendations.

Once you have selected the criteria you want to apply, select where the output should go and press << Ok >>, and the report will be generated.

7.4.3 Inspections by Inspector

This retrieval option permits you to retrieve information on which inspectors performed which inspections.

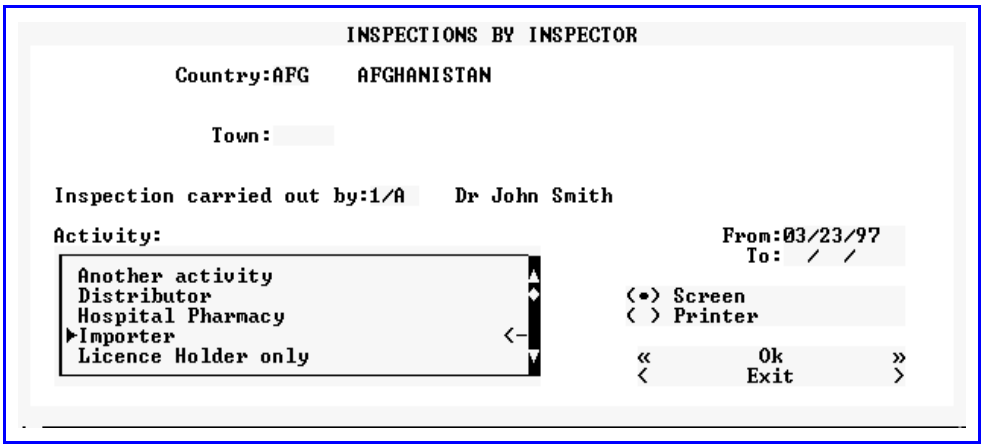


Figure 7-9: Inspections by Inspectors screen

Below is a description of the fields associated with this screen.

Country/Region/ District/Town

Specify the geographical area to be included in the retrieval process.

Inspection Carried Out By

Gives the code assigned to the Inspector who conducted the inspection.

Activity

Specify what activity area should be included i.e. manufacturer, distribution, etc.

From/To

Specify the date range in which the inspections were performed.

Once you have selected the criteria you want to apply, select where the output should go and press <<Ok>>, and the report will be generated.

7.4.4 Inspection Outcome

This retrieval option permits you to retrieve information on the outcome of various inspections. It also allows you to limit the search to a given geographical area.

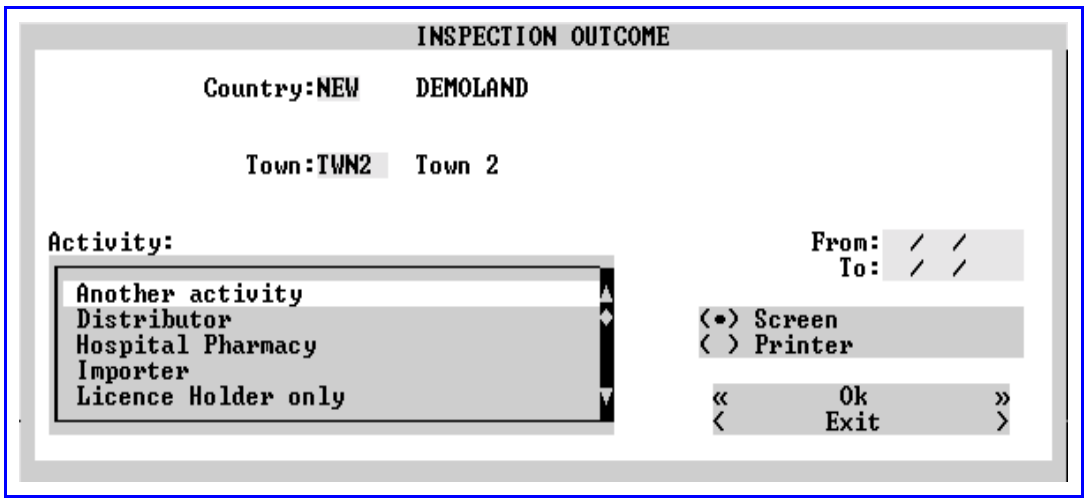


Figure 7-10: Retrieval of Inspection Outcome

The data to be entered is as follows:

Country/Region/ District/Town — Specify the geographical area to be included in the retrieval process.

Activity — Specify what activity area should be included i.e. manufacturer, distribution, etc.

From/To — Specify the date range in which the inspections were performed.

Once you have selected the criteria you want to apply, select where the output should go and press << Ok >>, and the report will be generated.

7.4.5 Companies with No Inspection

This retrieval option permits you to retrieve information on the companies that have not been inspected. It also allows you to limit the search to a given geographical area, and specify which activities should be included.

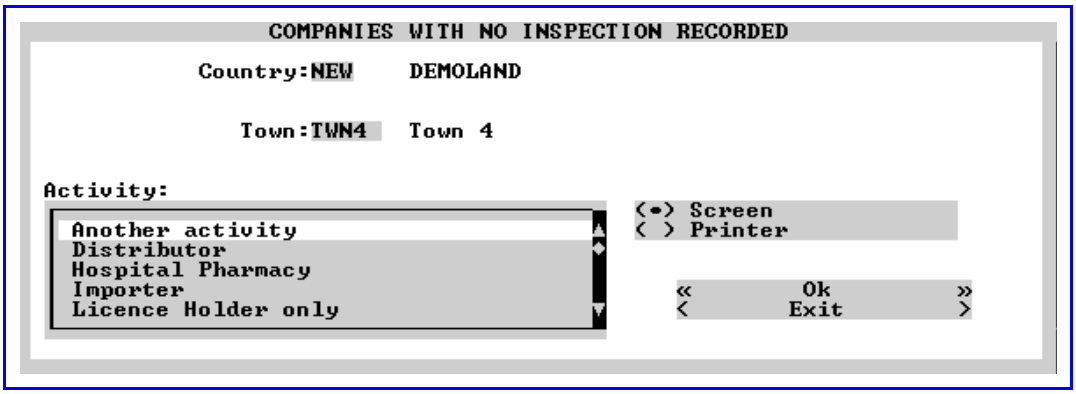


Figure 7-11: Companies without Inspection screen

Country/Region/ District/Town — Specify the geographical area to be included in the retrieval process.

Activity — Specify what activity area should be included i.e. manufacturer, distribution, etc.

From/To — Specify the date range in which the inspections were performed.

Once you have selected the criteria you want to apply, select where the output should go and press << Ok >>, and the report will be generated.

Chapter 8

8. DRUGS

The Drugs menu is divided into 5 basic functional sections that handle entry and updating of applications for new marketing authorizations, issue of new marketing authorization, revalidation/renewal of existing marketing authorization, variations to existing marketing authorizations, and two miscellaneous actions - changing applicant/holder or manufacturer name in all drug screens and deleting licences. These functional areas are detailed in this section

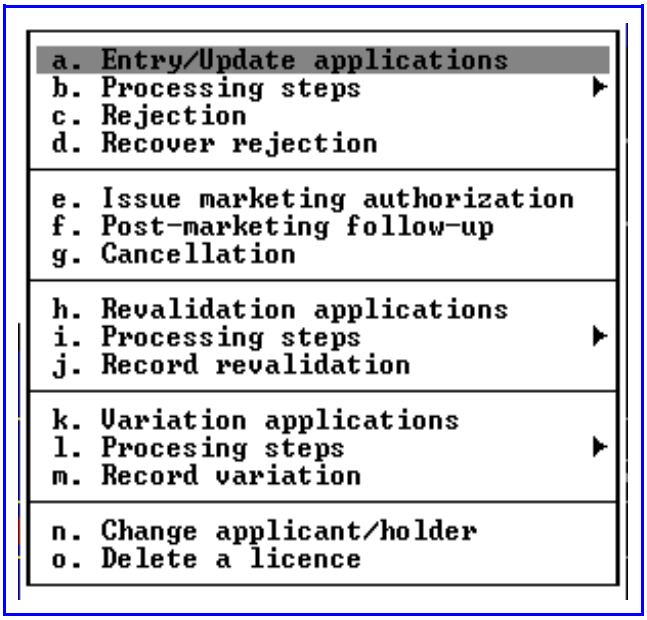


Figure 8-1: Drugs main menu

8.1 Entry/Update Applications

This option is the key part of SIAMED. It is from here that all entries on drug products are first created. The Entry/Update application options listed here below, permit you to perform various operations on drug licence applications.

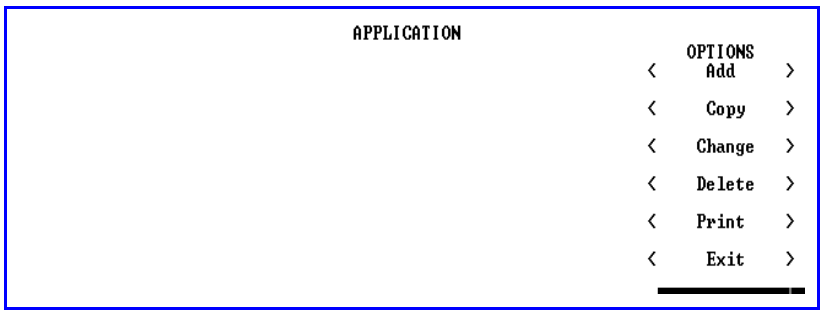


Figure 8-2: Entry/Update Application screen

To select the operation to perform, either point to the operation and click the left mouse button on the required option, or highlight it using the keyboard <**Tab**> or arrow keys and

press **<Enter>**. A basic overview of each operation is described below.

ADD Used to create a new entry

COPY Used to create a new entry by copying an existing application or licence.

CHANGE Used to alter any data (except the application number) in an application after it has been entered.

No data can be changed from this menu option once an application has been rejected or approved into a licence. However changes can be recorded through the Variations to licences menu option. ***NOTE:*** The history of variations to licences is recorded in a separate file together with date and password in use while the variation was entered.

DELETE This option is used to remove an entry from the file, leaving no record of it. Thus, its application number can be used again (except in automatic numbering mode). Data can not be edited in this mode.

PRINT Prints, in draft form, all information entered regarding an application. Data can not be edited in this mode.

EXIT Returns you to the main menu.

All of these functions utilize the same screen. However, in the case of the Copy option, the screen shown below appears prior to the standard drug screen.

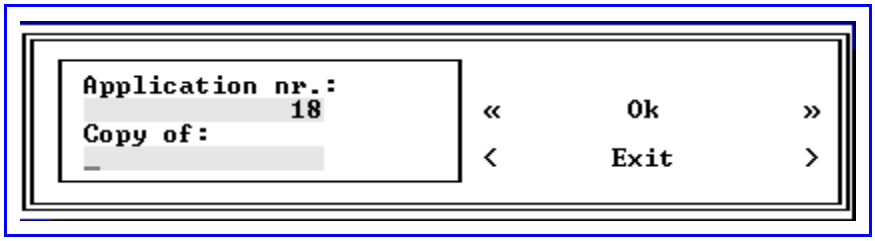


Figure 8-3: Screen used to initiate the Copy process.

Application Nr Enter the application number that you will use for your new entry.

Copy of: Enter the application number that you wish copy in order to add a new entry, and press **<F2>** to select the application or licence from the list.

Below is the standard drug screen which appears when you add a new entry (Add), add a new entry by copying an existing application/licence (Copy), update (Change), delete or print an existing application. In all cases, the mode (Add, Copy, Change, Delete or Print) is always shown on the upper right hand corner of the screen.

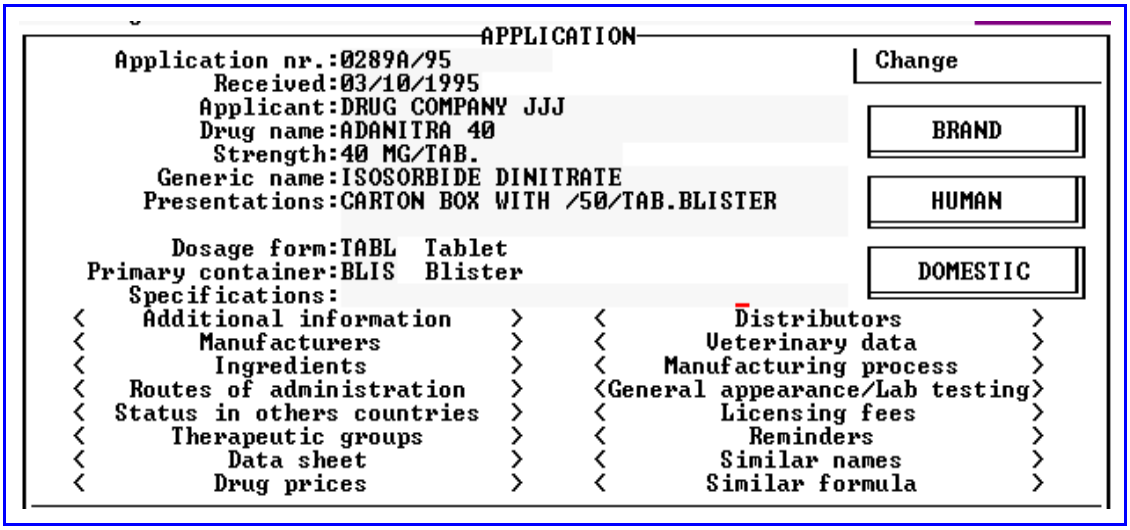


Figure 8-4: Drug Application screen

Below is a description of each field on the screen.

Application Nr — A number unique to a particular product. This number can be a maximum of 15 numbers or characters, and can not be duplicated within the system in the Add mode. You will be warned if the number already exists in the system. If you have selected automatic application numbering in the configuration, a computer-generated number will appear and you will not be able to enter anything in this field.

Received — The date on which the application has been received. By default the system proposes today's date.

Applicant — The name of the company submitting the application. You can press **<Enter>, <F2>** or click the right mouse button to get a list and select the desired item.

Drug Name — The label name of the product, which may be the generic name. The name can be a maximum length of 70 numbers and/or characters.

Strength

Describes the strength of the product as per label. Description can not exceed 20 characters. In the case of fixed dose combinations where stating each individual strength would be confusing, it is suggested that you type COMBINATION or MULTIPLE in this field.

Generic Name

In this context, generic name is meant as a name by which all drug items (generally only drugs with one or two active ingredients) with the same or equivalent active ingredient can be identified as a group. See Glossary for additional details on Generic Name.

For example: ERYTHROMYCIN can be chosen as generic name for all drugs containing any salt of erythromycin. This would permit you to retrieve all these drugs as a group using the generic name as a single searching criterion. In addition, combining generic name with strength and dosage form as searching criteria would permit you to retrieve all drug items that, in principle, should be therapeutically equivalent.

In the case of fixed dose combinations where stating the generic name of each individual active principle would be confusing, it is suggested to leave the field blank or enter general labels. *Example:* multivitamin, minerals, see formula, etc., as appropriate. See notes on Generic Names catalogue.

To enter a generic name, you may type in the generic name of the drug, press **<F2>** or click the right mouse button to see a list of existing generic names. You can also press **<F3>** to see the substance names file from where a name can be selected (and then edited if necessary) to be used as the drug generic name.

Unlike other catalogues, new generic names can be created during drug application data entry with the system adding them automatically to the catalogue. Users must be careful not to create unnecessarily large numbers of generic names.

When determining generic name, it is strongly recommended that the information provided below be given careful review.

Drug Products with Only <u>One</u> Active Ingredient

In this case, the generic name is the name of the base that constitutes the active ingredient, regardless of the form used in the formulation - unless a specific salt has unique therapeutic uses unrelated to those of the base. For example: The generic name, ampicillin, applies to all drugs containing either ampicillin trihydrate, ampicillin sodium, ampicillin hydrochloride, etc.

This simplification applies only to the generic name field of an application. It does not limit the possibility for users to record the full name and quantity of the active substance(s) in the ingredient fields. Thus, searches can be based on either the generic name or the individual full substance names of the ingredients.

Drug Products with Two Active Ingredients

In this case, the generic name reflects the names of the base that constitutes the two active ingredients, regardless of the form used in the formulation - unless a specific salt has unique therapeutic uses unrelated to those of the base.

These two names need to be entered in the same field. It is therefore recommended that, to avoid repetitions, a fixed format is used to enter them. For example, one could use a plus sign to separate the two names and enter them only in alphabetical order: e.g. amoxycillin+clavulanic acid instead of clavulanic acid+amoxycillin.

Drug Products with *More Than Two* Active Ingredients

Building a generic name by adding those of the individual components is not practical. In addition, it is infrequent that a rational drug has three or more active ingredients. The proposed approaches are these:
1) enter, in the generic name field, the same predefined term for all drugs e.g. combination, see composition, or
2) enter an arbitrary term to indicate a loosely homogeneous group, and use a predefined term for those drugs for which an homogeneous group is not easily identified e.g. multivitamin, minerals, minerals+multivitamin, electrolytes, electrolytes+glucose, cold preparation, combination, see conposition.

The use of these arbitrary generic names does not limit search on the basis of an individual ingredient name. On the other hand, it contributes to establishing searching criteria that permit you to group together drugs that have the unusually large number of active ingredients in common.

Presentations

This is a free text field of unlimited length. It is used to describe the different presentations of the drug as appropriate. *Example:* bottle with 30 capsules; box with 10 dark glass ampules plus 10 solvent clear glass ampules; bottles with 30, 50, and 100 tablets; etc.

NOTE: Assigning separate application and licence numbers to each individual presentation of the same product is technically more rigorous and offers the obvious advantage of making much simpler drug utilization and consumption studies. On the other hand it requires a little more work in the drug registration process. The choice between one option and the other is left with the licensing authority.

Dosage Form

Enter the code of the dosage form, or either press **<F2>** or click the right mouse button to get a list and select the desired item.

Primary Containers

Type in the code of primary container, or either press **<F2>** or click the right mouse button to get a list and select the desired item.

Specifications

Refers to characteristics of primary container. *Example:* dark glass, scored ampule, etc. Maximum length 70 characters.

The screen also displays three “pop-up” boxes which perform the following functions:

Generic/ Brand

Displays a pop-up menu which allows you to specify whether the product is a generic product or a brand name.

Branded generic products would fall either under brand because they are not labeled with the generic name only, or under generic depending on national regulations.

Human/ Veterinary

Select the option that is appropriate to describe whether the drug is for human use or veterinary use.

Domestic/ Imported/ Both

Select the option that is applicable in your national context.

The screen also displays 16 additional options that allow you to provide more detailed information about the current application. Each of these options, when selected gives access to an additional window that contains more data field. To select an option, simply click the desired screen button and enter the data requested. The following is a description of the subsequent screens that appears when a selection is made.

8.1.1 Additional Information

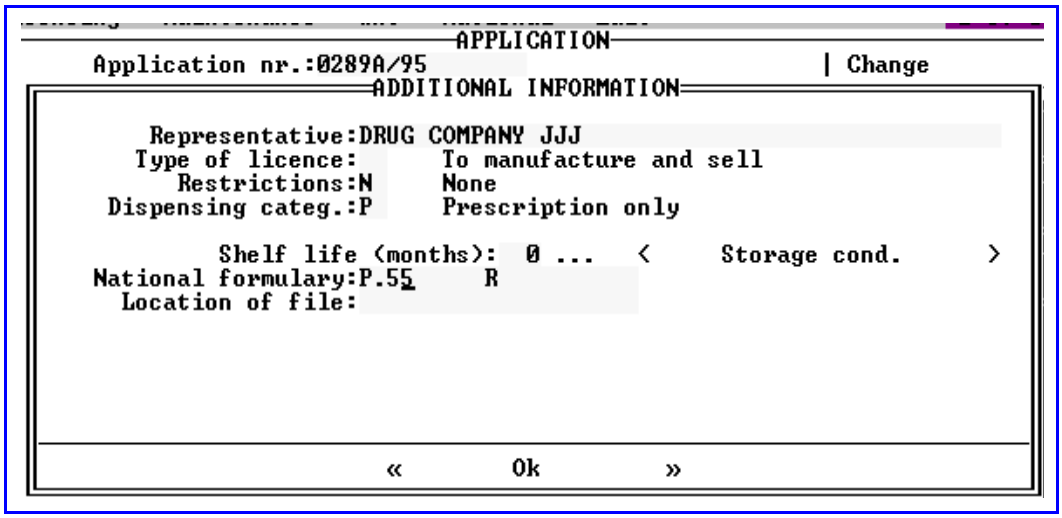


Figure 8-5: Additional Information screen

Representative

This field may be left blank if it is the same as the company on the original application screen, if the company submitting the application is being represented by a separate company enter the other company's name here. You can press **<Enter>, <F2>** or click the right mouse button to get a list and select the desired item.

If the concept representative is irrelevant to your national context, you can ignore this field or simply assign it whatever function that is meaningful to you. It is just an option that permits to relate a second company to an application.

Type of Licence

This field indicates the type of licence. This field is linked to the type of licence catalogue. Pressing **<F2>** or clicking the right mouse button will provide a list of options from which you may select.

Restrictions

This field indicates if there are any restrictions that are placed on the distribution of the drug product. Press **<F2>** or click the right mouse button to get a list of restrictions and select the desired code. This field is linked to the availability restrictions catalogue.

Dispensing Category

This field is used to specify the dispensing category for this particular application and is linked to the dispensing category catalogue. Press **<F2>** or click the right mouse button to get a list of dispensing categories and select the desired code.

Shelf Life Type in the number of months of shelf life established by the manufacturer and approved by the licensing authority. When the available information is insufficient to make a decision, a symbolic figure or zero should be entered. Press the <Storage conditions> button to enter unlimited notes about storage conditions and shelf life information. See below.

Storage Conditions Selecting this button results in a window where you can type unlimited information about storage conditions.

National Formulary Type in a national formulary/list code or reference number, if applicable. This field permits to link the drug registration database with another database such as procurement or reimbursement list.

Location of File Used to indicate where the physical file(s) can be found.

The optional fields set at configuration would also appear in this screen. The contents of any of these fields are defined by the user. The system is set up to allow retrieval of information using these fields as searching criteria. Once all data is entered, press << Ok >> to return to the main entry screen.

8.1.2 Manufacturers

This option is used to provide detailed information about any and all manufacturer's of the drug item that has been identified for this application.

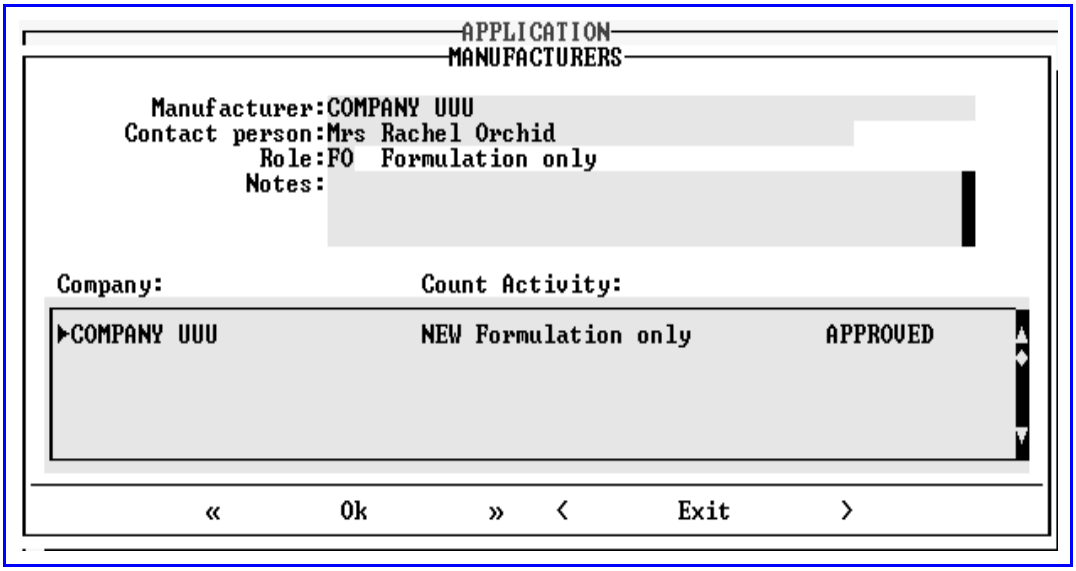


Figure 8-6: Application/Manufacturer's screen

Manufacturer This field is for the name of any company that is involved in the manufacturing process of the drug listed on the application. Press <**F2**> or click the right mouse button to get a list and select the desired item. This can be chosen only from those companies for which the activity manufacturer has been selected during data entry for companies, and whose status is different than cancelled. Users may enter any number of manufacturers for each application.

Contact Person The responsible individual who handles company activities.

Role Indicates what part of the production process is carried out by each company participating in the production of the drug being entered. This information is taken from the roles entered in the manufacturer role catalogue.

Notes A free text field used to record free notes of any length (only limit being hard disk space).

To complete the entry, press <<Ok>>. Summary information on manufacturer(s) entered appears in a "manufacturers window" placed in the lower part of the screen. Clicking with the mouse on any company that appears in that window will permit you to edit data of that company or delete it. You can also edit or remove a manufacturer from that window by typing in its name again at the manufacturer name prompt, or <**Tab**> as many times as is necessary to highlight the manufacturer's window and move to the company you want with the arrow keys. To return to the main application entry screen, simply press <Exit>.

8.1.3 Ingredients

Both active and inactive ingredients are entered here. There is no limit to the number of ingredients that can be entered. Provisions have been made to accommodate drugs (e.g. some oral contraceptives) that have multiple formulae in the same presentation.

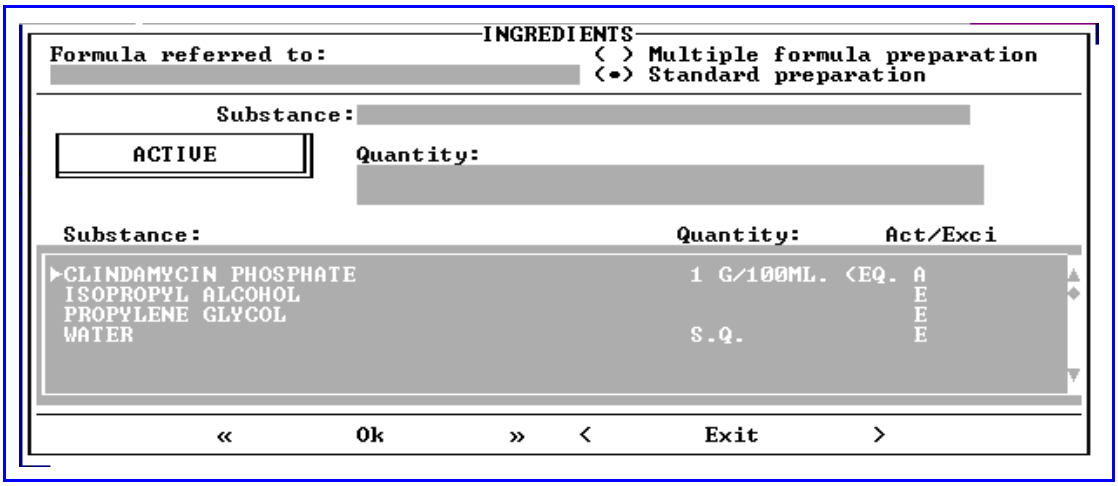


Figure 8-7: Application/Ingredients screen

Formula Referred To

This field is used to describe what unit the formula is referred to. For example: "Each tablet contains," "5 ml contain," "one sachet contains," "one metered dose delivers," etc.

Multiple Formula Preparation/ Standard Preparation

Select the appropriate option between multiple formula preparation and standard preparation. We have called multiple formula preparation a drug, like some oral contraceptives, where the same container comes with tablets of different appearance that have different formulae. If you select Multiple Formula Preparation, see detailed information below.

Substance

Enter the ingredient name. This can be accomplished using one of the following options.

1. Type in the name of the ingredient and press **<Enter>**. It may seem to be the simplest and easiest way, but it is not always so. See options b and c.
2. Press **<F2>** or click the right mouse button to get a list and select the desired item. This is the preferred option.
3. Type part of the name of the ingredient and press **<F3>**. A list will appear showing only substance names containing the string you have entered regardless of its position in the name (i.e. entering "AMPI" will display ampicillin, bacampicillin etc.). Select the item you need.

If the substance name you entered or selected is accepted by the system, it means that the name had already been previously used and established as Preferred National Name. If the name you typed in **is not** accepted, you should first look for synonyms in the substance names dictionary by pressing **<F2>** or right mouse button. If you do not find any synonyms, or if the one you find is not convenient for you, then you need to add the new substance name to the system. See Section 5.13.

Active/Excipient/ Other Indicate whether the ingredient is Active, Excipient or Other (other is meant to help differentiate excipients to be mentioned on the label like alcohol, tartrazine, amaranth etc.).

Quantity Enter the quantity of such ingredients in free text space (up to 90 characters).

Press <<Ok>> to save your entry and it will appear in an "ingredients window" together with its quantity and the indication of Active, Excipient or Other. All subsequent ingredients will appear in that window the same way. Ingredients listed in the window can be edited or deleted by clicking on them or retyping their name at the substance prompt, or **<Tab>** as many times as is necessary to highlight the ingredient's window and move to the item you want with the arrow keys. When all ingredients have been entered you can return to the main application entry screen by pressing <Exit>.

8.1.3-1 Multiple Formula Preparations

If you selected multiple formula preparations you do not need to enter anything in the field labeled 'Formula referred to' placed at the left upper corner of the screen.

After selecting multiple formula preparation, enter in the substance field, as is done for normal formulations, all ingredients regardless of their presence in all units of the preparation (example: for a preparation of 7 tablets with ingredients A and B, and 7 tablets with ingredients A and C, enter ingredients as if all tablets contained A, B and C) without specifying quantity.

When entry of ingredients is completed, a field will appear where in an unlimited-size free text form you can type the exact formulae with number of units etc. as you want it to appear on the printouts. It is probably better to format your text so as to get a nicer presentation of the formula.

The requirement to enter ingredients in the ingredient field as it is done for normal formulations has been set to enable the system to search by ingredient(s) although the formula is displayed as entered in the free text field.

8.1.4 Routes of Administration

An unlimited number of routes of administration can be entered for each application.

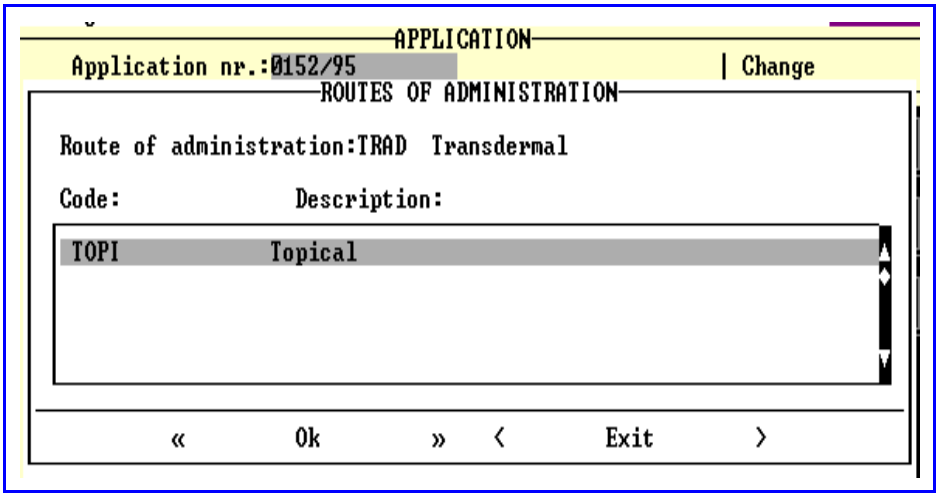


Figure 8-9: Application/Route of Administration screen

Routes of Administration

This field is linked to the Route of Administration catalogue. Type in a code and press <**F2**> to obtain a list of the items in the routes of administration catalogue file.

Press <<Ok>> to save your entry, and it will appear in a window in the lower part of the screen. Selecting an item listed in the bottom portion of the screen, and double clicking on it, reveals a window option to <Delete> the entry, or <Go Back> one step. Items listed in the "Routes of Administration" window can be deleted by double clicking on any item and selecting <Delete>. When all information has been entered, press <Exit> to return to the main application entry screen.

8.1.5 Status In Other Countries

This option offers free text fields where users can record notes about the regulatory status in other countries or any other information drawn from authorities of other countries which is considered relevant for decision making in the drug registration process. An unlimited number of references about regulatory status of the drug in other countries can be entered for each application. This is an optional field to be set at configuration.

Country This field is linked to the countries catalogue. Press <**F2**> to obtain a listing of countries, and select the desired country.

Date Type in the date on which such information was valid.

Notes Free text field for additional information.

Press <<Ok>> to save your entry, and it will appear in a window in the lower part of the screen. Selecting an item listed in the bottom portion of the screen, and double clicking on it, reveals a window option to <Change> or <Delete> the entry, or <Go Back> one step. Items listed in the "Status in Other Countries" window can be deleted by double clicking on them and selecting <Delete>. When all information has been entered, press <Exit> to return to the main application entry screen.

8.1.6 Therapeutic Groups

This option is used to specify the various therapeutic classes under which a drug may fall based on its clinical use. An unlimited number of therapeutic groups can be entered for each application.

Group This code specifies the therapeutic group in which the drug item submitted on the current application can be categorized. Press <**F2**> or click the right mouse button to get a list and select the desired item.

Press <<Ok>> to save your entry, and it will appear in a window in the lower part of the screen. Selecting an item listed in the bottom portion of the screen, and double clicking on it, reveals a window option to <Delete> the entry, or <Go Back> one step. Items listed in the "Therapeutic Groups" window can be deleted by double clicking on them and selecting <Delete>, or <**Tab**> as many times as is necessary to highlight the therapeutic group's window and move to the item you want with the arrow keys. When all information has been entered, press <Exit> to return to the main application entry screen.

8.1.7 Data Sheet /Product Information

This is an optional field to be set at configuration. It offers an unlimited-length text for indications, contraindications, etc. Information can be either typed in, or imported from an ASCII file, submitted by applicants or drawn from any other source, which of course can be edited. ASCII format is an output mode provided by virtually all word processing packages sometimes also called DOS text mode, or text file, or ASCII file.

Importing files which are not in the ASCII format may be impossible, or may require long editing work to render text readable. In addition to importing an entire file, you can also open an external text file while working on the data sheet. You can select and transfer parts of such file to the data sheet. To provide an example of this feature, some text files have been added to the system under the WHO menu pad.

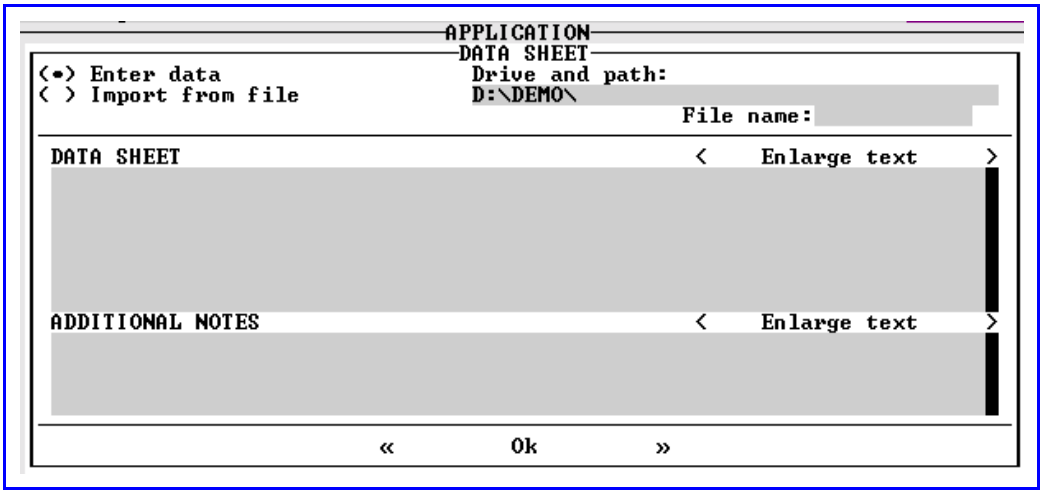


Figure 8-10: Application/Data Sheet screen

Enter Data — If this option is selected, you may then use the Data Sheet and additional free notes screen below to enter or edit the data sheet.

Import from File — If this option is selected, you will need to specify the drive, the path and the file name. Keep in mind that this file should be an ASCII or text file. Press <F3> to view new listing of files in directories. Use copy (**<Ctrl>+<C>**) and paste (**<Ctrl>+<V>**) to import the data.

Data Sheet — You may use this free text box to enter any detailed information regarding indications, contradictions, known reactions or any other pertinent information relating to the drug specified in this application.

Additional Notes — This free text field may be used to provide any additional information not listed in the data sheet section. The information here commonly refers to any information that the licensing authority may wish to link to an application or licence without having it to appear on licence certificates or data sheets.

For additional information on using the data sheet see the Appendix.

8.1.8 Drug Prices

Drug Prices allows you to record several different types of prices for each application, if applicable in your national context. This permits you to link a variety of prices to each application, e.g. price at importation, maximum retail price, hospital price, maximum wholesale price, etc.

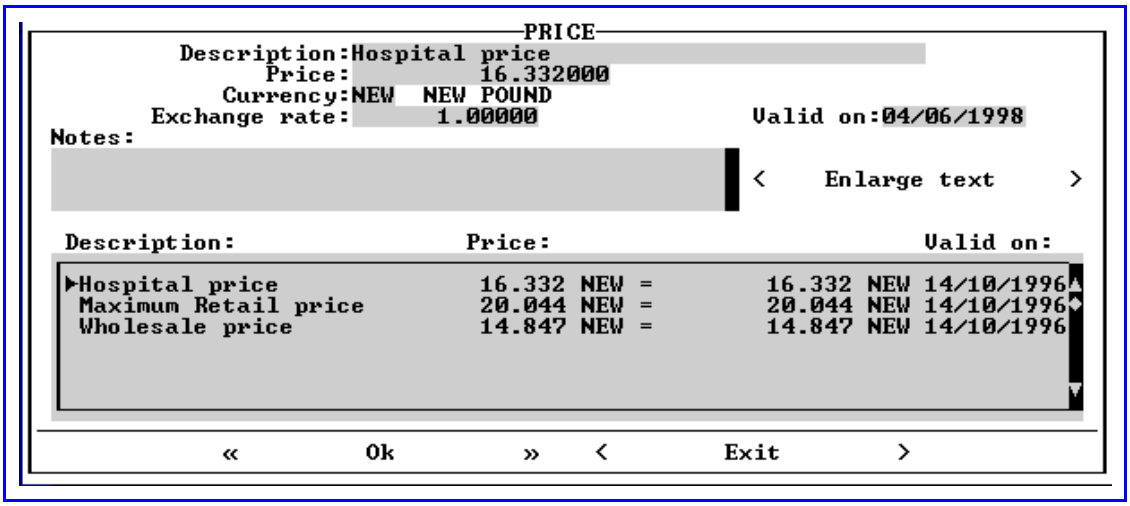


Figure 8-11: Application/Drug Price screen

Description — This field describes the price type. Hospital price, maximum retail price, and wholesale price description are examples of price descriptions. This field is linked to the types of price catalogue, therefore pressing **<F2>** will allow you to select a price description from the available entries in the catalogue.

Price — Use this field to enter the price of the drug for this particular description.

Currency — This field displays the currency in which the above price is quoted. This field is linked to the currency catalogue, therefore selecting **<F2>** will provide you with a list of currencies that have been entered in the original catalogue system.

Exchange Rate — The currencies exchange rate for the item will be automatically displayed in this field, if a currency was selected from the currency catalogue.

Valid On — This field displays the date on which the exchange rate is valid. This date will automatically be displayed if a selection is made from the currency catalogue.

Notes — This is a free text field that allows you to enter any additional information relating to the pricing standards for this particular drug.

Press <<Ok>> to save your entry, and it will appear in a window in the lower part of the screen.
Selecting an item listed in the bottom portion of the screen, and double clicking on it, reveals a window option to <Change> or <Delete> the entry, or <Go Back> one step. Items listed in the "Drug Prices" window can be deleted by double clicking on them and selecting <Delete>, or <**Tab**> as many times as is necessary to highlight the drug price's window and move to the item you want with the arrow keys. When all information has been entered, press <Exit> to return to the main application entry screen.

8.1.9 Distributors

Distributors can be chosen only from those companies for which the activity distributor has been selected during data entry for companies. Users may enter any number of distributors for each application.

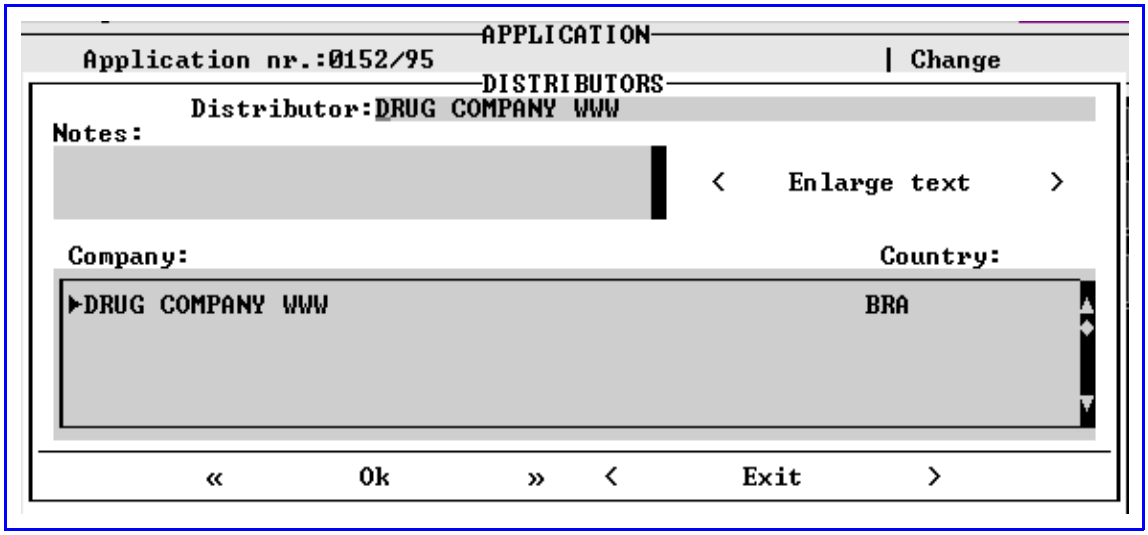


Figure 8-12: Application/Distributor screen

Distributors To enter the full name of the company, you can either type it in, press <**F2**> or click the right mouse button to get a list and select the desired item

Note Free text field for additional information.

To complete the entry press <<Ok>>. Summary information on distributors entered appears in a "Distributors" window placed in the lower part of the screen. Selecting an item listed in the bottom portion of the screen, and double clicking on it, reveals a window option <Delete> the entry, or <Go Back> one step. Items listed in the "Distributors" window can be deleted by double clicking on them and selecting <Delete>, or <**Tab**> as many times as is necessary to highlight the distributor's window and move to the item you want with the arrow keys. When all information has been entered, press <Exit> to return to the main application entry screen.

8.1.10 Veterinary Data

This windows displays a free text field in which unlimited information can be entered relating to veterinary drugs or the veterinary use of human drugs, e.g. withdrawal periods, species- or animal product-related information.

Retrieval of veterinary data is performed by searching words in the entire text. Thus, it is important to assure consistency of terms used in data entry to get meaningful retrieval.

8.1.11 Manufacturing Process

This option permits you to enter critical information, if any, regarding important steps of the manufacturing process. Information is entered as free text.

Retrieval of manufacturing process information is performed by searching words in the entire text. Thus, it is important to assure consistency of terms used in data entry to get meaningful retrieval.

8.1.12 General Appearance/ Laboratory Testing

This option permits you to enter critical information, if any, regarding the general appearance of the drug, its organoleptic characteristics, and analytical methods for quality control purposes.
Information is entered as free text.

Retrieval of general appearance/lab testing information is performed by searching words in the entire text. Thus, it is important to assure consistency of terms used in data entry to get meaningful retrieval.

8.1.13 Licensing Fees

This option allows you to list the various licensing fees that are related to the specific application. An unlimited number of fees can be entered for each application.

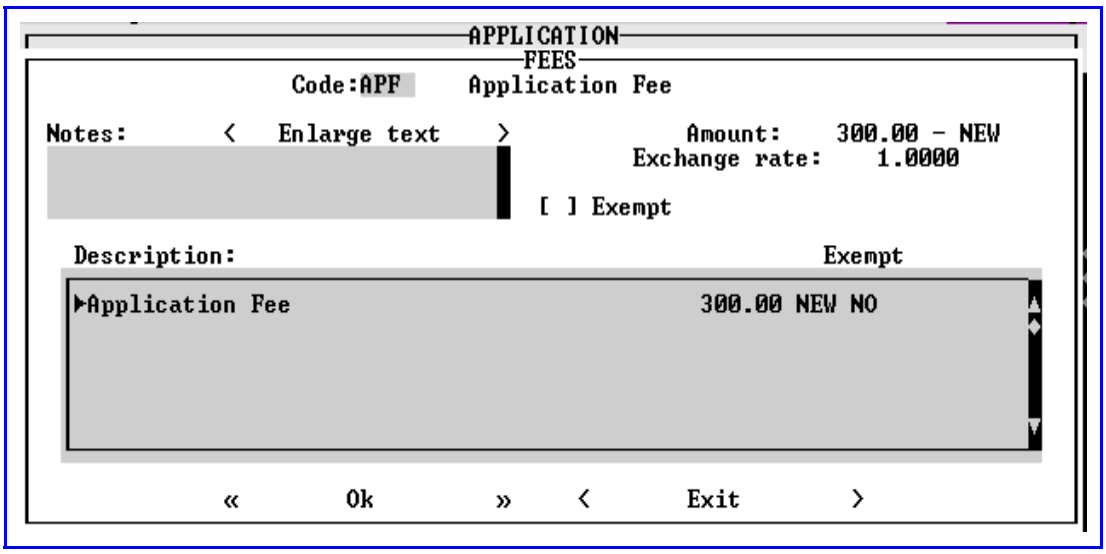


Figure 8-13: Application/Licence Fees screen

Code — The unique code for the fees. This option is linked to the Fees catalogue, therefor pressing **<F2>** will reveal all options listed in this catalogue and you can select the desired fee. Once selected, information on the amount of the fee, and the exchange rate will be displayed.

Notes — This is a free text field which allows you to enter any additional information relating to the selected fee for this particular application.

Exempt — Check the Exempt check box in cases where an application is exempt from fees.

To complete the entry press <<Ok>>. Summary information on licensing fees entered appears in a "Licensing Fees" window placed in the lower part of the screen. Selecting an item listed in the bottom portion of the screen, and double clicking on it, reveals a window option to <Delete> the entry, or <Go Back> one step. Items listed in the "Licensing Fees" window can be deleted or changed by double clicking on the desired item and selecting the appropriate button, or <**Tab**> as many times as is necessary to highlight the licensing fee window and move to the item you want with the arrow keys. When all information has been entered, press <Exit> to return to the main application entry screen.

8.1.14 Reminders

The Reminders option permits you to enter brief notes in a file. These notes, unless deactivated, will pop up automatically at the time of issuance of the marketing authorization. The same notes, can be used to communicate with colleagues having access to the same file in order to draw their attention to any specific issue.

To enter a reminder into the system:

1. Type in any notes. Press <<Ok>>. The first 40 characters of the entered text will be shown in the window placed in the lower part of the screen together with the date on which the note has been entered, the date - if any - on which the note has been deactivated, and the status sign: + means active note, - means deactivated note.

2. Mark the deactivate check box to prevent the notes from popping up automatically at the time of issuance of the marketing authorization.

To complete the entry, press <<Ok>>, or <**Tab**> as many times as is necessary. Summary information on reminders will appears in a "Reminders" window placed in the lower part of the screen. Double click on an item to <Change>, <Delete>, or <Go Back> on the option window. When all information has been entered, press <Exit> to return to the main application screen.

8.1.15 Similar Names

Selecting this button makes the system search for drug names starting with the same five first letters. If data is found, a list is shown with all matches. This retrieval option allows you to verify whether the same brand name has already been used by another applicant.

8.1.16 Similar Formula

Selecting this button causes the system carry out tow simultaneous searches. The first reveal search is aimed at retrieving and displaying all drug items having at least one active ingredient "Similar Ingredient" in common with the item being used. You may then select <Print>, to print the results of the search, or after viewing select <Exit>. When you click <Exit>, the other search is revealed which displays all items that have the "Same Ingredient and Dosage Form".You may again select <Print>, to print the results of the search, or after viewing select <Exit> return to the main application entry screen.

NOTE: If you press <Exit> before you saved your entry, you will be warned that all your entry will be lost unless you save it.

8.2 Processing Steps

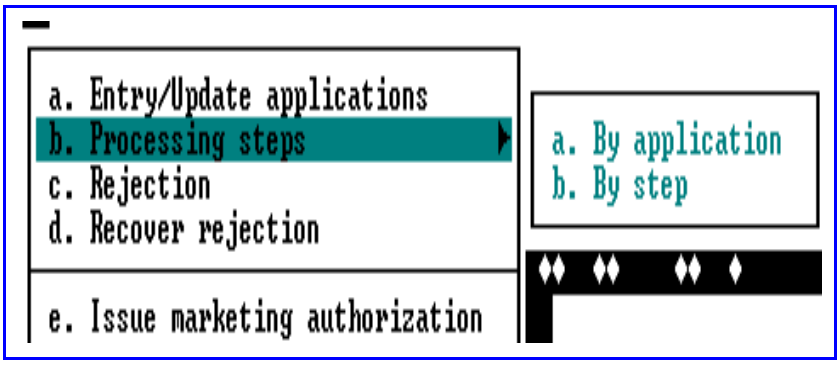


Figure 8-14: Processing Steps menu

This option, if properly used allows you to track the status of applications at each processing step, and to locate applications that have been forgotten in the processing path.

Users that wish to implement this option should have entered as many steps as appropriate in the Processing Steps catalogue. Only steps entered in such a catalogue can be used in this feature.
It is important to remember that you can only retrieve information that has been entered. Thus, users are expected to enter the necessary data at each step about whether a decision has been made, and what action has been taken. If necessary, you can also type a brief explanation for the actions that have or have not been taken.

NOTE: **The processing steps detailed in 8.2.1 and 8.2.2, also apply to the processing steps for Revalidation Applications and Variation Applications.**

8.2.1 Recording Processing Steps by Application

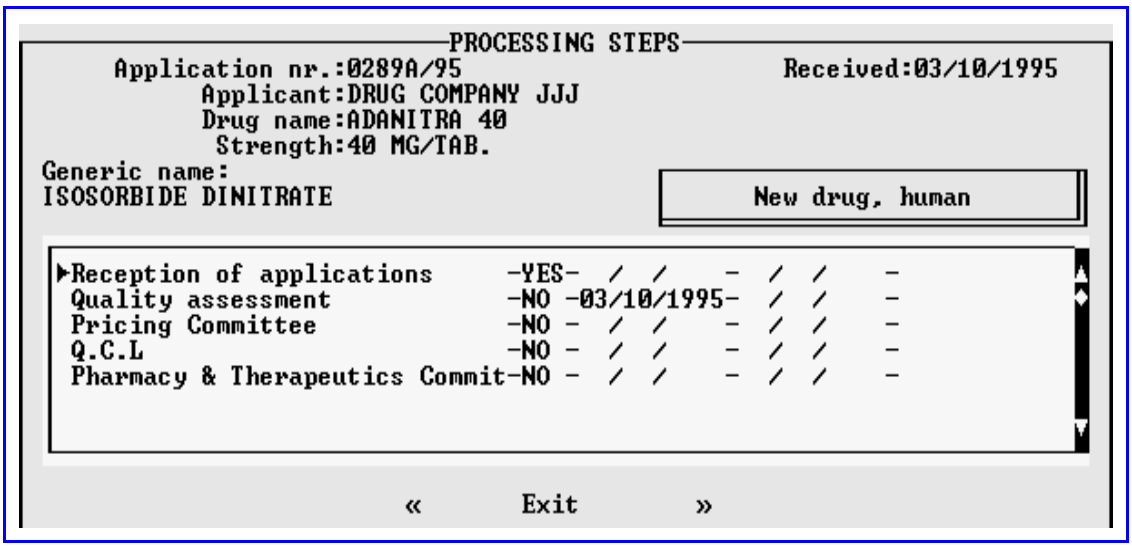


Figure 8-15: Processing Steps by Application

The following is a discussion of all fields found in the Processing Steps screen.

Application Nr.

The unique number that identifies the specific application being reviewed. Type in the application number and press **<Enter>**. You can also press **<F2>** or click the right mouse button to reveal a list of choices. The list will show only applications that have not been rejected or approved. Thus if you do not find the application you are looking for, it means that this has been rejected, or it has become a marketing authorization.

When you have selected the application number, summary information such as applicant, drug name, strength, generic name, and processing steps are displayed.

After a processing procedure is assigned, all processing steps appear in the window below. At this point you may click on any step to enter detailed information relating to the step. A new screen will appear.

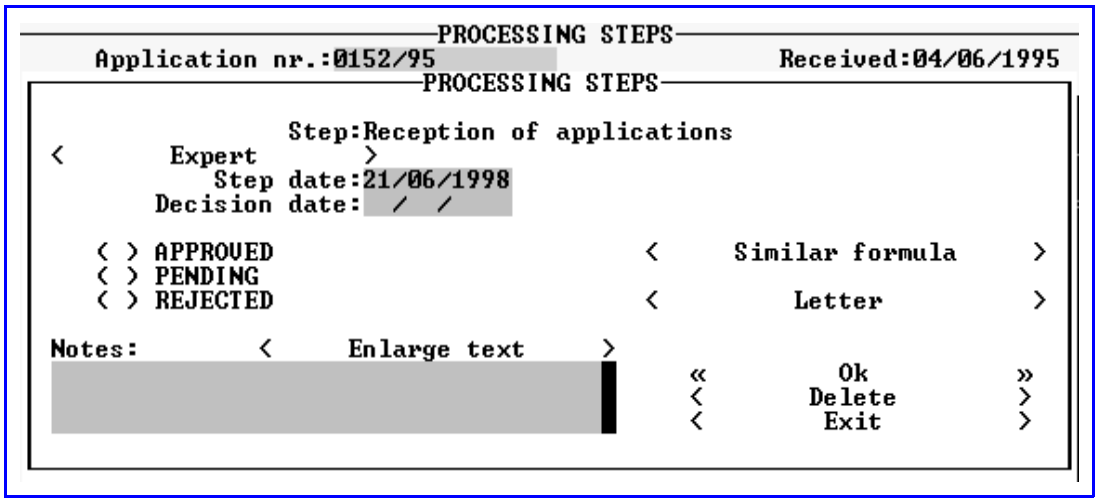


Figure 8-16: Secondary Processing Steps screen

For each step in the process, a detailed window is be displayed. All entries can be edited at any time provided the application has not been rejected or approved. The following information is displayed in the detailed processing steps screen.

Step — This field displays the name or description of the step.

Expert — This button gives access to an additional window which list any experts or sub-steps that have been assigned to the step in its catalogue.

Step Date — The starting date for this particular step.

Decision Date — The date a decision was made regarding the status of the application as it pertains to this processing step.

Approved/ Pending/ Rejected — These options are meant to summarize the outcome or decision made at the step.

Similar Formula — This button allows you to carry out two types of search. The first is aimed at retrieving and displaying all drug item (regardless of their status as application and/or licence) having at least one active ingredient in common with the item being entered. The second will retrieve and display all items having at least one active ingredient in common with and the same dosage form as the item being entered.

Letter — This button allows you to prepare and print a letter to advise the applicant or another addressee about the decisions taken at this step. See Section 12.10, for details on how to prepare a letter.

Notes This text field can be used to provide any additional information relative to the decision made in the step.

8.2.2 Recording Processing Steps By Step

This feature allows you to assign any number of pending applications to a given step. This is particularly useful when preparing for committee meetings where several applications are reviewed on the same date.

When this option is selected, a search screen will be displayed listing all the processing steps defined in the processing steps catalogue. Select the desired step, and a new screen will be displayed (see below).

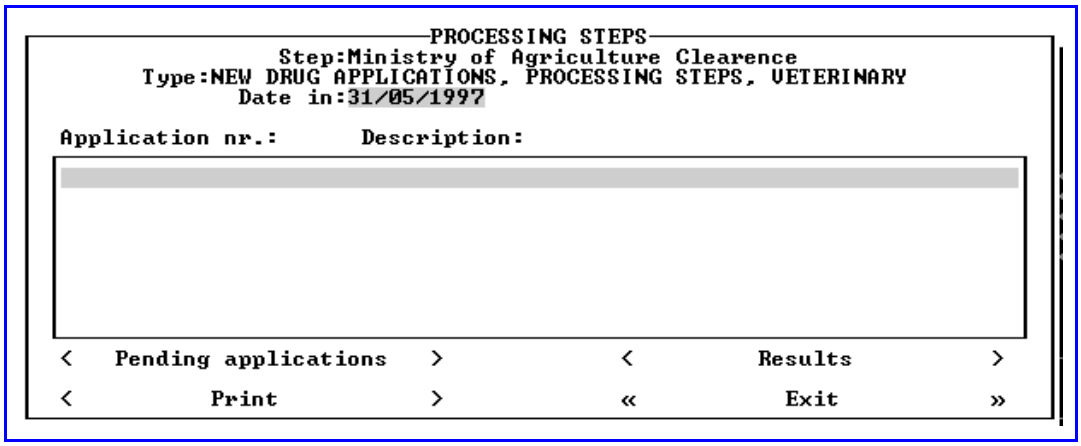


Figure 8-17: Application Processing Steps by Step

The screen displays the Step and the processing step type. The following is a description of all additional data fields displayed on this screen.

Date in This field requires that you enter a date corresponding to a time period that an application has entered a particular processing step. If no application had previously been put in relation with that step and date. The screen will remain empty otherwise it will show those applications already related to the selected step and date.

Pending Applications Press the <Pending applications > button. The system will show a list of pending applications, that have not started, nor completed the selected step. Select one by one, those you want to relate to the step and date. Then press <<Ok>>. The screen will show all applications that have an established relation with the step and date you are working on.

Results This button allows you to enter information on decisions made for this particular step. All applications that have been previously assigned to this particular step will be listed, **allowing you to enter decisions for multiple applications at once**. Enter a decision date, and result. Additional notes can be entered in the Notes text box. After completing the results information, press <<Ok>> to save your changes, or <Exit> to return to the previous screen.

Print Select this option if you wish to have detailed information printed to your local printer.

8.3 Rejecting Applications

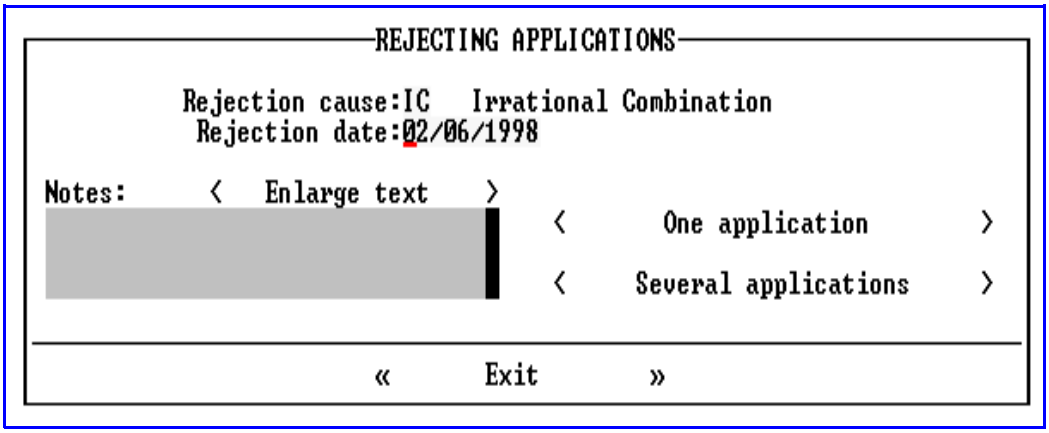


Figure 8-18: Rejecting Application screen

This option allows you to record the decision to reject one or more applications.

Rejection Cause This field should display the code and description of the rejection. This field is linked to the Rejection Causes catalogue, therefore pressing **<F2>** will allow you to select a code from this option.

Rejection Date Records the date the application was rejected. By default the system enters the current date. However, if the rejection date is different, you may change the date.

Notes Free text field for additional information.

Select whether this rejection refers to one specific application, or is common to a number of them. A specific screen will appear for each option.

8.3.1 One Application

Select this option if you wish to specify a single application which should be rejected. Selecting this option displays the screen below:

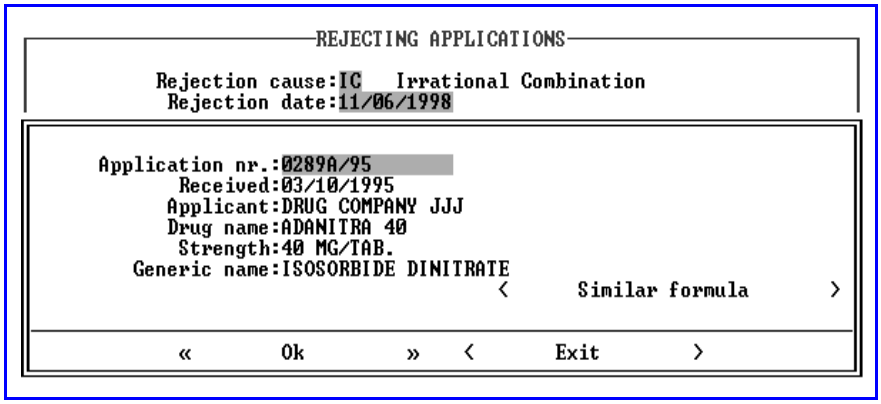


Figure 8-19: Rejecting One application screen

Application Number

Type the application number which you want to record the rejection, or press <**F2**> to obtain a list of applications which have not been rejected or approved.

After selecting the application, the specific information relating to the application number will be displayed. This information includes the date the application was received, the applicant, the drug name, the strength and if applicable, the generic name.

<Similar Formula> is an additional option that can be selected from this screen. Selecting the <Similar Formula> button causes the system to find and retrieve all drugs having at least one active ingredient in common with the item on the application which you want to reject. After reviewing the information, you may then select <Print>, to print the report, or select <Exit>. At this point, the system will retrieve and display all drug items with similar ingredients and the same dosage form as the drug listed on the application which you wish to reject. After reviewing this information, you may again then select <Print>, to print the results of the search, or select <Exit> return to the previous screen.

At this point, selecting <<Ok>> would indicate that the application has been rejected. The system will then prompt you to indicate whether you want to print a rejection letter. See Section 12.10 for details on how to prepare a letter. Simply select <<YES>> or <NO>. After a selection is made you will be returned to the previous screen. Press <Exit> return to the rejection application screen.

8.3.2 Several Applications

Select this option if you wish to specify several applications which should be rejected. Selecting this option displays the screen below:

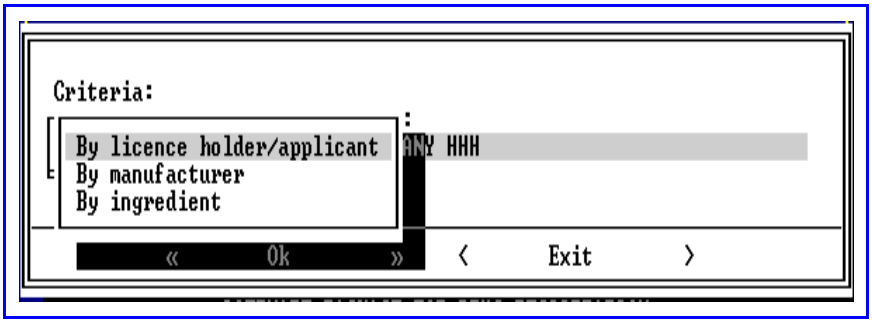


Figure 8-20: Rejecting Multiple Applications screen

Criteria This pop-up field displays 3 criteria which you can use for rejecting applications. Select one of the following criteria: By licence holder/applicant, by manufacturer, or by ingredient.

Name This field will be dependent upon the criterion selected: name of applicant/licence holder, manufacturer, or ingredient. Once you have entered the appropriate item, press <<Ok>>. This option confirms that you wish to reject all applications that have been submitted based on the criterion selected. The system will prompt you to confirm your action or go back. The system will them ask you whether or not you wish to print the rejection letter. If you select <<YES>>, the system will generate rejection letters for all applications based on your criteria selected. See Section 12.10 for details on how to prepare a letter.

You can select <Exit> to return to the previous Rejection Application menu.

8.4 Recover Rejected

This option permits you to recover an application that has been rejected.

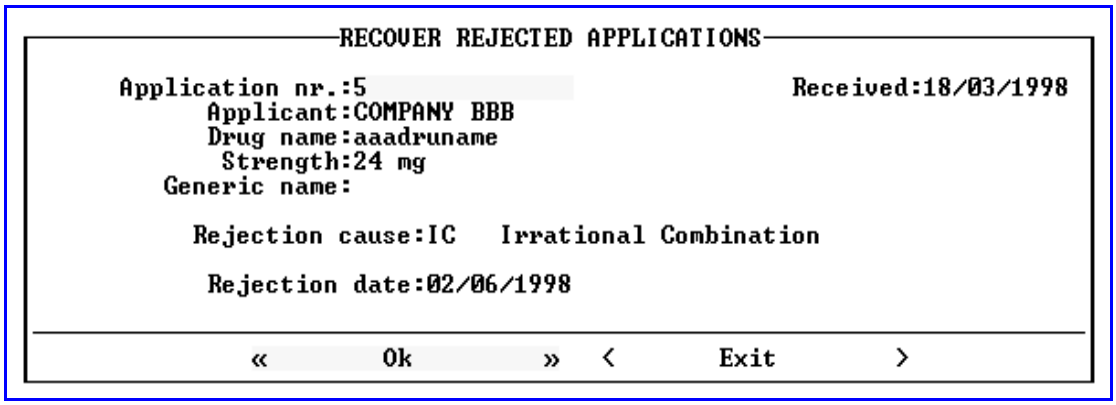


Figure 8-21: Recover rejected application screen

Application Nr

Type in the application number and press <**Enter**>. You can also press <**F2**> or click the right mouse button to select from the list showing only applications that have been rejected. Thus if you do not find the application you are looking for, it means that this has not been rejected.

When you have selected the application number, summary information such as date received, applicant, drug name, strength, generic name, rejection cause and rejections date are displayed.

When you have selected the application, summary information is shown and you can press <<Ok>> to recover your entry. If <<Ok>> is selected, the system will prompt you as to whether or not you wish to print a letter to send to the applicant indicating that the application has been recovered from rejection. See Section 12.10 for details on how to prepare a letter. Press <Exit> to return to the main menu.

8.5 Issue Marketing Authorization

This option permits you to record the decision to approve an application making it a marketing authorization.

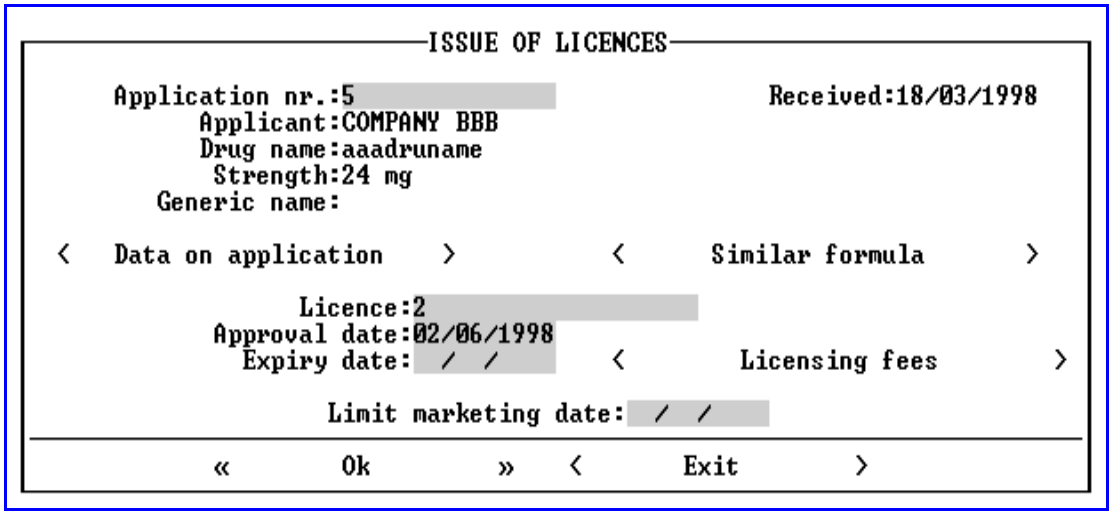


Figure 8-22: Marketing Authorization

The following is a description of each field listed on the Issue of Licences screen.

Application Number

Type in the application number and press <**Enter**>. You can also press <**F2**> or click the right mouse button to view the list showing only applications that have not been rejected or approved and that have completed at least the compulsory processing steps. If you do not find the application you are looking for, it means that this has been rejected, has already been approved, or has not completed at least the compulsory processing steps.
When you have selected the application, summary information such as applicant, drug, name, strength and generic name will be displayed. If there are any pending Reminders, the system will prompt you. Then if there are any fees that have not been paid, the system will display a message where you can select <Yes> or <No>. Choosing <Yes> allows you to continue to update the record.

Data on Application

This button when selected, displays an additional screen that provides detailed information on the drug in the application. Information in this screen is for display purposes only. No editing functions can be performed in this screen.

Similar Formula

Selecting this button causes the system carry out tow simultaneous searches. The first reveal search is aimed at retrieving and displaying all drug items having at least one active ingredient "Similar Ingredient" in common with the item being used. You may then select <Print>, to print the results of the search, or after viewing select <Exit>. When you click <Exit>, the other search is revealed which displays all items that have the "Same Ingredient and Dosage Form" as the item being entered (unless automatic numbering has been selected at configuration). The system checks that the number is not already in use.You may again select <Print>, to print the results of the search, or after viewing select <Exit> return to the main application entry screen.
NOTE: If you press <Exit> before you saved your entry, you will be need that all your entry will be lost unless you save it.

Licence

This field will either display an automatic licence number, or will allow you to enter the licence number being issued to the applicant. Automatic numbering is available *only* if it was selected at the time of configuration. If entered manually, the system checks that the number is not already in use.

Approval Date

By default the system automatically enters the current date as the approval date. However, enter a separate date if necessary.

Expiry Date

The system automatically enters an expiry date of five years after the approval date. This date however can be changed.

Licensing Fees

Selecting this option causes an additional window where you may enter any additional licensing fees that may apply to the licence if necessary. See Section 8.1.13 for details on adding licensing fees.

Limit Marketing Date

Use this field to specify a deadline date by which the applicant must begin marketing the product.

After completing the approval screen, select <<Ok>> and the system will prompt you to indicate whether or not you want to print an approval letter. See Section 12.10 for details on how to generate a letter. Press <Exit> to return to the main menu.

8.6 Post-marketing Follow-up

This option allows you to record any summary data that has been collected on marketed products. You may also use this same option to retrieve any marketing information on the same product.

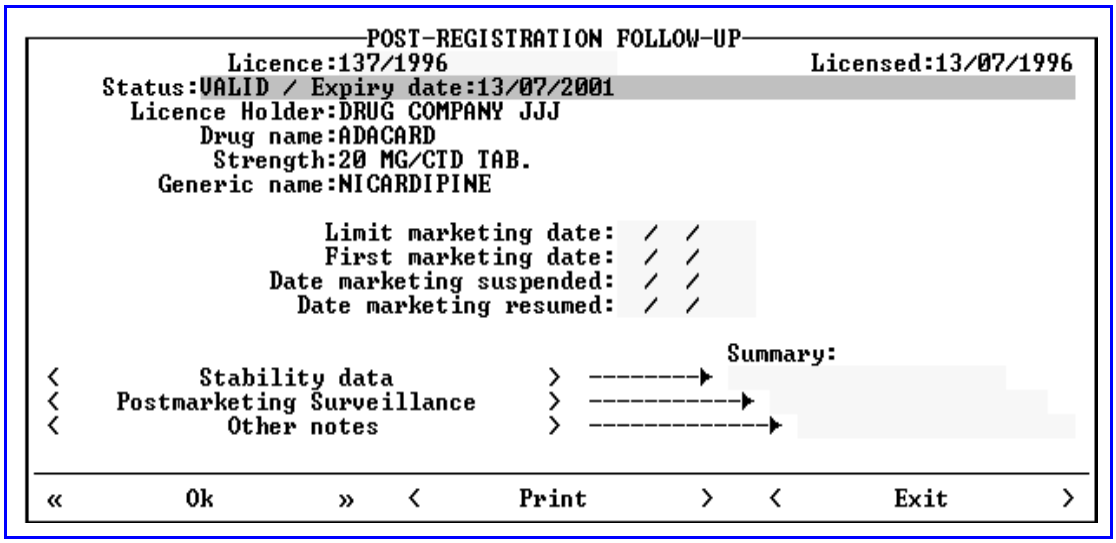


Figure 8-23: Post-marketing Follow-up screen

Licence

This field displays the licence number for the application. Press **<F2>** to obtain a list of all marketing authorizations.

Once a licence number has been selected, the following predefined information is displayed on screen: the date the licence was issued, the licence holder, the drug name, the strength of the drug and the generic name if applicable. These fields are for display purposed only, and no information can be changed.

Limit Marketing Date

Use this field to specify a deadline date by which the applicant must begin marketing the product. If no date has previously been defined, you may enter one here.

First Marketing Date

This field should display the first date the licence holder began marketing the product.

Date Marketing Suspended

This field is used to display the date on which marketing for this product has been suspended. A marketing suspension can either be issued by the licensing authority or by the licence holder.

Date Marketing Resumed

This field is used to display the date on which marketing has been resumed. This date should always be a date after the suspension date.

Stability Data

Selecting this option displays a free text window in which any data relating to updates of stability information can be entered. Adjacent to this field, a summary field exists in which up to 20 characters can be entered that can be used to summarize the contents of this window.

Post-Marketing Surveillance

This field is used to enter any information relating to post-marketing surveillance studies. Adjacent to this field, a summary field exists in which up to 20 characters can be entered that can be used to summarize the contents of this window, such as a rare adverse reactions to a drug.

Other Notes

This is field gives access to a free text window where additional information regarding the marketing performance of the product can be entered here. Adjacent to this field, a summary field exists in which up to 20 characters can be entered that can be used to summarize the contents of this window.

Once you've completed entering this information, press <<Ok>> to save your entry. If you wish, you may also select a print option to provide a hard copy output of the information entered in the Post-registration Follow-up screen.

8.7 Cancellation

This option permits you to record the decision to cancel or suspend one or more licences. Cancelled licences can be validated again using the Revalidation menu option. This procedure is also used to reactivate suspended licences. The distinction between cancelled and suspended licences can be entered as a specific cancellation cause or as free notes.

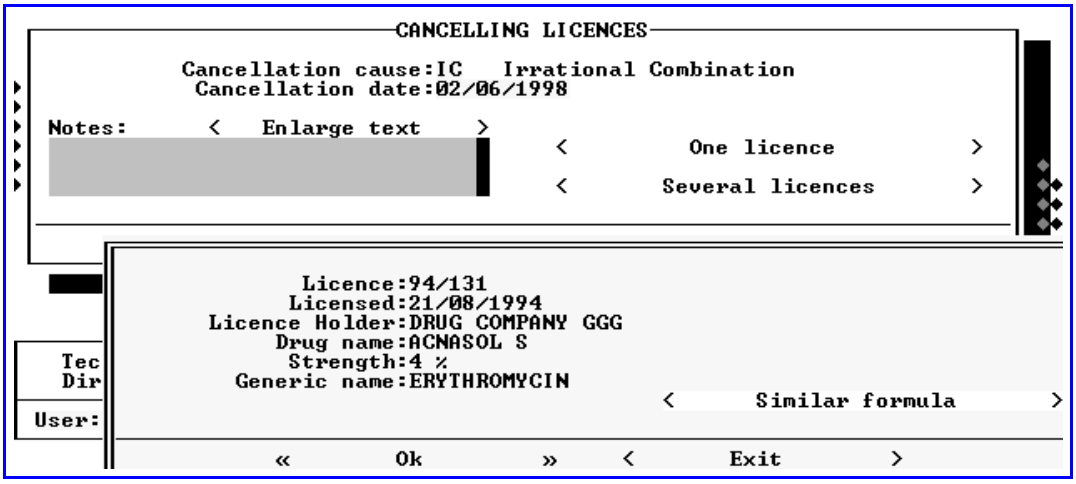


Figure 8-24: Licence Cancellation screens

Cancellation Cause

This field requires that you enter the code that corresponds to the cause of cancelling the licence. This field is linked to the Cancellation Causes database. Therefore, pressing **<F2>** will display a list of causes from which you can select.

Cancellation Date

By default, the system enters the current date (today's date) as the cancellation date. You may accept this value or change it if the cancellation date is

Notes

Any specific information relating to the cancellation cause can be entered in the notes field. This is a text field that can contain unlimited data.

Select whether this cancellation refers to one specific licence, or is common to a number of them. A specific screen will appear for each option.

8.7.1 One Licence

Select this option if you wish to specify a single licence which should be cancelled. Selecting this option displays the screen below:

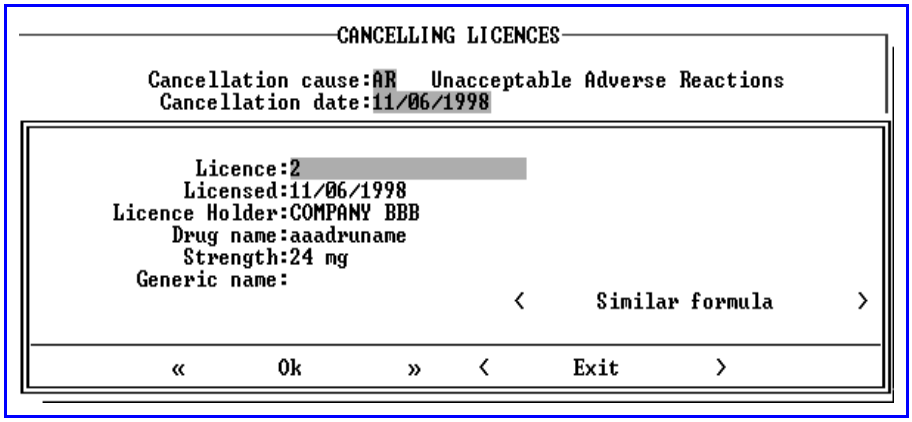


Figure 8-25: Cancelling One Licence

Licence Press <**F2**> to select a valid licence number. This screen will only show a list of all licences that have NOT been cancelled, nor expired.

After selecting the licence, the specific information relating to the application number will be displayed. This information includes the date the application was received, the applicant, the drug name, the strength and if applicable, the generic name.

<Similar Formula> is an additional option that can be selected from this screen. Selecting the <Similar Formula> button causes the system to find and retrieve all drugs having at least one active ingredient in common with the item on the licence which you want to cancel. After reviewing the information, you may then select <Print>, to print the report, or select <Exit>. At this point, the system will retrieve and display all drug items with similar ingredients and the same dosage form as the drug listed on the licence which you wish to cancel. After reviewing this information, you may again then select <Print>, to print the results of the search, or select <Exit> return to the previous screen.

At this point, selecting <<Ok>> would indicate that the application has been cancelled. The system will then prompt you to indicate whether you want to print a cancellation letter (See Section 12.10). Simply select <<YES>> or <NO>. After a selection is made you will be returned to the previous screen. Press <Exit> return to the cancellation licence screen.

8.7.2 Several Licences

Select this option if you wish to specify several licences which should be cancelled. Selecting this option displays the screen below:

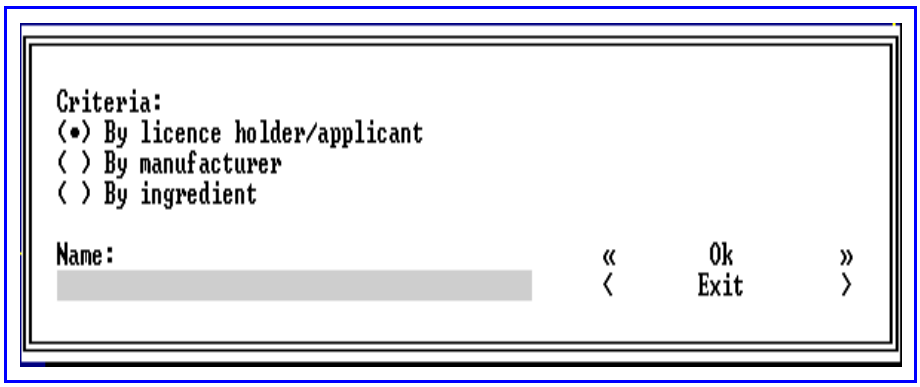


Figure 8-26: Cancelling Multiple Licences screen

Criteria This pop-up field displays 3 criteria by which you use for cancelling licences. Select one of the following criterion: By licence holder/applicant, by manufacturer, or by ingredient.

Name This field will be dependent upon the criterion selected: name of licence holder/applicant, manufacturer, or ingredient. Once you have entered the appropriate item, press <<Ok>>. This option confirms that you wish to cancel all licences that have been submitted based on the criterion selected. The system will prompt you to confirm your action or go back. The system will them ask you whether or not you wish to print the cancellation letter. If you select <<YES>>, the system will generate cancellation letters for all licences based on your criteria selected. See Section 12.10 for details on generating a letter.

You can select <Exit> to return to the previous Cancellation Licence menu.

8.8 Revalidation Applications

The Revalidation (licence renewal) Applications option permits you to record information about renewal of licence validity.

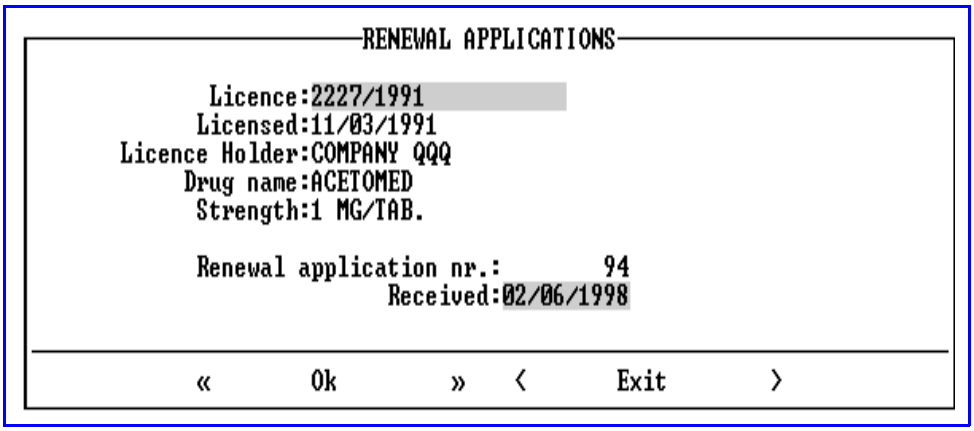


Figure 8-27: Revalidaion (Renewal) Application screen

Revalidation also enables you to re-validate a cancelled/suspended licence. In any case, the old licence number is kept. Licence renewal takes place in two or three steps:

- First, a renewal application number needs to be generated by the computer
- Second, the renewal application can be retrieved (though the above mentioned number) to record decisions made at the different processing steps. This is not compulsory.
- Finally, the decision to renew, or to cancel the licence is recorded.

The procedure for revalidating an application is as follows:

- From the Licensing Menu, select Drug and then Revalidation Application.
- Type in the licence number and press <**Enter**>. You can also press <**F2**> or right mouse to get a list of file contents. This displays the file contents list showing all "renewable" licences, i.e. valid, cancelled, and expired licences. If you do not find the licence you are looking for, it means that this has never been entered or has been removed from the system.
- After you have selected the licence, summary information (licence date, licence holder, drug name, and strength) is shown together with a computer-generated renewal application number. This number is a unique identifier for the renewal application. It serves as a reference tool via which users can record information related to the processing steps as well as the final decision.
- Enter the date on which the renewal application was received.
- Press <<Ok>> to record the entry. The system prompts you to select whether or not you wish to have a letter printed (Section 12.10). Press <Exit> to return to the previous screen.

For Processing Steps, see Section 8.2 - This option is virtually identical to the processing steps described in section 8.2. Please refer to Section 8.2 for details on using this feature.

8.9 Record Revalidation

This feature is used to record the decision to extend the validity of licence or to revalidate a suspended licence.

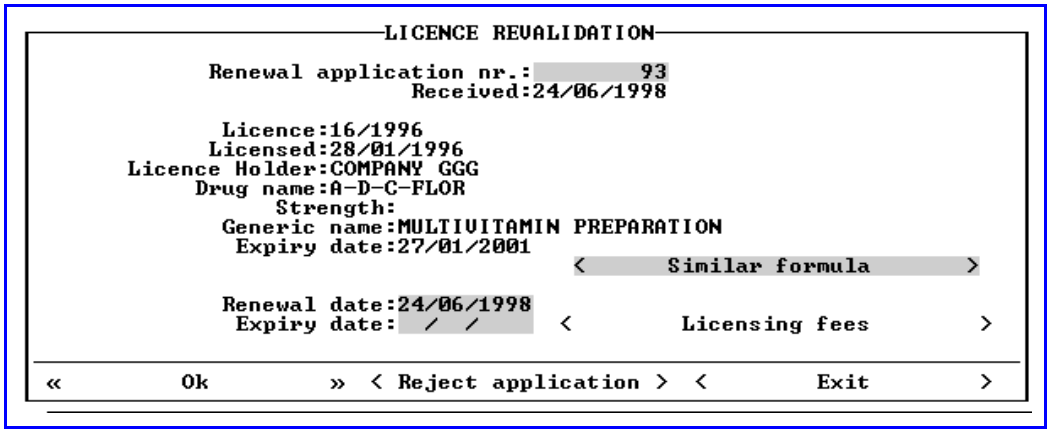


Figure 8-28: Record Revalidation (Renewal) screen

To record revalidation, complete the following steps:

- Press <**F2**> or click the right mouse button to select from a list of pending renewal applications the one you want to work on. Summary information such as date received, licence, licensed, licence holder, drug name, strength, generic name and expiry date are revealed.
- Select <Similar formula> if you wish to check which other products share at least one active ingredient with the one you are entering.
- Select <Licensing fees> to check or add the fees associated with this licence.
- Enter the revalidation date and the new expiry date.
- Press <<Ok>> to record the decision. The system will then prompt you to indicate if you wish to print the letter of revalidation (Section 12.10), select <<Yes>> or <No>. From this screen you may also reject the application, i.e. no extension of validity granted. Selecting the <Reject Application> button displays an additional screen in which you may choose a rejection cause (linked to the Rejection Cause database), and the rejection date. Select <Exit> to return to the main menu.

8.10 Variation Application

Variations to licences differ from changes to applications in that all variations are recorded to specific file where the history of all variations are kept and from where it can be retrieved.

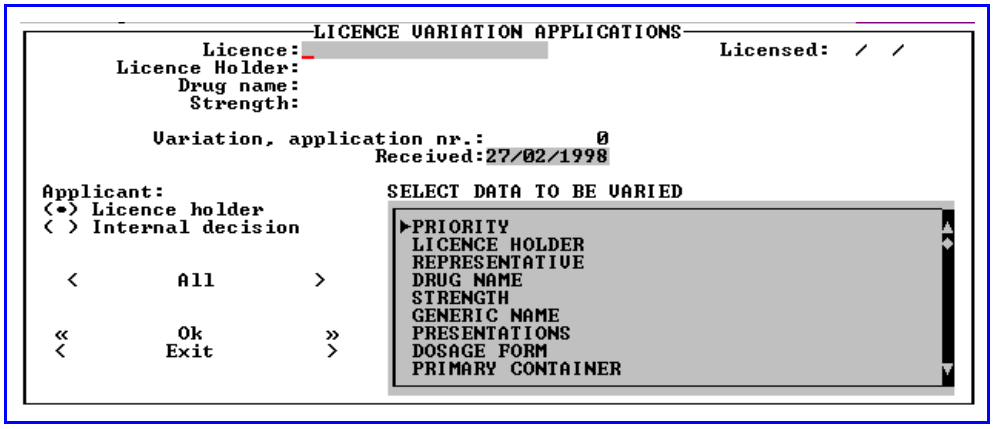


Figure 8-29: Variations to Application screen

Data entry is carried out in two or three steps:

- First, a variation application number needs to be generated by the computer
- Second, the variation application can be retrieved (though the above mentioned number) to record decisions made at the different processing steps. This is not compulsory.
- Finally, the decision to record the variation(s) to the licence is recorded.

The procedures for recording variations to application are as follows:

1. Type in the licence number and press **<Enter>**. You can also press **<F2>** or click the right mouse button to get a list of file contents. This list of file contents will show valid licences only. If you do not find the licence you are looking for, it means that this has never been entered, has been removed from the system, has been cancelled, or is expired.

2. After you have selected the licence, summary information such as licence holder, drug name, strength is shown together with a computer-generated variation application number. This number is a unique identifier for the variation application. It serves as a reference tool via which users can record information related to the processing steps as well as the final decision.

3. Enter the date on which the variation application was received.

4. Indicate whether the request for variation has been submitted by an applicant (usually the licence holder) or is an internal decision of the licensing authority.

5. Indicate which piece(s) of information may be varied. You can select < All > by pressing the appropriate button, or double click on individual items to select them (you can select any number of them). ***Note:*** **Only the items selected here will be editable when using the facility to record variations.**

6. Press <<Ok>> to save your changes. The system will then prompt you to indicate if you wish to print the letter of variation (See Section 12.10), select <<Yes>> or <No>. Select <Exit>to return to the Main Menu.

For Processing Steps, see Section 8.2 - This option is virtually identical to the processing steps described in section 8.2. Please refer to Section 8.2 for details on using this feature.

8.11 Record Variation

Variations entered into the system are recorded here. The process of entering data is similar to that of entering or updating an application for a new licence. Only the fields that have been selected for variation at the first step of the variation process are editable.

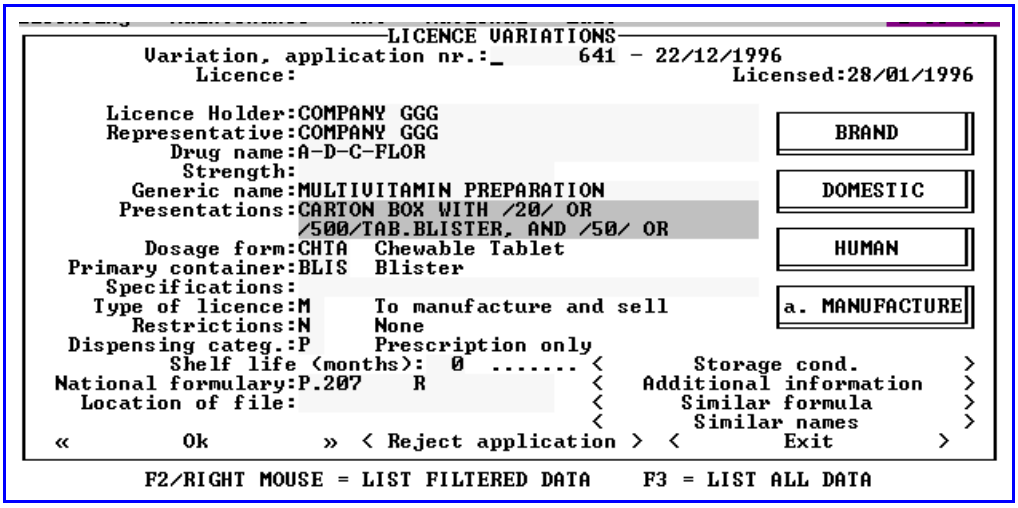


Figure 8-30: Record Variations screen

Once the relevant data has been entered, press <<Ok>>, a red window will appear asking to indicate whether all variations regarding this variation application have been recorded, or if a decision is still pending regarding further variations.

If you select the first option, the variation application will be removed from the list and no further variations can be recorded (unless a new application for variation is entered through step one of the variation process). If you select the second option, the variation application will be accessible for recording further variations. In any case, each individual variation recorded takes immediate effect.

At this point the system will then prompt you to indicate if you want to have a letter printed now.

The following example should clarify this process:

You have received an application for varying two excipients and the commercial presentations of a product with a valid licence.

> You must enter this application as step one of the variation process. When you come to a final decision regarding one excipient, (i.e. you decide to accept the variation), you may record that decision (i.e. you record the variation of one excipient) and exit the data entry screen telling the computer that further variations may be recorded. At this point, if you print or display licence information, that one variation made will be reflected even if the other two are still pending.

8.12 Change Applicant/ Holder

This option permits you to automatically change the name of the applicant/licence holder, representative, manufacturer, distributor in all applications and licences. This feature is available to save time in those cases where companies change name or change their proprietary status.

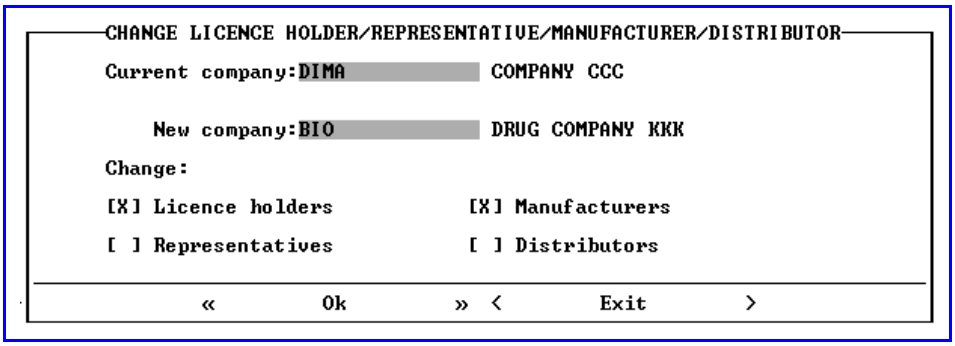


Figure 8-31: Change Applicant/Holder screen

Current Company — Enter the existing name of the applicant/licence holder, representative, manufacturer, or distributor. You can press **<F2>** to select from the list of available companies.

New Company — Enter the new name which will replace the existing applicant/licence holder, representative, manufacturer, or distributor. You can press **<F2>** to select from the list of available companies from which you may make your selection. Reminder: The new company name must exist in the database or the system will display an error message.

Change: Licence Holders/ Representatives/ Manufacturers/ Distributors — Select the appropriate check box for the organization to which this change applies.

If you need to change this information only in a few items you should use the appropriate menu options for changing information in applications and record variations to licences. After selecting the options to be changed, click <<Ok>> to save your entry. The system will prompt you to confirm your action or allow you to go back. After you have confirmed your action, the system will begin processing and update all relevant information throughout the program. Press <Exit> to return to the Main Menu.

8.13 Deleting Licences

This option permits you to remove a licence from the database. **No information about deleted licences can be retrieved once it has been deleted.** The database will act as if that licence never existed even as an application. This makes it possible to use its number again, unless automatic numbering is used.

Utilize the function for deleting licences very carefully since there is no possibility to recover deleted information. This option has been added only to permit you to remove a licence and "free up" its number after a data entry mistake.

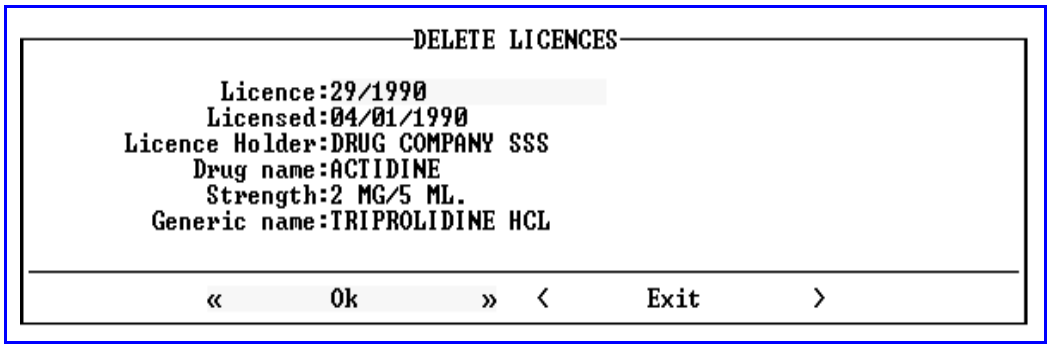


Figure 8-32: Deleting Licence screen

The process for deleting licences is as follows:

1. Type in the licence number and press <**Enter**>. You can also press <**F2**> or click the right mouse button to access a list from which you can select a licence. If you do not find the licence you are looking for, it means that this has already been removed from the system.
2. After you have selected the licence, summary information such as licence, licensed, licence holder, drug name, strength and generic name is displayed.
3. Press <<Ok>> to confirm deletion. You must then again confirm the operation.
4. Press <Exit> to return to the Main Menu.

8.14 RETRIEVAL: Drugs

The Retrieval option permits you to retrieve information as outlined here below.

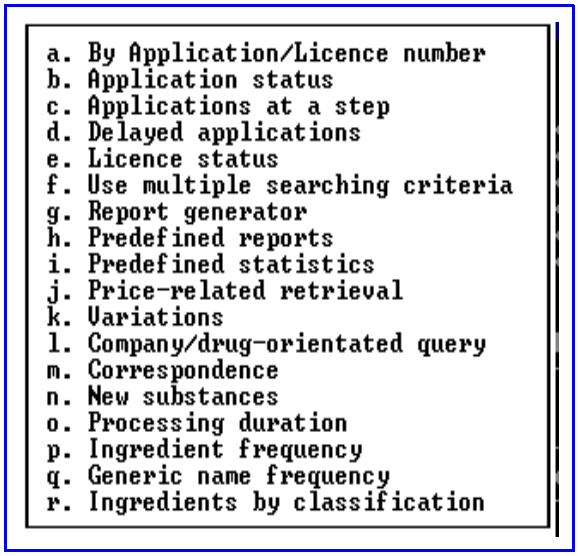


Figure 8-33: Retrieval menu

All instructions indicate that you should type in the information requested. Although, not stated, you also have the option of simply pressing **<F2>** or clicking the right mouse button to reveal a list showing all applications and/or licences from which you can choose that which applies to your needs.

In the case where both application and licence numbers are retrieval options, the system will automatically distinguish among the two types of numbers. However, if the same number exists for both an application and a licence, only the application will be retrieved.

8.14.1 By Application/Licence Number

This option permits you to print an application or a licence in draft form.

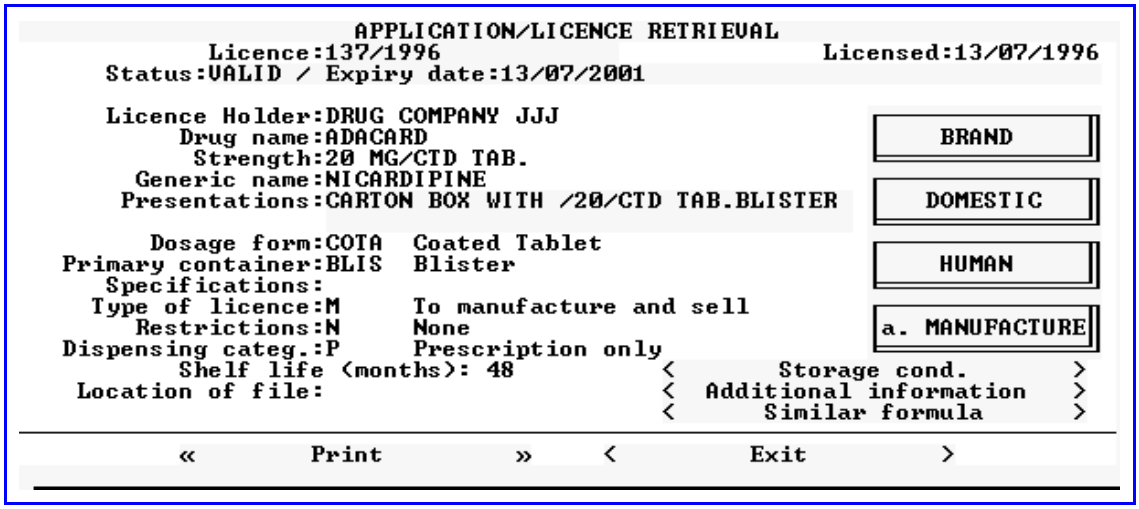


Figure 8-34: Retrieval by Application/Licence Number

To do this report, complete the following steps:

1. Type in the application or licence number, or press <F2> to select from the file contents list which shows you ALL applications and licences that have been entered into the system.
2. Once selection is made, press **<Enter>** to reveal information on the chosen item in the retrieval window.

   To review information on manufacturers, ingredients, routes of administration, status in other countries, therapeutic groups, data sheets, prices, distributors, veterinary data, manufacturing process, general appearance and analytical information, fees and Reminders, relating to the particular application or licence selected, use the highlighted pop-up window in the lower right corner of your screen.

   You can also select any of the push buttons, <Storage Cond.>, <Additional information>, or <Similar formula>, in the lower right corner of the screen to review information/notes relating to the selected application or licence. If the <Similar formula> button is selected, this will initiate a search for items with at least one active ingredient in common with the selected application/licence followed by a search of items with at least one active ingredient in common with, and the same dosage form as the retrieved item. See Section 8.1.16 Similar formula for details.
3. Select <<Print>>, if you wish to print the data, or <Exit> to return to the Main Menu.
4. If <<Print>> is selected, the system will prompt you to indicate if you first wish to print a letter (Section 12.10), and then a licence.

To see information on another item, just click in the application number field and repeat all steps.
If you do not find the licence you are looking for, it means that it has been removed from the system.

8.14.2 Application Status

This option, if properly used, permits you to find out the status of applications at each processing step and to locate applications that have been "forgotten" in the processing path. It is important to remember that you can only retrieve information that has been entered. Therefore, users are expected to enter the necessary data at each step about whether a decision has been made, and, if necessary, to type a brief explanation for the decision taken or not taken.

The use of this option is not compulsory. Users that prefer not to take this option should simply ensure that the Processing Steps catalogue is empty. However, users that wish to implement this option should enter all steps in the catalogu, and then record dates and decisions related to each individual processing step.

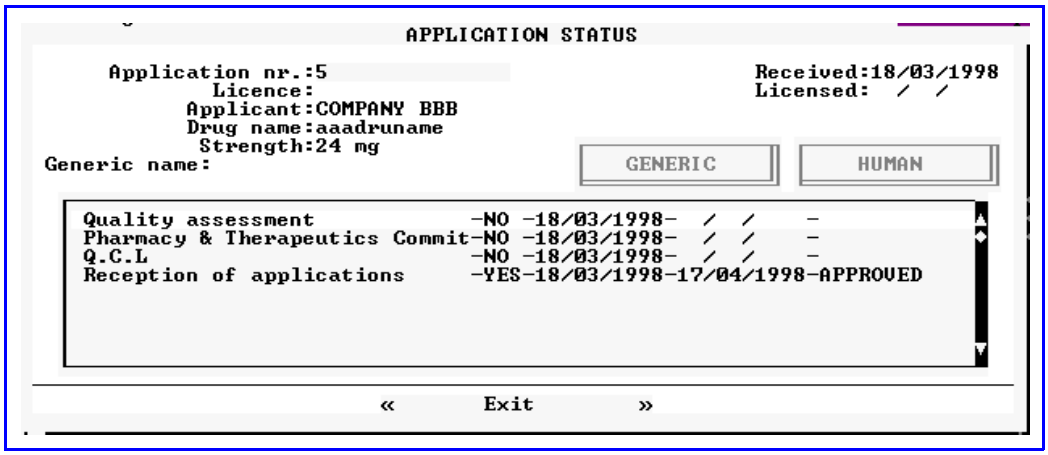


Figure 8-35: Retrieval by Application Status screen

To find out about application status, complete the following steps:

1. Type in the application/licence number, or press **<F2>** to select from the file contents list.
2. Once selection is made, summary information is shown indicating at which steps the application is pending. For more details on each step, click on any step, or sub-step. This will give you detailed information about the situation at such step. In addition, you will be able to send data to the printer or to the screen.
3. Press <Exit> to return to the Main Menu.

To see information on another item, just click in the application number field and repeat all steps.
If you do not find the application you are looking for, it could mean that the application has completed its processing, has been rejected, or has been approved.

8.14.3 Applications at a Step

The Applications at a Step option permits you to display applications that are pending at a given step. This information can be viewed on the screen or printed. Applications that have not yet started a step, or have completed it, are not shown.

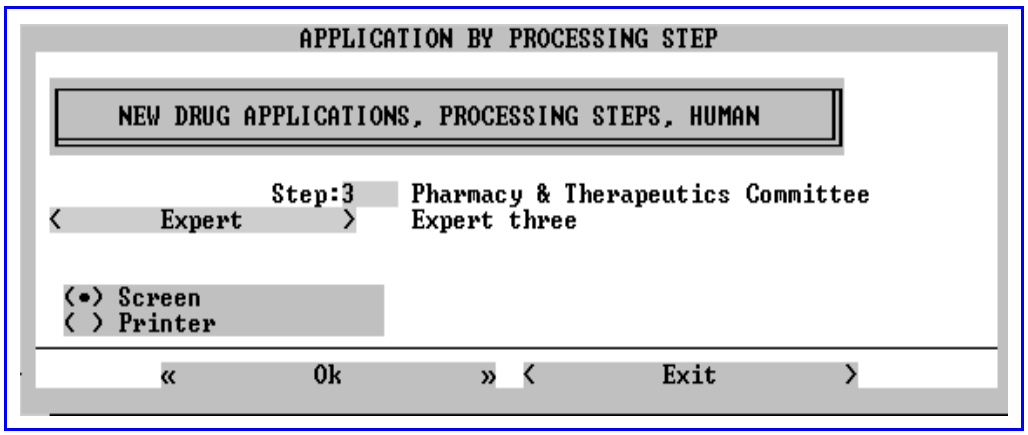


Figure 8-36: Retrieval of Application by Processing Step

To generate this report, complete the following steps:

1. Select the appropriate type of processing.
2. Specify how you want the information retrieved.
   - ♦ To retrieve **by step**, type in the step number or press <**F2**> to select the step from the revealed list. If you **do not** select a step, you will be shown pending applications at all steps grouped in step order.
   - ♦ To retrieve **by an assigned expert**, click on <Expert> and select from the file content list.
3. Select where the output should go and press <<Ok>>, or <Exit> to return to the Main Menu.

8.14.4 Delayed Applications

This option permits you to display all the applications that have been pending at a given step for longer than the period established by the user when creating the step entry in the appropriate catalogue. This information can be viewed on the screen or printed.

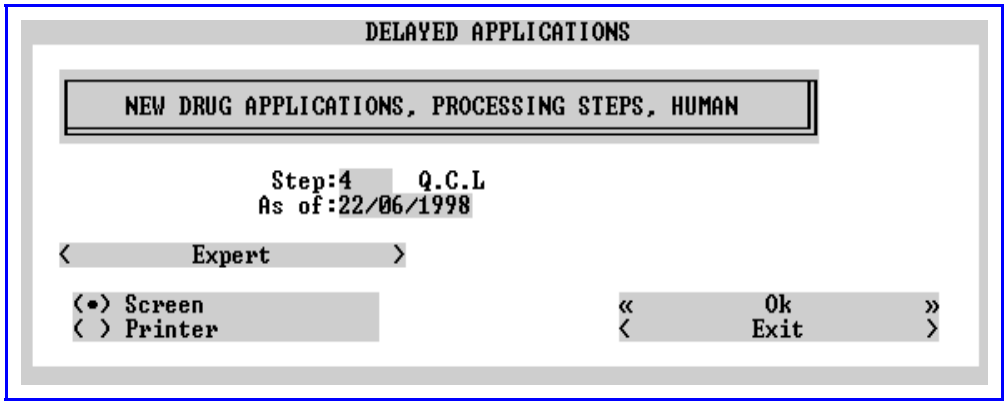


Figure 8-37: Retrieval of Delayed Applications screen

To generate the delayed applications report, complete the following steps:

1. Select the appropriate type of processing.
2. Specify how you want the information retrieved.
   - ♦ To retrieve **by step**, type in the step number or press <**F2**> to select the step from the revealed list. If you **do not** select a step, you will be shown pending applications at all steps grouped in step order.
   - ♦ To retrieve **by an assigned expert**, click on <Expert> and select from the file content list.

   NOTE: If you do not select any step, the report will display information on ALL steps giving a global overview of delayed applications
3. The system will automatically enter the current date for the "As of" date. To specify a different date, simply type in the new date.
4. Select where the output should go and press <<Ok>>, or <Exit> to return to the Main Menu.

8.14.5 Licence Status

This retrieval option allows you to see the status of a licence including any renewals, variations, or cancellations. Typing in the licence number will display data regarding the applicant, drug name, strength and generic name. Click on any line that appears in the lower window to be shown more detailed information.

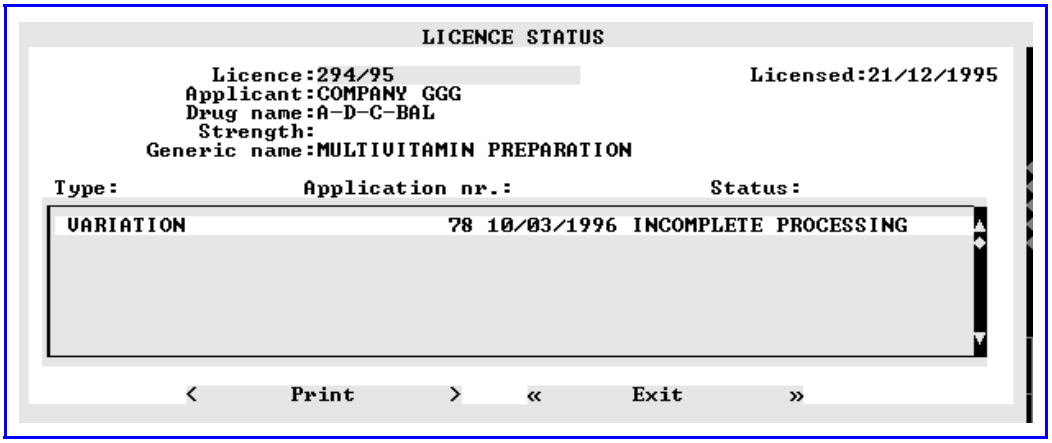


Figure 8-38: Retrieval by Licence Status

8.14.6 Multiple Searching Criteria

This is a powerful information retrieval option that permits you to search data using a variable number of searching criteria.

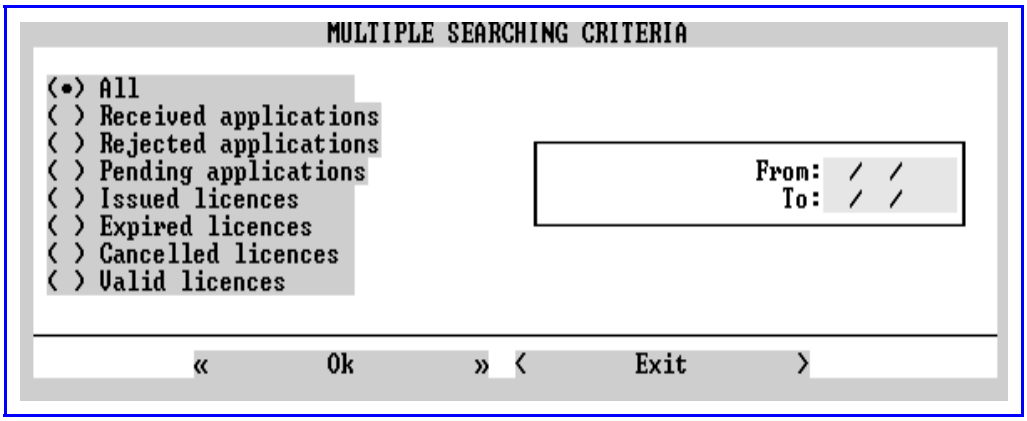


Figure 8-39: Multiple Search Criteria screen

To generate a report using multiple searching criteria, complete the following steps:

1. Define the scope of the search using the available options: All, Received Applications, Rejected Applications, Pending Applications, Issued Licences, Expired Licences, Canceled Licences, and Valid Licences.

2. Press <<Ok>> to be shown the second searching criteria window or <Exit> to return to the menu.

In the second window the following steps must be taken:

1. Select the search field double clicking on it. This will activate the box in the upper right portion of your screen.
2. This upper right side, when active, consists of a pop up box that permits you to select a relational operator. **The relational operators are: equal, greater than, smaller than, not equal, range, and contains.** This latter operator is to be used for text search, e.g. to search for a specific word or group of words within a given field or text. *For example:* operators will be active or not depending on the type of field you want to use as a searching criterion (e.g. if you want to search on the basis of dosage form you will be able to select only equal or not equal).
3. Choose a desired search field from the list on the left side of the screen. The fields are not in alphabetical order, so you can view the list by scrolling, typing the first letter in the name of the field, or clicking on the desired field. *(A description of the fields by which you can search is provided below - 8.14.6-1 Fields You Can Use to Search).*
4. Below the pop-up box, enter the data that the system will use to carry out the search. *Example:* If you want to search all items available as tablet, you will select Dosage form from the list that appears on the left side of the screen, then you will select "equal" from the operators pop up window, then you will enter "tablet" in the field below the operator box either directly or drawing it from a list as usual.
5. Press <<Ok>> to save your completed entry. After you have done that, in most cases the cursor goes back to the upper left side of the screen to select additional searching criterion. add another searching criterion.

   If you were searching by ingredients, combination of ingredients or combination of therapeutic groups, after you pressed <<Ok>> the cursor stays in the upper right side of the screen to permit you to enter additional data related to the same field e.g. other ingredient names to complete the fixed-dose combination. In these cases, press <Exit> to leave the upper right side of the screen.
6. Select one of the three buttons on the lower right side of the screen that is most appropriate for your task. The <See searching criteria> button opens a window showing all the criteria you have entered so far. The << Execute >> button executes the search using the selected searching criteria. The <Exit> button permits you to quit the search.

8.14.6-1 Multiple Search Criteria Inclusion Options

As indicated above, the first step in establishing a multiple search criteria is to define the scope of the search.

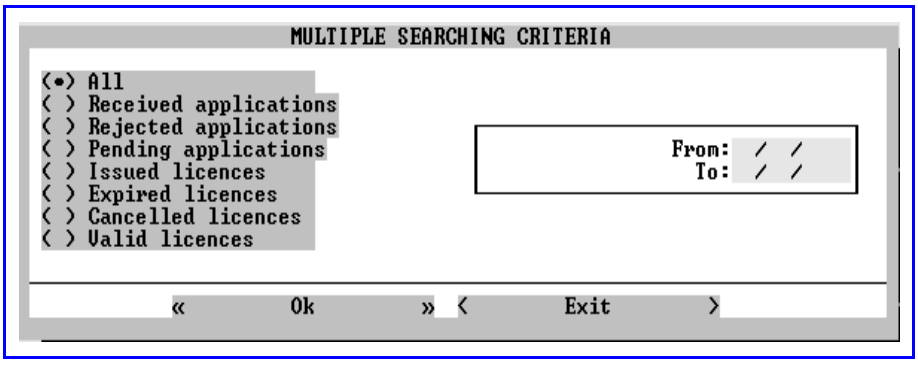


Figure 8-8: Multiple Searching Criteria screen

Below is a description of what those choices are.

All — Includes the entire file, i.e. both applications and licences regardless of their validity status.

Received Applications — Search is limited to applications received within a date range that you are prompted to specify. If you do not specify an end date, the system includes the oldest received application and/or the most recently received, as applicable. Please note: the searching criterion is the date of reception, not the fate of applications. Thus, applications are included even if they have later been rejected or approved.

Rejected Applications — Search is limited to applications rejected within a date range that you are prompted to specify. If you do not specify an end date, the system includes the oldest rejected application and/or the most recently rejected, as applicable.

Pending Applications — Search is limited to applications pending on a specific date that you are prompted to specify. If you leave the date field blank, the system will give meaningless results. Applications cannot be pending within a date range.

Issued Licences — Search is limited to licences issued within a date range that you are prompted to specify. If you do not specify an end date, the system includes the oldest issued licences and/or the most recently issued, as applicable. Please note: the searching criterion is the date of approval, not the fate of licences. Thus, licences that have later been cancelled or are expired fall within the searching criteria.

Expired Licences Search is limited to licences expired within a date range that you are prompted to specify. If you do not specify an end date, you run the risk of getting meaningless results because the system includes the oldest expired licences and/or those that will be expired on 31 December 9999, as applicable.

Cancelled licences Search is limited to licences cancelled within a date range that you are prompted to specify. If you do not specify an end date, the system includes the oldest cancelled licences and/or the most recently cancelled as appropriate.

Valid Licences Search is limited to applications valid on a specific date that you are prompted to specify. If you leave the date field blank, the system will give meaningless results. Licences cannot be valid within a date range.

IMPORTANT!!

When range is selected, two dates should be entered, in all other cases only one. If you enter no date, the system uses 11 November 1111 to carry out the search with EQUAL, GREATER THAN, SMALLER THAN, NOT EQUAL. It uses 11 November 1111 as the *"from"* date and 31 December 9999 as the *"to"* date when RANGE is selected. This, in many cases, would result in meaningless data, if any, being retrieved.

Fields You Can Use To Search

The fields that appear in the left side of the window are discussed here below. In all cases where company names or data of a catalogue are involved (e.g. dosage form, primary container, etc.) a list is available as usual by clicking the right mouse button or the **<F2>** key.

GENERAL RULES FOR SEARCH FIELDS

- If you select the same field more than once, the occurrences will be grouped and related with "**OR**" (e.g. priority=1 OR priority=essential drugs OR etc.).
- If you select a field in connection with another, the two will be related with "**AND**" e.g. priority=essential drugs AND licence holder=Bayer).
- If you select fields in "disordered" order, the system will take care of grouping them as appropriate. Thus, if you first select dosage form=tablet, then licence holder=Bayer, then dosage form=capsule, the system will build the following relation:

  (dosage form=table **OR** dosage form=capsule) **AND** licence holder=Bayer.

Some items do not follow the general rule. This is the case with: fixed-dose combinations, combinations of therapeutic groups, and items that can be logically chosen only once (e.g. human/veterinary, generic/brand). Further details are offered here below.

Priority

Permits you to search by priority degree (e.g. list all items with priority EQUAL 1, list all items with priority NOT EQUAL essential drugs, etc.). Follows the general rule. Applicable operators are EQUAL and NOT EQUAL. List is available through right mouse button or <**F2**> key.

Licence Holder

Permits you to search by applicant/licence holder. The system will interpret licence holder if you restrict the search to licences. It will interpret applicant in all other cases. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL.

Representative

Permits you to search by representative. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL.

Drug Name

Permits you to search by drug name or part of it. Follows the general rule. Applicable operators are EQUAL, NOT EQUAL and CONTAINS. Use Contains to search by part of the drug name. *Example:* To list all items where the drug name contains the string "DOLDOL,"select drug name from the fields list, then the operator CONTAINS, then enter the string "DOLDOL" and press <<Ok>> and << Execute >>. The retrieved items will include "DOLDOL." "DOLDOL PAEDIATRIC," "DOLDOL FORTE," "EXTRA STRENGTH DOLDOL," "NEO-DOLDOL."

Strength

Permits you to search by strength or part of the strength definition string. Follows the general rule. Applicable operators are EQUAL, NOT EQUAL and CONTAINS. Use Contains to search by part of the
strength definition string. *Example:* To list all items where the strength definition string contains the wording "25 mg," select strength from the fields list, then the operator Contains, then enter the string "25 mg" and press <<Ok>> and << Execute >>. Obviously the search is more meaningful when the strength field is used in conjunction with other fields.

Generic Name

Permits you to search by generic name or part of it. Follows the general rule. Applicable operators are EQUAL, NOT EQUAL and CONTAINS. Use CONTAINS to search by part of the generic name *Example:* To list all items where the generic name contains the string "SALBUTAMOL", select drug name from the fields list, then the operator CONTAINS, then enter the string "SALBUTAMOL"and press <<Ok>> and << Execute >>. The retrieved items will include "SALBUTAMOL", "SALBUTAMOL INJECTION", "SALBUTAMOL TABLETS", "EXTRA STRENGTH SALBUTAMOL").

Dosage Form

Permits you to search by dosage form. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL.

Primary Container

Permits you to search by primary container. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL.

Specification

Permits you to search by specification of primary container or part of it. Follows the general rule. Applicable operators are EQUAL, NOT EQUAL and CONTAINS. Use CONTAINS to search by part of the string. *Example:* To list all items where the specification of primary container contains the string "dark glass," select drug name from the fields list, then the operator CONTAINS, then enter the string "dark glass"and press <<Ok>> and <<Execute>>. The retrieved items will include dark glass, dark glass bottle, dark glass ampule, 5 dark glass ampules.

Type of Licence

Permits you to search by type of licence. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL.

Availability Restrictions

Permits you to search by availability restrictions. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL.

Marketing Conditions

Permits you to search by marketing conditions. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL

National Formulary Code

Permits you to search by national formulary code. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL. Field not related to catalogue, no list available.

Location of File

Permits you to search by location of file. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL. ***Field not related to catalogue, no list available.***

Shelf Life

Permits you to search by shelf life. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL. ***Field not related to catalogue, no list available.***

Withdrawal Period

Permits you to search by withdrawal period. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL. ***Field not related to catalogue, no list available.***

Generic/ Brand

Permits you to limit the search to either brand or generic items. It *does not* follow the general rule because it can be selected only once. If it is not selected both branded and generic items are retrieved.

Domestic/ Imported/ Both	Permits you to limit the search to either option. It *does not* follow the general rule because it can be selected only once. If it is not selected, items are retrieved regardless of their origin.
Human/ Veterinary	Permits you to limit the search to either option. It *does not* follow the general rule because it can be selected only once. If it is not selected both human and veterinary items are retrieved.
Reception Date	Permits you to search by application reception date. It *does not* follow the general rule because it can be selected only once. Applicable operators are EQUAL, GREATER THAN, SMALLER THAN, NOT EQUAL, RANGE. *See General Rule for Dates.*
Cancellation Date	Permits you to search by licence cancellation date. It *does not* follow the general rule because it can be selected only once. Applicable operators are EQUAL, GREATER THAN, SMALLER THAN, NOT EQUAL, RANGE. *See General Rule for Dates.*
Expiry Date	Permits you to search by licence expiry date. It *does not* follow the general rule because it can be selected only once. Applicable operators are EQUAL, GREATER THAN, SMALLER THAN, NOT EQUAL, RANGE. *See General Rule for Dates.*
Renewal Date	Permits you to search by licence renewal date. It *does not* follow the general rule because it can be selected only once. Applicable operators are EQUAL, GREATER THAN, SMALLER THAN, NOT EQUAL, RANGE. *See General Rule for Dates.*
Number of Active Ingredients	Permits you to search by number of active ingredients. Follows the general rule. Applicable operators are EQUAL, GREATER THAN, SMALLER THAN, NOT EQUAL, RANGE.
Narcotic/ Non-Narcotic	Permits you to limit search to items containing internationally controlled substances. It *does not* follow the general rule because it can be selected only once. If it is not selected, both items containing and not containing internationally controlled substances are retrieved.
Classification N1..N3, P1..P4	Permits you to retrieve selectively items containing substances listed in tables 1, 2 or 3 of the narcotics convention, or in tables 1,2,3, or 4 of the psychotropics convention. Follows the general rule. Applicable operators are EQUAL, and NOT EQUAL.
Multiple Formula Preparation	Permits you to retrieve selectively multiple formula preparations. It *does not* follow the general rule because it can be selected only once. If it is not selected both standard and multiple formula preparations are retrieved.

Manufacturer

Permits you to search by manufacturer. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL.

Manufacturer's Country of Origin

Permits you to search by manufacturer's country of origin. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL. All manufacturers matching the country criterion will be retrieved whichever role they played in the manufacturing process.

Ingredient

Permits you to search by ingredient. *Does not* follow the general rule it uses OR to relate to other ingredients and combination of ingredients, it uses AND for all other fields. Applicable operators are EQUAL, NOT EQUAL and CONTAINS. Use Contains to search by part of the ingredient name.

Example: To list all items containing any "CHLOROQUINE"salt, select ingredient from the fields list, then the operator CONTAINS, then enter the string "CHLOROQUINE"and press <<Ok>> and << Execute >>. The retrieved items will include "CHLOROQUINE," "CHLOROQUINE SULPHATE," "SULFATE DE CHLOROQUINE," "CHLOROQUINE DIPHOSPHATE". The string to enter *does not* need to be an entire word, if you enter "CILLIN," the retrieved items will include "PENICILLIN, AMPICILLIN, etc.).

Please Note: Ingredients entered through this field will be linked with the OR operator. That is, if you choose chloroquine and then ampicillin the system will look for items containing EITHER chloroquine OR ampicillin. To search for fixed-dose combinations (i.e. items containing BOTH chloroquine AND ampicillin) you should use the specific INGREDIENTS COMBINATION option. If you enter an ingredient name and press <**Enter**> the system will search exactly for the name you have entered. Thus, if you are not sure about the spelling or about the preferred national name then you should rather use the list to get the name you need to retrieve.

Ingredients Combination

Permits you to search by fixed-dose ingredients combination. It *does not* follow the general rule. Applicable operators are EQUAL and CONTAINS. See here above under INGREDIENT for the use of CONTAINS to search by part of the ingredient name. You can use in the same search both the EQUAL and CONTAINS operators. *Example:* To list all items containing any chloroquine salt and starch and tartrazine, select ingredients combination from the fields list, then the operator CONTAINS, then enter the string "CHLOROQUINE"and press <<Ok>>, then select the operator EQUAL and enter "STARCH"or get it from the list and press <<Ok>>, then enter "TARTRAZINE"or get it from the list and press <<Ok>> and << Execute >>.

	The maximum number of ingredients in combination that you can search for is five. ***Note:*** If you enter an ingredient name and press **<Enter>** the system will search exactly for the name you have entered. Thus, if you are not sure about the spelling or about the preferred national name then you should rather use the list to get the name you need to retrieve.
Active/ Excipient/ Other	Permits you to limit search to items where a given ingredient has been entered as either active, excipient or other. It *does not* follow the general rule because it can be selected only once. If it is not selected all items are retrieved. Obviously, this searching criterion is meaningful only when associated to an ingredient name.
Quantity of Ingredient	It is to be understood as the quantity of ingredient in the formula. This permits you to limit the search to items where a given ingredient is present in a certain quantity. Follows the general rule. Applicable operators are EQUAL, NOT EQUAL and CONTAINS. Obviously, this searching criterion is more meaningful when associated to an ingredient name.
Route of Administration	Permits you to search by route of administration. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL.
Therapeutic Group	Permits you to search by therapeutic group. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL.
Combination of Therapeutic Groups	Permits you to search by combination of therapeutic groups. It *does not* follow the general rule. Applicable operators are EQUAL and NOT EQUAL.
Distributor	Permits you to search by distributor. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL.
Distributor's Country of Origin	Permits you to search by distributor"s country of origin. Follows the general rule. Applicable operators are EQUAL and NOT EQUAL.
Data Sheet	Permits you to search items with specified text string in data sheet. Follows the general rule. Applicable operator is CONTAINS. *Example:* To list all items where "postpartum hemorrhage" is mentioned in data sheet, select data sheet from fields list, type "postpartum hemorrhage"at the appropriate prompt, then press <<Ok>> and << Execute >>.

Additional Notes

Permits you to search items with specified text string in additional notes field. Follows the general rule. Applicable operator is CONTAINS. *Example:* To list all items where “counterfeit” is mentioned in additional notes field, select additional notes from fields list, type “counterfeit”at the appropriate prompt, then press <<Ok>> and << Execute >>.

User Defined Fields

Fields defined by users when setting the configuration of the system can be used as searching criteria. They follow the general rule. Applicable operators are EQUAL and NOT EQUAL.

8.14.6-2 How the Multiple Search Criteria Retrieval Tool Operates

Example: You want to know how many licences were valid on 31 December 1993 for imported tablets or capsules containing salbutamol as the sole active ingredient.

Process: You select "valid licences", enter 31/12/1993 and press <<Ok>> in the first screen. Then:

1. Select Dosage Form from the field list. Select EQUAL from the drop down list.
2. Press <**F2**> or the right mouse button to choose tablet from the list.
3. Press <<Ok>>. Repeat the step 3 to choose capsule.
4. Select the number of active ingredients from the field list, select EQUAL and type "1", press <<Ok>>.
5. Select ingredient from the field list, select EQUAL and press <**F2**> or the right mouse button.
6. Select salbutamol from the list, press <<Ok>> then press <Exit>.
7. Select Imported/Domestic/Both from the field list by double clicking on it.
8. Select Imported from the pop-up window, press <<Ok>>.
9. Press the <See searching criteria> button to check your entry.
10. Press <<Execute>>. If data is found that matches the entered searching criteria, a red window appears prompting you to select where the output should go. (Specific help is available by pressing <**F1**> when that window is on the screen).

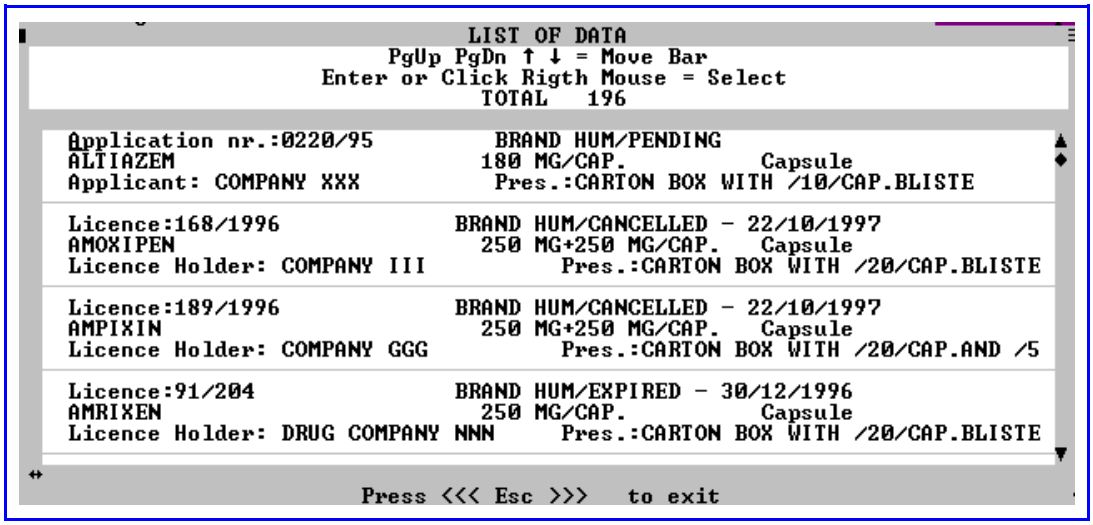


Figure 8-40: Data Output screen

Selecting Output Destination

The options you are offered here are to send the output either to the screen, to the printer or to a file.

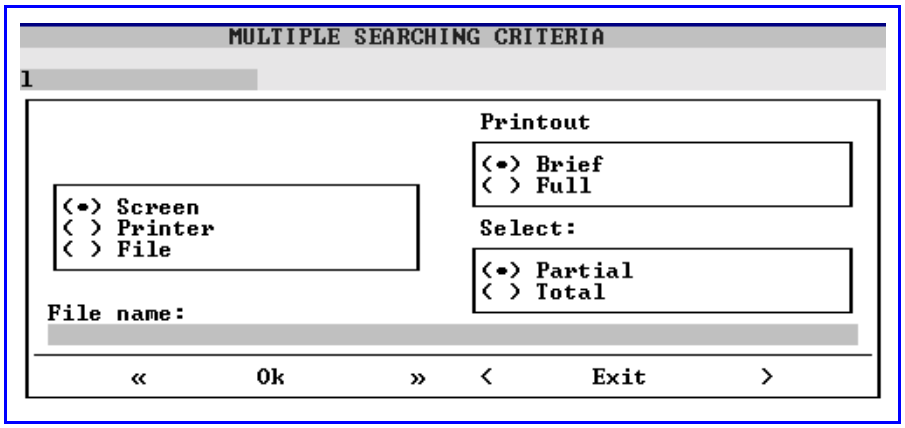


Figure 8-41: Selecting Destination for multiple search print out

Screen

After selecting screen, press <<Ok>> and you will be shown data on the screen. After viewing data, you are sent back to this screen and you will then be able to select printer or file.

Printer

If you select printer you are offered two additional options. First, you can choose between brief and full printout. The extent of information to be printed in these printouts is decided by the user at the time of customizing the system for routine use. Second, you can choose between partial or total printing. Total means that all the items retrieved will be printed without further prompt. Partial means that the items retrieved will be shown in a window from where the user can select those to be printed clicking on them one by one.

File

You can send the subset of data resulting from your search to a file. You can then use that file to prepare specific reports using the report generator provided with this system. You can choose a file name up to 50 characters long.

8.14.7 Report Generator

This tool permits you to prepare printouts containing only user defined information. Users can select the report title, the fields that should be shown in each column, their width, and the set of data to be shown. To print information referred to a specific set of data, users should carry out a multiple searching criteria retrieval, save the set of data matching such criteria to a file, and finally use that file as source of data for the report generator.

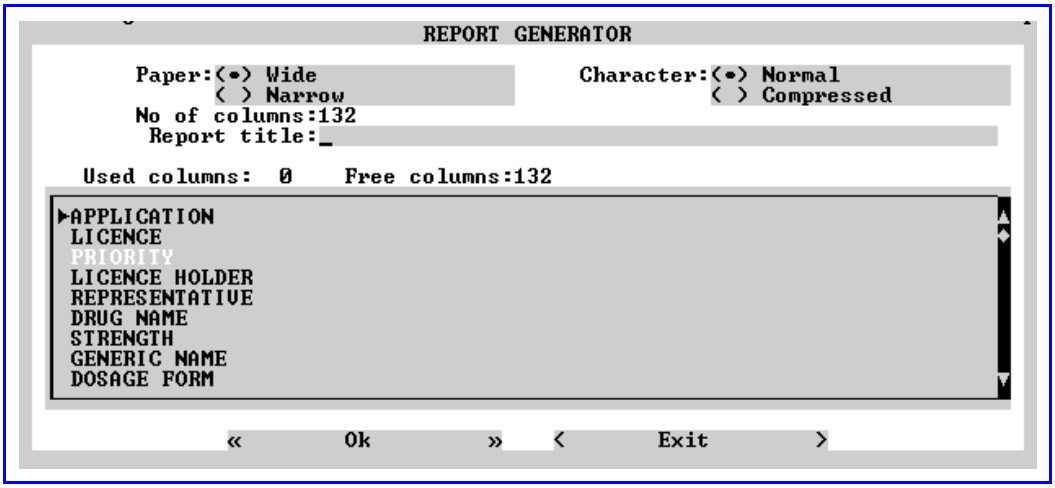


Figure 8-42: Report Generator screen

To utilize the report generator, complete the following steps:

1. Select paper width and normal or compressed characters (narrow paper permits a maximum of 80 normal or 132 compressed characters per line, wide paper permits a maximum of 132 normal or 217 compressed characters per line). The maximum number of characters is shown on the screen as maximum number of columns.
2. Type the report title and press <**Enter**>.
3. Select from the list of fields, that appears in the lower left side of the screen, the fields you wish to see printed. You can select them either with the light bar and <**Enter**> key, or by clicking on the field with the mouse.
4. Type in the width for these data.
5. To remove a selected item, just select it again, and/or set field width to 0 (zero). Selected items are identified by a number, indicating width, and an arrow sign. The remaining number of columns is shown on the screen after each item selection. Some items (indicated by the absence of the column width number) do not use up column space because they are printed on separate lines.
6. Click <<OK>> after completing the selection of columns.
7. On the new screen click the “Order by:” pop-up window. This pop-up window shows all items that you selected to appear in columns. Any of them can be chosen to define the order in which data are printed.

8. You can now restrict the range of items to be printed to Human/Veterinary/Both, and to a variety of application/licence statuses. This is done selecting as appropriate from the respective lists.
9. Press <<Ok>> to continue or <Exit> to return to the Main Menu.
10. The left side of the screen lists all the items you have selected in the previous screen. Click the left mouse button on the double arrow sign at the left of any item and, keeping the button pressed, move the mouse up or down. The item will change its position in the window. This will be reflected in its position on the printout: the first item on top of the list will appear as the first column on the left of the printout, and so on.
11. Select the source of data from the two available options: ***entire registration file*** (includes all data as selected in the previous screen) or ***user defined files*** (files generated by the user as a result of a multiple searching criteria retrieval)

    In the latter case a report could be generated to include for example only licences valid on 31 December 1993 for imported tablets or capsules containing salbutamol as the sole active ingredient, or licences approved between 1 January 1993 and 31 December 1993 for veterinary tablets or capsules containing either sulphamethoxazole plus trimethoprim or chloramphenicol involving a manufacturer based in Switzerland and a distributor based in Liechtenstein, etc.
12. Select destination of output. If you chose to output to a file, you will be able to pick up the table with a wordprocessor and further edit/format it before printing.
13. Press <<Ok>> to print or <Exit> to return backwards.

8.14.8 Predefined Reports

The Predefined Reports option permits you to prepare standard reports grouped or ordered by a number of preset criteria.

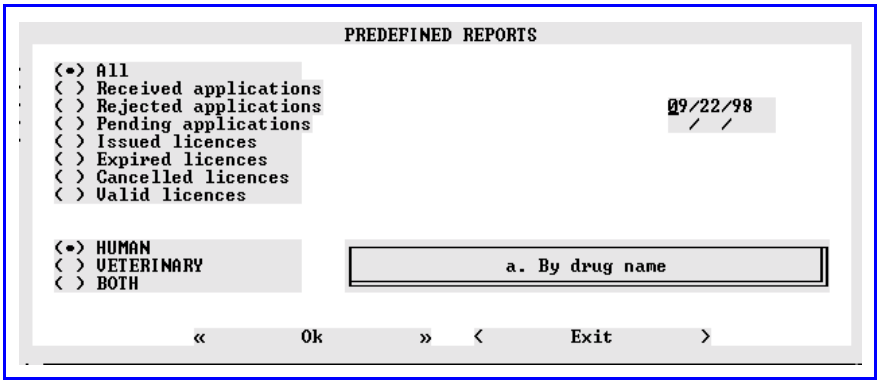


Figure 8-43: Predefined Reports

To generate a predefined report, complete the following steps:

1. Define the scope of the search using the available options: All, Received Applications, Rejected Applications, Pending Applications, Issued Licences, Expired Licences, Canceled Licences, and Valid Licences. *(These available options are described in Section 8.14.6).*
2. Select whether Human/Veterinary/Both drugs are to be included in the printout.
3. Select the printing order criterion from the following list:

a.	By drug name
b.	By ingredient
c.	By licence holder/applicant
d.	By manufacturer
e.	By representative
f.	By number of active ingredients
g.	By dosage form
h.	By dispensing modalities
i.	By availability restrictions
j.	By therapeutic classification
k.	by product origin
l.	With narcotic ingredients
m.	By licence type
n.	By generic name
o.	by priority
p.	By application/licence number
q.	By distributor

Figure 8-44: Pre-defined Report options

4. Select whether you want to print the entire file, or only a specific item. For example: After selecting drug name as printing order criterion, the user can decide to print all items alphabetically ordered by drug name or only the items with a drug name entered by the user. In the same way only drugs of one licence holder, or manufacturer, or dosage form, etc., can be printed.
5. Press <<Ok>> to print or <Exit> to return to the Main Menu.

8.14.9 Predefined Statistics

The Predefined Statistics option, permits you to display and print a set of predefined statistics. Data concerning drug items will show separate figures for human and veterinary items, as well as a total.

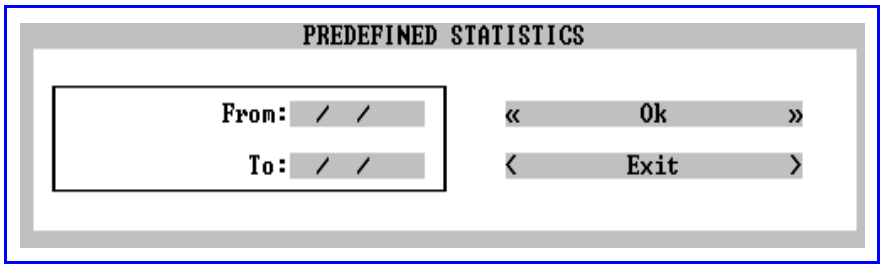


Figure 8-45: Predefined Statistics screen

For company data, separate figures will be shown for the statuses **Approved, Cancelled, and Term to Comply**, as well as for the total. To begin generating this report, you must enter the date range, i.e. begin date (From) and the end date (To), that you want to include. The system will retrieve predefined statistics limited to the specified time periods. *SeeSample Report below.*

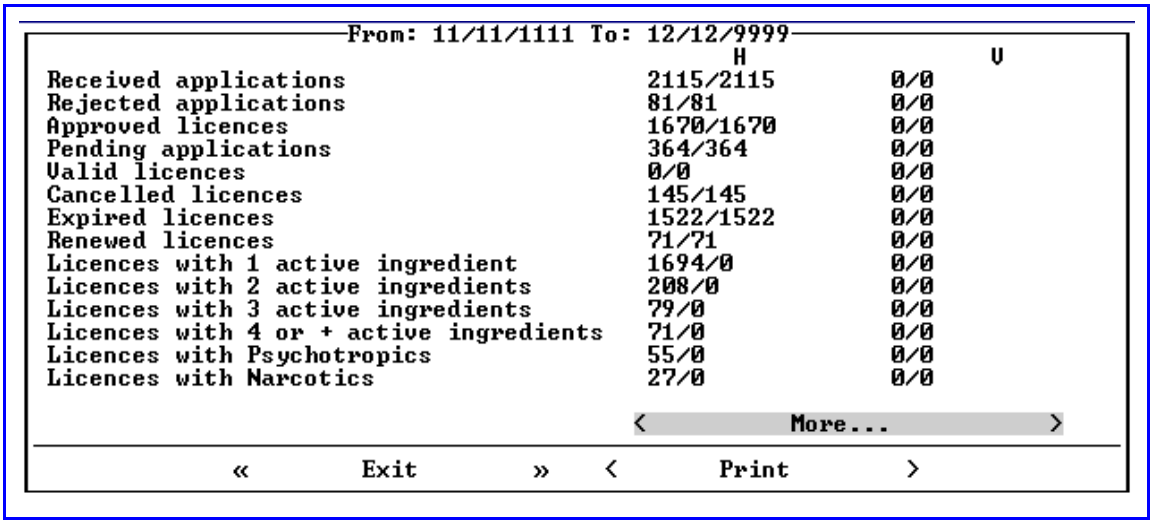


Figure 8-46: Sample of Predefined Statistic report

8.14.10 Price-Related Retrieval

This retrieval option allows you retrieve information based on price data (e.g all items with retail price lower than a given value).

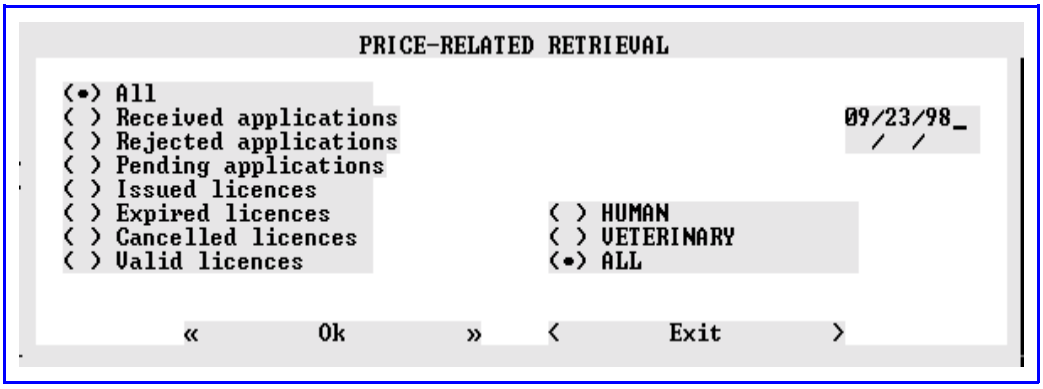


Figure 8-47: Price Related Retrieval screen

To implement price-related retrieval, complete the following steps:

1. Define the scope of the data. The options you are offered on the screen are: All, Received Applications, Rejected Applications, Pending Applications, Issued Licences, Expired Licences, Canceled Licences, and Valid Licences. These available options are described in Section 8.14.6.
2. Select whether Human/Veterinary/Both drugs are to be included in the printout. *Note:* You will also be able to change this setting after having selected the searching price.
3. Press <<Ok>> to continue (then see the specific help screen), or <Exit> to return to the Main Menu.

8.14.11 Variations

This option permits you to print a list of all variations recorded for a given licence.

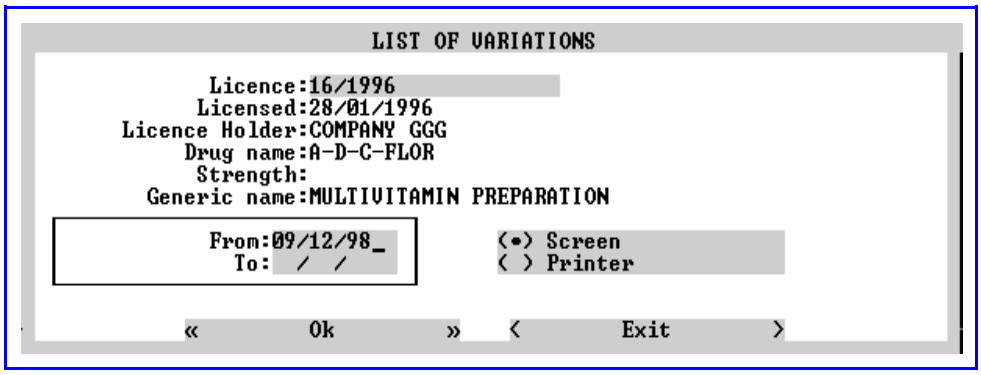


Figure 8-48: Retrieval by Variations screen

To generate this report, complete the following steps:

1. Select the licence whose variations you wish to print.
2. Set an optional date range to limit the printout only to variations made within that date range. If no dates are entered the printout will include all variations.
3. Press <<Ok>> to print.

8.14.12 Company/Drug-orientated Query

This query option allows you to retrieve data on all licence holders, manufacturers, or distributors of a given group of drug products. The drug product groups can be identified by their product name, generic name, or ingredient name.

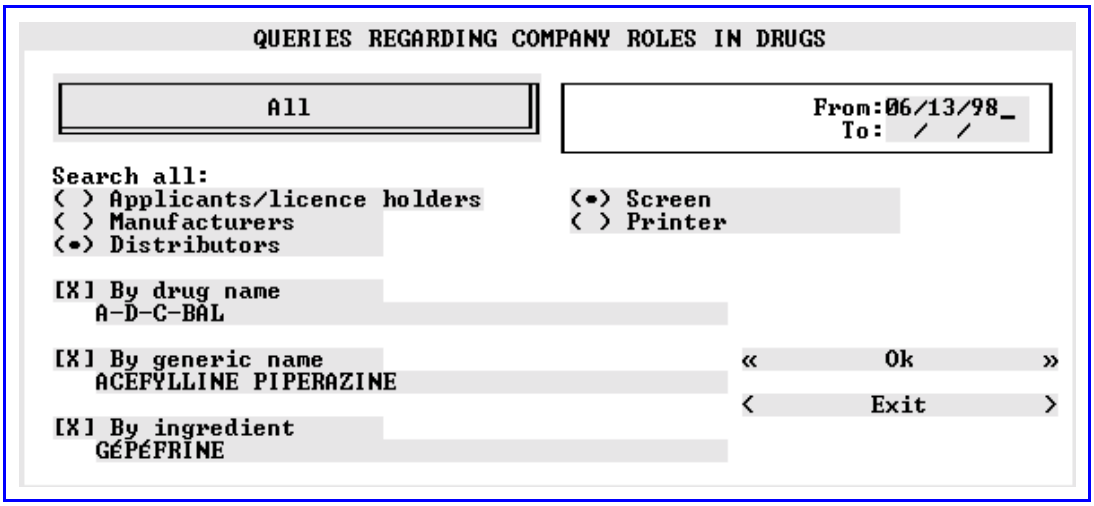


Figure 8-49: Query screen used to retrieve Company/Drug information

To generate this report, complete the following steps:

1. Define the scope of the data. The options you are offered on the screen are: All, Received Applications, Rejected Applications, Pending Applications, Issued Licences, Expired Licences, Canceled Licences, and Valid Licences. These available options are described in Section 8.14.6.
2. Select between applicant, licence holders, manufacturers, and distributors, as appropriate.
3. Select one or more searching criteria. If you select more than one, the search will yield all items that match either one of the searching criteria indicated.

   Example: If you choose as a searching criteria, the product name “DRUGGOLINE” and generic name “PARACETAMOL,” all items with generic name “PARACETAMOL” will be included, even if their name is not “DRUGGOLINE.” In addition, all items named “DRUGGOLINE” will be included even if their generic name is not “PARACETAMOL”.
4. Press <<Ok>> to get the list of companies matching the searching criteria, or <Exit> to return to the main menu..

8.14.13 Correspondence

This option permits you to retrieve all the correspondence issued for a given application or licence.

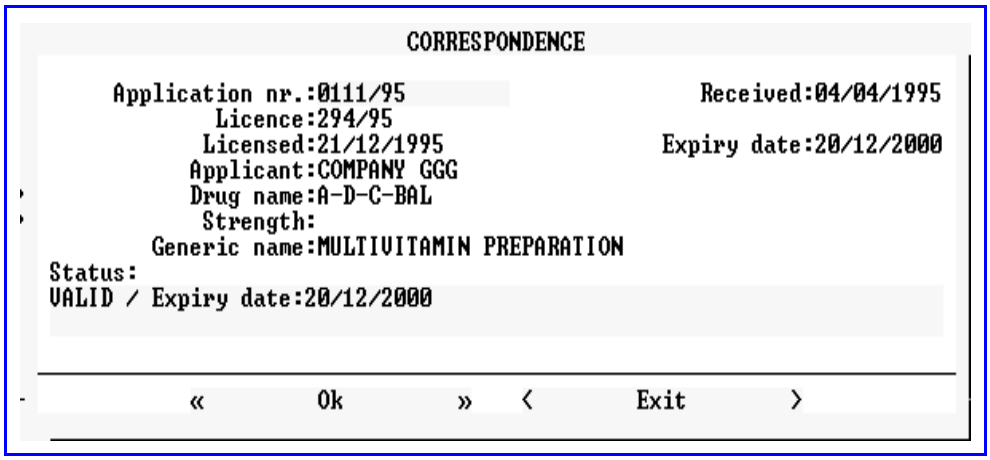


Figure 8-50: Correspondence format screen

To retrieve correspondence, complete the following steps:

1. Enter either an application or licence number, as appropriate. In the case where both application and licence numbers are retrieval options, the system will automatically distinguish among the two types of numbers. However, if the same number exists for both an application and a licence, ***only*** the application will be retrieved.
2. Move to the appropriate field and select the item.
3. Press <<Ok>> to get access to the correspondence.
4. In the correspondence list, double click on the “Memo” label to see the full text of the correspondence.

8.14.14 New Substances

This retrieval option permits you to search and list the substances that for the first time have been included in an application or licence received/issued within a given date range.

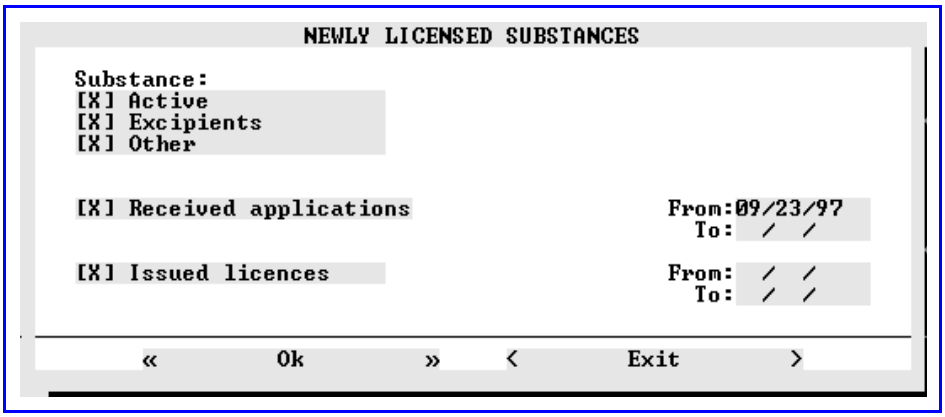


Figure 8-51: Retrieval of New Substances screen

To generate this report, complete the following steps:

1. Select whether the search should include substances entered as active, excipient and/or other.
2. Indicate whether the search should include applications received within a given date range.
3. Indicate whether the search should include licences issued within a given date range.
4. To conduct the search, press <<Ok>>, or <Exit> to return to the main menu. If <<Ok>> is selected, a second screen is revealed that provides a summary of the result of the search.
5. To see list of substances meeting the searching criteria, press the <List substances> button. You may then select a substance to see a list of applications/licences that contain it. At this stage, you may press <**Enter**> on a specific application or licence to view detailed information. Press <**Esc**> or <Exit> to return to the previous screen.
6. To print the list, press < Print >, or <Exit> to return to the previous screen.

8.14.15 Processing Duration

This option permits you to retrieve information on drug licence applications based on their processing duration.

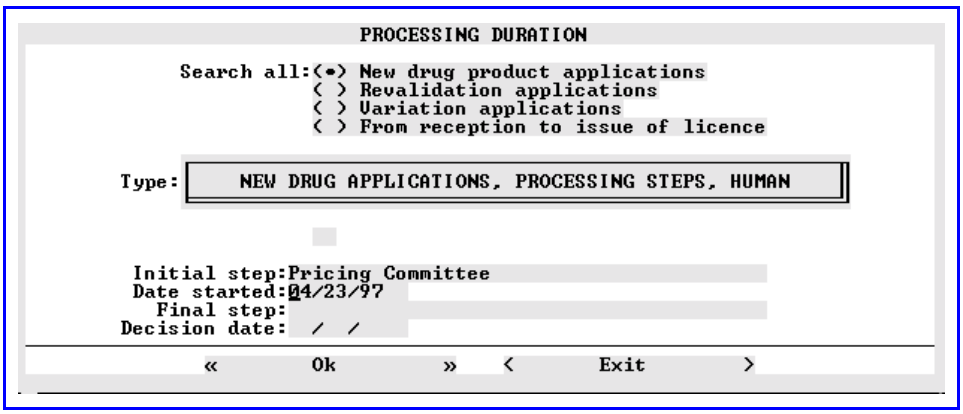


Figure 8-52: Retrieval of Processing Duration

To generate this report, complete the following steps:

1. Select whether the search should include new drug product applications, revalidation applications, variation application substances, or all applications from reception to licence issue.

   If the option *'From Reception to Issue of Licence'* is selected, then you ***will not*** have the option to enter initial step and final step. If the other 3 options (new drug product applications, revalidation applications, variation application substances) are selected, you must enter what the initial step is and the date on which the initial step began, and you must also enter the final step and the decision date for the final step.

2. Select the type of processing.

3. Select a priority level (optional)

4. Type in the initial step, or press **<F2>** to select from the file content list.

5. In the date started field, enter the date on which the initial step began, i.e. the search will include all applications that have started that step on, or after, that date.

6. Type in the final step, or press **<F2>** to select from the file content list.

7. In the decision date field, enter the date on which the final step ended, i.e. the search will include all applications that have started that step on, or after, that date.

8. To conduct the search, press <<Ok>> or <Exit> to return to the Main Menu. If <<Ok>> is selected, the system will then display all the applications that fit the criteria, and display the duration in days for each application. The bottom portion of the screen displays the average duration in days.

   Selecting a specific application by double clicking on it, displays all steps based on the initial criteria entered and allows you to view any detailed information available.

For any Notes fields displayed, if the entry indicates “MEMO” in upper case letters, this means that the system contains information that can be viewed by pressing either **<Ctrl>+<Page Down>**, or double clicking on the memo field. To return to the list, simply press **<Esc>**. You may also continuously press **<Esc>** until you are returned to the main processing duration screen. At that point you must select **<Exit>** to return to the main menu.

Below is a sample of the report, using ‘From Reception to Issue of Licence’ criteria.

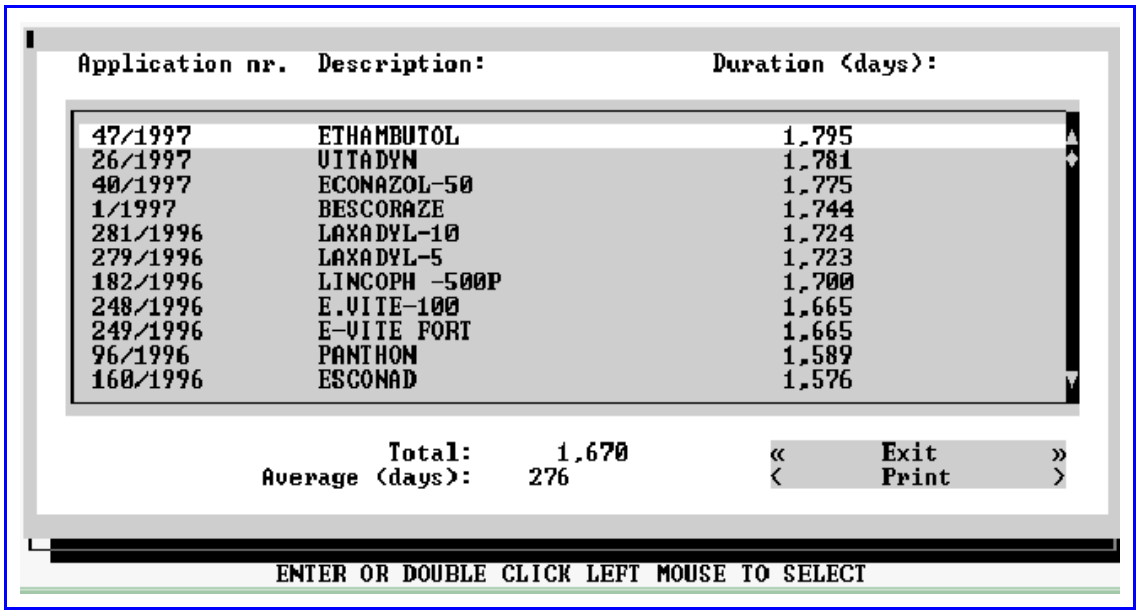


Figure 8-53: Processing Duration output screen

8.14.16 Ingredient Frequency

This option permits you to retrieve information on the frequency of ingredients in drug applications/licences.

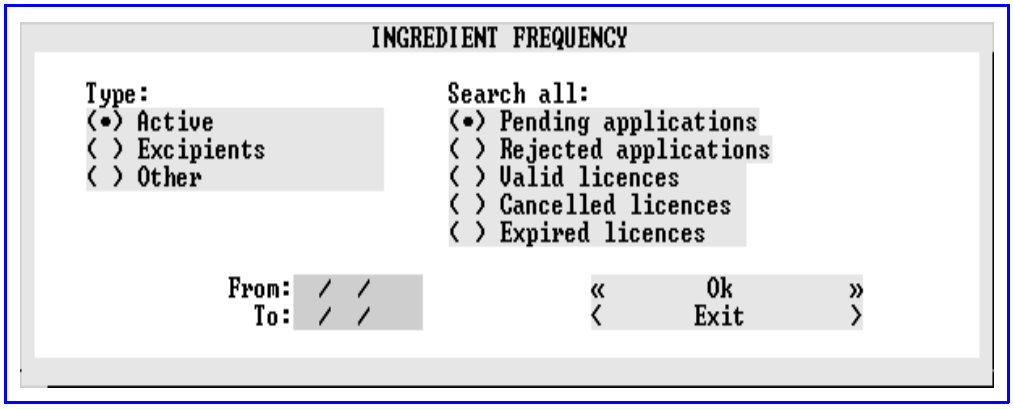


Figure 8-54: Retrieval of Ingredient Frequency

To generate this report, complete the following steps:

1. Select whether the search should include active, excipients or other ingredients.
2. Specify if the search should include pending applications, rejected applications, valid licences, cancelled licences, or expired licences.
3. Specify the date range (from/to) to be included in the report.
4. To conduct the search, press <<Ok>> or <Exit> to return to the Main Menu.

8.14.17 Generic Name Frequency

This option permits you to retrieve information on the frequency of a generic name appear in drug applications/licences.

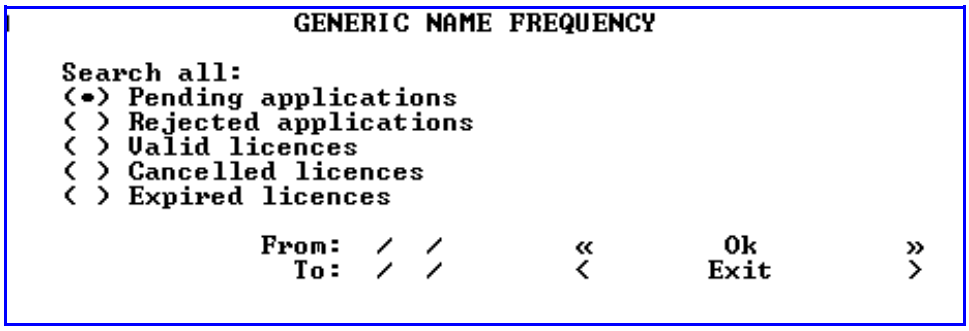


Figure 8-55: Retrieval by Generic Name Frequency

To generate this report, complete the following steps:

1. Specify if the search should include pending applications, rejected applications, valid licences, cancelled licences, or expired licences.
2. Specify the date range to be included in the report.
3. To conduct the search, press <<Ok>> or <Exit> to return to the Main Menu.

8.14.18 Ingredients by Classification

This option permits you to retrieve information on ingredients sorted by their classification.

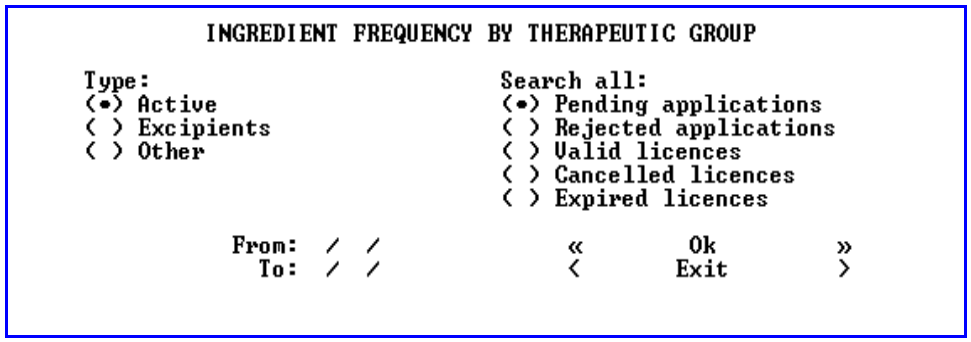


Figure 8-56: Retrieval of Ingredient by Classification

To generate this report, complete the following steps:

1. Select whether the search should include active, excipients or other.
2. Specify if the search should include pending applications, rejected applications, valid licences, cancelled licences, or expired licences.
3. Specify the date range to be included in the report.
4. To conduct the search, press <<Ok>> or <Exit> to return to the Main Menu.

Chapter 9

9. FEES

The SIAMED process utilizes different types of fees. For example, there can be application fees, licence fees for imported products, licence fees for domestic products, and QC laboratory fees.

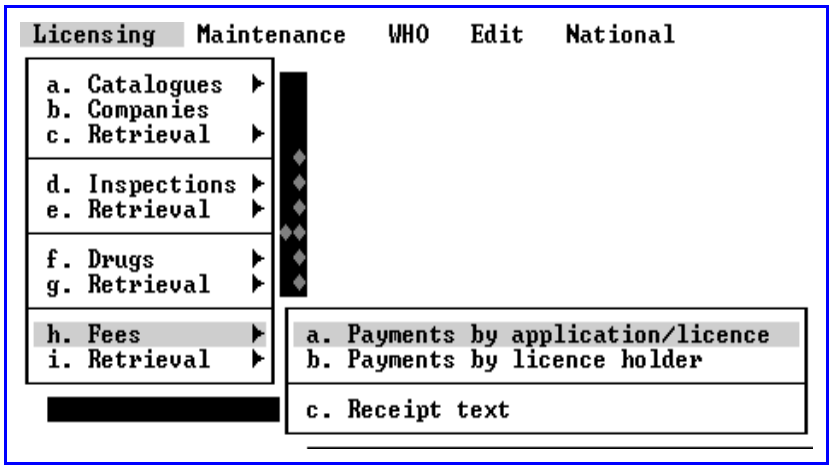


Figure 9-1: Fees main menu

The system uses the following processes to function effectively.

Defining Fees

Fees used within the system are defined through the Fees catalogues.

Relating Applications/ Licences to Fees

Users then establish a relationship between fees and applications/ licences. This is not done automatically by the system. By establishing the relation, the system is then able to tell the user when a fee is due for a given application or licence.

A relation can be set in three ways leading to the same results:

a. by selecting the relevant fee(s) while entering application data

b. when issuing a marketing authorization, or

c. from the fees submenu option (shown above: Payments by application/licence)

Issuing Invoices

This feature is used to print invoices to applicants/licence holders, remind them of payments due, or simply to issue lists of fees due. Issuing Invoices is done through the Retrieval: Fees submenu options.

Recording Payments & Issuing Receipts

This feature is used to record payments through the Fees submenu options. After recording a payment, a receipt is automatically numbered and printed. This can be done either for each individual application/licence through Fees/Payments by application/licence, or for all fees of a given company using Fees/Payments by licence holder.

9.1 Payments by Application/Licence

This option permits to establish a link between application/licence and one or more fees, and to record information about fees and individual fee payments. It is intended for managing any type of fee - like application fee, QC laboratory testing fee, licence fee, retention fee, certificate fee, etc. To operate effectively this feature requires that fees exist in the appropriate catalogue.

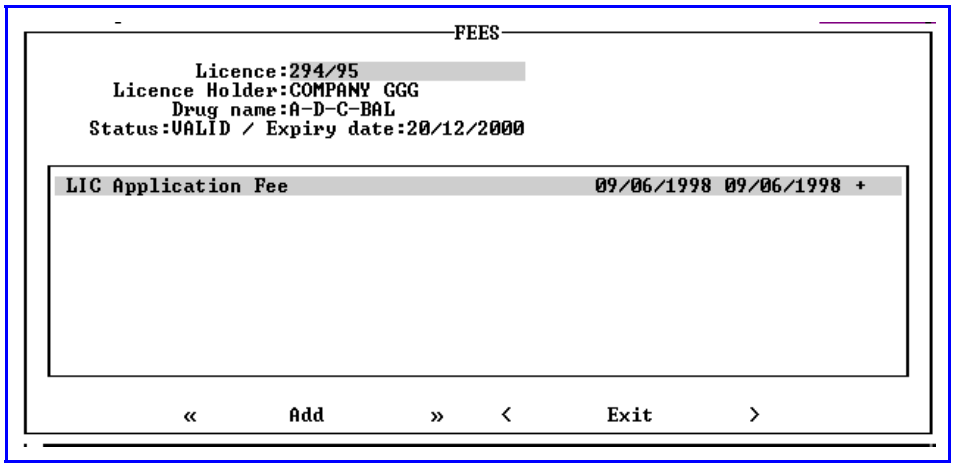


Figure 9-1: Payment of Fees by Application/Licence

Application Number or Licence Number

This is the unique number associated with each application/licence.

The system will first search the applications database. If the same number exists for both, the application will be found. Or you can press **<F2>** to pick up the item you wish from a list. This will automatically retrieve summary information describing the selected item.

Applicant

This field displays the name of the applicant/company.

Drug Name

Displays the name of the drug for which the licence has been sought.

Status

Describes what phase of processing the application/licence is in.

The central part of the screen displays the description/name of any fee linked to the

application, the date on which payment is/was due, and the date on which payment was made/recorded. This data may be displayed with one of several "*signs*"such as:

"**+**" (plus) sign indicates that payment has been made.

"**-**" (minus) sign indicates that payment is still pending,

"**A**"(letter A) indicates that this fee was cancelled.

If you select an item with any of the signs indicated under Status, your actions will be limited as follows:

- plus (+) sign, you will only be permitted to cancel the fee, or print a letter related to the application or licence to which the fee refers.
- minus (-) sign, a window will be revealed where you can record information on payment.
- "A", you can make no changes to this item.

You can however, utilize the <<Add>> key to add a new fee, or <Exit> to return to the main menu.

9.2 Payments by Licence Holder

This fee option permits you to record information about fee payments by licence holder. It is intended for managing any type of fee such as an application fee, QC laboratory testing fee, licence fee, retention fee, certificate fee, etc. In order to function, this feature requires that fees and their date-due have been previously recorded.

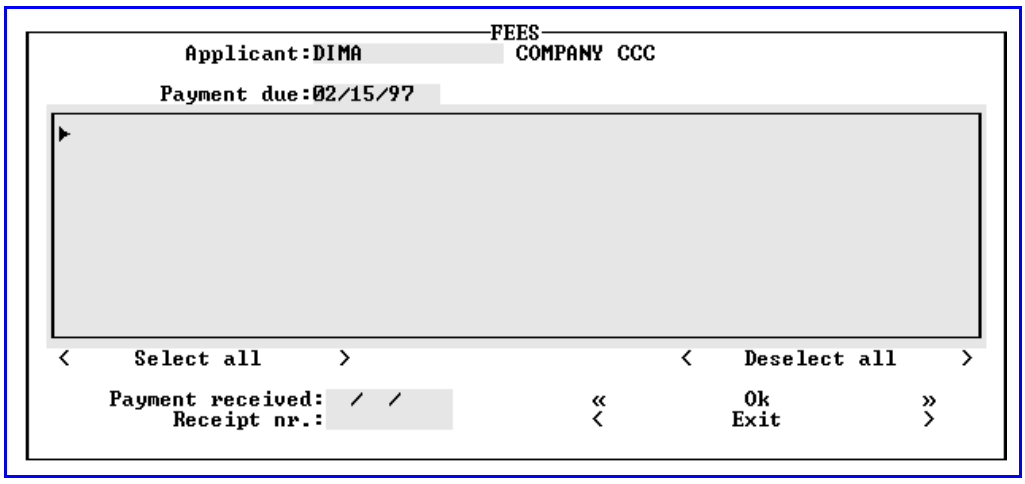


Figure 9-2: Payment of Fees by Licence Holder

Applicant — Enter the name of the applicant/company. You can also press **<F2>** to select from a list of applicants.

Payment Due (date) — Use this field to enter a date which the computer will use to generate a list of all fees due from the licence holder by the date indicated. If information on fees or payments has been entered into the system, the generated list will display payments status.

Select All/ Deselect All — Use these push buttons to select from the list of items generated. Selecting an item includes it in the list of items for which payment has been received on a given date, and for which the same receipt number will be used.

Payment Received — Enter the date on which payment was received.

Receipt Nr. — Type the receipt number.

Once data entry has been completed, press <<Ok>> to save your entry. The system will automatically print a payment receipt for all selected items, if a payment has been recorded. Press <Exit> to return to the main menu.

9.3 Receipt Text

The Receipt Text function allows you to prepare and edit the text that will accompany the list of items for which fee payment has been received.

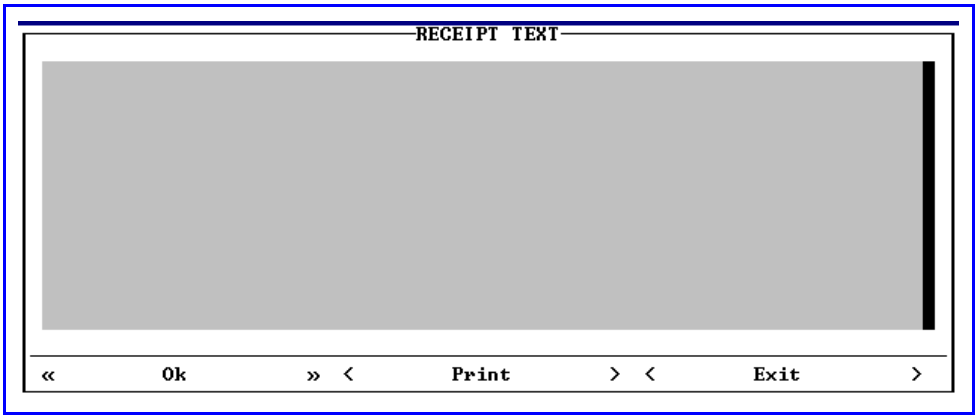


Figure 9-3: Receipt Text screen

9.4 RETRIEVAL: Fees

The Retrieval section under the Fees menu option consist of three sub-menus - Fees Due, By Type of Fee, and By Licence Holder.

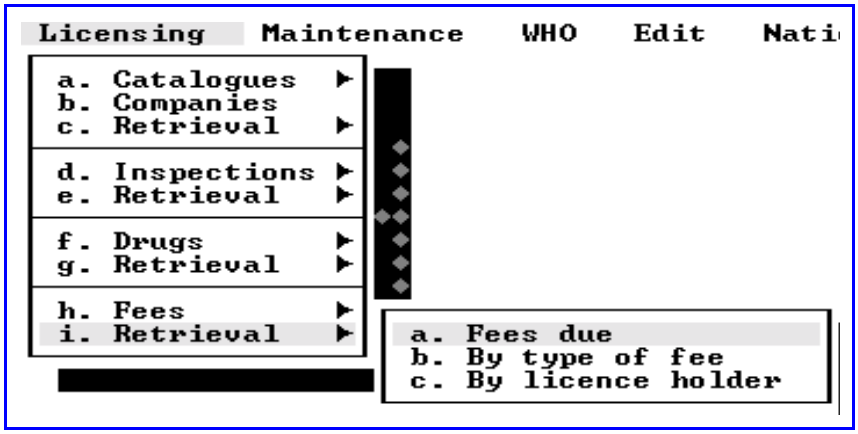


Figure 9-4: Retrieval: Fees menu screen

9.4.1 Fees Due

This feature allows you to display and print a list of fees due before a given date. The printout can be used as an invoice or aide-memoire (reminder) to be sent to companies before payments are due.

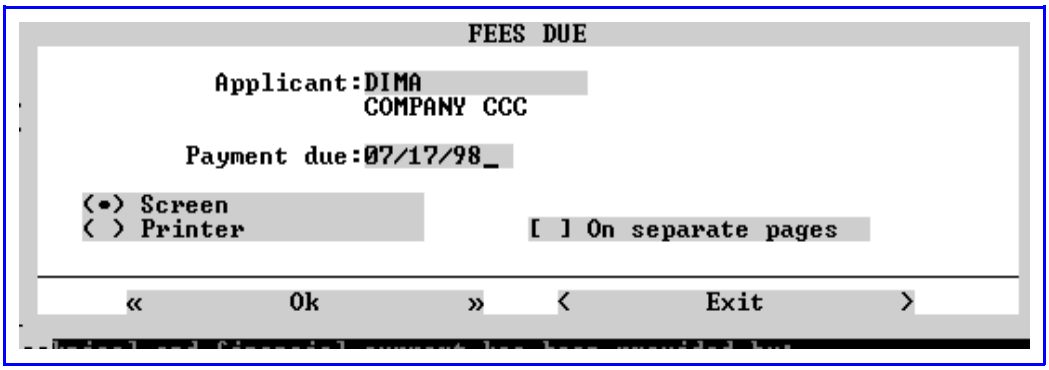


Figure 9-5: Fees Due screen

Applicant — Use **<F2>** to select the company for which the listing should be done. If you choose to leave this field blank, the computer will list all fees due for all companies by company name.

Payment Due — Enter the date on which the payment is due.

Once data is entered, select where the output should go. If you are printing information on multiple companies, you can select the check box, *On Separate Paper* to specify that the fees of each company should be listed on separate pages. Press << Ok >> to execute or < Exit > to return to the main menu.

9.4.2 By Type of Fee

This option permits you to print a list of all fees grouped by type of fee.

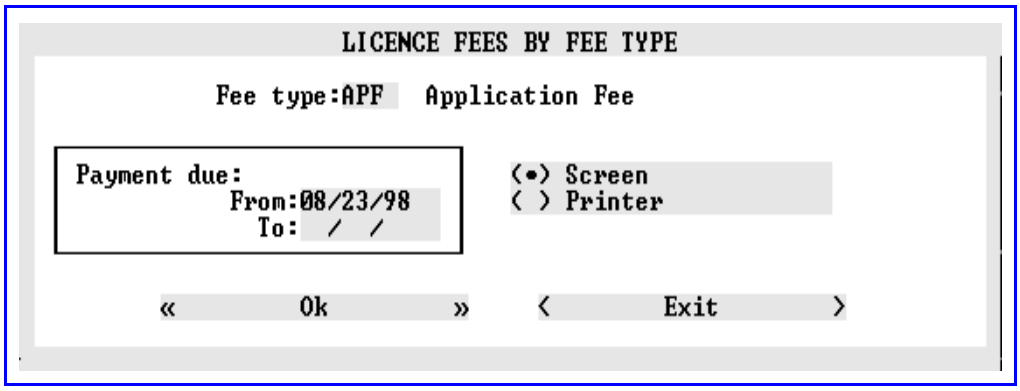


Figure 9-6: Sample of Licence Fees by Fee Type screen

Fee Type Specify the fee type or use **<F2>** to select from the list.

Payment Due From/To Enter the date on which the payment is due.

The list produced under this option shows application/licence number, drug name, fee name, amount, date payment is/was due, status (+/-/A), as well as date payment was received.

9.4.3 Fee by Licence Holder

This feature permits you to print a list of all fees, grouped by applicant/licence holder.

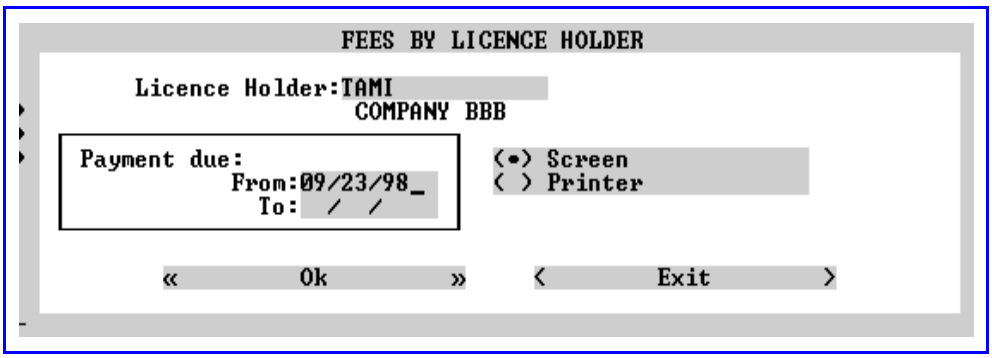


Figure 8-7: Fee by Licence Holder screen

Licence Holder Specify the licence holder or use **<F2>** to select from the list.

Payment Due Enter the date on which the payment is due.

From/To

The list produced under this option shows application/licence number, drug name, fee name, amount, date payment is/was due, status (+/-/A), as well as date payment was received.

Chapter 10

MAINTENANCE

10. MAINTENANCE

The Maintenance menu option gives access to all operations related to the maintenance of the system.

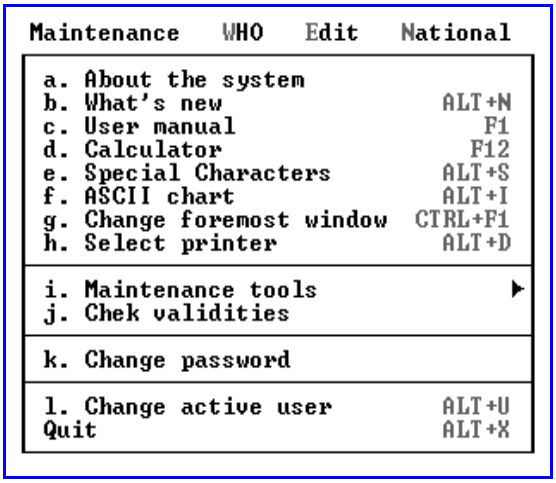


Figure 10-1: Main Maintenance menu

To activate these options, either press the letter indicating the option, move the bar to the option to be selected using the keyboard arrow keys and press **<Enter>**, or just point and click using the mouse. The following is a discussion of all available options in the Maintenance label.

About the System Displays a series of screens with credits and general information on the system. The information displayed when this option is selected includes contact numbers (phone and fax) for assistance when using SIAMED.

User Manual This option gives access to the context-sensitive help screens. These screens are also shown when pressing the **<F1>** key from any window while using the system.

Calculator This option activates a pull-down calculator that can be used at any time while operating the system. Pressing the **<F12>** key will activate the calculator while in any screen in the system.

Special Characters This option activates a pull-down window from where users may select and use characters not always available on all keyboards. Pressing the **<Alt>+<S>** keys will activate this window while anywhere in the system.

ASCII Chart

Selecting this option will cause a chart of ASCII characters to be displayed. Pressing the **<Alt>+<I>** keys will activate this window while anywhere in the system. From the list, users can identify codes for special functions e.g. Inserting a page break in a text

Change Foremost Window

Selecting this option brings to the front, one after the other, all windows open at a given moment. It is used to bring to the front an active window that, because of its size, is hidden by larger windows. You will rarely need to use this feature; however, if needed, the option is also available by pressing the **<Ctrl>+<F1>** keys. See Section 3.2 - Working with Multiple Windows.

Select Printer

When selected, this option opens a window that permits you to select among a number of printers. If your printer is not listed, please try each one of the available options. If none meets your requirements, please get in touch with us. This window can also be activated by pressing **<Alt>+<D>**.

Maintenance Tools

When selected displays options to access password assignment, user log, configuration, national version, initialization, indexation, year-end optimization, backup and restore. See Section 9.1 for details.

Chek Validities

Checks for expired company operating licences and drug licences and permits to make a report.

Change Password

This option allows you to change your existing user password. The password screen requires that you enter “previous data” - your existing password and “current data” - your new password.

Change Active User

This option permits you to swap to another password without leaving the system. Selecting this option activates the Password Checking process. Activate this option at anytime by pressing **<Alt>+<U>**.

Quit

This option closes all open files and leaves the system. Pressing the **<Alt>+<X>** keys or the **<F7>** key will activate the same process.

10.1 Maintenance Tools

This menu option allows you to structure your system to be used by several different individuals while defining the extent of each user's access within the system.

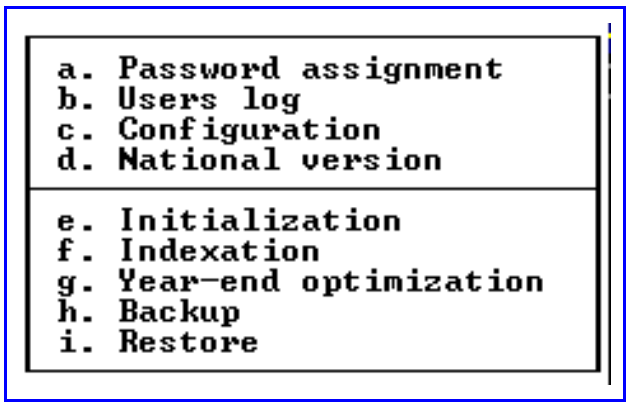


Figure 10-2: Maintenance Tools menu

Note for Network Users: There are several options which are unavailable if more than one user is logged on the system

10.1.1 Password Assignment

Use the main menu option "Maintenance," select "i. Maintenance Tools" and then "a. Password assignment" to reveal the screen via which passwords can be assigned to each user.

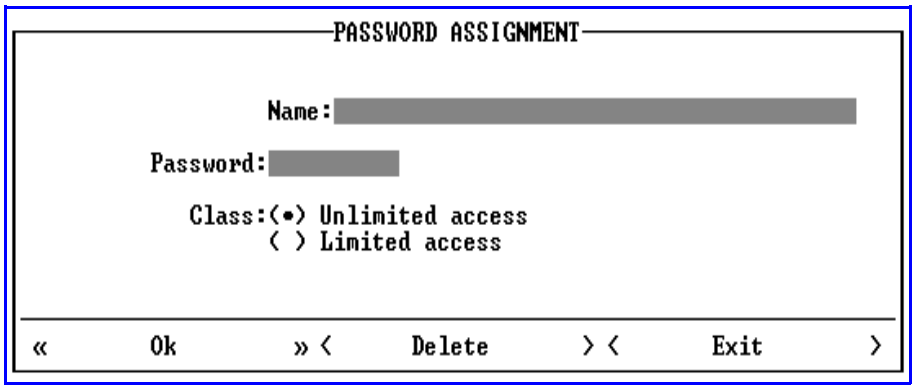


Figure 10-3: Password Assignment screen

Passwords are used to determine the level of access a user has to menu entries. Password options are:

- ♦ unlimited access passwords
- ♦ limited access passwords

An *Unlimited* password always has access to all system facilities. A *Limited* password only has access to menu entries selected at the time the password was established. (See Figure 10-

4).

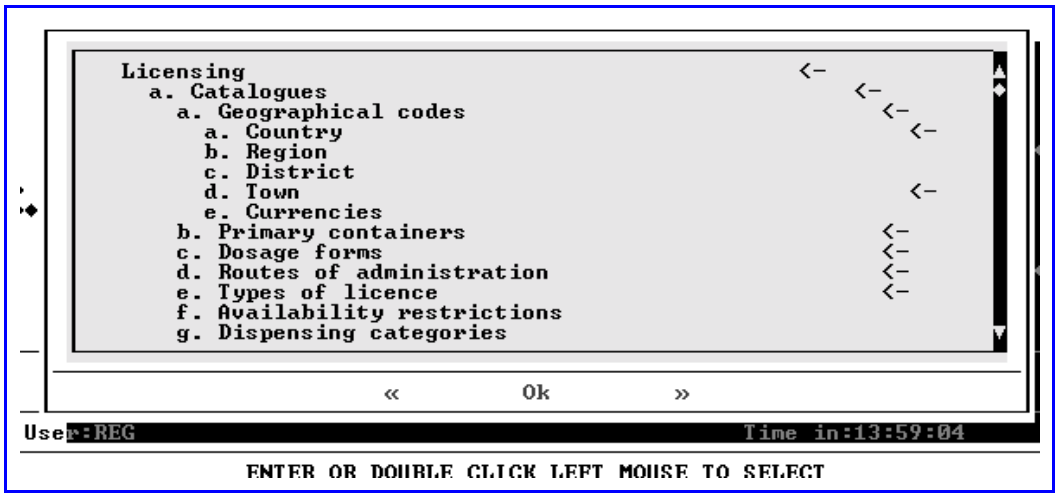


Figure 10-4: Limited Access assignment screen

The system is preset with **REG** as unlimited-access password. Using this, you can create any number of user passwords. All user passwords can be deleted, but there must always be a valid unlimited-access password in place to be able to use the system.

Below is a description of the fields used to assign user passwords.

Name

This field is used to indicate the user name to which a password is to be assigned. To create a new entry, type in the user name and press <**Enter**>. To edit an existing entry, press <**F2**> or click the right mouse button.

Password

This field is used to indicate the password for the assigned user. Enter the password you want to create, it must be a minimum of 2 characters, and a maximum of 10 characters. Users will be able to change the assigned password anytime, but those with access to the password assignment option will be able to see what the new password is.

Class: Unlimited Access/ Limited Access

This field is used to identify what level of access the user will have, i.e. unlimited or limited access.

If you select limited access, this will reveal a window where all menu options are shown. Simply click on the menu options that you wish to assign to that password. Click again if you want to remove a selection already made. Press <<Ok >> when entry is completed.

If you select unlimited access, the user will have access to ALL SIAMED modules and catalogues, and be authorized to make changes to the data within the system.

Click <<Ok>> to save the password just created, <Delete> to remove an existing password, <Exit> to return to the main menu.

Please Note: To activate a new or an edited password, you must either quit the system and

enter again, or use the menu option **Change Active User** that permits you to shift to another password.

10.1.2 Users Log

This option permits you to display or print a list indicating system usage statistic for all users.

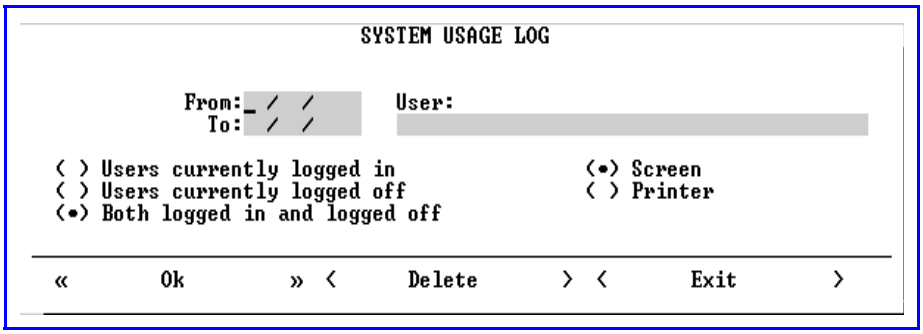


Figure 10-5: Users Log screen

The following is a brief description of the fields in Users Log

From/To — These fields are used to establish the range of dates to be included in the search.

User — This field is used to limit the search to one particular user. If you leave this option blank, the search will include all users.

Users Currently Logged In, Users Currently Logged Off, Or Both Logged in and Logged Off — Selecting these radio buttons help to further establish the search criteria for generating a user log. The options allow you to display data regarding users currently logged in, users currently logged off, or both which will cause the system to include all users. If no radio button is selected, the option of including both logged in and logged off users is used as the system default.

Once all criteria have been established, select where the output should go and press <<Ok>> to complete the search. Pressing <Delete> will clear the user log. If *both* logged in and logged off users are selected, delete will end **your** current sessions as well. Press <Exit> to return to the Main Menu.

10.1.3 Configuration

This option allows you to configure the system to better suit user requirements. Use the main menu option "Maintenance," select "Maintenance Tools" followed by "Configuration" to access the Configuration of Drug Licensing Module screen. This screen shows the preset configuration options. The following information may be edited as it applies to your SIAMED specifications.

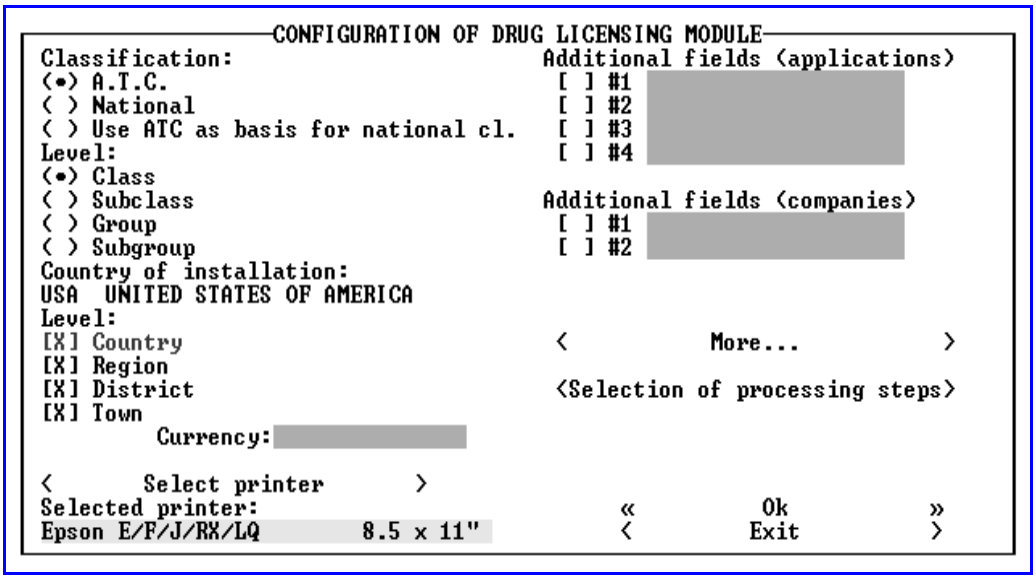


Figure 10-6: Sample of Configuration screen

Classification

You may choose to adopt the A.T.C. classification as it is, use it as the basis to prepare your national classification or establish your national drug classification. If you choose the last two options you will be prompted to indicate the number of levels of such classification.

The maximum number of levels of the classification is four. Indicatively, they have been named CLASS, SUBCLASS, GROUP, SUBGROUP. These labels may be changed using the National Version option. See Section 10.1.4 for details.

Country of Installation and Levels of Geographical Classification

The country of installation of the system is preset and cannot be edited. You can select which levels of geographical codes you will use. Indicatively the levels have been called COUNTRY, REGION, DISTRICT, TOWN. These labels may be changed using the National Version option. See Section 10.1.4 for details.

You cannot change the COUNTRY level. If you choose any of the three lower levels, you will have to enter all the relevant data regarding the country of installation of the system in the appropriate catalogues. If, for example, you select all four levels,

then you should enter all Regions, all Districts, and all Towns of your country before entering any domestic company or institution. If you do not enter such geographical details, you will still be able to use the system with the following limitations: you will not be able to programme company inspections on a town- or district- or region-specific way, and you will not be able to retrieve information using town, district, or region as searching criterion. You may, of course, configure the system to use only country and town, in which case you do not need to define regions or districts. The use of this type of detail is particularly important for those who will use the system to monitor national companies at a high degree of geographical/administrative detail.

Currency

Type the name of your national currency as you want it to appear on printouts. *Note:* Do not forget that several countries use the same name and/or symbol for their currency; try to be sure to avoid confusion.

Printer

Press this button to be shown a set of printers. Click on the one that is applicable to you and then click <<Ok>>. If you do not find your printer in the list, try first to use one of those listed and look at the quality of the printouts. If no acceptable solution is found, please get in contact with us.

Additional Fields

Four fields have been prepared in the system to be defined by the end user to store additional information related to applications/licences. If necessary, you may include up to four additional entries from here. If you are unable to use this option alone, WHO/PAHO can provide assistance.

Additional fields (applications) - [ ] #1, [ ] #2, [ ] #3, [ ] #4

Two fields have been prepared in the system to be defined by the end user to store additional information related to companies. If necessary, you may include up to 2 additional entries from here. If you are unable to use this option alone, WHO/PAHO can provide assistance.

Additional fields (companies) - [ ] #1, [ ] #2

When the button < More... > is selected, a new pop-up window appears which provides the user with the following screen options.

Authorization

Up to three different fields have been added to the system to accommodate identification numbers given to companies in several countries. You can decide here whether or not you will use any of them. Click on the [ ] to mark it as[X] for each field you need to use. You will then be able to change the field label from Authorization 1, 2 or 3 to any appropriate one using the National Version facility (see the National Version help topic).

Additional Configuration Options

Some fields can be *switched on and off* and not used during routine system operation. These include:

[X] Priorities [X] Data sheet
[X] Notes [X] National formulary code
[X] Location of file [X] Drug prices
[X] Licensing fees

Automatic or Manual Numbering: Application

Use the radio buttons listed on the screen to specify whether you wish to have the system automatically generate application numbers, or if you wish to manually enter them. If selected to have the system automatically generate the numbers, please enter in the field to the right, the number you want the system to begin using.

Automatic or Manual Numbering: Licence

Use the radio buttons listed on the screen to specify whether you wish to have the system automatically generate licence numbers, or if you wish to manually enter them. If selected to have the system automatically generate the numbers, please enter in the field to the right, the number you want the system to begin using.

Justification of Application Numbers

If your system will use numerical application numbers only, specify whether you want the system to right justify these numbers. This means that all numbers will be aligned on the right margin of the application.

Automatic Correspondence Prompt

This radio button requires that you select whether or not you wish the system to automatically prompt you to generate correspondence for a specific licence or application, every time you complete an entry

Market Limit

.In some countries, licences lose validity if the licenced item is not marketed within a certain number of months. You must enter the number of months as appropriate.

Once data entry is complete click on <<Ok>> to save your entry and return to the main configuration window.

Selection of Processing Steps

From the main configuration window, if you click on the <Selection of processing steps> button, another screen will appear. Mark as appropriate to indicate that you will be using the processing steps facility for new drug licence applications, renewal applications, variation applications. Click <<Ok>> to save your entries and return to the main configuration screen.

The purpose of this option is for you to indicate which processing steps you will be using in this application. Click <<Ok>> to set the new configuration or on <Exit> to quit without saving.

10.1.4 National Version

SIAMED is available in Brazilian, English, French, Portuguese and Spanish. All messages you see on the screen or on the printouts are drawn from a separate file, which is different for the different languages. This file can accommodate an alternative expression that can be defined by the user and changed any time.

The option National Version, allows you to locate the text you want to change and permits you to edit it, regardless of caps status (i.e. whether text is lower or upper case lettering or both), and to the position of the word in the string. In this way you may replace any text string and produce screens and printouts which are more meaningful to your specific context. For the changes to take effect you may have to Exit the system and start up again.

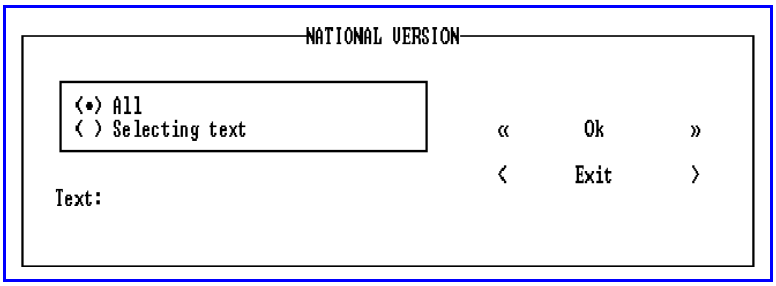


Figure 10-7: National Version selection screen

Below is a brief description of the fields used to locate and edit text.

All Selecting *All* indicates that you wish to be shown all text messages existing in the system.

Selecting Text This option allows you to define the specific text string you wish to see. Selecting this latter option, activates the Text field

Text This field is used to enter the words, phrases or sentences that you want the system to locate for editing purposes.

Once selections are made, press <<Ok>> when done and a new screen will appear displaying the text strings you requested, or press <Exit> to return to the Main Menu.

Selecting Text to Translate

- Select the text to edit by clicking on it, or pressing **<Enter>** when the bar is on it.
- After the text has been selected you will be able to type in the new text and press **<Enter>**.
- Then press the up or down arrow key on the keyboard to see the entry changed in the window. You can edit any text as many times as necessary.

NOTE: THE SAME TEXT IS SOMETIMES USED IN VERY DIFFERENT CIRCUMSTANCES. IT IS RECOMMENDED THAT YOU USE AS GENERIC A TEXT AS POSSIBLE TO MAKE IT USABLE IN MANY DIFFERENT CIRCUMSTANCES.

Messages codes are obviously the same for all languages. Unfortunately the **message text is not.** For this reason, you may find that the same message or word is shown more than once. This is due to the fact that depending on the context in which the word is used, the same English word may require two or more different words in another language. Thus if you know that you have already translated a word and you still find it ther in the old form, you just have to do the translation one more time.

10.1.5 Initialization

This option allows you to empty and clean out the company and application/licence files after you have carried out tests of the system using imaginary data entered to familiarize yourself with the system.

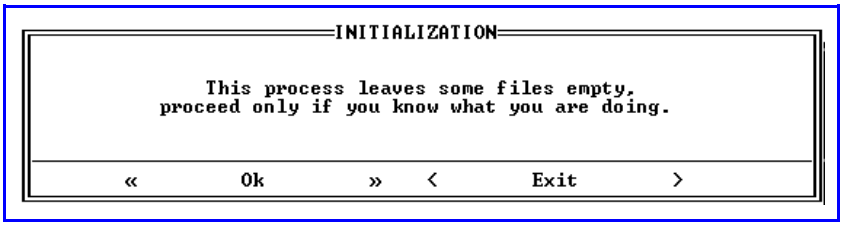


Figure 10-7: Initialization warning screen

If you choose the initialization option by selecting <<Ok>>, a warning message is then displayed asking you to confirm your action by clicking <<Ok>> , or ignoring your selection by clicking <Go back>. If you select <<Ok>>, the system will begin initializing company and application/licence files. You will then be prompted to *Press Any Key* when completed. This will return you to the main Menu. If you select <NO>, you will be returned to the previous screen. Contact WHO for additional information on how to implement this process,

before proceeding.

10.1.6 Indexation

The indexation option permits you to regenerate all system indexes. This feature is utilized only when so instructed by a system message that may appear when you cannot locate information that you know is there, or when the alphabetical search windows do not seem to work properly.

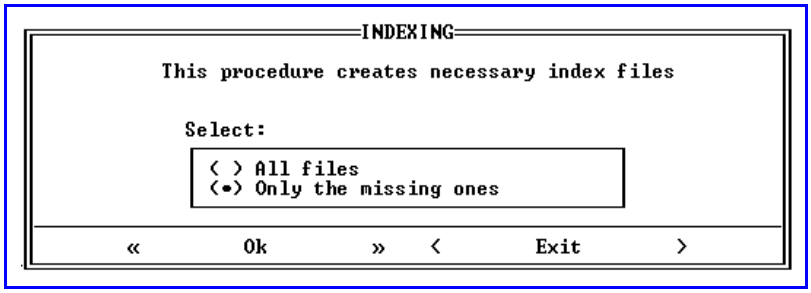


Figure 10-8: Indexation screen

You may choose to rebuild all files, or only the files that are missing. After making your selection, press <<Ok>>. The system will begin regenerating the indexes, and will prompt you to *Press Any Key* when completed. You Will probably never need to use this option.

10.1.7 Year-end Optimization

This option allows to remove only the useless information that you have deleted during the routine use of the system. Optimization may be carried out once a year. It is useful to reduce the use of disk space and may help to speed up the system's performance.

If you select the year-end optimization option, you must confirm if you want to proceed with the optimization process by selecting <<Ok>>. A warning message is then displayed asking you to confirm <<YES>> or go back <NO>. If you select <<YES>>, the system will begin optimizing files. You will then be prompted to *Press Any Key* when completed, which will return you to the main Menu. If you select <NO>, you will be returned to the previous screen.

10.1.8 Back-Up

This option is used to back-up information to diskettes. Follow the instructions you have been given when the system was installed, or those appearing on the screen.

Selecting this option requires that you have up to 8 formatted diskettes. All information on the diskettes will be deleted in order to facilitate the back-up process. The Copy To: option requires that you select the destination drive (A or B) containing the diskettes. Click the <<Ok>> button to begin the back-up process.

IMPORTANT! **Database files do get corrupted** and selected information may become

unusable. Making **daily backups** means that at most you can lose one (1) day of work. Backing up on a weekly basis means that you may lose up to a week of work!

10.1.9 Restore

This option is used to restore information from back-up diskettes prepared by the regulatory authorities. After selecting this option, you will be prompted to indicate what kind of data is being imported, and the source drive (A or B). After making your selections, click the <<Ok>> button to begin the restoration process.

10.1.10 Troubleshooting Steps

For any Notes fields displayed, if the entry indicates "MEMO" in upper case letters, this means that the system contains information that can be viewed by pressing either **<Ctrl>+<Page Down>**, or double clicking on the memo field. To return to the list, simply press **<Esc>**. You may also continuously press **<Esc>** until you are returned to the main processing duration screen. At that point you must select **<Exit>** to return to the main menu. (Pulled from ch. 8 - drugs Section 8.14.15 - Processing Duration.

WHO / NATIONAL

Chapter 11

11. WHO/ NATIONAL

This chapter combines information on the menu options under WHO and National.

11.1 WHO

The WHO menu screen is composed of three sections: WHO Scheme's Certificate, WHO Documents and UN Consolidated List of Products. The functions under this menu option permit you to access various types of information, and/or organisational documents.

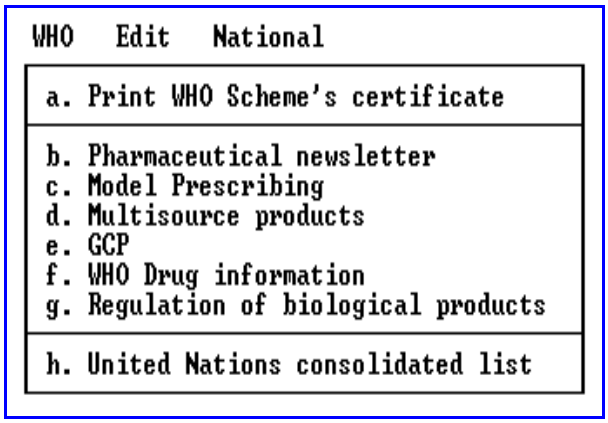


Figure 11-1: Who Main menu

11.1.1 Print WHO Scheme's Certificate

The first section is Print WHO Scheme's Certificate. This option enables you to print a product certificate for licenced products containing all the information required by the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. The certificate provides detailed information regarding the drug's name, application number, strength, presentations, specifications, type of licence, drug restrictions, shelf life, etc.

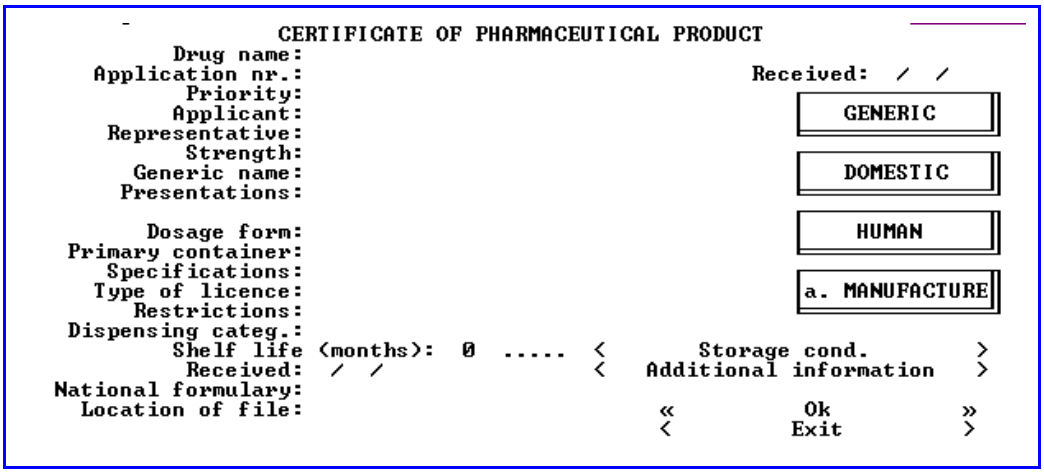


Figure 11-2: Sample of Scheme's Certificate

11.1.2 Accessing WHO Documents

The second section of the WHO menu provides you with several options for accessing select WHO documents. This information can be read on screen, or printed. You can also open these text files simultaneously while you work on a data sheet. You have the flexibility of selecting and transferring parts of the file to the data sheet. The documents that have been included are there only to provide an example of this option. Users can add their own reference documents to be used for reference or for copying text when working on licences.

To copy selected parts of the available document into an application/licence data sheet:

1. Click on WHO on the upper menu bar to pull down the WHO Menu
2. Select a document. The document opens on the screen.
3. Select the text you want to transfer by clicking and dragging with the mouse.
4. Click on Edit on the upper menu bar to pull down the Edit Menu
5. Select Copy. The selected text is now in memory.
6. Click on the small box on the upper left corner of the window in front of you to make it disappear. You are now back to your data sheet.
7. Move the cursor to the position where you want the text to be transferred
8. Click on Edit on the upper menu bar
9. Select Transfer. The text is transferred.

In this example we have used a WHO document as source of text to be copied. However, at the time of installation, any other national document can be linked to the system. This would permit you to standardize parts of your data sheets and save time.

The examples of selected documents which can be viewed under this menu option are:

Pharmaceutical Newsletter

Provides an informational overview of drug regulatory decisions made by the national regulatory authorities.

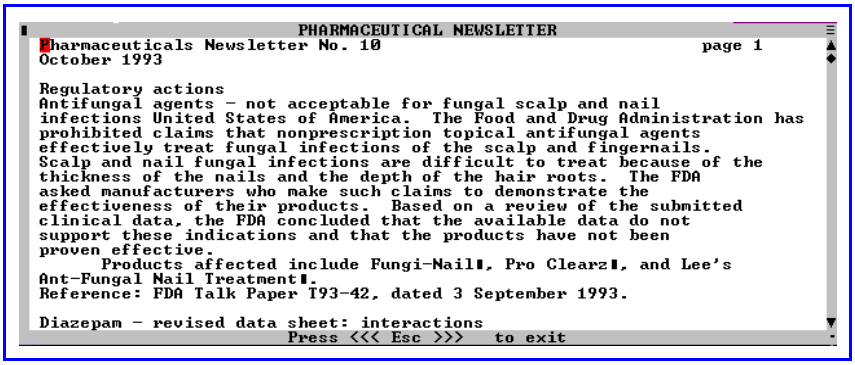


Figure 11-3: Sample of Newsletter screen

Model Prescribing

Provides an example of the WHO series model prescribing information which provides information n drug use.

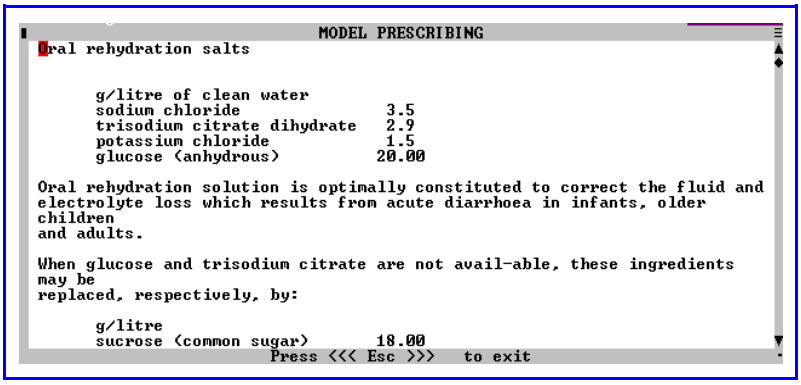


Figure 11-4: Model Prescribing screen

Multisource Products

This is a consultative document pharmaceutical products from multiple sources which may or may not be therapeutically equivalent drug products. Multisouce Pharmaceutical are also referred to as generics.

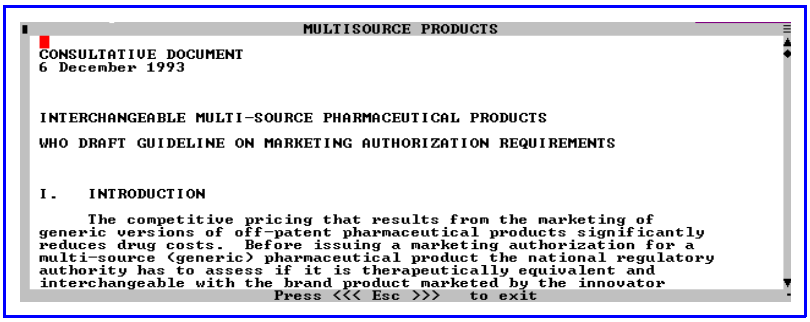


Figure 11-5: Multisource Products screen

GCP

This is a detailed guideline of Good Clinical Practice (GCP) for trials on pharmaceutical products designed to set globally applicable standards for the conduct of biomedical research on human subjects.

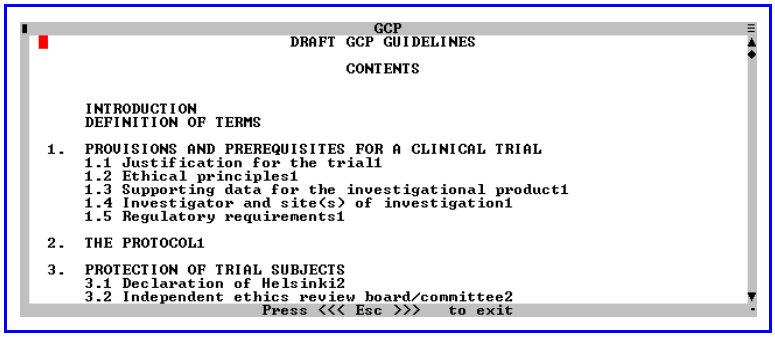


Figure 11-6: GCP screen

WHO Drug Information

Provides an example of the quarterly WHO publication, *WHO Drug Information.*

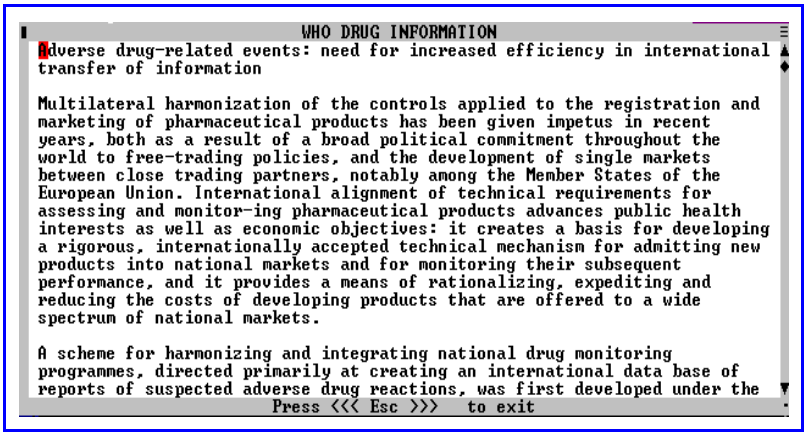


Figure 11-7: Drug Information screen

Regulation of Biological Products

This displays a text screen of a WHO guideline on biological products.

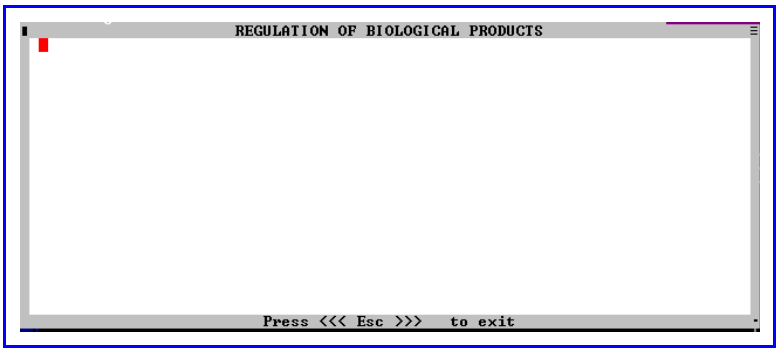


Figure 11-8: Regulation of Biological Products screen

11.1.3 UN Consolidated List of Products

The final section under the WHO menu enables the user to consult the UN Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or not Approved by Governments.

The screen displayed with this option requests a substance name which you can enter manually or select from the pop-up which appears when you press **<F2>**. Once a selection is made, additional information provided by the UN is displayed about the product.

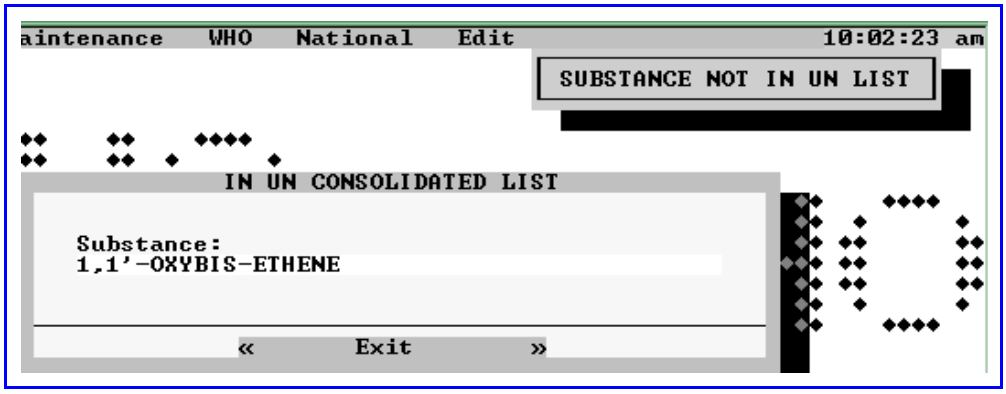


Figure 11-8: UN Consolidated List screen

11.2 National

This option is there for facilities meeting specific national requirements. These requirements will be developed after installation.

Chapter 12

12. EDIT

The EDIT menu option gives access to some text editing functions. These features are accessible only when the user is editing a text such as recording inspections results, and entering drug data sheets.

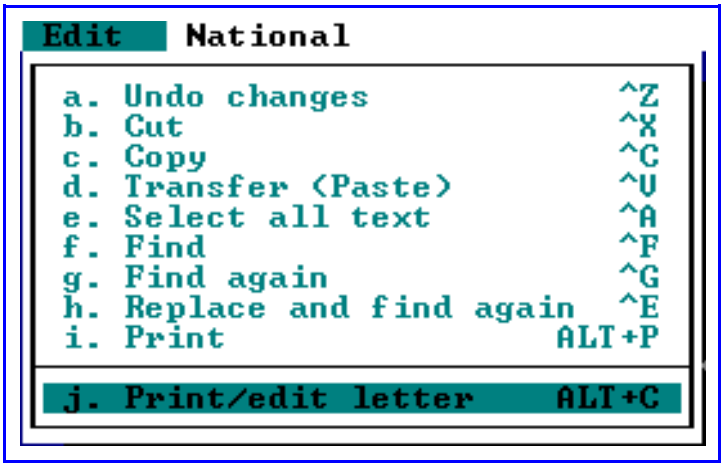


Figure 12-1: Edit menu

12.1 Undo Changes

This option allows you to Undo your last changes.

12.2 Cut

This option allows you to cut a word, phrase, or entire section of text and move it to another location, or to simply delete it.

12.3 Copy

This option allows you to copy a word, phrase, or entire section of text and move it to another location.

12.4 Transfer (< Paste >)

This option allows you to transfer a previously cut or copied word, phrase, or section, transfer it to a new area, and paste it into that area.

12.5 Select All Text

This option allows you to select all text information on a screen, and then move it elsewhere using the Cut, Copy, and Transfer <**Paste**> functions.

12.6 Find

This option allows you to search various fields for specific information. To use this option you must be in a search field. Select the Search option and another window will be displayed with the following information:

Look for Enter the information you want to search for.

Replace with Leave this option blank. You are provided with several option that you can select as desired: Ignore Case, Match Words, Wrap Around, Search Forward, and Search Backward. After all entries have been selected, click <**Find**>. The system will then find references matching the information/text you typed into the Look for field

12.7 Find Again

This option allows you to repeat your last *Find* procedure using the search parameters previously established when the initial Find data was entered.

12.8 Replace and Find Again

This option allows you to replace and find data. When selected, the Replace and Find Again option will display another window with the following descriptions:

Look for Enter the information you want replaced.

Replace with Enter the data that is to replace the existing word or phrase. Whatever information you enter in this field, the system will replace the data you want replaced with the new information just entered. The system will look for the next option/occurrence where this replacement can be implemented again.

12.9 Print

This option allows you to print the information displayed in the text field

12.10 Print/Edit Letter

This option allows you to print a letter or edit the text before printing.

When this option is first selected, you are prompted to enter an application or licence number. Press <**F2**> to obtain a list of available applications or licences and then select <Print>.

The subsequent screen allows you to retrieve a standard letter or certificate format and have it automatically filled with the specific of the application or licence on which you are working. You may then format and print the correspondence directly, or you may save the text for later printing. In addition, the system also allows you to export the text under the form of an ASCII file which can then be formatted and printed using an external word processor.

The lower portion of the screen contains six (6) options which allows you to do the following:

Formats

This option permits to select the required format from the list of available correspondence forms. When you select a letter format, the system will then replace all variables in that letter format with the data from the application or licence which you selected in the previous step.

A letter will then be displayed in the large gray window. If there is any additional information which you would like to add, you may do so here. The text in the gray window can be edited and formatted as required.

NOTE: When adding a new letter, you will be prompted to add another application. This prompt only occurs if using automatic numbering.

F6 = Select Steps

If you wish to add information related to one or more processing steps, select this option and a list of steps appears. You may then select a step. Upon such a selection, the following information will be transferred automatically to your letter - Step: Initial and Decision Date, Conclusion (Approved, Pending Rejected) and any notes written in the column window.

Use Old Letter

This option permits to allow one to pick up a letter that had been generated in an earlier session and needs revision, or you simply wish to copy it.

F5 = Print This option allows you to print your letter.

Save Letter Selecting this option permits to save a letter generated by the computer. This can be done in one or both ways:

1. Recorded As Is i.e. in the format as it appeared in the previous screen. In this way, it is retrievable within the system. To save AS IS, simply type under Letter Title, the name under which you would like to save this file.
2. Copied in ASCII format - In this way it is retrievable through an external word processor for editing, formatting and printing like any other document. To copy this file to an ASCII format file, first select the destination drive, then type in a valid DOS filename, select <<Ok>> when done.

Press <Exit> to return to the main menu.

Glossary

GLOSSARY

Active Ingredient - That portion of a drug which produces the intended therapeutic effect.

Alphabetical Search Window - A screen that lists file contents of your database in alphabetical order.

ASCII - an output mode that allows information to be converted into a text file that is useable by virtually all word processing packages.

A.T.C. (Anatomical Therapeutic Chemical) Classification - An international coding system maintained by the WHO that provides a common basis for drug classification to facilitate comparative data for drug consumption between different countries.

Authorization - refers to the issuing agency giving a company/organization the go ahead to operate, or market a product in the host country. There are three basic forms of authorization - marketing, company operating and Company-related. See Section 1.3.1 for details.

Back-up - A process initiated by the user to copy information stored in the computer onto a diskette or tape drive to insure that if the computer should malfunction, the data will still be available. In essence, when you perform a back-up you are creating a duplicate of the data in your computer.

Catalogues/Catalogue Files - a set of files containing codes, abbreviations and descriptive data used throughout the QCL system. These codes are used for describing data relating to equipment, reagents, reference materials, type/purpose of analysis, procedures, tests, and standard operating procedures.

Check Boxes - Screen objects used for data that can have only two values, like YES, NO, or very specific choices. Unlike radio buttons, many boxes can be checked at the same time.

Classification - The structure used to designate where a drug should be classified. The designations include class, subclass, group and sub-group.

Company Files - Files that contain information on the companies that participate in the drug registration programme.

Configuration - A configuration of a computer is used to set the parameters in which the software will operate, and establishes the default settings for the system.

Currency - A medium of fiscal exchange including coins, bank notes, government notes, etc.

DMP - Drug Management Policies. A division of the World Health Organization that is primarily responsible for the creation and development of the Quality Control Laboratory prototype system.

Dispensing Categories - Used to indicate how drugs are dispensed to consumers, i.e. over-the-counter, prescription only medication, etc.

Drop Down List - See pop-up window

Equipment - Instruments used in the laboratory.

Error Message - A notice that the computer displays on screen to let the user know that something is wrong with an action they are trying to perform.

Exchange Rate - The rate at which currency of one country is exchanged for the currency of another country.

Fields - Refer to the rectangular boxes on the screen where information is entered by the user, or displays data that the user had entered previously. In some cases, the data that appears in a field may have been generated automatically by the QCL system.

Foremost Window - The current active window displayed on screen. If working with multiple windows, the window on top is the foremost window.

Form Window - A screen version of an actual form containing the information that you need to manage such as data on companies, items to be tested, and samples.

Formulary (National) - A list of approved and recommended drugs compiled by an individual practitioner or a group of medical and scientific professionals for the purpose of a specific medical practice or supply system.

Frozen - Refers to a situation where the system does not seem to be working, i.e. you type or click the mouse but nothing happens. Often occurs when working with multiple windows. To resolve this situation, see Working with Multiple Windows in chapter 3.

Generic Name - Generic Names are also called common names for pharmaceutical substances, or when available, International Non-proprietary Name (INN) or modified INNs. In a computerized system, information on substance names needs to be entered in two separate database fields: a) fields describing the composition. We shall call these fields ***ingredient name fields***. In these fields, substance names are entered specifying the exact form, e.g. chloroquine phosphate and b) a field indicating only the active part of the molecule used to prepare the dosage form, e.g. chloroquine. This field will contain chloroquine for all products containing any salt of chloroquine, regardless of dosage form or strength. We shall call this field ***generic name field***, referring to the active component. Two drug products may have the same generic name, but have different ingredient names and dosage form and strength

To use this concept of generic name in the context of computer assisted-drug registration, we propose the following principles:

Drug Products with Only <u>One</u> Active Ingredient

In this case, the generic name is the name of the base that constitutes the active ingredient, regardless of the form used in the formulation - unless a specific salt has unique therapeutic uses unrelated to those of the base. For example: The generic name, ampicillin, applies to all drugs containing either ampicillin trihydrate, ampicillin sodium, ampicillin hydrochloride, etc.

This simplification applies only to the generic name field of an application. It does not limit the possibility for users to record the full name and quantity of the active substance(s) in the ingredient fields. Thus, searches can be based on either the generic name or the individual full substance names of the ingredients.

Drug Products with <u>Two</u> Active Ingredients

In this case, the generic name reflects the names of the base that constitutes the two active ingredients, regardless of the form used in the formulation - unless a specific salt has unique therapeutic uses unrelated to those of the base.

These two names need to be entered in the same field. It is therefore recommended that, to avoid repetitions, a fixed format is used to enter them. For example, one could use a plus sign to separate the two names and enter them only in alphabetical order: e.g. amoxycillin+clavulanic acid instead of clavulanic acid+amoxycillin.

Drug Products with *More Than Two* Active Ingredients

Building a generic name by adding those of the individual components is not practical. In addition, it is infrequent that a rational drug has three or more active ingredients. The proposed approaches are these:
1) enter, in the generic name field, the same predefined term for all drugs e.g. combination, see composition, or
2) enter an arbitrary term to indicate a loosely homogeneous group, and use a predefined term for those drugs for which an homogeneous group is not easily identified e.g. multivitamin, minerals, minerals+multivitamin, electrolytes, electrolytes+glucose, cold preparation, combination, see conposition.

The use of these arbitrary generic names does not limit search on the basis of an individual ingredient name. On the other hand, it contributes to establishing searching criteria that permit you to group together drugs that have the unusually large number of active ingredients in common.

Hard Drive - The physical device in your computer which is used for storage of data. The letter C is commonly used to refer to the drive or disk in your computer.

Inactive Ingredient - That portion of a drug which **does not** produce the intended therapeutic effect.

Main Register File - Consolidates all information relating to each application and licenced product. It is linked to other files containing information on ingredients, manufacturers, regulatory status, etc.

Mouse Buttons - Refers to the left and right buttons on the "mouse" which is used to move the user around the screen or document.

Multiple Formula Preparation - Used to indicate that a drug may have the same container, but different appearances and formulae.

Multiple Searching Criteria - Utilized within the QCL retrieval system to search for data using specific criteria or guidelines depending on the information you want to extract.

Multiple Windows - Refers to the user having more than one form window open on screen.

National Version - A screen option via which individual laboratories can define functions and terms that are unique to their operation. It allows the user to change words, strings of text, and to translate text into terms appropriate for the nation in which the laboratory functions. Changes to the national version are implemented throughout that laboratory's version of QCL.

Network - a group of computers connected together in a small area for the purpose of sharing peripherals, applications and files.

Operating licence - Physical document given to a company/organization that is authorized to operate/perform a specific activity within the host country.

Peripherals - devices that are in some way connected to the computer, and enables it to function, and/or function better. Peripheral devices include printers, keyboards, the mouse, etc.

Pop-up Window - This is a field or screen that provides a list of specific data from which you can make a selection that best suits your needs. Pop-up windows can be accessed by selecting **<F2>** or clicking the right mouse button. Often referred to as a pop-up screen, pop-up field or drop down list.

Pre-Defined Reports - Reports generated by the system for which the search parameters have already been built into the report when the software was developed.

Preferred National Name - This serves as a system default, so that if an item already exists in the system, and the user attempts to enter the same item under a different name, the system will automatically correct the user's entry to the name that already exists. Preferred National Name is established by each individual laboratory when a substance is first selected. This reduces duplicate entries. See Section 5.13 or 7.1.3 for more information.

Presentations - A text field used to describe how the drug is presented to the consumer, i.e. a bottle with capsules in it, a box with ampules in it, etc.

Primary Container - The container in which the drug is contained, e.g. a vial, tube, etc.

Processing Steps - used to define how long an application will be in processing before an authorization is issued. Also used to indicate at what phase of the process an application is currently in.

Product Licence - Physical document given to a company/organization stating that it is authorized to market a product within the host country.

Push Buttons - Buttons designated by a single set (< >), or double set (<< >>) of opposing arrows, which are usually found across or near the bottom of an active screen. These buttons are used to activate functions such as the completion of an entry, searches, exit the screen or give the user access to secondary form windows.

Radio Buttons - Used to indicate options where **only one** choice can be made. The choices available via a radio button are referred to as reciprocally excluding options, i.e. if option "A" is selected, then option "B" can not be selected.

RAM - Random Access Memory. Memory which PCs use to store information. This type of memory is volatile, therefore it loses the information, once the computer loses power.

Read-only - Indicates that the data displayed on screen can only be viewed by the user. The data can not be altered in anyway.

Reagents - Chemicals used to carry out the analysis of a sample. An example of a reagent is calcium carbonate.

Reference Substances - Details the substances that are used during the performance of analyses.

Restricted Substances - A substance whose consumption has been banned, restricted or not approved in the country of installation.

Routes of Administration - Defines the various routes via which an item or drug product can be administered, e.g. oral, topical, etc.

Secondary Form Windows - An additional window or screen version of an actual form that is accessed from the form window. The secondary form window may allow the user to enter additional information, or it may be a read-only screen.

Select - Used throughout the manual to indicate which action to use to activate a QCL function, such as clicking a mouse, or typing the letter that corresponds to the desired

function. The word “press” may sometimes be used in place of select, but the function is the same.

Similar Formula - A search criteria that retrieves information based on drugs with at least one active ingredient and/or dosage form in common.

Similar Name - A search criteria that retrieves information on drugs that have the same first five letters of their name in common.

SOP - An acronym for Standard Operating Procedures

Strength - Defines how strong the drug dosage is. Strength is always indicated on the product label.

Substance Names Dictionary - A file that contains over 80,000 different non-proprietary names of pharmaceutical substances, cross-related synonyms and their anatomical therapeutic classification.

Synonyms - Provides a list of substance names and possible alternate names that may refer to the same item.

Variation - Refers to the process of recording to a specific file, any changes/ alterations made to an application. This enables the user to retrieve a history of any and all variations associated with an application.

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