

Setting up a computerized drug registration & allied information system



A User's MANUAL



World Health Organization

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INTRODUCTION

There are three parts to this user manual: Part 1 outlines the minimum requirements needed before setting up to computerize the drug registration system. It then describes the drug registration and information system in general. An overview of the drug registration system with emphasis on the hardware and the software needed to install a computerized drug registration system and finally, the data preparation requirements is presented; Part 2 presents, in detail, how to install the application systems. A step by step guide is presented to aid the user during the actual installation process; and Part 3 explains the details of the three subsystems under the **DRUG REGISTRATION SYSTEM AND INFORMATION SYSTEM** and it provides in depth illustrations on the use of the installed subsystems.

Introducing a computerized **DRUG REGISTRATION AND INFORMATION SYSTEM** in a drug regulatory authority will entail investment in terms of time and energy. The benefits derived in using such a system however, cannot be overemphasized. Not only will the system facilitate the systematic organization of data, a computerized system can also help the drug registration staff reduce the amount of time spent on clerical work. The drug registration staff can thus concentrate more on the technical evaluation of product applications.

A computerized **DRUG REGISTRATION AND INFORMATION** system will greatly reduce the amount of clerical errors that abound in most manual systems. Management information reports can easily be prepared when using a computerized system. Preparation and printing of the certificates for product registration (CPR) and the licenses to operate (LTO) for establishments may be automated. The tremendous reduction in the time for the staff in preparing certificates results in a more efficient management of resources. Preparation of reports is a keystroke away and can be redesigned using *MSWord™* or *MSEXcel™* to suit user preferences. Ultimately, this results in a more professionally run drug regulatory agency.

Users of the system will also appreciate that moving from a manual to a computerized drug registration and information system is an investment well spent in the long run.

Developed as a tool for Drug regulatory agencies (DRA) implementing a computerized system for the registration of pharmaceutical products, the system is designed to aid the DRA in countries in the management of drug registration data. The system was developed to provide for a fast and efficient way for recording and retrieving data. With the information generated by the system, sound management decisions may be enhanced which may help countries regulate and ensure the quality of drugs available in the market.

The system was purposely made as simple as possible and has been pre-tested in several installations for user-friendliness. It is also designed to encourage the DRA to implement a computerized system with resources that may already be available. No other special equipment or software other than the basic windows office suite is required. Because Microsoft Office Suite is commonly used in most drug regulatory offices, the **DRUG REGISTRATION AND INFORMATION SYSTEM** was developed using one of the office suite packages: *MSAccess™*. Another version of the same system may also be available, with the same user interface, recoded in *Visual Basic™*. The recoded version of the system can be used in a multi-user environment in a true client-server relational database management system such as Microsoft SQL™ server, where tighter security may be a prerequisite.

The primary reason for using *MSAccess™* as the database management system was to simplify future maintenance. With the system, the user can easily transport the data to another database management system. The entire dataset can then be moved to *Dbase™*, *FoxPro™*, *SQL™*, *MS Excel™*, or *Oracle™*. Abandoning the database will not be necessary in the event of a policy change to use another database management system. This will save the user countless time and resources in reentering the data.

A generic report preparation scheme is employed in the **DRUG REGISTRATION AND INFORMATION SYSTEM**. The *MSWord*[™] word-processing and the *MSExcel*[™] spreadsheet programs are utilized to maximize user familiarity with these programs - a plus for user acceptance of the drug registration system.

Data can easily be exported to other *Microsoft*[™] office products as well as to similar database engines. Thus, upgrading to a true client-server database management systems like *SQL Server*[™], *Oracle*[™], or some other highly scalable database management system as the back-end database will be less daunting. The main database was purposely not split into smaller tables, as would normally be done, for the very same reason.

PART 1

1. DECIDING TO COMPUTERIZE DRUG REGISTRATION

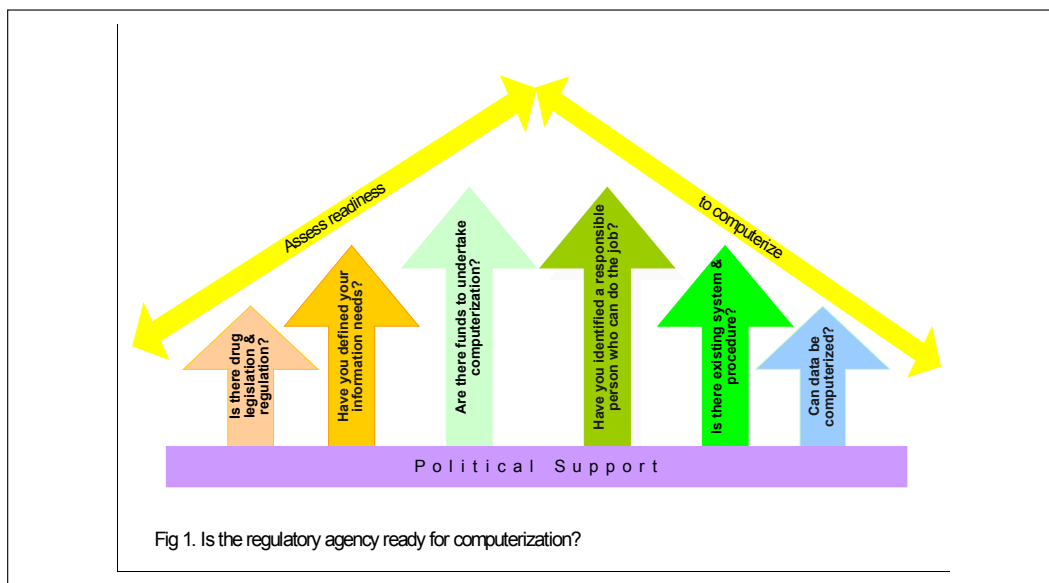
A crucial step towards the computerization of a **DRUG REGISTRATION AND INFORMATION SYSTEM** is the planning phase. This step is often taken for granted when managers want to get on with the project, reasoning that “events will just fall in place.” Embarking on computerizing a manual drug registration system is not a quick fix remedy to flaws that may be inherent in the manual registration system. The procedures followed should be in consonance with the provisions spelled out in the drug legislation and regulation of the country. Although training of the staff in using a computerized system for drug registration is part of setting up a computerized drug registration and information system, computerization per se should not replace technical drug registration training that is necessary to equip the staff with skills to examine product registration dossiers.

Managers in drug regulatory agencies (DRA) should be aware that prerequisites to computerization must first be met in order to successfully implement a computerized **DRUG REGISTRATION AND INFORMATION SYSTEM**. The absence of these conditions may mean a low success rate and, although the project may eventually succeed, the entire computerization process may take a little longer to accomplish.

2. FULFILLING THE REQUIREMENTS

The management of drug regulatory agencies must establish its readiness to undertake the computerization of the **DRUG REGISTRATION AND INFORMATION SYSTEM** or risk not accomplishing the desired objectives. The ultimate goal is to get the system running and be able to retrieve up-to-date drug registration reports. Management should also be able to maintain and upgrade the system in the future. Figure 1 lists the pre-requisites that the DRA management must meet before installing and implementing the

drug registration and information system. Political support is the foundation upon which all the other prerequisites rest. Without it there will be no basis to carry on with the computerization of the drug registration and information system. Figure 1 illustrates important questions to answer before starting this project.



2.1 Is there a drug legislation and regulation in place?

Legislation establishes the general framework for the government to act. It is the legal basis that creates the drug regulatory authority in the country. From the legislation, a regulation document is prepared that outlines the operating procedures. It is essential, therefore, that legislation and regulation are clear and well articulated.

2.2 Can the information needs be defined?

If an existing reporting system exists in the drug regulatory authority, then the time needed to convert from a manual to a computerized system is greatly reduced. Management should decide which reports it needs to aid them in future decisions and directions. Gather all generated reports, tabular lists and other ad hoc reports in the existing manual system and examine their contents. Because we wish to generate similar reports and lists in the future using the **DRUG REGISTRATION AND INFORMATION SYSTEM**,

the data must be contained in the Drug Registration System database. A plan is then needed in order to extract them from the drug dossiers and other registration application forms.

2.3 Do you have the funds to undertake computerization?

Without the proper logistical support, planning to implement a computerized drug registration system is an exercise in futility. Resources in terms of hardware, software, personnel and training will be required to make the plan operational. Take away one and the system will be incomplete.

2.4 Can you identify a responsible person who shall act as the lead person for the project?

If an existing drug registration system is operational, then the most likely candidate to act as the leader of the project will be the person who is in-charge of the present manual drug registration system. There may be some resistance if this person feels that computerization is too complex an undertaking. The goal of this user manual is to simplify the process by explaining the tasks involved in setting up a computerized drug registration system.

The drug registration system was designed to be as simple as possible. That is why it was developed in the *MSAccess™* environment.

2.5 Do you have an existing system of drug registration procedures?

A systematic way of receiving, evaluating and approving of product applications in the regulatory authority should already exist. Computerization of the registration system will not work if decisions for the registration of are made arbitrarily. There must be a clearly defined path from the receipt of the application up to the issuance of the product marketing authorization certificate stages. If there is no such system, then a manual system must be prepared before starting a computerized system of registration.

2.6 Can your drug registration data be computerized?

The drug registration data must be in a format that can be entered into a computer. If there is existing drug registration data, can the data be entered in an electronic format? If not, the data must be converted into a format

that the computer can understand. Can the data be extracted for all products and not just for some product applications? Information for all of the products in the registry must be complete and consistent throughout all the fields in all levels.

3. SETTING UP A COMPUTERIZED DRUG REGISTRATION SYSTEM

3.1 Identify the data and information

The **DRUG REGISTRATION AND INFORMATION SYSTEM** requires two basic sets of data. These data are gathered from two drug regulatory activities: licensing of establishments and product registration. In some drug regulatory authorities, these functions may sometimes be assigned to different units and therefore are performed by different staff. In the computerized **DRUG REGISTRATION AND INFORMATION SYSTEM**, the data in the product registration system is shared with the licensing of establishments system data, and vice versa in order to minimize data redundancy. Both systems' data in turn are shared with the third system, the drug import monitoring system.

Tables 1 and 2 enumerate the data that are needed in the implementation of the computerized **DRUG REGISTRATION AND INFORMATION SYSTEM**. These are the basic data that will have to be gathered and will later be required to be entered into the computerized drug registration and information system:

The current drug registration data in the drug regulatory agency may be in a different format. The data might be contained in an index card, printed in stocks of papers, printed in continuous forms or even be in electronic format. Common electronic data formats in DRAs are *Lotus123™*, *Microsoft Excel™*, *dBase™*. Some DRAs have entered their drug registration data in a word processing format. If so, it will be necessary to convert the records to the *MS Access™* database format. Conversion of the contents of the record files from the existing format in the Access format may not be a straight forward process. This is because the existing database template may not exactly match with the template of the **DRUG REGISTRATION AND INFORMATION SYSTEM**. To systematically do the conversion, a strategic plan may have to be formulated. This will help prevent a disruption of the operations of the existing drug registration system.

Table 1. Licensing of establishments data

1. Application number
2. Name of company
3. Licensing classification
4. Type of company
5. Address: street
6. Address: district
7. Address: province / state
8. Address: country
9. Address: zip code
10. Telephone number
11. Fax number
12. Email address
13. Company URL (website)
14. Contact person
15. Date of birth of contact person
16. Contact person's street address
17. Contact person's district address
18. Contact person's province address
19. Contact person's position in company
20. Contact person's educational attainment
21. University graduated
22. Date graduated
23. Years in service
24. License to operate number
25. Date registered
26. Expiration date
27. Application status

Conversion of the data is a critical step towards implementing a computerized drug registration system. In instances where data are too numerous, planning the conversion process will greatly contribute to a successful project. Planning the conversion with an experienced strategic planner will be helpful when thousands of records are already in existence. In these installation, a parallel run of the old system vis-à-vis the new computerized drug registration and information system may be necessary.

Table 2. Product registration data

1. Application number
2. License owner
3. Manufacturer
4. Brand name
5. International nonproprietary name
6. Dosage form
7. Storage conditions
8. Shelf life
9. Primary packaging
10. Packing size
11. Dispensing category
12. Anatomical therapeutic chemical classification code
13. Pharmacological classification
14. Listed as essential drug in country?
15. Description
16. Country of import
17. Registration number in country of import
18. Date of registration in country of import
19. List of active ingredients and dosages
20. Indications
21. Contraindications
22. Side effects
23. Unit price
24. Activity / status of product
25. Date of application
26. Product registration number
27. Date of registration
28. Date of expiration

3.2 Determine the required resources

Three kinds of resources are necessary to carry out the drug registration and information system:

3.2.1 Hardware

This is the equipment used for input, output and storage of data. Hardware is normally the computer and hard drive. The minimum hardware required to run the drug registration and information system is listed below:

- 486 Microprocessor 1xx Mhz or higher;
- 32 MB random access memory (RAM);
- 5 Gigabytes hard disk;
- 1.44 MB disk drive;
- CD ROM drive;
- Super video graphics adaptor monitor;
- Mouse;
- Keyboard;
- Printing device.

3.2.2 Software

The software is a set of instructions that tell the hardware what to do. To implement the DRUG REGISTRATION AND INFORMATION SYSTEM, an operating system and two application systems are needed to get the system up and running. The Microsoft Office Suite, preferably *MSOffice2000™*, must be installed before finally installing the **DRUG REGISTRATION AND INFORMATION SYSTEM**. Below is a list of the minimum software requirements needed to install and run the **DRUG REGISTRATION AND INFORMATION SYSTEM**. After installing the operating system and the MSOffice Suite, the **DRUG REGISTRATION AND INFORMATION SYSTEM** software can be installed as described in the section under the heading, “Installing the **DRUG REGISTRATION AND INFORMATION SYSTEM**.” Follow the instructions outlined in the appropriate section of the user manual. The **DRUG REGISTRATION AND INFORMATION SYSTEM** application software is contained in the CDROM as a package with this user manual.

Shown below are the minimum software needed in order to install the system:

- *Windows98™* operating system;
- *MSOffice2000™* (*MSWord™*, *MSExcel™*, *MSAccess™*);
- DRUG REGISTRATION AND INFORMATION SYSTEM

Because the Computerized Drug Registration and Information System was developed in the *MSAccess™* environment, the *MSOffice* office suite together with the *Windows™* operating system must be preinstalled in each computer where the application systems will reside.

3.2.3 Human resources

In computer jargon, peopleware is the term used to refer to the users of computer systems. No special computing skills are required from users to operate the **DRUG REGISTRATION AND INFORMATION SYSTEM**. Users should know how to operate a computer, how to type (or use a typewriting machine), and how to use *MSWord™* and *MSExcel™*.

Users will have to undergo training on how to use the system. The users must understand the relationships among the different functions in the registration system. This will give them a working knowledge about how the different functions coordinate as a whole. Users must also learn how to prepare back-up copies of the databases and how to act as a facilitator in training other staff.

A responsible person, preferably one who is already in charge of the product evaluation, should be identified to act as the key personnel for the computerized **DRUG REGISTRATION AND INFORMATION SYSTEM**. The person in charge must ensure that data entered in the **DRUG REGISTRATION AND INFORMATION SYSTEM** are accurate, up-to-date and kept physically secured. Future enhancements to the system may also be necessary because of policy changes in the regulatory body.

To ensure that the drug registration system is kept up to date with current technological advances, the person in charge of the system must also be abreast of advances in the field so as not to be at risk of technological obsolescence.

In most DRAs installing a computerized system for the first, a full time IT staff (computer personnel) is usually not employed. This makes the role of the person in charge a more challenging endeavor because the person will be expected to know some maintenance chores needed to keep the system fit at all times. Maintenance consists of two components: hardware maintenance, which is usually deputized to a computer hardware supplier;

and software maintenance, usually done in-house. Depending on how complex the existing installed system is and how secure the network is from outside intrusion such as virus infections, software maintenance can be as complex as the system setup is.

The person in charge also has to ensure that procedural changes in the organization will be added into the computerized system in order to keep it up to date with the ever changing policies in the organization. Once again, this makes the role of the person in charge a challenging task.

4. DESCRIPTION OF THE SYSTEMS

The **DRUG REGISTRATION AND INFORMATION SYSTEM** consists of three application subsystems: a licensing of establishments system; a product registration system; and a drug import monitoring system.

The **DRUG REGISTRATION AND INFORMATION SYSTEM** is an integrated system consisting of smaller systems built and designed according to function, i.e. licensing of establishments, product registration, drug import monitoring. The system was built modularly for obvious reasons. This makes it possible for the **DRUG REGISTRATION AND INFORMATION SYSTEM** to evolve with the growing information requirement in a drug regulatory agency. Each system has a corresponding database that is maintained and “owned” by the office or unit performing the said function. For example, the “product registration system” shall be operated and maintained by the unit performing the evaluation of products for registration while the “licensing of establishments system” shall be used and maintained by the unit performing the licensing of the different establishments.

Each system in the **DRUG REGISTRATION AND INFORMATION SYSTEM** has its own set of catalogue files. The catalogue files will ensure that consistent and uniform data is entered in the **DRUG REGISTRATION AND INFORMATION SYSTEM**.

The staff or the office in the regulatory body performing a function updates its own database. Data in different databases are shared with others in the **DRUG REGISTRATION AND INFORMATION SYSTEM**, making it one

whole and integrated system within the same drug regulatory office. The different databases can later be linked to new application systems that may be designed and developed in the future.

The licensing of establishments system contains the list of registered establishments transacting pharmaceutical products in the country. These establishments may be imports, agents, manufacturers, exporters, repacking companies, pharmacy outlets, or donors. After an evaluation of the activities of these establishments, and presuming that the establishment passes the minimum standards set for registration, a license to operate (LTO) certificate is issued by the regulatory authority. The list of registered establishments is “shared” information with the product registration (see below) and the drug import monitoring (see below) systems. Essentially, each product has a license holder/ marketing authorization owner who is the referred applicant in the product registration system. If an applicant is not registered, then the product registration system cannot accept the product application because the applicant company is not a registered company.

The product registration system is a database of products registered with the regulatory authority. Basic information of registered products can be retrieved and reports printed when required. A product registration certificate is issued once the criteria for product registration has been met. The list of registered products is shared information with the drug import monitoring system.

Once data for “licensing of establishments” and the “product registration” systems have been entered, information on the importations of drugs can be monitored using the drug import monitoring system. This will be done by entering the data on importations in the system. The system checks that the product being imported is a registered product. Likewise, the importer will be checked against the information in the licensing of establishments system. If one is not in the system, importation details cannot be entered in the system and an importation certificate cannot be issued. The system generates numerous management information reports that will describe the drug importation profile.

Drug importation data are checked against the product registration system and against the licensing of establishments databases. Importation data are entered into the drug importation and monitoring subsystem. An importer must be a registered establishment and the product being imported must have already been registered. The system can generate various reports that enable the regulatory authority to monitor the importation profile of drug products in the country.

Figure 3 is a data diagram of the relationship between the product registration and the licensing of establishments systems in the integrated **DRUG REGISTRATION AND INFORMATION SYSTEM**.

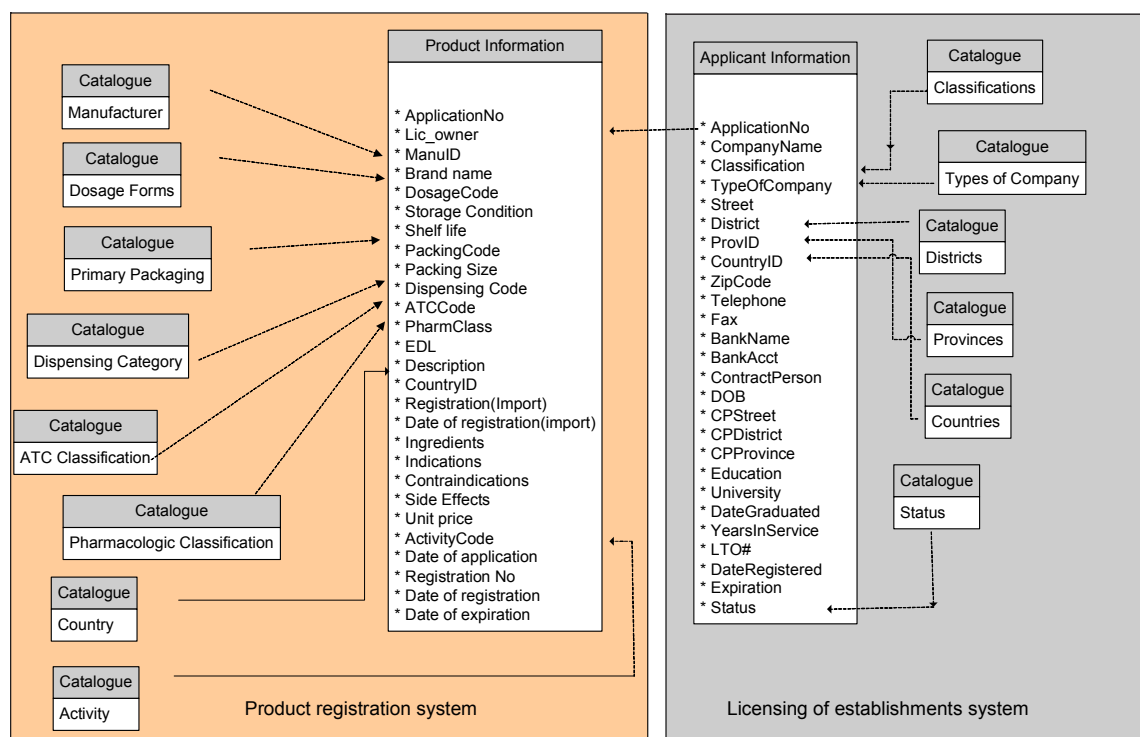


Fig 3. Product registration vis-à-vis the licensing of establishment system

5. APPLICATION FORMS

To facilitate data entry into the systems, two application forms are provided in the Computerized Drug Registration and Information System: an application form for a license to operate (LTO); and an application form for product registration. The application forms are provided in the respective subsystems. It is suggested that the provided application forms will be used.

5.1 Licensing of establishments application form

An LTO (license to operate) application form is provided. It will be used in conjunction with the Licensing of establishment subsystem. The form will facilitate data entry of the information into the Licensing of establishment subsystem.

5.2 Product registration application form

An application form for the registration of the products is also provided for data entry into the product registration and information system. The form was designed to facilitate data entry of the drug registration data. Data are grouped according to applicant information, manufacturer information, product information and finally, status of application information. It is suggested, therefore, that evaluators use the application form as a working sheet in the performance of the evaluation of the products. Evaluators are encouraged to make corrections on the worksheet.

Together with the product application form is a routing slip. This form may be used to manually transmit the product dossier to key personnel involved in the evaluation of a product application. The drug registration committee can later refer to the routing slip information during its committee deliberation meetings. The routing slip contains the summary of the decisions made for a particular product application. This form can be used to update the application status for each product application into the **DRUG REGISTRATION AND INFORMATION SYSTEM**.

PART 2

1. INSTALLING THE DRUG REGISTRATION AND INFORMATION SYSTEM

A compact disc containing three self-extracting subsystems in the **DRUG REGISTRATION AND INFORMATION SYSTEM** is provided together with this manual. To install the complete drug registration system, you have to repeat the procedure three times. First, install the Licensing of Establishments subsystem; second, install the Product Registration subsystem; and third, install the Drug Import System.

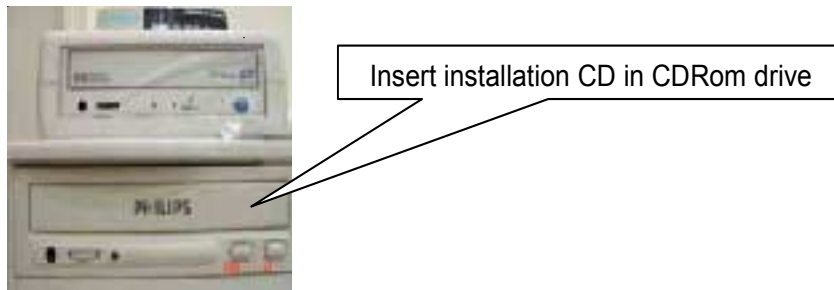
The three subsystems may be used by three separate units in the drug regulatory agency (DRA). The three subsystems share common databases in order to eliminate redundancy of information in the same DRA. Even though each subsystem has its own core database, data is shared with the other systems when needed. In smaller DRAs, the three functions may be integrated as a function of one unit or may even be performed by one personnel in the DRA. The integration of the functions in one unit or to one person is immaterial on how the drug registration system will be used in such environments.

Sample database records are included, on installation, with each subsystem. Installing the system with a sample database will enable the user to use fictitious data and familiarize himself or herself with the operations of the system before finally using the drug registration system.

2. GETTING STARTED

2.1 Insert the install CD in the CDRom Drive (usually drive D).

NOTE: The installation disc contains three executable installation files: "Licensing of establishments.exe"; "Product registration.exe"; and "Drug import.exe."

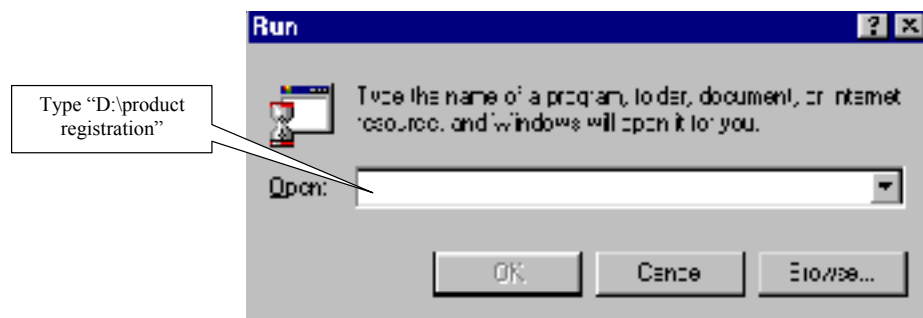
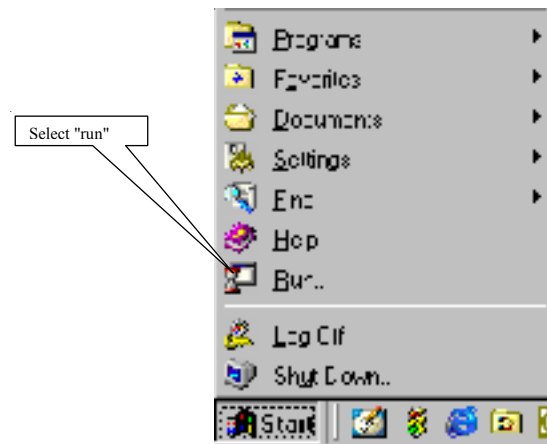


2.2 At the WindowsXX desktop, click the mouse on "Start";



Note: XX – 95; 98; 2000

2.3 Then, select “Run.”



2.4 The “run” window appears.

2.5 At the “Open” dialogue box, type

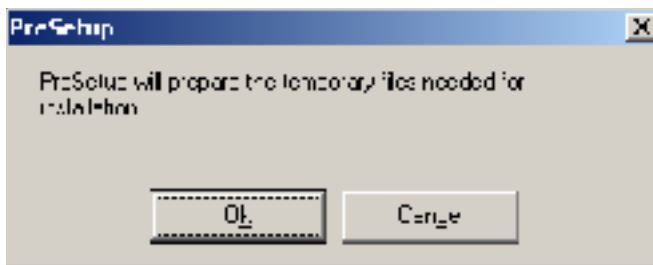
D:\XXX

Where: “D:” is the CD Rom drive and XXX will be one of the following:
product registration;
licensing of establishments; or
drug import system.

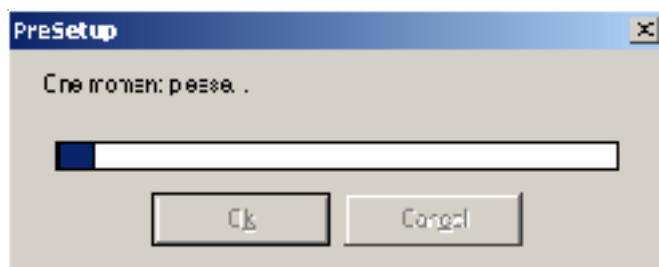
The user will do this procedure for each of the subsystems above.

2.6 Click “OK”.

2.7 The “PreSetup” dialogue box appears. Press the “OK” button to continue the installation process.



2.8 Another dialogue box appears (see below), informing the user that installation is in progress.



2.9 The appropriate subsystem installation window appears e.g. the product registration subsystem window appears as shown next.



Press the “Next” button to continue the installation of the appropriate subsystem.

After pressing the “Next” button, the options window appears as shown below.



In the options window, you now have a choice of whether to install the subsystem with a sample database or to install the subsystem with an empty database in order to start entering your own data.

Position the mouse button on the desired choice and press the left mouse button while positioned on the small box, (For example “Sample database” or “Blank database”.)

After making the selection, press the “Next” button. Another window appears.



Follow the instructions by pressing the “Next” button after each window until the Setup dialogue box informs you that installation is complete. Press the “OK” button.

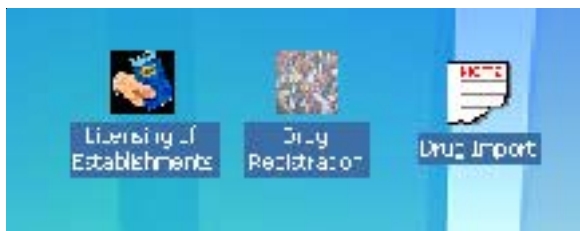


Repeat the same steps above to install the other two subsystems.

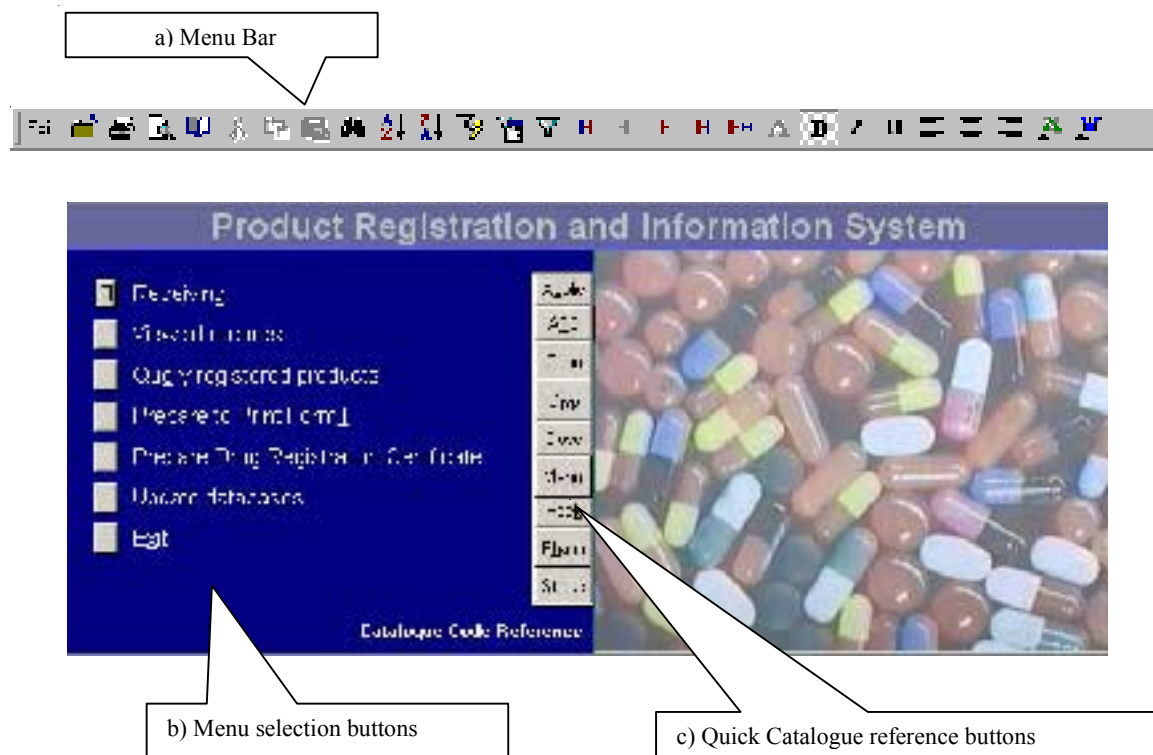
After the installation process is completed, three application system icons will appear on your active Windows desktop.

3. THE WINDOWS DESKTOP

After installation of the drug registration subsystems, three icons will appear on the Windows desktop: a) Licensing of establishments; b) Product registration; and c) Drug import.



To launch a subsystem, position the mouse cursor on one of the three icons. Once positioned on the desired application, click the “left” mouse button. The desired application is launched, showing the Main Menu screen of the application. All three subsystems’ main menu screens all have a consistent look and feel. Each has the following: a) Menu bar; b) Menu selection buttons; and c) Quick catalogue reference buttons.



4. MENU BAR

The Menu bar at the top enables the manipulation of the records in the database. Once the records are displayed, use the icons on the menu bar to search, filter, sort and print records in the database based on the criteria you have set. The function of each button is explained below:

4.1 - Exit.

This exits or quits the subsystem and brings you back to the Windows desktop.

4.2 - Close

Closes the current open window and goes up one menu level.

4.3 - Print

Print whatever is on the window to the default printed. To change the printer settings, you have to make the change from the “control panel” in the Windows operating system settings.

4.4 - Preview.

View the list of records or view the current window on the computer screen before printing.

4.5 - Find button. This button searches for a specified text in the open table / database.

4.6 The Sort buttons

These buttons sort records based on a selected column in ascending / descending order.

Sorts the selected items in order from the beginning of the alphabet, the lowest number, or the earliest date and visa versa using the column that contains the insertion point.

4.7 Filter buttons

4.7.1  - Filter by selection.

In the field or column, find one instance of a value you want records to contain in order to be included in the filters results.

4.7.2  - Filter by form.

A form with empty fields is presented. This filtering technique allows you to type in the values in the fields of a form for extracting a subset of records from a database.

4.7.3  - Apply filter (on/off). This is an on/off filter button switch. This is a toggle button. If the figure is depressed, it indicates that the filter is on. To turn filtering to off, press the same button. To turn it back on, press the button again.

4.8 Format buttons

4.8.1  Character format buttons.

4.8.2  Paragraph format buttons.

4.9 Go-to buttons - You use the navigation buttons to move the records in the database forward or backward one record at a time.

4.9.1  - This button takes you to the FIRST record in the database.

4.9.2  - This button takes you to the PREVIOUS record from where the cursor is.

4.9.3  - This button takes you to the NEXT record from where the cursor is.

4.9.4  - This button takes you to the LAST record in the database.

4.9.5  - Press this button to Add a new record in the database. The add button () that is found on the menu bar or at the bottom of the data entry form (). Pressing the >* button brings up a blank entry form. Enter data in the new form.

4.10 Report preparation buttons

4.10.1  - Send selected records to the *MSEXelÔ* program.

4.10.2  - Send selected records to the *MSWordÔ* program.

5. QUICK CATALOGUE REFERENCE BUTTONS

To the right of the Main Menu selections are vertically aligned buttons with a single underlined letter on each button face. These are the **Quick Catalogue Code Reference** selection buttons. Each button represents a catalogue-table that is used by the subsystem. In a field that depends on data from a catalogue file, if an item being entered is NOT already an existing item in the catalogue file, then the record will not be acceptable to the system and a data entry error will be displayed. For the data to be acceptable to the system, the item being entered first be entered in the appropriate catalogue file.

The catalogue files ensure consistency and accuracy in the data entry process. This is a way to minimize typographical errors that may be entered into the databases.

Positioning the mouse cursor in any of the catalogue file buttons and simultaneously clicking the left button activates the catalogue file to open. Once displayed, the catalogue file window can be closed by bringing the mouse cursor to the “X” mark on the upper right hand side of the active window and left-clicking the mouse button. This closes the active window. The main menu reappears.

The same activation and closing techniques can be used to close active windows throughout the subsystems.

Another method to activate a command button is to use a shortcut. To activate the same button for example is to press the “alt”-key on the keyboard simultaneously with the alphanumeric key of the letter that is underlined.

6. MENU SELECTION BUTTONS

The main menu selection buttons contain the needed tasks to enter new records, to view and to edit existing records, to update the status of a record, to update catalogue files and, finally, to prepare and to print needed reports. The buttons are grouped by a common activity: updating/ adding new records; viewing and searching records; editing records; and printing.

6.1 Combo – boxes ()

Several of the fields in the drug registration system get their contents from catalogue files. The fields have a consistent combo-box look, similar to the one shown here (). Combo-box field allows entry only from existing records that are contained in a catalogue file.

If an error message is displayed after trying to enter data in a combo-box, it is an indication that what you are entering is not found in a catalogue file. Data entry of the item is not allowed. The item must first be entered in the catalogue file.

7. SEARCHING AND FILTERING

Filtering is a searching technique we shall employ to find an item or several items throughout the drug registration system.

To do a search, filter buttons (  ) are used extensively throughout most of the forms. There are two filter buttons on all the drug registration menu toolbars, the “filter by selection” and the “filter by form” buttons. The type of button to use depends on user preference and the individual situation when a search is needed. If what you are looking for is already found on the form, then the filter by selection is the most appropriate button to use.

7.1 Filter by selection (): In using the “filter by selection” button, an instance of the item you want filtered is already found on the form or a sub-form in the window on your computer screen.

To use the button, position the cursor on the field where the item is found and then click the “filter by selection” button. How you select the value determines what records the filter will return. Repeat the same steps until

you have the set of records you want. The number of reported records is reduced when the “filter by selection” button is repeatedly clicked because that would have set several criteria on the dataset.

7.2 Filter by form (): Clicking the “filter by form” button will blank out the contents of the fields on the form or a sub-form on the window. You are expected to enter the item or items on the blank fields. After entering the data you want filtered, activate the “apply filter” button () and the set of records based on the criteria you typed on the blank fields are presented on your computer screen. In the “filter by form” searching methodology, you enter all the criteria in one form without having to keep on filtering the dataset one at a time until a subset of the desired data has been derived.

Note: The result of the filter, based on the criteria you specified are the number of records shown. The total number of records found, based on the criteria you have typed in the blank fields in the form, is shown on the navigation buttons on the lower portion of the form or sub-form (). Notice the word “filtered” right beside the number of records. This indicates that filtering is still “on.” Take note that the “apply filter” button on the drug registration menu bar is depressed (). The “apply filter button” is a toggle button – “on/off switch.” To turn off filtering, depress the button and the record set is reset to all records in the database. Note that once filtering is off, this is how the icon will look . The apply filter is not depressed. It is important that you take note of whether filtering is ON ( icon depressed) or OFF ( icon not depressed).

8. SORTING BUTTONS

Another interesting buttons that are found on the main drug registration menu toolbar are the  buttons. Positioning the cursor on the field where you want the records to sort and then pressing either the  or the  button will arrange the records in the database in alphabetical or numerical order, in ascending or descending order depending on which of the two buttons was pressed.

9. LIMITATIONS

In most small installations where only a few staff are involved in the management of drug registration data, security of the data in the system is not of primary concern. Most drug regulatory installations operate with a limited number of personnel, meaning data security is not a major problem. Data security can easily be managed by keeping a physical lock on the system. In contrast, a multi-user environment enables multiple users to simultaneously work on the same database with each user having a different access capability. Keeping track of who has permission to change or who changed data in the system is an issue that has to be dealt with in such environments.

To use the system in a multi-user environment, the present drug registration system will need recoding to ensure the tighter security measures needed in a multi-user system and for tracking changes made by users updating records in the database. In such environments, a multi-tier architecture may be a more appropriate setup as compared to the present two-tier traditional client/server architecture.

10. MOVING AROUND

Use the keyboard as you would normally use a typewriter. On the right hand side of the keyboard is a numeric keypad that can be used to key in numbers (see figure below).



To use the numeric keypad to type in numbers, press the *numlock* key. Once enabled, you can now type numbers straight from the numeric keypad. If not enabled, the keys will move the cursor left (number 4), right (number 6), up (number 8) or down (number 2).

PART 3

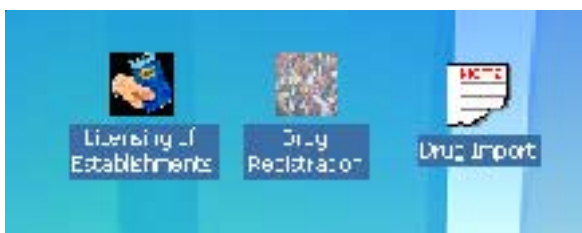
The remaining portion of this user manual is best used in conjunction with the installed “DRUG REGISTRATION AND INFORMATION SYSTEM”.

Before one can use any of the installed systems, ensure that your computer has been booted up. Otherwise, perform the following steps:

1. Turn on your computer.

At this time, your computer must be connected physically to a power outlet. Depending on how your system was installed, you may be asked to enter a network password or a windows desktop password.

2. At the Windows95™ or 98 Windows98™ desktop windows, you will find three (3) icons. These are the three subsystems in the computerized drug registration and information system.
3. Click the icon for the system you want to use.



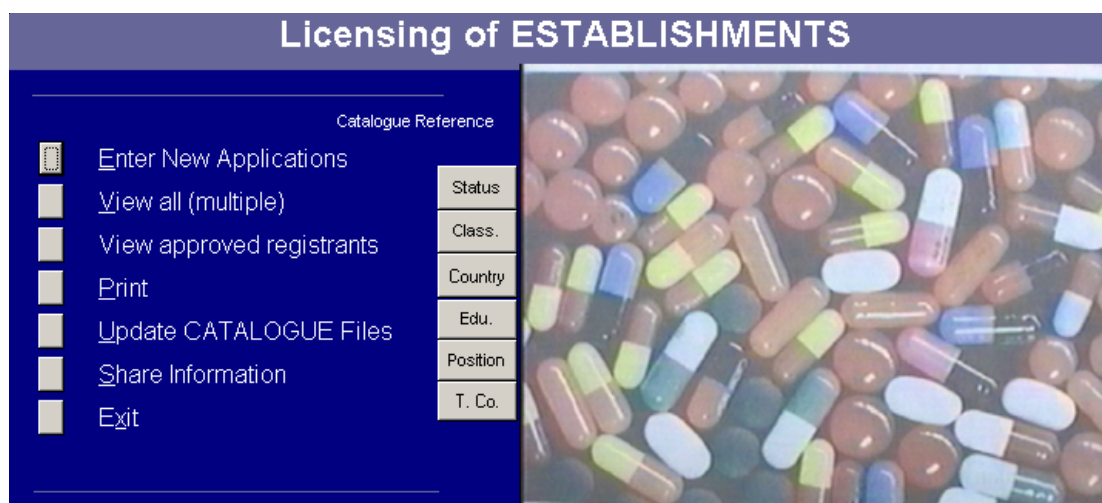
LICENSING OF ESTABLISHMENTS SUBSYSTEM

Double clicking the Licensing of Establishments shortcut icon  will load the Microsoft Access2000™ program and subsequently load the **Licensing of Establishments System** from within the Access 2000™ environment. The Licensing of Establishment System main menu will open. The licensing of establishments system contains the list of registered establishments transacting pharmaceutical products in the country. These establishments may be importers, agents, manufacturers, exporters,

repacking companies, pharmacy outlets and donors. After an evaluation of the activities of these establishments, and presuming that the establishment passes the minimum standards set for registration of an establishment, a regulatory authority issues a license to operate (LTO) certificate for that establishment. The list of registered establishments is “shared” information with the product registration (see below) and the drug import monitoring (see below) systems.

Essentially, each product has a license holder or owner who is the applicant of a product being registered in the product registration system. If an applicant is not registered, then the product registration system cannot accept the product application data that is being entered because the applicant company is not already a registered company and therefore will not be found in the system.

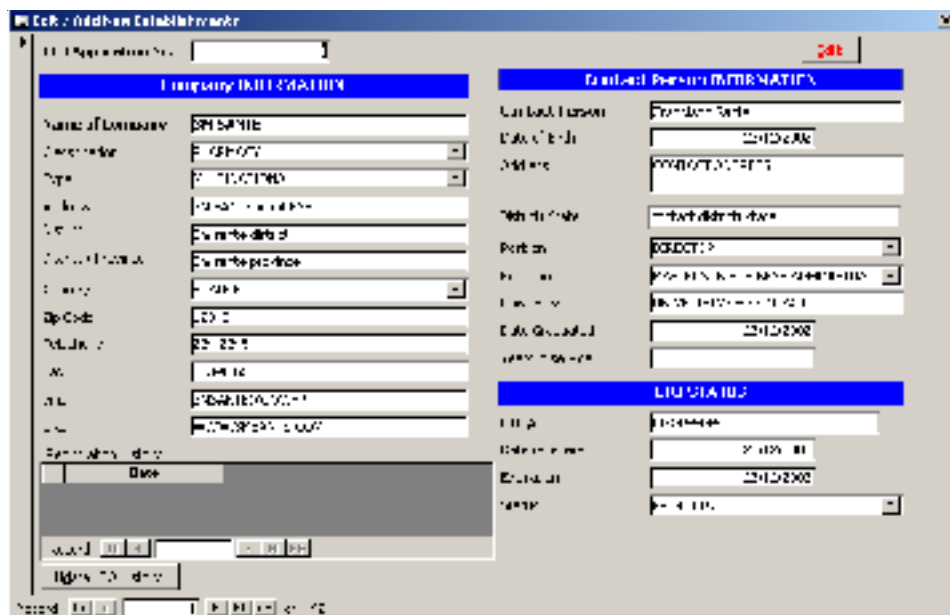
Shown below is the Licensing of Establishments System’s main menu with the various activity choices.



Menu	Explanation
1. Enter New Applications	Select this menu selection button to enter a new LTO application or to search and view existing establishments data records. A single form is presented on the screen. Use the filtering technique to search or to set the conditions of the search.
2. View all (multiple)	All LTO application records are shown in spreadsheet format.
3. View approved registrants	Various submenu choices for approved registrants will be shown. Approved registrants are based on the condition that the LTO # field in the dataset is not empty or left blank, indicating that the establishment has an existing LTO # assigned. The list of approved registrants does not consider whether the LTO license has expired.
4. Print	This selection button allows you to print the LTO certificate / license, a generic letter or a copy of an LTO sample application form.
5. Update catalogue Files	This menu selection button will be used for maintaining the data in catalogue files. Additions and/or corrections made on the catalogue files will immediately be reflected in the database records. The descriptions of catalogue files can be changed.
6. Share Information	Once new LTO applications are entered, the new data only resides in the Licensing of Establishments System database. The most recent record updates are only shared with the product registration system once this selection button is pressed. Sharing replaces the old licensing of establishments subset records that was last copied into the product registration system database.
7. Exit	This button closes all forms and exits the Licensing of Establishments System.

1. ENTERING A NEW APPLICATION

1. This form presents single documents of all the LTO applicants in the Licensing of Establishments System. Press the navigation buttons to the right () or to the left () to move records forward or backward. Press  to go to the first record on file (based on the sorted field) or  to go to the last record.



2. To enter a new application, press ">*" on the bottom of the form. A blank form is presented.
3. Using the application form, enter the data contained on the form, starting with a unique LTO application number.
4. After data entry, close the form by clicking on the "x" button on the top right of the open form.

2. VIEW ALL (MULTIPLE)

Application #	Company Name (Applied)	LTO Number	Date of Issue	Expiration Date	Status/Activity	Conditions	Type of Case
1	1	1	1	1	1	1	1
2	2	2	2	2	2	2	2
3	3	3	3	3	3	3	3
4	4	4	4	4	4	4	4
5	5	5	5	5	5	5	5
6	6	6	6	6	6	6	6
7	7	7	7	7	7	7	7
8	8	8	8	8	8	8	8
9	9	9	9	9	9	9	9
10	10	10	10	10	10	10	10
11	11	11	11	11	11	11	11
12	12	12	12	12	12	12	12
13	13	13	13	13	13	13	13
14	14	14	14	14	14	14	14
15	15	15	15	15	15	15	15
16	16	16	16	16	16	16	16
17	17	17	17	17	17	17	17
18	18	18	18	18	18	18	18
19	19	19	19	19	19	19	19
20	20	20	20	20	20	20	20
21	21	21	21	21	21	21	21
22	22	22	22	22	22	22	22
23	23	23	23	23	23	23	23
24	24	24	24	24	24	24	24
25	25	25	25	25	25	25	25
26	26	26	26	26	26	26	26
27	27	27	27	27	27	27	27
28	28	28	28	28	28	28	28
29	29	29	29	29	29	29	29
30	30	30	30	30	30	30	30
31	31	31	31	31	31	31	31
32	32	32	32	32	32	32	32
33	33	33	33	33	33	33	33
34	34	34	34	34	34	34	34
35	35	35	35	35	35	35	35
36	36	36	36	36	36	36	36
37	37	37	37	37	37	37	37
38	38	38	38	38	38	38	38
39	39	39	39	39	39	39	39
40	40	40	40	40	40	40	40
41	41	41	41	41	41	41	41
42	42	42	42	42	42	42	42
43	43	43	43	43	43	43	43
44	44	44	44	44	44	44	44
45	45	45	45	45	45	45	45
46	46	46	46	46	46	46	46
47	47	47	47	47	47	47	47
48	48	48	48	48	48	48	48
49	49	49	49	49	49	49	49
50	50	50	50	50	50	50	50
51	51	51	51	51	51	51	51
52	52	52	52	52	52	52	52
53	53	53	53	53	53	53	53
54	54	54	54	54	54	54	54
55	55	55	55	55	55	55	55
56	56	56	56	56	56	56	56
57	57	57	57	57	57	57	57
58	58	58	58	58	58	58	58
59	59	59	59	59	59	59	59
60	60	60	60	60	60	60	60
61	61	61	61	61	61	61	61
62	62	62	62	62	62	62	62
63	63	63	63	63	63	63	63
64	64	64	64	64	64	64	64
65	65	65	65	65	65	65	65
66	66	66	66	66	66	66	66
67	67	67	67	67	67	67	67
68	68	68	68	68	68	68	68
69	69	69	69	69	69	69	69
70	70	70	70	70	70	70	70
71	71	71	71	71	71	71	71
72	72	72	72	72	72	72	72
73	73	73	73	73	73	73	73
74	74	74	74	74	74	74	74
75	75	75	75	75	75	75	75
76	76	76	76	76	76	76	76
77	77	77	77	77	77	77	77
78	78	78	78	78	78	78	78
79	79	79	79	79	79	79	79
80	80	80	80	80	80	80	80
81	81	81	81	81	81	81	81
82	82	82	82	82	82	82	82
83	83	83	83	83	83	83	83
84	84	84	84	84	84	84	84
85	85	85	85	85	85	85	85
86	86	86	86	86	86	86	86
87	87	87	87	87	87	87	87
88	88	88	88	88	88	88	88
89	89	89	89	89	89	89	89
90	90	90	90	90	90	90	90
91	91	91	91	91	91	91	91
92	92	92	92	92	92	92	92
93	93	93	93	93	93	93	93
94	94	94	94	94	94	94	94
95	95	95	95	95	95	95	95
96	96	96	96	96	96	96	96
97	97	97	97	97	97	97	97
98	98	98	98	98	98	98	98
99	99	99	99	99	99	99	99
100	100	100	100	100	100	100	100

Clicking on the View all (multiple) button presents all the LTO applications in spreadsheet format. The data of all product records are shown on your screen in a spreadsheet format.

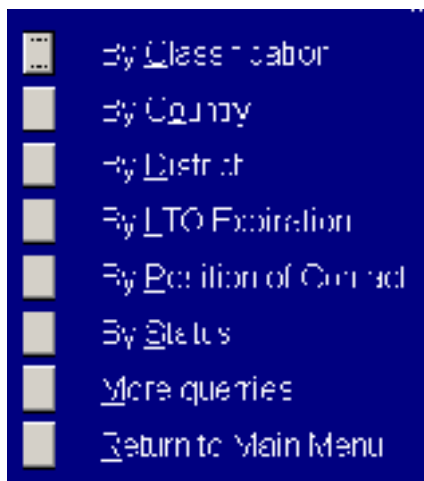
Each row represents one product on file and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).

Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one full screen up or down at a time.

Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).

To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3. VIEW APPROVED REGISTRANTS



This submenu is a selection of all approved registrants regardless of whether or not the LTO licenses are expired. The registration # field of all approved registrants are assumed to contain a registration # which is tagged by the system as having an existing license.

3.1 By Classification

Pressing the “By classification” button displays all approved applications arranged by Classification type. (i.e. agents, donors, distributors, exporters, importers, manufacturers, and pharmacies).

Use the filtering techniques discussed earlier to extract the desired classification type.

By Classification : Select Query						
	Classification	Applica	Company Name (Applic)	Contact Person	LTO# issued	Date registered
▶	PHARMACY*	1	3M SANTE	SANTE FRANCE	LTO444444	23/12/2002

3.2 By Country

Pressing this button displays all the applicants with APPROVED LTOs arranged by their country of origin.

Use the filtering technique to extract the applicants according to their country.

By Country : Select Query							
Country (Applic)	Applica	Company Name (Applic)	Type of Company	Contact Person	LTO# issued	Date registered	Expiration
FRANCE	1	3M SANTE	MULTINATIONAL	SANTE FRANCE	LTO444444	23/12/2002	23/12/2003

3.3 By District

Pressing this button displays all the applicants with APPROVED LTOs arranged by the district.

Use the filtering technique to extract the Applicants according to district.

By District : Select Query							
District (Applic)	Applica	Company Name (Applic)	Classification	Type of Company	Street (applic)	District (applic)	
SANTE FRANCE	1	3M SANTE	MULTINATIONAL	MULTINATIONAL	3M SANTE - JULES KERNEL	SANTE FRANCE	

3.4 By LTO Expiration

Pressing this button displays all the applicants with APPROVED LTOs sorted by the LTO expiration dates.

Again, use the filtering techniques to extract the desired applicants by their expiration dates.

By LTO Expiration : Select Query						
Expiration	Applica	Company Name (Applic)	Type of Company	Contact Person	LTO	
23/12/2003	1	3M SANTE	MULTINATIONAL	SANTE FRANCE	LTO444	

3.5 By Position of Contact

Pressing this button displays all the applicants with APPROVED LTOs sorted by the position of the contact person in the company.

Again, use the filtering techniques to extract the desired applicants by their positions in the company.

By Position of Contact : Select Query						
Position (Contact)	Applica	Company Name (Applic)	Type of Company	Contact Person	L	
DIRECTOR	1	3M SANTE	MULTINATIONAL	SANTE FRANCE	LTO	

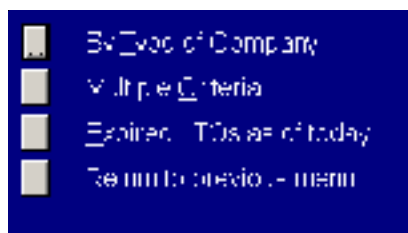
3.6 By status

Pressing this button displays all the applicants with APPROVED LTOs sorted by the status or activity tagged to the application.

Use the filtering techniques to extract the desired applicants according to the status or activity of the application.

By Status : Select Query					
Status / Activity	Applicants	Company Name (Applic)	Type of Company	Contact Person	LTO
APPROVED	1	EM SARRE	MULTI-NATIONAL	EMTE FRANCE	LTO4

3.7 More Queries



3.7.1 By Type of Company

You can have another category for which to classify the establishments. An example of this is the classification of the pharmacy outlets based on what type of pharmaceutical products they can carry or the dispensing category they are allowed. The same may be true for the other establishments you issue a license for.

By Type of company : Select Query					
Type of Company	Applicants	Company Name (Applic)	Contact Person	LTO	
MULTI-NATIONAL	1	EM - GSK -	- GSK - FRANCE -	00	

This menu selection presents all the approved registrants in spreadsheet format. From the list presented, use the sorting and filtering technique in order to extract the desired records according to a set of conditions.

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Agency	Name of Company	Class Number	Type of Company	Village	Market	Country	Zip Code	Telephone
1	1.1.1.1	1.1.1.1	1.1.1.1	1.1.1.1	1.1.1.1	1.1.1.1	1.1.1.1	1.1.1.1
2	2.2.2.2	2.2.2.2	2.2.2.2	2.2.2.2	2.2.2.2	2.2.2.2	2.2.2.2	2.2.2.2
3	3.3.3.3	3.3.3.3	3.3.3.3	3.3.3.3	3.3.3.3	3.3.3.3	3.3.3.3	3.3.3.3
4	4.4.4.4	4.4.4.4	4.4.4.4	4.4.4.4	4.4.4.4	4.4.4.4	4.4.4.4	4.4.4.4
5	5.5.5.5	5.5.5.5	5.5.5.5	5.5.5.5	5.5.5.5	5.5.5.5	5.5.5.5	5.5.5.5
6	6.6.6.6	6.6.6.6	6.6.6.6	6.6.6.6	6.6.6.6	6.6.6.6	6.6.6.6	6.6.6.6
7	7.7.7.7	7.7.7.7	7.7.7.7	7.7.7.7	7.7.7.7	7.7.7.7	7.7.7.7	7.7.7.7
8	8.8.8.8	8.8.8.8	8.8.8.8	8.8.8.8	8.8.8.8	8.8.8.8	8.8.8.8	8.8.8.8
9	9.9.9.9	9.9.9.9	9.9.9.9	9.9.9.9	9.9.9.9	9.9.9.9	9.9.9.9	9.9.9.9
10	10.10.10.10	10.10.10.10	10.10.10.10	10.10.10.10	10.10.10.10	10.10.10.10	10.10.10.10	10.10.10.10
11	11.11.11.11	11.11.11.11	11.11.11.11	11.11.11.11	11.11.11.11	11.11.11.11	11.11.11.11	11.11.11.11
12	12.12.12.12	12.12.12.12	12.12.12.12	12.12.12.12	12.12.12.12	12.12.12.12	12.12.12.12	12.12.12.12
13	13.13.13.13	13.13.13.13	13.13.13.13	13.13.13.13	13.13.13.13	13.13.13.13	13.13.13.13	13.13.13.13
14	14.14.14.14	14.14.14.14	14.14.14.14	14.14.14.14	14.14.14.14	14.14.14.14	14.14.14.14	14.14.14.14
15	15.15.15.15	15.15.15.15	15.15.15.15	15.15.15.15	15.15.15.15	15.15.15.15	15.15.15.15	15.15.15.15
16	16.16.16.16	16.16.16.16	16.16.16.16	16.16.16.16	16.16.16.16	16.16.16.16	16.16.16.16	16.16.16.16
17	17.17.17.17	17.17.17.17	17.17.17.17	17.17.17.17	17.17.17.17	17.17.17.17	17.17.17.17	17.17.17.17
18	18.18.18.18	18.18.18.18	18.18.18.18	18.18.18.18	18.18.18.18	18.18.18.18	18.18.18.18	18.18.18.18
19	19.19.19.19	19.19.19.19	19.19.19.19	19.19.19.19	19.19.19.19	19.19.19.19	19.19.19.19	19.19.19.19
20	20.20.20.20	20.20.20.20	20.20.20.20	20.20.20.20	20.20.20.20	20.20.20.20	20.20.20.20	20.20.20.20
21	21.21.21.21	21.21.21.21	21.21.21.21	21.21.21.21	21.21.21.21	21.21.21.21	21.21.21.21	21.21.21.21
22	22.22.22.22	22.22.22.22	22.22.22.22	22.22.22.22	22.22.22.22	22.22.22.22	22.22.22.22	22.22.22.22
23	23.23.23.23	23.23.23.23	23.23.23.23	23.23.23.23	23.23.23.23	23.23.23.23	23.23.23.23	23.23.23.23
24	24.24.24.24	24.24.24.24	24.24.24.24	24.24.24.24	24.24.24.24	24.24.24.24	24.24.24.24	24.24.24.24
25	25.25.25.25	25.25.25.25	25.25.25.25	25.25.25.25	25.25.25.25	25.25.25.25	25.25.25.25	25.25.25.25
26	26.26.26.26	26.26.26.26	26.26.26.26	26.26.26.26	26.26.26.26	26.26.26.26	26.26.26.26	26.26.26.26
27	27.27.27.27	27.27.27.27	27.27.27.27	27.27.27.27	27.27.27.27	27.27.27.27	27.27.27.27	27.27.27.27
28	28.28.28.28	28.28.28.28	28.28.28.28	28.28.28.28	28.28.28.28	28.28.28.28	28.28.28.28	28.28.28.28
29	29.29.29.29	29.29.29.29	29.29.29.29	29.29.29.29	29.29.29.29	29.29.29.29	29.29.29.29	29.29.29.29

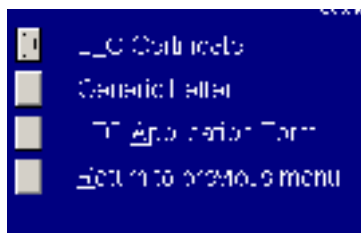
This selection lists all APPROVED licenses that are expired as of the computer's system date. Make sure that the computer's clock is set on the correct day or the result of this query may be erroneous.

[illegible]

This selection takes you back to the previous menu selection.

4. PRINT

The printing submenu opens a set of printing selections. Below is the list of printing options:

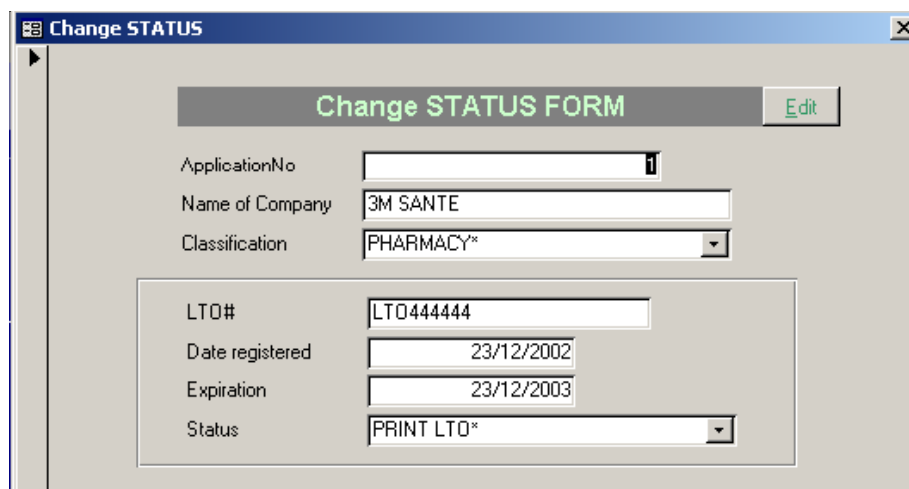


4.1 LTO Certificate

This selection allows you to prepare and automate printing of LTO Certificates. Selecting this option opens the submenu below. Follow through steps 1 and 2 to automate the printing of the certificates.

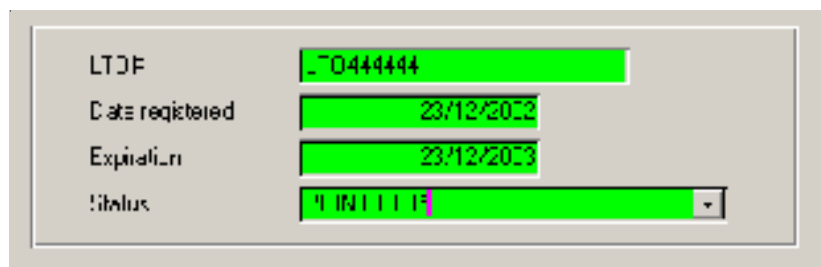
4.1.1 Step 1: Set appropriate status

Selecting this option opens the “Change Status” form as shown below.



Change STATUS FORM	
ApplicationNo	
Name of Company	3M SANTE
Classification	PHARMACY*
LTO#	LTO444444
Date registered	23/12/2002
Expiration	23/12/2003
Status	PRINT LTO*

Position the cursor on the “Status” field on the form and double click the left mouse button. All the field color changes to green, indicating that data in the fields can be changed. Please see below:

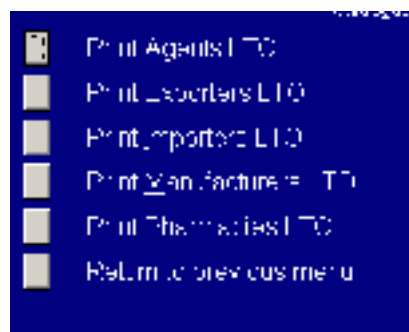


LTOF	044444
Date registered	23/12/2012
Expiration	23/12/2013
Status	PRINT LTO

Change the “status” field to “PRINT LTO*.”

Go to the next record and follow the same procedure above for the rest of the applications for which you want to print an LTO Certificate. After you have changed the status field of all the records you want to print certificates for, close the “change status form.” Proceed to Step 2.

4.1.2 Step 2: Print LTO



Making this selection will open a submenu. The submenu allows you to choose the certificate type you wish to print. For example, you want to print an agent’s LTO certificate,: two conditions must be met: a) the agent’s STATUS field must first be set to “PRINT LTO*”; b) the establishment’s classification must be that of an agent. Unless these two conditions are met, the LTO certificate for that agent will not be printed. The same is true for the rest of the other establishments such as an importer or manufacturer.

4.1.3 Print [Agents/Exporters/Importers/Manufacturers/Pharmacies] LTO

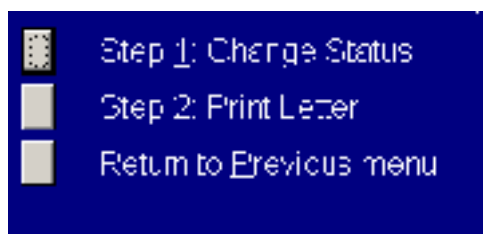
This selection will start the merging of the licensing of establishments data for the desired establishments for which you wish to print an LTO certificate. The data is merged into a template document. The certificates are now ready for printing in *MSWord™*.

4.1.4 Return to Previous menu

This selection takes you back to the previous menu selection.

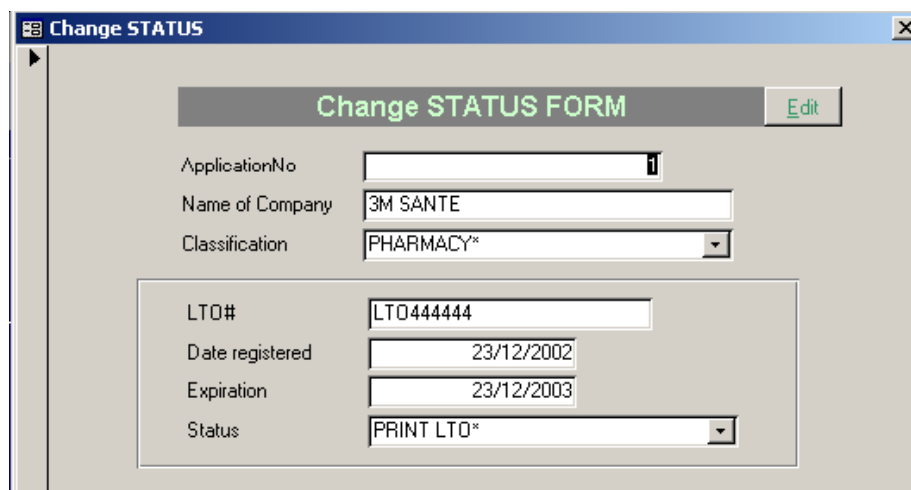
4.2 Generic Letter

This selection allows you to prepare and automate printing of a Generic Letter you can later send to establishments that are listed in the Licensing of Establishments database. Selecting this option opens the submenu below. Follow steps 1 and 2 to automate the printing of the generic letter.



4.2.1 Step 1: Set appropriate status

Selecting this option opens the “Change Status” form as shown below.

A screenshot of a software window titled 'Change STATUS'. The window has a title bar with a close button. Inside, there's a header 'Change STATUS FORM' with an 'Edit' button. Below the header, there are several input fields and dropdown menus. The fields are: 'ApplicationNo' (text box), 'Name of Company' (text box with '3M SANTE'), 'Classification' (dropdown menu with 'PHARMACY*'), 'LTO#' (text box with 'LTO444444'), 'Date registered' (text box with '23/12/2002'), 'Expiration' (text box with '23/12/2003'), and 'Status' (dropdown menu with 'PRINT LTO*').

Position the cursor on the “Status” field on the form and double click the left mouse button. All the field color changes to green, indicating that data in the fields can be changed. Please see below:

LTOF	LT044444
Date registered	23/12/2012
Expiration	23/12/2013
Status	WRITE LETTER*

Change the “status” field to “Write letter*.”

Go to the next record and follow the same procedure above for the rest of the applications for which you want to print an LTO Certificate. After you have changed the status field of all the records you want to print certificates for, close the “change status form.” Proceed to Step 2 below.

4.2.2 Step 2: Print letter

The submenu will start the merging process in order to start printing the generic letter. Take note that the STATUS field must first be set to “WRITE LETTER*”

4.2.3 Return to Previous Menu

This selection takes you back to the previous menu selection.

4.3 LTO application form

This option will print an LTO application form.

4.4 Return to Previous Menu

This selection takes you back to the previous menu selection.

5. UPDATE CATALOGUE FILES

This option will open the CATALOGUE file tables. There are six CATALOGUE tables in the licensing of establishments system: 1) Activity; 2) Classification; 3) Country; 4) Education; 5) Position; and 6) Type of Company.

The screenshot shows a window titled "CATALOGUE: Form". It has a tabbed interface with tabs for "Activity", "Classification", "Country", "Education", "Position", and "Type of Company". The "Activity" tab is selected. Below the tabs is a table with two columns: "Type" and "Activity". The table contains several rows of data, including "EXPIRED", "51 TO FCP SIGNATURE", "1 NEW APPLICATION", "2 PRIME LIFE", "7 UNDER EVALUATION", "6 WITHDRAWN", and "1 WITHDRAWN". A callout box points to the "Catalogue file tab" label above the table.

Type	Activity
	EXPIRED
	51 TO FCP SIGNATURE
	1 NEW APPLICATION
	2 PRIME LIFE
	7 UNDER EVALUATION
	6 WITHDRAWN
	1 WITHDRAWN
*	Number)

Records: 1 of 1

To enter a new catalogue item, select the catalogue file tab. In the example above, the activity catalogue file is displayed. To enter a new item, click on the  icon below the form. Enter the new item in the blank row. Close the form after entering the item or items by clicking the  icon on the top right of the form.

6. SHARE INFORMATION

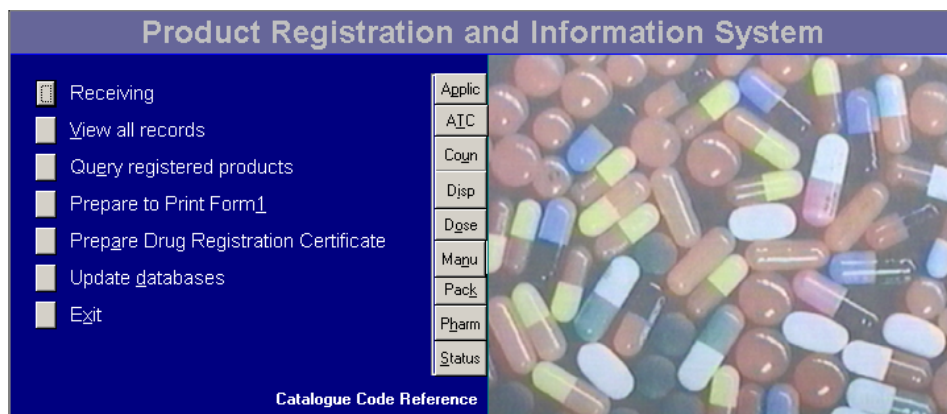
Sharing the information selection will copy a subset of the list of establishments records into the product registration database. This essentially overwrites the old licensing of establishments records that was last shared with the product registration system with the most recent recordset.

7. Exit

This closes all windows and subsequently closes all databases and then quits the application system.

PRODUCT REGISTRATION SYSTEM

To activate the product registration system, double click the  icon on your windows desktop. The product registration system MAIN MENU is presented as shown below.



To select an item (e.g. View all records), move the mouse pointer to the selection you wish and then double click the left button. Each item in the selection has an underlined letter. You can use this as a keyboard shortcut to call up the underlying submenu. For example in **View records**, the letter V is underlined so you can simply press V on the keyboard to activate the selection.

The product registration system is an application system that keeps track of drug product applications for drug registration. Basic information such as registered products can be retrieved and various reports printed as needed. Reports can be printed using *MSWord*[™] or *MSExcel*[™]. Printing of the product registration certificate is automated.

THE PRODUCT REGISTRATION SYSTEM

1. RECEIVING

The screenshot shows a software window titled "Receiving New Product Application". It contains the following fields and controls:

- Application No:** An empty text box.
- Applicant / MA Holder:** A dropdown menu with "3M SANTE" selected.
- Manufacturer:** A dropdown menu with "3M SANTE" selected.
- Brand Name:** A text box containing "ASPIRINE PH 8TM 500MG".
- Dosage Form:** A dropdown menu.
- Applied:** A text box containing the date "23/12/2002".
- Print Acknowledgement:** A button located at the bottom right of the form area.
- Record Navigation:** At the bottom left, it says "Record: 1 of 4682" with navigation icons (back, forward, first, last, etc.).

Choose this menu selection to do the following:

- o To enter new PRODUCT APPLICATIONS into the drug registration system database
- o To print an acknowledgement receipt for the product applications
- o To print a routing slip document to be attached to the dossier for product applications
- o To print routine reports on product applications received on a specified time frame/s, arranged by applicant or marketing authorization holder, by name of Manufacturer or by pharmaceutical dosage format of the products. The general layout of the report can be designed by user preference with the use of the *MSWord™* or *MSExcel™* office suite programs. It is assumed that the user is familiar with either using the *MSWord* and/or *MSExcel* applications.
 1. At this stage, it is presumed that you have examined all the items on the application form and that the entries have been completed.
 2. On the "Product Registration System" MAIN MENU, double click on the 'RECEIVING' button.

3. The “Receiving New Product Application” window opens.
4. To add a new application, click the “>*” button found on the bottom of the receiving window or the same button that is found on the drug registration system menu bar.
5. A blank form opens (the cursor is positioned on the Application number field).
6. There are 6 items you will need to enter:
 - a. Application number;
 - b. Applicant name;
 - c. Name of manufacturer;
 - d. Brand name / trade name;
 - e. Dosage form; and
 - f. Date of application.
7. Enter a unique application number on the application number field.
8. From the product application form that was submitted, enter the required data.
9. At the end of the data entry process, move the records forward or backward by pressing “>” or “<” to save the data you just entered.
10. To print an acknowledgement receipt and routing slip document for each of the applications you just entered, press the “Print Acknowledgement” button.
11. A dialogue box opens.
12. On the “Enter begin #” field, enter the application # of the product application where you want to begin the printing of the acknowledgement receipt and/or routing slip.
13. Enter “OK”.
14. A second dialogue box appears.
15. On the “Enter end #” field, enter the application # from where you want to end printing.

16. After entering the “end #”, an *MSWord*[™] word processing document opens.
17. What you have in front of you is a *MSWord*[™] template.
18. Click on the “merge” icon on the drug registration menu bar.
19. A “merge” dialogue box opens.
20. You have a choice of where to print your document (a printer or another file).
21. After making your choice, click the “merge” button on the “Merge window ” dialogue box.

Note: If you chose the *MSWord*[™] document to be printed to another file instead of directly to a printer, the documents are presented on your screen and are now ready for printing.
22. Print the document as you would normally print an *MSWord*[™] document (by pressing the selections File-Print on the *MSWord*[™] program).
23. To close each window on your screen, click the “x” button found on the top right portion of each open window.

2. VIEW ALL RECORDS

Choose this menu selection to do the following:

- o To view product records in individualized forms (one record at a time)
- o To view product records in a spreadsheet format (several records at a time)
- o To search and find records using one several criteria
- o To print record data based on the set criteria
- o To print generic-type reports, based on set criteria, using *MSWord*[™] or *MSExcel*[™]

2.1 View individual record

- 2.1.1 The first product record on file is shown on the screen - the order will depend on the sorting order when the records were last saved.
- 2.1.2 The screen is divided in four distinct parts: product data; applicant holder data; manufacturer data and product status (shown as “Status”-button next to the Application # field).

Search the records based on the searching and filtering techniques (under the “Searching / Filtering Records” topic)

View Drug Registration DATA	
Application No	Status
Product INFORMATION License Owner INFORMATION	
Brand Name	ASPIRINE PH 8TM 500MG
INN	ASPIRINE PH 8TM 500MG
Dosage Form	
Storage	
Shelf Life	
Primary Packaging	
Pack Size	8/5 X 10 CP.
Dispensing Category	PRESCRIPTION ONLY
ATC Classification	
PharmClass	ANALGESICS & ANTI-INFLAMMATORIES
EDL?	☒
Description	SDASDF
Country	FRANCE
Registration No (importing)	31/12/2002
Date of registration (importing)	23/12/2002
Ingredients	ASPIRINE PH 8TM 500MG
Indications	ASDFS
Contraindications	ASDFS
Side Effect	AFASD
Unit price	88
Remarks	
Company Name	3M SANTE
Classification	EXPORTER*
Type Of Company	MULTINATIONAL
Address	3m sante address
District	3m sante district
Province	3m sante province
Country	FRANCE
Zip code	12345
Telephone	234-2345
Fax	333-4565
Contact Person	sante france
LTO#	lto444444
DateRegistered	23/12/2002 18:20:38
Expiration	23/12/2003 18:20:38
Product Manufacturer INFORMATION	
Name	3M SANTE
Street	123 RUE
Province	LYON
Country	FRANCE
Zip Code	123
Telephone Number	111-2222
Fax Number	222-3333

2.2 View multiple records

1. All data of all product records are shown on your screen in a spreadsheet format.
2. Each row represents one product on file and each column represents the data for that field item (e.g. application #, brand name, etc.)

3. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
4. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic)
5. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet

View Drug Registration DATA									
Application No	Status								
<table border="1"> <thead> <tr> <th>Product INFORMATION</th> <th>License Owner INFORMATION</th> </tr> </thead> <tbody> <tr> <td> Brand Name ASPIRINE PH 8TM 500MG INN ASPIRINE PH 8TM 500MG Dosage Form Storage Shelf Life Primary Packaging Pack Size B/5 X 10 CP. Dispensing Category PRESCRIPTION ONLY ATC Classification PharmClass ANALGESICS & ANTI-INFLAMMATORIES EDL? ☒ Description SDASDF Country FRANCE Registration No (importing) 31/12/2002 Date of registration (importing) 23/12/2002 Ingredients ASPIRINE PH 8TM 500MG Indications ASDFS Contraindications ASDFS Side Effect AFA5D Unit price 88 Remarks </td> <td> Company Name 3M SANTE Classification EXPORTER* Type Of Company MULTINATIONAL Address 3m sante address District 3m sante district Province 3m sante province Country FRANCE Zip code 12345 Telephone 234-2345 Fax 333-4565 Contact Person sante france LTO# lto444444 DateRegistered 23/12/2002 18:20:38 Expiration 23/12/2003 18:20:38 </td> </tr> <tr> <td colspan="2"> Product Manufacturer INFORMATION </td> </tr> <tr> <td colspan="2"> Name 3M SANTE Street 123 RUE Province LYON Country FRANCE Zip Code 123 Telephone Number 111-2222 Fax Number 222-3333 </td> </tr> </tbody> </table>		Product INFORMATION	License Owner INFORMATION	Brand Name ASPIRINE PH 8TM 500MG INN ASPIRINE PH 8TM 500MG Dosage Form Storage Shelf Life Primary Packaging Pack Size B/5 X 10 CP. Dispensing Category PRESCRIPTION ONLY ATC Classification PharmClass ANALGESICS & ANTI-INFLAMMATORIES EDL? ☒ Description SDASDF Country FRANCE Registration No (importing) 31/12/2002 Date of registration (importing) 23/12/2002 Ingredients ASPIRINE PH 8TM 500MG Indications ASDFS Contraindications ASDFS Side Effect AFA5D Unit price 88 Remarks	Company Name 3M SANTE Classification EXPORTER* Type Of Company MULTINATIONAL Address 3m sante address District 3m sante district Province 3m sante province Country FRANCE Zip code 12345 Telephone 234-2345 Fax 333-4565 Contact Person sante france LTO# lto444444 DateRegistered 23/12/2002 18:20:38 Expiration 23/12/2003 18:20:38	Product Manufacturer INFORMATION		Name 3M SANTE Street 123 RUE Province LYON Country FRANCE Zip Code 123 Telephone Number 111-2222 Fax Number 222-3333	
Product INFORMATION	License Owner INFORMATION								
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Product Manufacturer INFORMATION									
Name 3M SANTE Street 123 RUE Province LYON Country FRANCE Zip Code 123 Telephone Number 111-2222 Fax Number 222-3333									

2.3 Return to Main Menu

1. Clicking the “Return to Main Menu” button brings you back to the previous menu selection screen (The Drug Registration Main Menu).

3. QUERY REGISTERED PRODUCTS

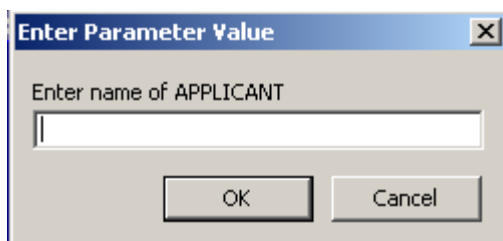
Choose this menu selection to do the following:

- o To view all registered product records in a spreadsheet format (several records at a time).
- o To search and find records of only registered products on file using one or multiple criteria.
- o To print record data based on the set criteria.
- o To print generic-type reports of registered products based on set criteria using *MSWord™* or *MSExcel™*.

NOTE: The system assumes all product applications have been approved when the REGISTRATION # field of the record is not empty.

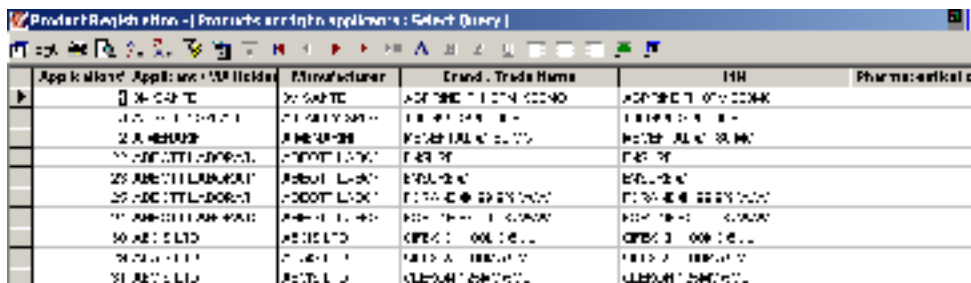
3.1 Products by Applicant

1. A dialogue box appears on the screen after clicking the “PRODUCTS BY APPLICANT” button.



2. Enter the name of the applicant as it was spelled exactly when it was entered in the database. If you are unsure of the spelling, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.
3. Click the “OK” button to start the search process.

- The data of all APPROVED product records, in spreadsheet format, based on the applicant field criteria you have earlier specified is shown on the screen.



Application#	Applicant Name	Manufacturer	Brand / Trade Name	INN	Pharmaceutical
1	ABC	XYZ	ABC	XYZ	ABC
2	DEF	GHI	DEF	GHI	DEF
3	JKL	MNO	JKL	MNO	JKL
4	PQR	STU	PQR	STU	PQR
5	VWX	YZA	VWX	YZA	VWX
6	BCD	EFG	BCD	EFG	BCD
7	HIJ	KLM	HIJ	KLM	HIJ
8	NOP	QRS	NOP	QRS	NOP
9	TUV	WXY	TUV	WXY	TUV
10	ZAB	CGH	ZAB	CGH	ZAB

- Each row represents one APPROVED product on file based on the applicant field criteria earlier set. Each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
- Search the records based on the searching and filtering methodologies (Under the “**Searching / Filtering Records**” topic).
- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.2 Products by Anatomical Therapeutic Chemical Classification Codes

- A dialogue box appears on the screen after clicking the “PRODUCTS BY ATC CODES” button.
- Enter the exact ATC Code of the product. If unsure of the code, then make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.

NOTE: A listing of ATC Codes is available in the CATALOGUE CODE REFERENCE found on the MAIN MENU. The code listing can be sorted by ATC codes or by the drug classification.

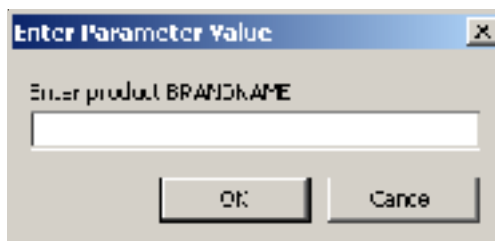
3. Click the “OK” button to start the search process.
4. The data of all APPROVED product records, in spreadsheet format, based on the ATC criteria you have earlier specified is shown on the screen.

Application#	Application Name	Manufacturer	Brand / Trade Name	INN	Pharmaceutical
01	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN
02	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN
03	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN
04	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN
05	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN
06	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN
07	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN
08	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN
09	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN
10	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN	ASPIRIN

5. Each row represents one APPROVED product on file based on the ATC criteria earlier set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.3 Products by Brand Name

1. A dialogue box appears on the screen after clicking the “PRODUCTS BY BRAND NAME” button.



2. Enter the exact BRAND NAME of the product. If unsure of the code, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.
3. Click the “OK” button to start the search process.

Product Registration [Products by Brandname: select query]

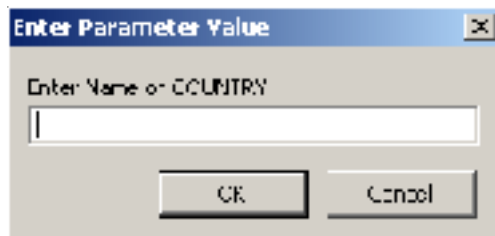
Application#	Application#	Brand / Trade Name	Manufacturer	INN	Pharmacia
3541	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3542	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3543	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3544	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3545	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3546	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3547	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3548	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3549	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3550	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3551	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3552	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3553	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3554	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3555	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3556	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3557	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3558	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3559	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3560	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3561	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3562	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3563	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3564	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3565	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3566	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3567	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3568	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3569	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3570	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3571	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3572	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3573	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3574	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3575	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3576	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3577	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3578	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3579	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3580	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3581	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3582	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3583	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3584	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3585	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3586	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3587	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3588	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3589	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3590	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3591	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3592	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3593	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3594	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3595	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3596	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3597	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3598	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3599	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	
3600	3-400000	CALCIBON-1000000000	3-400000	CALCIBON-1000000000	

4. The data of all APPROVED product records, in spreadsheet format, based on the Brand Name criteria you have specified is shown on the screen.
5. Each row represents one APPROVED product on file, based on the BRAND NAME criteria set, and each column representing the data for that field item (e.g. Application #, Brand Name, etc.).

6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full, up or down, at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.4 Products by Country

1. A dialogue box appears on the screen after clicking the “PRODUCTS BY COUNTRY” button.



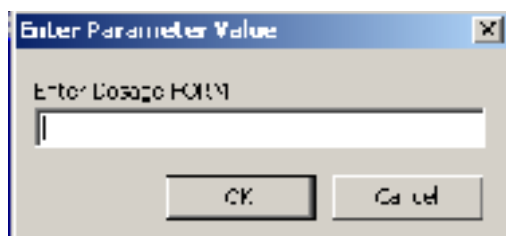
2. Enter the exact name of the country from where the product is manufactured or imported from. If unsure of the exact spelling of the country, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.
3. Click the “OK” button to start the search process.
4. The data of all APPROVED product records, in spreadsheet format, based on the name of country criteria you have specified is shown on the screen.

Application#	Applicant / M	Country of origin	Manufacturer	Brand / Trade Name	INN
3630	SIGMA PH/	AUSTRALIA	SIGMA PHARMA	LOGICIN COUGH MIXTURE FOR CO	LOGICIN COUGH MIXTURE FOR CC
2903	PFIZI	Sort Descending			
4679	RP SCHER	AUSTRALIA	PFIZER (AUS)	NORVASC* 5MG	NORVASC* 5MG
3624	SIGMA PH/	AUSTRALIA	RP SCHERER HC	GARLIC PEARLS	GARLIC PEARLS
3625	SIGMA PH/	AUSTRALIA	SIGMA PHARMA	GASTROGEL TABLETS	GASTROGEL TABLETS
3626	SIGMA PH/	AUSTRALIA	SIGMA PHARMA	GASTROGEL ORAL LIQUID	GASTROGEL ORAL LIQUID
3764	STEPHEN F	AUSTRALIA	SIGMA PHARMA	GASTROGEL ORAL LIQUID 250MG-	GASTROGEL ORAL LIQUID 250MC
1737	HERRON	AUSTRALIA	STEPHEN HUNTE	GASTROSTAT	GASTROSTAT
1738	HERRON	AUSTRALIA	HERRON	GOANNA HEAT CREAM	GOANNA HEAT CREAM
2794	PAN PHAR	AUSTRALIA	HERRON	GOANNA HEAT CREAM	GOANNA HEAT CREAM
1739	HERRON	AUSTRALIA	PAN PHARMA (	GW COLD	GW COLD
				HERRON PARACETAMOL 500MG	HERRON PARACETAMOL 500MG

- Each row represents one approved product on file based on the name of the country criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full, up or down, at a time.
- Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.5 Products by Dosage Forms

- A dialogue box appears on the screen after clicking the “PRODUCTS BY DOSAGE FORMS” button.
- Enter the exact name of the DOSAGE FORM of the product. If unsure of the exact spelling of the dosage form, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.



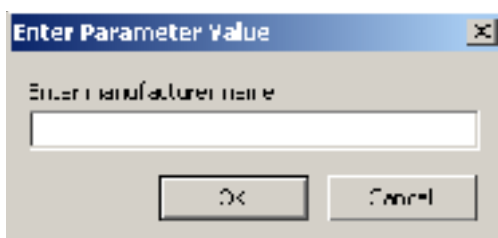
- Click the “OK” button to start the search process.
- The data of all approved product records, in spreadsheet format, based on the dosage form criteria you have specified is shown on the screen.

Product Registration - [Products accdg to dosage forms : Select Query]						
	Application#	Applicant / M	Pharmaceutical dosag	Manufacturer	Brand / Trade Name	INN
	532	BURAPHA	TABLET	BURAPHA	DIARA 2MG	DIARA 2MG
	633	CPE	TABLET	CPE	HALOPERIDOL CPE 5MG	HALOPERIDOL CPE 5MG
	3085	RANBAXY	TABLET	RANBAXY	ENHANCIN 375 TABLETS 250+125	ENHANCIN 375 TABLETS 250
	618	CPE	TABLET	CPE	DEXAMETHASONE 0.5MG CPE	DEXAMETHASONE 0.5MG CP
	617	CPE	TABLET	CPE	DEXAMETHASONE 0.5MG CPE	DEXAMETHASONE 0.5MG CP
	1728	HANMI PHA	TABLET	HANMI PHARMA	DERMATRIS® CREAM	DERMATRIS® CREAM

- Each row represents one approved product on file based on the dosage form criteria set, and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
- Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.6 Products by Manufacturer

- A dialogue box appears on the screen after clicking the “PRODUCTS BY MANUFACTURER” button.
- Enter the exact name of the manufacturer of the products. If unsure of the exact spelling of the country, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.



- Click the “OK” button to start the search process.
- The data of all approved product records, in spreadsheet format, based on the Name of Manufacturer criteria you have specified is shown on the screen.

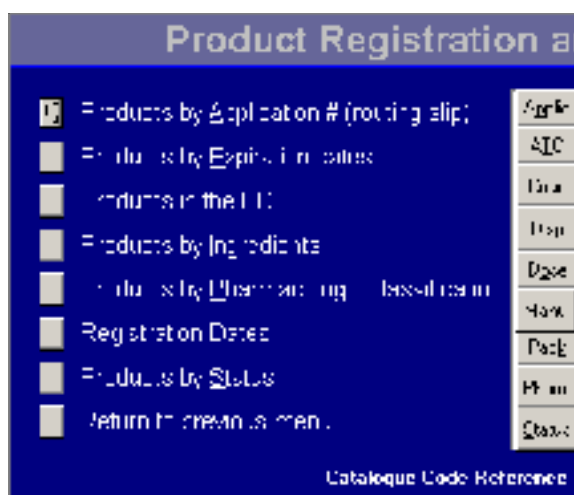
Product Registration: [Products apply to manufacturer: Selected Query]

Application #	Application #	Manufacturer	Brand / Trade Name	INN	Pharmaci
14	14	ABEON	ABEON	ABEON	
15	15	ABEON	ABEON	ABEON	
20	20	ABEON	ABEON	ABEON	
22	22	ABEON	ABEON	ABEON	
23	23	ABEON	ABEON	ABEON	

5. Each row represents one approved product on file based on the name of the manufacturer criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time;
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic)
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7 More Queries

1. Clicking the “..... more Queries” button activates another set of Query buttons.
2. The ...more Queries menu appears on the screen.



3.7.1 Products by Application # (Routing Slip)

1. A dialogue box appears on the screen after clicking the “PRODUCTS BY APPLICATION # (Routing Slip)” button.
2. Enter two sets of numbers: a beginning number, the application number of the first in the range of records you wish to retrieve; and an end number, the last in the range of records you want to retrieve.

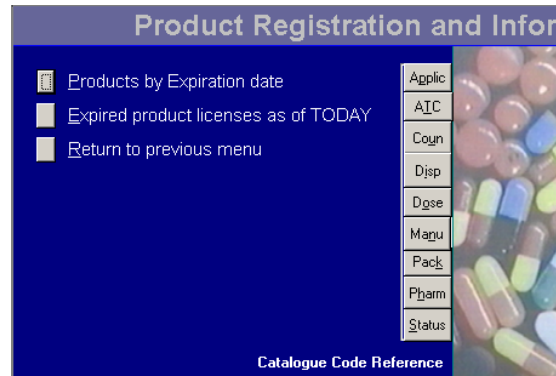
For example, if you wish to retrieve application numbers 1 through 100, the beginning number is 1 and the end number is 100. Enter the appropriate numbers.

- Click the “OK” button to start the search process.
- The data of all approved product records, in spreadsheet format based on the application number ranged criteria you have specified is shown on the screen.

Application#	Applicant / M	Manufacturer	Brand / Trade Name	INN	Pharm
5	AJC PHARI	AJC PHARMA	PARACETAMOL 500MG	PARACETAMOL 500MG	
6	ANB LAB	ANB LAB	A.N.B 100 COMPLEX	A.N.B 100 COMPLEX	
7	ANB LAB	ANB LAB	AMPAVIT 1000MCG INJ.	AMPAVIT 1000MCG INJ.	
8	ANB LAB	ANB LAB	ATROPINE SULPHATE 1/100GR	ATROPINE SULPHATE 1/100GR	
9	ANB LAB	ANB LAB	CAMPBOR VIFORT INJ. 300MG/2M	CAMPBOR VIFORT INJ. 300MG/2I	
10	ANB LAB	ANB LAB	CHLORAMPHENICOL (250MG+30M	CHLORAMPHENICOL (250MG+30I	
11	ANB LAB	ANB LAB	DEXTROSE 10 % IN DISTILLED W/A	DEXTROSE 10 % IN DISTILLED W/A	INFUSI
12	ANB LAB	ANB LAB	DEXTROSE 5 % IN DISTILLED W/A	DEXTROSE 5 % IN DISTILLED W/A	INFUSI
13	ANB LAB	ANB LAB	DEXTROSE 5% + 0.9% NORMAL S	DEXTROSE 5% + 0.9% NORMAL :	
14	ANB LAB	ANB LAB	DEXTROSE 5% + 1/2 NACL	DEXTROSE 5% + 1/2 NACL	
15	ANB LAB	ANB LAB	DEXTROSE 5% + 1/3 NACL	DEXTROSE 5% + 1/3 NACL	INFUSI
16	ANB LAB	ANB LAB	GLUCOSE 50% INJ.	GLUCOSE 50% INJ.	INFUSI
17	ANB LAB	ANB LAB	ISOTONIC SODIUM CHLORIDE 0.9 %	ISOTONIC SODIUM CHLORIDE 0.9 %	
18	ANB LAB	ANB LAB	LACTATED RINGER'S SOL. INJ.	LACTATED RINGER'S SOL. INJ.	
19	ANB LAB	ANB LAB	PYRIDOXINE HDROCHLORIDE 10C	PYRIDOXINE HDROCHLORIDE 1C	
20	ANB LAB	ANB LAB	QUININE DIHYDROCHLORIDE 600M	QUININE DIHYDROCHLORIDE 600I	
21	ANB LAB	ANB LAB	STERILE WATER FOR INJECTION	STERILE WATER FOR INJECTION	
22	ABBOTT L.	ABBOTT LABOF	ENSURE	ENSURE	

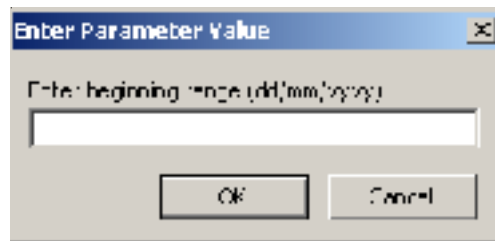
- Each row represents one approved product on file based application number range criteria set, and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
- Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.2 Products by Expiration Dates

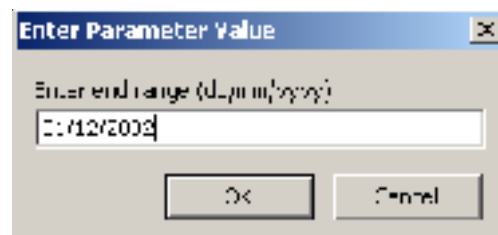


1. A dialogue box appears on the screen after clicking the "PRODUCTS BY EXPIRATION DATES" button.
2. You are expected to enter two dates – the beginning and ending dates that enclose the group or groups of approved product records based on the expiration date field.

(NOTE: Date format is of the form: dd/mm/yyyy)



3. Click the "OK" button to start the search process.



- The data of all approved product records, in spreadsheet format, based on the expiration dates criteria you have specified is shown on the screen;
- Each row represents one approved product on file based on the name of the expiration date criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).

Product Registration - [Products accdg to expiration dates : Select Query]

MA expirat	Application#	Applicant / M	Manufacturer	Brand / Trade Name	INN
08/01/2000	438	BIOLOGIQL	BIOLOGIQUE (FI	ALOPLASTINE SIMPLE	ALOPLASTINE SIMPLE
08/01/2000	441	BIOLOGIQL	BIOLOGIQUE (FI	ANTEBOR B6 LOTION	ANTEBOR B6 LOTION
08/01/2000	439	BIOLOGIQL	BIOLOGIQUE (FI	ANTÉBOR LOTION	ANTÉBOR LOTION
08/01/2000	440	BIOLOGIQL	BIOLOGIQUE (FI	NEUROCALCIUM	NEUROCALCIUM
09/01/2000	3540	SCAT	SCAT	MUCOTHIOL 100MG	MUCOTHIOL 100MG
09/01/2000	3539	SCAT	SCAT	MUCOTHIOL 100MG	MUCOTHIOL 100MG
09/01/2000	3541	SCAT	SCAT	OZOTHINE À LA DIPROPHYLLINE IN	OZOTHINE À LA DIPROPHYLLI
09/01/2000	3542	SCAT	SCAT	OZOTHINE À LA DIPROPHYLLINE S	OZOTHINE À LA DIPROPHYLLI
09/01/2000	3543	SCAT	SCAT	OZOTHINE À LA DIPROPHYLLINE S	OZOTHINE À LA DIPROPHYLLI
09/01/2000	3544	SCAT	SCAT	OZOTHINE INJECTABLES	OZOTHINE INJECTABLES
09/01/2000	3546	SCAT	SCAT	OZOTHINE SUPP. ADULTES	OZOTHINE SUPP. ADULTES
10/01/2000	973	CLINMIDY	CLINMIDY	TRANXÈNE 10 MG	TRANXÈNE 10 MG
10/01/2000	3259	RHONE PO	RHONE POULEN	TERPINE GONNON 100MG + 5MG	TERPINE GONNON 100MG + 5I
10/01/2000	63	AQUETTA	AQUETTANT	MANNITOL 20%	MANNITOL 20%
10/01/2000	4035	THERAMEX	THERAMEX	HEPTYLATE DE TESTOSTÉRON 2	HEPTYLATE DE TESTOSTÉRO
10/01/2000	974	CLINMIDY	CLINMIDY	TRANXÈNE 5MG	TRANXÈNE 5MG
10/01/2000	972	CLINMIDY	CLINMIDY	THIOPHÉNICOL 750MG/5ML	THIOPHÉNICOL 750MG/5ML
10/01/2000	971	CLINMIDY	CLINMIDY	THIOPHÉNICOL 250MG	THIOPHÉNICOL 250MG

- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
- Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.2.1 Products Expiring as of Today

- Activating the “Products Expiring as of Today” button displays, in spreadsheet format, the list of all approved application records in the database whose current registration certificates have expired as of the current date.

Product Registration - [Expired product licenses as of today : Select Query]

Application#	MA expirat	Brand / Trade Name	Pharmaceutical dosage form	Ingredients	MA registration #	Applicant / M
1262	25/12/2002	NAPAMIDE 2.5MG TABLET		NAPAMIDE 2.5M 01-1921		DOUGLAS
3659	25/12/2002	DEXTROSE 5% IN SALINE (		DEXTROSE 5% I 00-1610		SINTONG C
3130	25/12/2002	ROSCILLIN® 1000MG INJ.		ROSCILLIN® 10 99-1165		RANBAXY
3135	25/12/2002	ROSCILOX® 500MG CAPS	CAPSULE	ROSCILOX® 50 99-1164		RANBAXY
3080	25/12/2002	CIFRAN 500MG		CIFRAN 500MG 99-1203		RANBAXY
3147	25/12/2002	TOBITIL 20 MG TABLETS		TOBITIL 20 MG 99-1163		RANBAXY
3090	25/12/2002	GRAMONEG® 500MG TAI		GRAMONEG® 5 99-1166		RANBAXY
2393	24/12/2002	TELFAST® BD 60MG		TELFAST® BI 00-1661		MARION &
614	23/12/2002	CIPROFLOXACIN 0,3% EYE / EAR DROPS		CIPROFLOXACIN 98L-0013		CPE

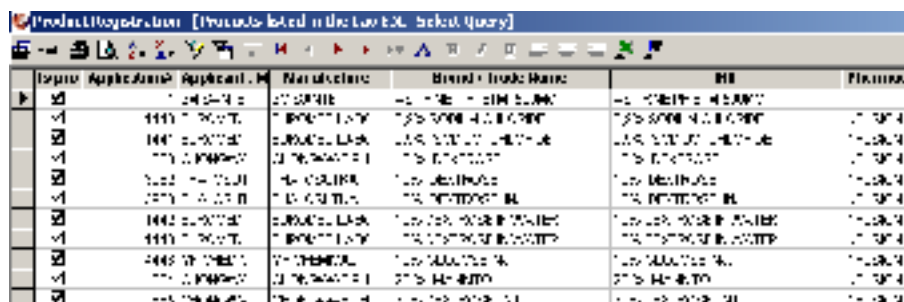
- Each row represents one approved product on file and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
- Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.2.2 Return to Previous Menu

- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.
- Clicking the “Return to Main Menu” button brings you back to the previous menu selection screen (... more Queries sub Menu)

3.7.3 Products In the essential drugs list

- Activating the “Products In the EDL” button displays, in spreadsheet format, the list of all approved application records in the database that are listed as essential drugs in the country.



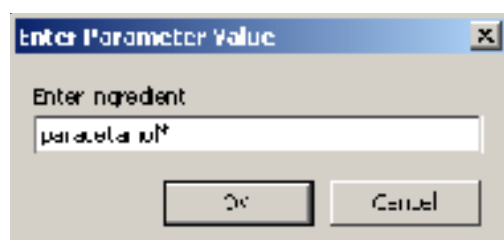
Application #	Applicant	Manufacturer	Brand/Trade Name	Price
1111	ABC Pharma	ABC Pharma	Aspirin	1.00
1112	ABC Pharma	ABC Pharma	Paracetamol	1.00
1113	ABC Pharma	ABC Pharma	Ibuprofen	1.00
1114	ABC Pharma	ABC Pharma	Aspirin	1.00
1115	ABC Pharma	ABC Pharma	Paracetamol	1.00
1116	ABC Pharma	ABC Pharma	Ibuprofen	1.00
1117	ABC Pharma	ABC Pharma	Aspirin	1.00
1118	ABC Pharma	ABC Pharma	Paracetamol	1.00
1119	ABC Pharma	ABC Pharma	Ibuprofen	1.00
1120	ABC Pharma	ABC Pharma	Aspirin	1.00

- Each row represents one approved product on file in the essential drugs list and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
- Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).

- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.4 Products by Ingredients

- A dialogue box appears on the screen after clicking the “Products By Ingredients” button.



- Enter a known ingredient of a product. If unsure of the exact spelling of the ingredient, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.
- Click the “OK” button to start the search process.
- The data of all approved product records, in spreadsheet format, based on the name of ingredient specified is shown on the screen.

Product Registration - [Products by ingredient : Select Query]

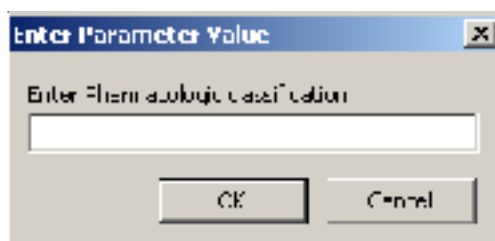
Application#	Applicant / M	Manufacturer	Brand / Trade Name	INN	Phar
399	AJC PHARI	AJC PHARMA	PARACETAMOL 500MG	PARACETAMOL 500MG	
650	BINH DINH F	BINH DINH PHAR	PARACETAMOL 500 MG	PARACETAMOL 500 MG	
651	CPE	CPE	PARACETAMOL CPE 100MG	PARACETAMOL CPE 100MG	TABI
652	CPE	CPE	PARACETAMOL CPE 500MG	PARACETAMOL CPE 500MG	TABI
653	CPE	CPE	PARACETAMOL 500MG	PARACETAMOL 500MG	
654	CPE	CPE	PARACETAMOL CPE 100MG	PARACETAMOL CPE 100MG	TABI
740	CADILA HE	CADILA HEALTH	PARACETAMOL CPE 500MG	PARACETAMOL CPE 500MG	TABI
1049	CREAT	CREAT	PARACETAMOL 500 MG TAB.	PARACETAMOL 500 MG TAB.	
1050	CREAT	CREAT	PARACETAMOL 500 MG	PARACETAMOL 500 MG	
1571	FLAMINGO	FLAMINGO PHA	PARACETAMOL 500MG	PARACETAMOL 500MG	
2219	LARK LAB	LARK LABO	PARACETAMOL 500MG	PARACETAMOL 500MG	
2337	LYKA LAB	LYKA LABS	PARACETAMOL 500MG TAB.	PARACETAMOL 500MG TAB.	
			PARACETAMOL 500MG	PARACETAMOL 500MG	

- Each row represents one approved product on file based on the name of the manufacturer criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
- Search the records based on the searching and filtering methodologies (Under the “**Searching / Filtering Records**” topic)

8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

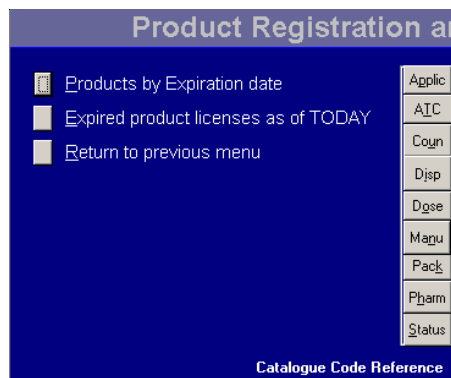
3.7.5 Products by Pharmacologic Classification

1. A dialogue box appears on the screen after clicking the “Products By Pharmacological Classification” button.
2. Enter a pharmacological classification description. If unsure of the exact spelling of the pharmacology classification, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.



3. Click the “OK” button to start the search process.
4. The data of all approved product records, in spreadsheet format, based on the specified pharmacological classification is shown on the screen.
5. Each row represents one approved product on file based on the pharmacological classification criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic)
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

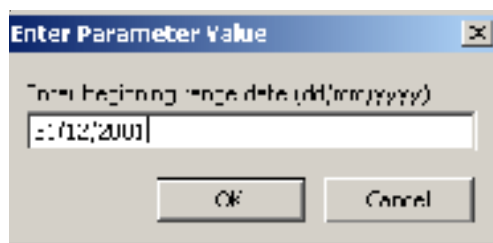
3.7.6 Products by Registration Dates



3.7.6.1 Current Registration License

1. A dialogue box appears on the screen after clicking the “Current Registration License” button.
2. You are expected to enter two dates – a beginning and an end dates that encloses the group or groups of approved product records based on the current registration license date field.

(NOTE: Date format is of the form: dd/mm/yyyy)



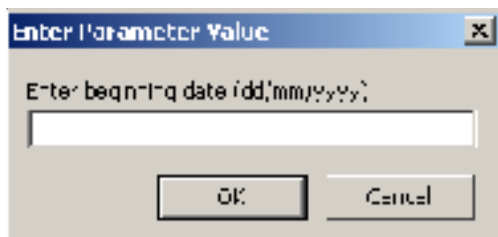
3. Click the “OK” button to start the search process.
4. The data of all approved product records, in spreadsheet format, based on the current registration date criteria you have specified is shown on the screen.

Product Registration - [Products by registration dates : Select Query]						
MA issue c	Application#	Applicant / M	Manufacturer	Brand / Trade Name	INN	
02/01/2000	1430	ETHYPHAF	ETHYPHARM	DELASMIL SR CAPS 50MG	DELASMIL SR CAPS 50MG	
02/01/2000	4287	UPSA	UPSA	PRODAFALGAN 2 G INJ.	PRODAFALGAN 2 G INJ.	
02/01/2000	1429	ETHYPHAF	ETHYPHARM	DELASMIL SR CAPS 400MG	DELASMIL SR CAPS 400MG	
02/01/2000	4288	UPSA	UPSA	SKENAN LP 100MG	SKENAN LP 100MG	
02/01/2000	4289	UPSA	UPSA	SKENAN LP 10MG	SKENAN LP 10MG	
02/01/2000	4290	UPSA	UPSA	SKENAN LP 30MG	SKENAN LP 30MG	
02/01/2000	1428	ETHYPHAF	ETHYPHARM	DELASMIL SR CAPS 200MG	DELASMIL SR CAPS 200MG	

5. Each row represents one approved product on file based on the current registration date criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.6.2 Historical (Range)

1. A dialogue box appears on the screen after clicking the “Historical (Range)” button.



2. You are expected to enter two dates – a beginning and an end date that enclose the group or groups of registered products based on the historical data field. For example, if you want to list all registered products during the year 1998 one will enter 01/01/1998 as the beginning date and 31/12/1998 as the end date value.

(NOTE: Date format is of the form: dd/mm/yyyy)

3. Click the “OK” button to start the search process.
4. The data of all approved product records, in spreadsheet format, based on the historical date criteria of the product you have specified is shown on the screen.
5. Each row represents one approved product on file based on the historical date of the product criteria set and each column representing the data for that field item (e.g. Application #, Brand Name, etc.)
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” keys to move a set of records one screen full up or down at a time.

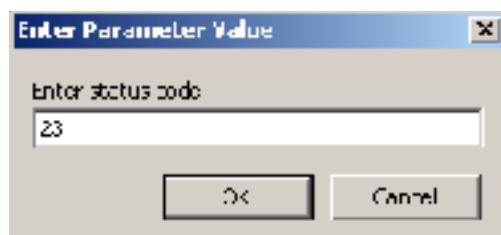
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.6.3 Return to Previous Menu

1. Clicking the “Return to Main Menu” button brings you back to the previous menu selection screen.

3.7.7 Products by Status

1. A dialogue box appears on the screen after clicking the “Products By Status” button.
2. Enter a status code of a product. If unsure of the status codes, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.



3. Click the “OK” button to start the search process.
4. The data of all APPROVED product records, in spreadsheet format, based on the status specified is shown on the screen.

Product Registration - [Products accdg to status : Select Query]				
Application#	Activity/Status	Applicant / MA Holder	Manufacturer	Brand / Trade
3814	TEMPORARY LI	SYNTHELABO	SYNTHELABO	DOGMATIL 50MG
722	TEMPORARY LI	CADILA HEALTHCARE	CADILA HEALTHCARE	DOMPERIDON 10 ME
2733	TEMPORARY LI	PT DANKOS LABORATOIRES TBK	PT DANKOS LABORATOIRES TBK	DOMETIC 10MG
4114	TEMPORARY LI	UNICHEM	UNICHEM	DOMADOL * 50 50N
4113	TEMPORARY LI	UNICHEM	UNICHEM	DOMADOL * 100 100
4112	TEMPORARY LI	UNICHEM	UNICHEM	DOMADOL 50MG
1939	TEMPORARY LI	INNTECH INTERNATIONAL	INNTECH INTERNATIONAL	DOLOTEC @ 500MG
4042	TEMPORARY LI	TORRENT	TORRENT	DICLOMAX-50 TABLE

5. Each row represents one approved product on file based on the product status criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.8 Return to Previous Menu

1. Clicking the “Return to Main Menu” button brings you back to the previous menu selection screen.

3.8 Return to Main Menu

1. Clicking the “Return to Main Menu” button brings you back to the Drug Registration Main Menu.

4. PREPARE TO PRINT FORM1

This menu selection allows you to print the Application Form (two pages), Routing Slip (one page) and the Checklist of Requirements (one page). The forms will again be displayed in *MSWord*™ and can be printed from the *MSWord*™ program.

APPLICATION FOR DRUG REGISTRATION

PART I. APPLICANT INFORMATION		APPLICANT	
CATALOGUE	Name		
	Address		
	Telephone		
	Fax		
	Contact person		
PART II. MANUFACTURER INFORMATION		MANUFACTURER INFORMATION	
CATALOGUE	Name		
	Address		
	Telephone		
	Fax		
	Contact person		
PART III. PRODUCT INFORMATION		PRODUCT	
LAD FOR DATA BASE			
Name			
Qty			
Name			
Qty			
Name			
Qty			

5. PREPARE DRUG REGISTRATION CERTIFICATE

This submenu is an office automation aid to print the Drug Registration Certificate. This will make printing of the certificates more efficient and less time consuming. Typographical mistakes will also be limited to the errors entered in the forms. This selection will be performed in two steps. Follow the steps in the order they are presented below.



5.1 Step 1. Set appropriate “Status?” number

This first step in the preparation of the Drug Registration Certificate is to check the status of the product record. Setting the status to “Print certificate” enables you to print the registration certificate for the product. After selecting this button, the “Change Status Form” is presented. Position the cursor on the Application No. field and press the “binoculars” icon to bring up the status of the product. The “Brand Name” and “Dosage Form” of the product is displayed together with the application number for you to confirm that the product you are referring to is indeed the one you want.

Change Status FORM

Application No. 00000

E.C. Name CCTV-40

Workstation CCTV-40

Grand Name CCTV-40

Binary Code RTT-05

Code

Date 2000/01/01

Log date 2000/01/01

User Admin

Notes CCTV-40 RTT-05

Note: Columns re-specified change only.

Set the mouse on the “Applied” field and double-click the field. The fields in the form should turn green. This allows you to change data in any of the green-colored fields. Go further down and pull down the selection button on the “Activity” field. A list of all the available “status/activities” is listed.

[illegible]

You can also change a group of records of the same current status to another status by clicking on the  icon on the form. A window asking you to enter a status code is shown. Look up the status codes on the quick reference guide on the product registration main menu.

5.2 Step 2. Print Certificate

The second step in the printing of the certificates will open the *MSWord™* program and then load the Drug Registration Certificate template. This step will open a file containing all the products whose “Activity/Status” is on or has been changed to “Print Certificate.” This will load the data of the products into the template. You are then ready to start merging the data with the

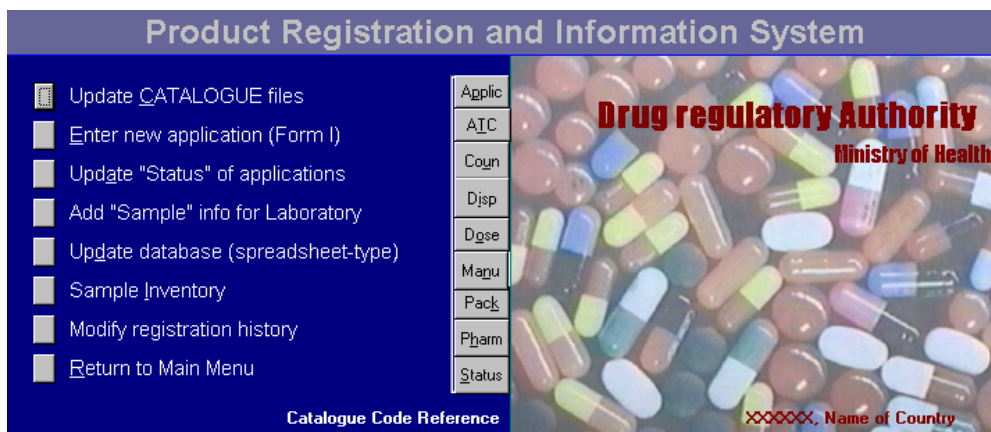
drug registration certificate template. Click the “merge icon” on the menu and a window asking you to start the merge will appear. Press “merge” on the *MSWord™* menu bar and the merge process will start. The different Drug Registration Certificates will be shown on your computer screen. You can now proceed by printing the Drug Registration Certificates as you would any other *MSWord™* document. The number of copies you wish to print can be set on the File-Print menu of the *MSWord™* program. Press the “printer” button to start the printing of the certificates. Once done, press the “X” in the upper right corner of the window or exit Microsoft Word without saving the documents.

5.3 Return to Main Menu

Selecting this button brings you back to the product registration system main menu.

6. UPDATE DATABASES

This section updates the data in the product registration system.

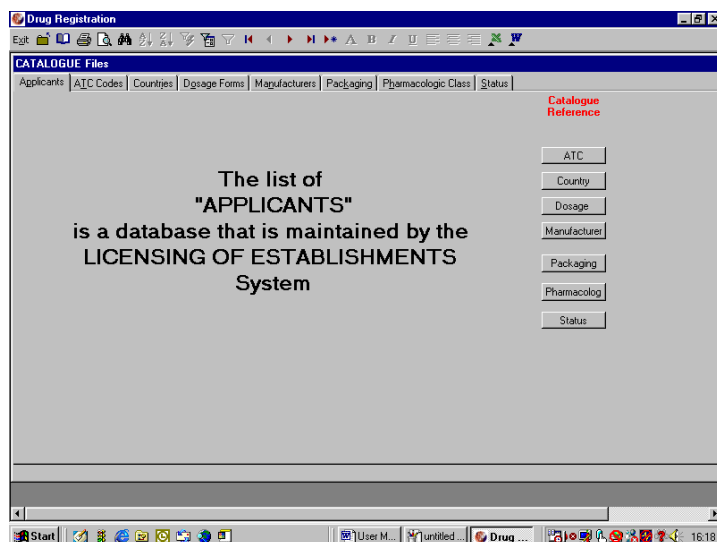


6.1 Update CATALOGUE files

There are eight catalogue files used in the product registration system. Each table contains the needed data used in the database. The catalogue files ensure uniformity when entering data into the system. Without these catalogue tables, variable data entry can be expected, and which can lead to inaccuracies when retrieving data.

For example, without the catalogue tables, the dosage form tablets can be entered in various different ways e.g. tab, tabs, tablet, tablets, tab., tabs.

1. Selecting the “Update Catalogue Files” button brings up the Update catalogue file form. The first tabbed catalogue, “applicants,” is shown. The applicants catalogue file cannot be updated from the Product Registration System.



Because the list of applicants is “shared” information from the Licensing of Establishments System, the product registration system cannot update this catalogue file. It can only be updated from the Licensing of Establishments System.

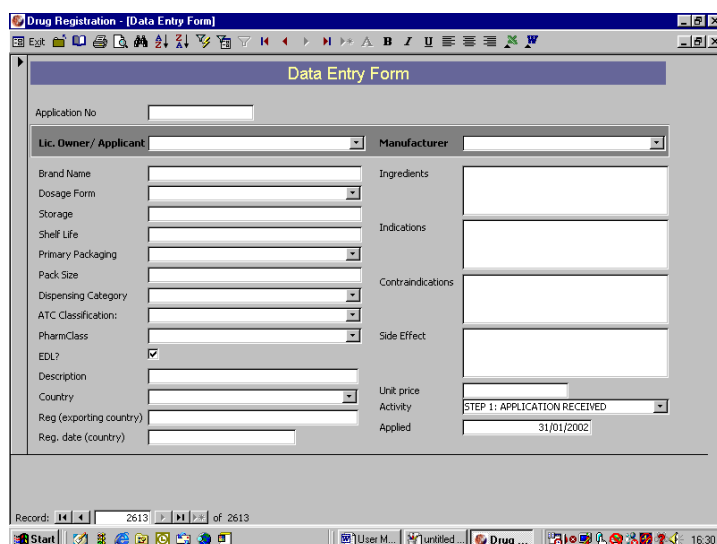
There are seven catalogue tables: ATC classification; Countries; Dosage Forms; Manufacturers; Packaging; Pharmacologic classification; and Status/Activity. The tabbed catalogues are arranged alphabetically.

2. Position the mouse pointer on the flap of the tab and the catalogue table of your choice is ready for data entry. You will need to add an item when the item that you are entering in Form 1 will not be accepted by the system because it is not known to the system i.e. it is not in the catalogue tables.

3. Use the add button  to add new catalogue data. Use the “Pgup-Pgdn” keys to scroll down the list.
4. After updating close the form by clicking on the “x” icon on the top right of the form.

6.2 Enter DATA for new application (Form 1)

1. Before entering the data for a new application, check that the entries needed by the new application are in the catalogue files. After updating the catalogue tables.
2. You can now start data entry. Always enter a unique number for a new application. Applications have been entered sequentially starting with 00001, 00002,05000....
3. The form is divided into four parts. This is similar to the form that was submitted by the applicant. Parts one and two are the applicant and manufacturer information respectively. Part three is the product information while Part four is the importation / status information. Most of the fields require that data should be entered or else the record will not be accepted by the database.



Drug Registration - [Data Entry Form]

Data Entry Form

Application No.

Lic. Owner/ Applicant Manufacturer

Brand Name Ingredients

Dosage Form Indications

Storage Contraindications

Shelf Life Side Effect

Primary Packaging

Pack Size

Dispensing Category

ATC Classification

PharmClass

EDL? ☒

Description

Country

Reg. (exporting country)

Reg. date (country)

Unit price

Activity

Applied

Record: 2613 of 2613

16:30

6.3 Update “Status” of applications

1. This will be the submenu selection you will use when you want to print a certificate, send the application for the Drug Control Committee, and send samples to laboratory.

Change STATUS Form

Application No: 00001

Lic. Owner: FACTORY NO. 2

Manufacturer: FACTORY NO. 2

Brand Name: DEXTROSE&NACL 1L

Dosage Form: INFUSION

Applied: [Empty Field]

Reg #: 00012016/01

Reg date: 07-Jul-01

Expiry: 06-Jul-06

Activity: PRINT IMPORT CERTIFICATE

Change By Group status

Note: Double click the Applied field to change status

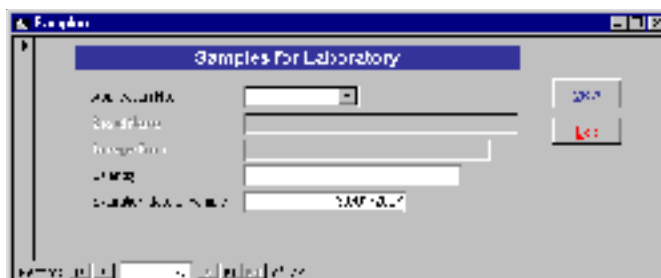
Record: 1 of 2612

2. When you want to group a batch of applications such as sending a group for the Drug Control Committee deliberation, you simply change the status of the group of applicants to a particular activity or status. As soon as you have done that, you are ready to print a report.
3. The same selection is used after evaluation is performed. When the application is referred to the Drug Registration Committee for deliberation, the application gets a new status by changing the status using this form. After the Drug Registration Committee deliberations, a new status is again assigned. When final action status is reached, the application has a final status that is either approved, rejected or abeyance, depending on the outcome of the deliberations by the Drug Registration Committee.
4. Once the application is approved, a registration number, date of registration and expiration date are assigned to the application using this same form.
5. The date of expiration was intentionally not pre-computed to provide for flexibility as to the number of years a product certificate will be given an expiration date.

6. Navigation tools are provided in the status form. A “status reference” is built into the form so that when you have forgotten a status code, you simply click on the status reference button from there. Also in the form is a button that will display the records of a particular status. This will allow the user to know the status of records.

6.4 Add “Sample” information for Laboratory

In regulatory agencies with laboratory facilities, you wish to track down the list of samples that have been sent to the laboratory for testing. This menu selection will give you the information of the samples that have so far been sent to the laboratory with the corresponding quantity and expiration dates. Follow the instructions below to enter a sample to be sent for testing.

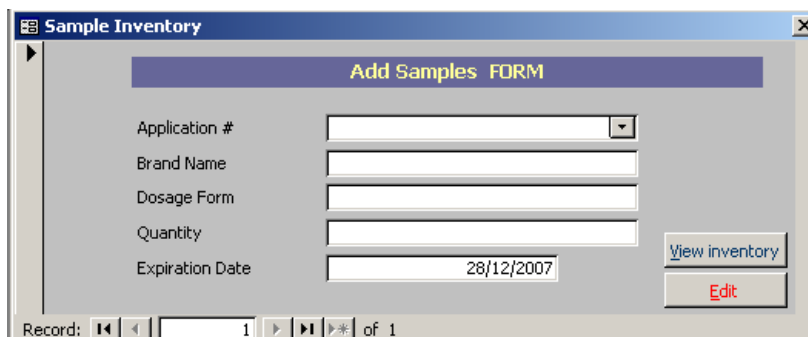


1. Enter the application number corresponding to the application number or routing slip of the samples. Use the  to enter a sample sent to laboratory.
2. Position the cursor on the application number field. A list of applications numbers will scroll down.
3. Enter the number of samples that will be sent and the expiration date of the samples. Exit by clicking on the exit (door) button.
4. You can view the report containing the products for analysis that will be sent to the laboratory by going to the print reports submenu under the submenu “List of Samples for Analysis.” The list of products in the report was positioned in the middle of the document. This was intentionally done so that a pre-printed document with the DRA header can be used. The format of the document can also be changed using MSWord™ to suit user preference.

6.5 Sample Inventory

This menu selection will give you an inventory of all samples and enables you to track down their expiration dates.

To enter data of a sample you wish to add in the inventory, press the  button and a blank “Add samples form” screen is presented. Go to the application# field and press the  button and the list of all the routing slip numbers is shown. Enter the routing slip number of the sample you wish to enter in the inventory list. Enter the quantity and the expiration date of the sample. Save the sample by moving the record forward or backward by pressing any of the  buttons at the bottom of the form.



The screenshot shows a window titled "Sample Inventory" with a sub-header "Add Samples FORM". The form contains the following fields:

- Application #: A dropdown menu.
- Brand Name: A text input field.
- Dosage Form: A text input field.
- Quantity: A text input field.
- Expiration Date: A text input field with the value "28/12/2007".

At the bottom right of the form are two buttons: "View inventory" and "Edit". At the bottom left, there is a record navigation bar showing "Record: 1 of 1" with navigation icons.

6.6 Modify Registration History

This selecting this button allows you to modify the registration history of products already in the registry. This option is provided in order to update the registration status of products that have been entered.



The screenshot shows a window titled "Product Registration [ModifyRegistrationHistory: Select Query]". It contains a table with the following columns:

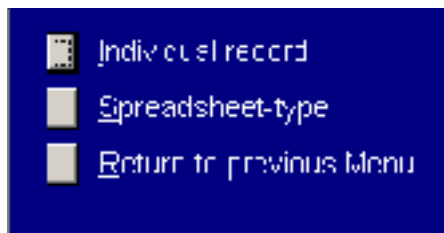
Application #	Registration #	Date of registration	Date of expiration
1	1	1/1/2007	31/12/2007

The table has a toolbar above it with various icons for editing and navigation. The first row of data is highlighted.

1. On the application # field, enter the application number of the product.
2. Enter the registration number, the registration date and expiration date of the product.
3. Press “exit” when finished.

6.7 Edit Records

This option allows you to edit the data of products in already in the registry.



6.7.1 Individual record

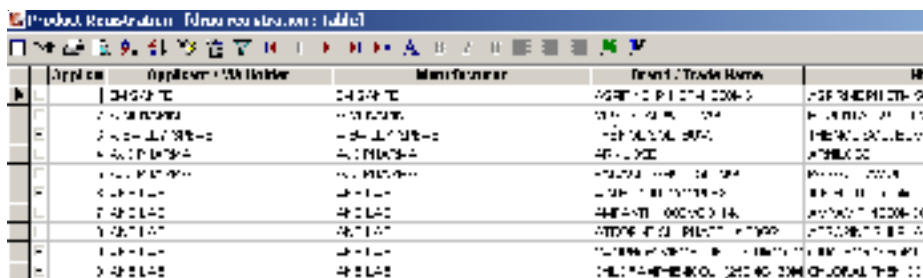
The form below is the complete data of one product in the registry. To edit the product information, enter the details on the fields. Use the searching techniques described in this manual in order to retrieve a product of interest.

A screenshot of a software window titled 'Edit Drug registration Data'. The window contains a form with multiple sections for entering product details. The sections include:

- Product Information:** Fields for 'Product Name', 'Manufacturer', 'Product Code', 'Registration Number', 'Registration Date', and 'Expiration Date'.
- Product Description:** A large text area for 'Product Description'.
- Product Classification:** Fields for 'ATC Code', 'Pharmaceutical Form', and 'Dosage'.
- Product Status:** Fields for 'Status' and 'Reason for Status'.
- Product History:** A section for 'Product History' with a 'Date' field.
- Product Notes:** A section for 'Product Notes' with a 'Date' field.
- Product Comments:** A section for 'Product Comments' with a 'Date' field.
- Product Footer:** Fields for 'Sub Product' and 'Product'.

6.7.2 Spreadsheet-type

Making this choice opens a list of products in the registry in spreadsheet format. Use the searching methods described in this manual to go to a particular product of interest.



	Supplier	Supplier's Name	Manufacturer	Product / Trade Name	ATC Classification
1	...	...	...	...	...
2	...	...	...	...	...
3	...	...	...	...	...
4	...	...	...	...	...
5	...	...	...	...	...
6	...	...	...	...	...
7	...	...	...	...	...
8	...	...	...	...	...
9	...	...	...	...	...
10	...	...	...	...	...

1. This menu selection uses the familiar interface of Microsoft Excel. When correcting a batch of records in this format, the Excel program is appealing.
2. On this screen, data can be edited or updated and records can even be deleted. This screen is provided to facilitate data entry and searching.

6.7.3 Return to Main Menu

Select this to return to the main menu.

7. Exit

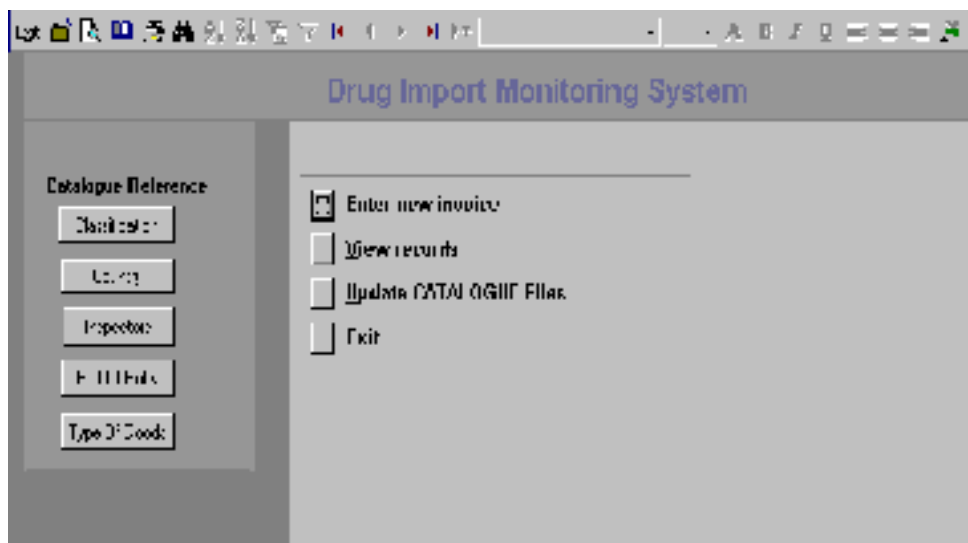
This closes the database and exits the Product registration subsystem.

DRUG IMPORT MONITORING SUBSYSTEM

MAIN MENU

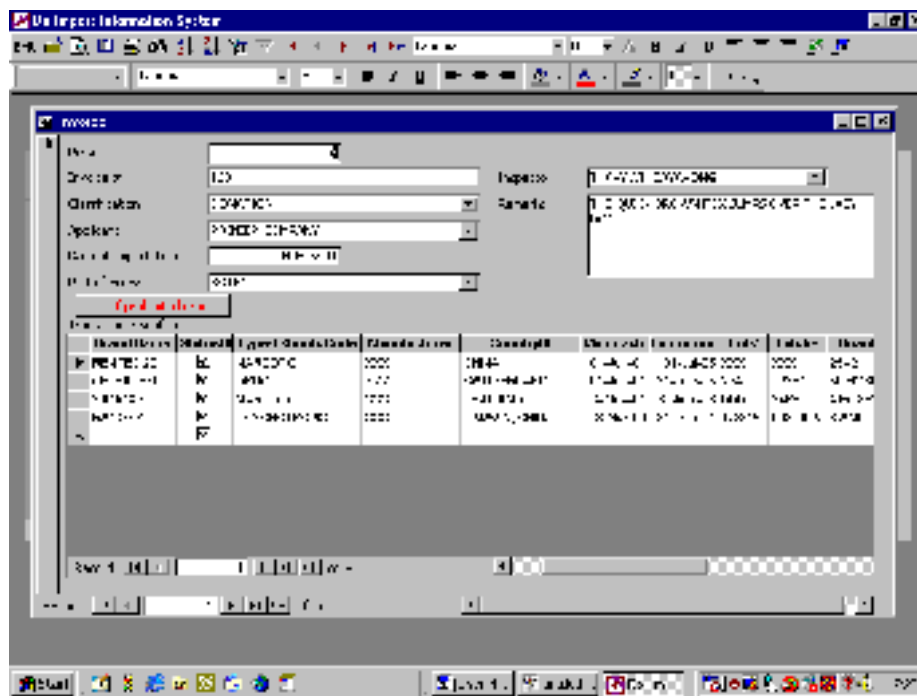
The Drug Import Monitoring Subsystem tracks down the importations of drugs based on the invoice documents submitted by importers. Importers who are not registered as duly registered establishments with the Licensing of Establishments System cannot transact an importation. Likewise, only products that are registered and listed in the Product Registration System can be entered.

The main menu window has several selections for entering new invoices, viewing and printing management reports and updating the Import Monitoring System catalogue files. On the left side of the Main Menu are the quick reference catalogue file buttons.



1. Enter new invoice
 1. Activating this selection will open the invoice data entry form. The form is organized into two parts. At the top portion is invoice information and at the lower portion are the transaction details. The transaction details outline the information about the drug being imported.

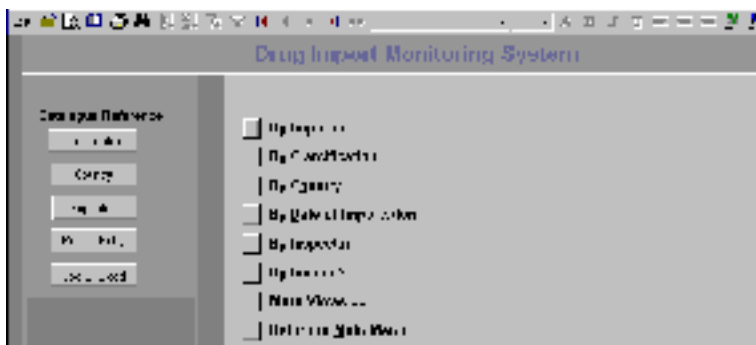
2. The subsystem checks two very important data: the applicant and the product. The applicant (also importer) should be a registered importer listed in the Licensing of Establishments Subsystem. Similarly, the product being imported should be a registered product and should be listed in the Product Registration System. If neither one is registered, then the importation should not be allowed.



3. A button that opens the list of prohibited drugs is provided on the same form as a guide for the type of goods (i.e. whether the product being imported is classed as a narcotic, psychotropic or precursor chemical) being imported.
4. Applicants and products must both be registered entities with the regulatory authority before importation is authorized and subsequently monitored in this subsystem.

2. View Records Menu

There are several options to view the contents in this database. Shown below are the available choices for viewing.



2.1 By importer

This option provides the list of importations made by importers (also called the applicant or product license holder). The list is alphabetically arranged according to the name of applicant or company. The second column (see below) shows the number products, weight in kilograms and the total importations made.

2.2 By classification

Choosing this option lists the products imported according to the classification of the product. Examples of importation classification include: commercial use; clinic use only; donated product; and hospital use only. The second column shows the number of products in the classification category and the weight and the total value of the product in the classification. Position the mouse in any portion on the form and the details of the importations will be shown. Close the windows one by one by clicking the  "close button" on the top menu.

Classification	No of products	Weight(Kg)	Total (USD)
Commercial Use	2	1,000.00	1,000.00
Clinic Use Only	2	115.00	1,000.00
Donated Product	1	1.00	1,000.00

Click anywhere on form to see details

2.3 By country

Using this option opens a window that shows all the importations by country and the number of products imported by the country. The weight in kilograms and the total value are also reflected. Double click on any part of the form and the details will be shown.

Country	Number of products	Weight (kg)	Total (R\$R)
Brazil	1	45.00	10.000
India	1	4.11	1.000
China	1	50.00	10.000
USA	1	70.00	10.000
...	...	...	...
South Africa	1	1.11	0.100
South Korea	1	45.00	10.000
...	...	...	...
Japan	1	10.00	10.000
...	...	...	...
...	...	...	...

Summary: Total: 10.000, Average: 10.000

Click on any part of the form to view details.

2.4 By date of importation

Viewing the importations by date is the most useful as far as drug importation monitoring is concerned. Most queries on drug importations are date-related so this will be the most widely used feature in the drug import monitoring. There will be varied queries from the drug regulatory staff. The data presented in the tables will have to be manipulated using MS Excel in order to answer the more complex queries. The dataset in this viewing option can be exported using the  (MS Excel) button provided on the top of the menu bar. Once exported, the data can be summarized or manipulated using various MS Excel techniques.

Clicking on any part of the form will display the importation details by date. Again, exporting the data to MS Excel provides a way to analyze the data. Staff training should be provided for maximum benefit.

Summary by DATE OF IMPORT

Month

Month	No of products	Value (Qst)	Total (USD)
January 2001	1	1000	95000
February 2001	1	1000	95000
March 2001	1	1000	95000
April 2001	5	5000	475000

Quater

Quater	No of products	Value (Qst)	Total (USD)
Q1 2001	2	2000	190000
Q2 2001	2	2000	190000
Q3 2001	1	1000	95000

YEAR

Year	No of products	Value (Qst)	Total (USD)
2000	1	1000	95000
2001	5	5000	475000

2.5 By inspector

Activating this option will show all importations by inspector. The list of drug inspectors in the regulatory authority should be entered in the catalogue file under the inspector heading. Once the inspectors' names are in the catalogue file, then entering the inspectors and the products they have inspected is just a click of a button away.

Summary by INSPECTOR

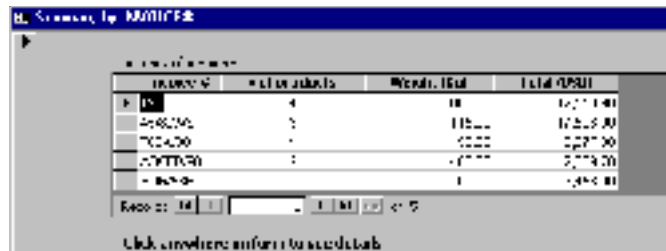
Inspector

Inspector	No of products	Value (Qst)	Total (USD)
Inspector 1	1	1000	95000
Inspector 2	1	1000	95000
Inspector 3	1	1000	95000

Click anywhere on the form to delete

2.6 By invoice number

Viewing importations by invoice number provides a way to look at the summary of product importations by invoice number. The invoices are the source document from where all the data in the drug import monitoring system are taken. The valuation summary is provided. Double click on any part of the form and the importation details per invoice will be shown.



Drug Import Monitoring System

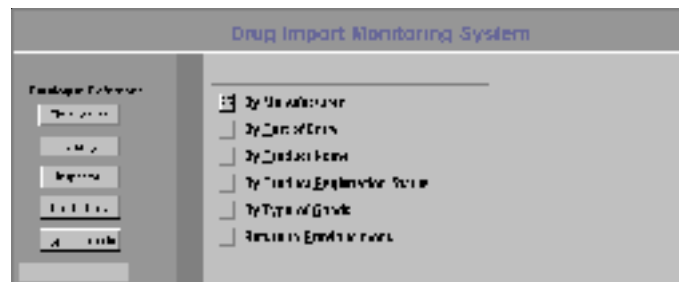
Manufacturer	Product Name	Quantity	Value	Total Value
1	1	10	1000	1000
2	2	10	1000	1000
3	3	10	1000	1000
4	4	10	1000	1000
5	5	10	1000	1000
6	6	10	1000	1000
7	7	10	1000	1000
8	8	10	1000	1000
9	9	10	1000	1000
10	10	10	1000	1000

Records: 10 / 10

Click anywhere in the table to view details

2.7 More views ...

Activating this option gives you more ways to view the drug import monitoring database.



Drug Import Monitoring System

Developer Extension

By Manufacturer

By Date of Entry

By Product Name

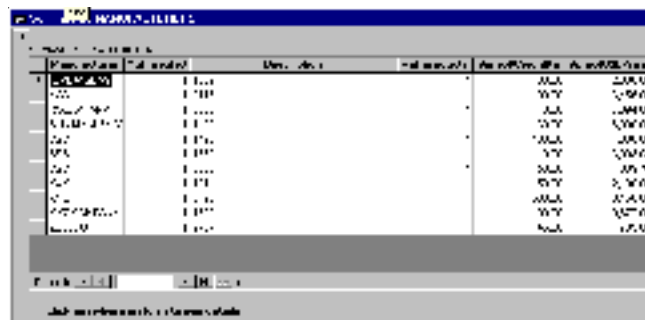
By Manufacturer Name

By Type of Goods

By Date of Entry

2.7.1 By manufacturer

This option shows all the product importations by manufacturer. The details of products imported by manufacturer are also provided by double clicking on any part of the form.



Drug Import Monitoring System

Manufacturer	Product Name	Quantity	Value	Total Value
1	1	10	1000	1000
2	2	10	1000	1000
3	3	10	1000	1000
4	4	10	1000	1000
5	5	10	1000	1000
6	6	10	1000	1000
7	7	10	1000	1000
8	8	10	1000	1000
9	9	10	1000	1000
10	10	10	1000	1000

Records: 10 / 10

Click anywhere in the table to view details

2.7.2 By port of entry

Selecting this option will show all drug importations from where they entered the country or their port of entry. Click on any part of the form and the details of all the products in each of the port of entry are shown.

[illegible]

2.7.3 By product name

Selecting this option lists the importations by product name. The trade name is used as the name of product. Click on any part of the form and the details of each product are listed.

[illegible]

2.7.4 By product registration status

Illegals	Non-Immigrants	Immigrants	Total
6	467	2477	3040
1	230	1210	1441

2.7.5 By type of goods

Selecting this viewing option shows the summary of drug importations by type of goods. The different types of goods will have to be determined by the drug regulatory authority. These are first entered in the catalogue file. Once in the catalogue file, each product being imported into the country can be classified when a request is made. Click on any part of the form and the details of each type of good are shown.



2.7.6 Return to previous menu

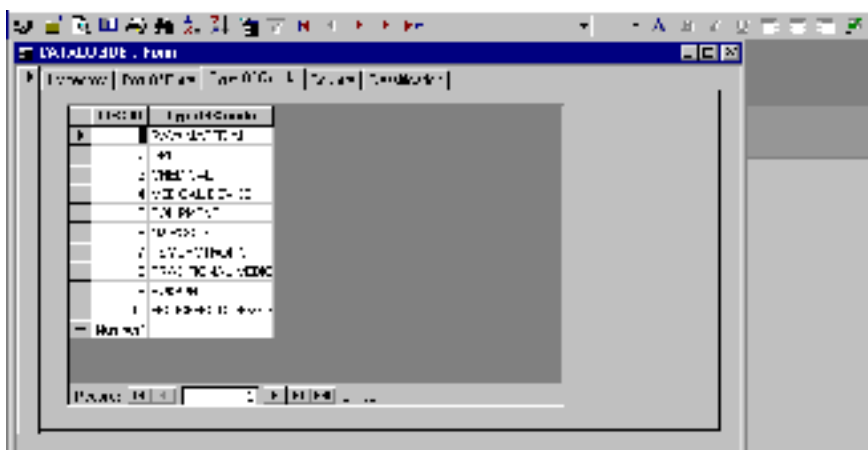
This selection will bring you back to the previous menu.

2.8 Return to Main Menu

Choosing this option brings you back to the Drug Import Monitoring Subsystem Main Menu.

3. Update CATALOGUE FILES

The catalogue files are an important part of each subsystem in the Drug Registration and Information System.



4. Exit

This option will close the Drug Import Monitoring Subsystem and bring you back to the Windows desktop.

ANNEX A.

GENERAL OUTLINE OF THE SYSTEMS

When using the integrated computerized drug registration system, begin by entering the data of the companies to be licensed with the DRA. This is under the Licensing of establishment subsystem. The list of companies that need to be registered include importers, agents, exporters, drug retail outlets (pharmacies), and all other establishments dealing with pharmaceutical products. When entering the data of the list of establishments, take note that certain fields take data from CATALOGUE FILES. In instances when the data that is being entered is not already an existing item in the catalogue file, you will have to enter the item in the appropriate catalogue file. To access the catalogue files, go to the “Update CATALOGUE file” sub menu. Update the list of establishments as needed when new establishments are registered.

Once the data on the information of all licensed establishments have been entered, then data entry for product registration can start because the product registration subsystem expects a legitimate licensed establishment as the holder of the marketing authorization issued by the DRA. Without a licensed product holder, data entry of the product application will not proceed.

The chart on the next page is a quick reference guide when entering new establishments for registration or when entering new products for registration.

Follow the flowchart and then refer to the succeeding pages for a step by step instruction.

P1: Launching the “*Product registration system*”

- o On the desktop window, click the “Drug registration” icon

P2: Checking if application is a new PRODUCT application

- o While on the “Product registration system” main menu click “View all records”.
- o Click “View multiple records”.
- o A list of all the records in the database in spreadsheet format opens.
- o Pan across the top of the spreadsheet and look for the “Brand Name” column.
- o Check if the product name is an item found under the “Brand Name” column
 - o Scroll down using arrow keys, or
 - o Use “filter by form” button and enter product name in “brand name” column.
- o If found, product is registered.
- o If not found, product not registered.

P3: Checking if APPLICANT already registered

- o Go to menu selections.
- o On the “CATLOGUE CODE REFERENCE” buttons column click the “Applic” button.
- o List of registered applicants, in spreadsheet format, appears.
- o Check if the applicant name is an item found under the “CompanyName” column.
 - o Scroll down using arrow keys, or
 - o Use “filter by form” button and enter product name in “CompanyName” column.
- o If found, applicant is registered.
- o If not found, applicant not registered.

P4: Checking if the manufacturer is already in database

- o Go to “Drug registration system” main menu.
- o On the “catalogue code reference” buttons column click the “Manu” button.
- o List of manufacturers in database, in spreadsheet format, appears.
- o Check if the manufacturer name is an item found under the “Name” column.
 - o Scroll down using arrow keys, or
 - o Use “filter by form” button and enter product name in “Name” column.
- o If found, name of manufacturer is in the database.
- o If not found, name of manufacturer is not in the database.

P5: Entering new manufacturer data

- o On the “Drug registration system” main menu click “Update database” button.
- o Click “Update catalogue files” button, catalogue files screen opens.
- o Select by clicking “Manufacturer” tab on the top of the form.
- o Click “>*” to add manufacturer data.
- o Blank row opens.
- o Enter appropriate data in the empty column fields.
- o When finished, close window by clicking the “x” on the top of the form.
- o Menu returns back to Update databases menu.

P6: Opening “Receiving” menu

- o On the “Drug Registration System” main menu click “Receiving” menu.
- o Receiving form opens.

L1: Launching the “*Establishments Licensing system*”

- o On the desktop window, click the “Licensing of Establishments” icon.

L2: Checking if APPLICANT already registered

- o On the main menu, click the “View All (multiple)” button.
- o List of all registered applicants, in spreadsheet format, appears.
- o Pan across top of spreadsheet and look for the “Name of Company” column.
- o Check if product name is an item found under the “Name of Company” column.
- o Scroll down using arrow keys, or
- o Use “filter by form” button and enter product name in “Name of Company” column.
 - o If found, APPLICANT is registered.
 - o If not found, APPLICANT is not registered.
- o When finished, close window by clicking the “x” on the top of the form.
- o Menu returns back to “*Establishments Licensing system*” MAIN MENU.

L3: Entering new APPLICANT data in “*Establishments Licensing system*”

- o On main menu, click “Enter New Applications” button.
- o The “Establishments” form opens.
- o Click “>*” button found on the bottom of the form / or “>*” found on the menu bar.
- o A blank form appears.
- o On the bottom of the screen, you will find the total number of applicants already registered.
- o Enter a new application number on the “LTO Application No.” field.
- o Fill in the rest of the APPLICANT data in the form.

- o To save your data, move the record forward or backward using the ">" or "<" buttons on the bottom of the form or on the menu bar.
- o When finished, close the window by clicking the "x" on the top of the form.
- o The "Establishments Licensing system" MAIN MENU reappears.