The changing role of a medicines agency

Regulatory authorities play a major role in the pharmaceutical sector for historical reasons. The thalidomide tragedy, for instance, resulted in thousands of babies being born with birth defects before the drug was withdrawn. As a result, marketing authorisation for medicines became mandatory, and recording adverse drug reactions standard practice.

In Finland, the marketing authorisation system was launched in 1964, making this year its 50th anniversary. It also marks the fifth anniversary of Fimea. Last year, Finland's national adverse drug reaction database reached the age of 40.

Over the decades, the process leading to marketing authorisation has become much more complicated. Thorough research and trials are required before a new drug is granted marketing authorisation. The adverse drug reaction database provides one channel for monitoring the safety of drugs available on the market.

While the pharmaceutical sector has seen many changes, the role of the regulatory agency has also changed. The first stages of new drug development increasingly take place in small companies akin to research institutes, and the manufacture, preclinical and clinical trials are often outsourced. Pharmaceutical regulation must be extensive in scope and proactive in nature.

It is in everyone's interest for drug development to navigate smoothly through the regulatory maze. The authorities are also working to establish practices and procedures that support this goal, such as by increasing regulatory and scientific advice.

This issue of Sic! contains articles on medicines development. Some of the areas addressed include the course of a drug development process and the challenges involved (Salonen, in this issue). The articles also provide perspectives on the different stages of drug research projects, from initial stage to price setting.

Pharmacotherapy currently provides a cure for very few diseases, which is why new drugs are needed and why enormous expectations are placed on drug development. The development of pharmacotherapies for cancers, for instance, has seen both small steps and big advances. The key priority in all drug development is the patient's interest. Achievement of this goal provides the inspiration for professionals like Professor Sirpa Leppä, who conducts clinical trials (Talvitie and Kalliokoski, in this issue).

We have now published four volumes of the Sic! magazine. Our aim continues to be improving the magazine by listening to our readers, so if you have any requests regarding themes and topics for articles, please send them to sic@fimea.fi.

We wish all our readers a happy and healthy 2015!

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