SIAMED 2000:

speeding up drug regulation in Europe

The European Medicines Evaluation Agency (EMEA) and the World Health Organisation (WHO) are close to completing their model system for computer assisted drug registration (***SIAMED*[♣] *2000***). Development of this system is proceeding rapidly and a fully operational version will be available by June 2001.

The aim of the joint project is to develop an upgraded system (***SIAMED 2000***) that enables the EMEA to track its core processes and retrieve key registration data, and which can also be modified for use by National Regulatory Authorities. Both organisations are keen to make ***SIAMED 2000*** freely available to such authorities world-wide. The EMEA in particular plans to make the upgraded product available to its partners within the European Economic Area (EEA), Central and Eastern European countries (CEEC) and other European countries to facilitate harmonisation of regulatory authority tracking systems within Europe with relevant benefits in terms of transparency and effectiveness of drug registration processes.

The World Health Organization originally developed SIAMED to help national authorities strengthen implementation of drug regulation as part of their overall public health activities. This was achieved through the provision of technical advice, a locally adaptable computer system and assistance to make effective use of the system in over 20 national drug regulatory agencies where it has already been installed. This system was developed in the early 1990's and required revision to take advantage of the current state of the art in information technology. Collaboration with EMEA offered the opportunity to revise the existing system.

The EMEA has an obvious need to introduce an operational computerised system to track applications submitted for evaluation by its Scientific Committees, the Committee for Veterinary Medicinal Products (CVMP) and the Committee for Proprietary Medicinal Products (CPMP). Such applications are considered to be critical activities to meet the Agency's public health goals.

A question & answer fact sheet on ***SIAMED 2000's*** technical features is annexed to this statement.

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[♣] SIAMED is a Spanish acronym which stands for **S**istema de **I**nformación **A**utomatizada sobre **Med**icamentos

Q&A on SIAMED 2000

What is SIAMED 2000?

It is a computer-based system that allows:

- tracking of information and assessment schedules for applications for new marketing authorizations as well as variations, extensions and renewals of existing marketing authorizations.
- follow-up of information, submissions, decisions concerning Periodic Safety Update Reports (PSURs), Follow-up-Measures (FuMs) and similar procedures related to valid marketing authorizations.
- establishment of automatic links between the assessment of applications and the coordination of Good Manufacturing Practices (GMP) and Good Clinical Practice (GCP) inspections to ensure implementation of inspections in parallel with the assessment of individual products.
- linking of process-related information with large text documents (e.g. assessment reports, Summary of Product Characteristics (SPC), inspection reports etc.).
- development of a dynamic database of information on Maximum Residue Limits (MRL) for substances intended for veterinary use
- the EMEA web-site to be loaded with up-to-date information on marketing authorizations and, for the benefit of restricted users, facilitate remote access to product certificates and the status of pending applications.

What type of information is stored in SIAMED 2000?

SIAMED enables users to record, update, and retrieve:

- information on companies: e.g. name; mailing address; premises address(es); phone and fax numbers; e-mail; contact persons/responsible officials; activity(ies); operating licences and their validity;

- information on inspections carried out at company premises, enabling maintenance of separate records for each individual activity that a company is or has been carrying out (manufacturer, wholesaler, importer, quality control laboratory, etc.);

- information on drug items: e.g. application number; date of reception; applicant name; company contacts; drug product name; generic name; dosage strength; dosage form; primary container and its specifications; dispensing categories; limitations of distribution; origin; shelf life and storage conditions; manufacturers involved in production and their roles; ingredients and their quantities; reference standards and functions; routes of administration; therapeutic classification; Summary of Product Characteristics (indications, contraindications, etc.); internal data sheet (information not to be published); prices; distributors/importers; veterinary information; general description of the drug item; analytical information; regulatory situation in other countries; presence of genetically modified organisms (GMO); source materials; and other;

- information on status and decisions made at the different steps of the pre-approval and post-approval procedures and events; the system enables users to create any number and type of evaluation procedures with any number of steps,

- information on decisions such as withdrawal of or refusal to approve applications, and approval, revocation, surrender, suspension or renewal of marketing authorizations, as well as variations to valid marketing authorizations, automatically keeping a record of any variations made;

SIAMED also enables users to:

- produce correspondence and certificates based on user-defined standard models, and to keep a record of the documentation issued;

- carry out data searches and produce reports on the basis of multiple searching criteria encompassing all the pieces of information entered into the system;

- create, expand, keep up to date, and make automatic or on-line use of national databases storing information on substances whose use is restricted, and on excipients (admitted uses, limitations, etc.);

- export reports and correspondence to user-selected external word processors in order to issue printouts in any format;

- post selected information on a web-site.

Who has developed and owns SIAMED 2000?

SIAMED has been developed as a joint project by EMEA and WHO. Both organizations have agreed to providing SIAMED free of charge to interested national authorities for any not-for-profit use.

What are the prerequisites for proper implementation of SIAMED 2000?

Availability of the required hardware and software is not enough to achieve efficient drug registration. Success in the implementation of a computer-based drug registration system depends on a number of factors. Experience has shown that the most important are: clear national regulatory policy with a well-defined legal and regulatory framework; availability of adequate resources for the efficient functioning of the drug regulatory authority; management and staff commitment to implement computer-assisted drug registration; and, finally, adaptation of the software to meet specific local requirements.

What resources are required for successful implementation of SIAMED 2000?

As mentioned here above, the introduction of computers and software is not enough to ensure proper implementation of SIAMED. Having said that, resource requirements for adoption of SIAMED in any national context can be calculated on the basis of the following parameters:

- assessment of suitability of SIAMED and degree of adaptations required,
- size of the regulatory authority and training needs,
- training of IT local IT expert to ensure maintenance and future adaptations.

When will SIAMED 2000 become available?

Development of this system is proceeding rapidly and a fully operational version should be available by June 2001. Currently the database has been loaded with data on medicinal products which have been approved through the centralised system. These data are in the process of being validated with Marketing Authorisation Holders. The reporting functionality of the system is being developed and will be tested through 1Q2001.