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Behind the drugs we use: the regulatory safekeeping

In 2008 patient safety problems in the USA which arose from the administration of heparin manufactured in China are a reminder of the need for pharmacovigilance.



Professor Henk de Jong

In January 2008 there was an increase in the frequency of adverse events reported in the USA which were associated with the use of heparin from Baxter. In February 2008 the FDA announced the discovery of a "heparin-like contaminant" in heparin active pharmaceutical ingredient (API) and sophisticated analytical methods for the detection and analysis of impurity were published on the FDA website. This contaminant, identified as oversulphated chondroitin sulphate (OSCS), was in affected products sourced from China. Eighty serious adverse reactions were then reported in Germany. Dr Ged Lee, from the BP & Laboratory Services, Medicines and Healthcare products Regulatory Agency (MHRA), UK, explained how the regulatory authorities in the EU reacted to the situation in order to guarantee patient safety. For example, samples of all heparin API used since December 2006 were tested for the presence of OSCS, at the same time a safety evaluation of OSCS and clinical alternatives were being investigated. The contamination was explained to healthcare providers and a caution in use alert was issued, with the advice to monitor patients closely. Although there was different usage of low molecular weight heparin across the EU, with Member States allowing levels of contamination of 2-5% to prevent supply shortages, data sharing between the regulatory authorities was good. Heparin is now available which is free from the contaminant and pharmacopoeia monographs have been amended requiring manufacturers to demonstrate absence of OSCS in heparin API. However, the role of the pharmacopoeia is to provide a quality standard for a medicinal substance that will control

known impurities arising from the manufacturing process. Therefore, it is important that all healthcare providers, including hospital pharmacists, are aware that this type of incident can occur and the need for constant pharmacovigilance.

Professor Henk de Jong, Chair of the European Pharmacopoeia, continued by discussing the regulatory requirements for medicinal products within the EU. The purpose of the European Pharmacopoeia (Ph. Eur.) is to have a harmonised pharmacopoeia for Europe. With respect to the quality of medicinal products (chemical, pharmaceutical and biological) he explained that all monographs of the Ph. Eur. are applicable to Member States and that the monographs of the Ph. Eur. are applicable to all substances, preparations and pharmaceutical forms appearing in it. For other substances each Member State may then require observance of its own national pharmacopoeia. The Ph. Eur. and its expert working groups elaborate general chapters and monographs, with the work programme based on substances already approved in at least one of the Member States. However, updating these in view of scientific and technical progress is continuous, as has been the case with the heparin monographs.

The future of hospital pharmacy: outcome from the FIP Global Conference, 2008

Hospital pharmacy has taken a first step in defining global standards. How can this translate into establishing them in every country?



Jacqueline Surugue
EAHP President

Lutz Vogel
PhD

Mrs Surugue, who is also the Vice President for the European Region in the hospital section of the International Pharmaceutical Federation, opened the seminar by summarising the purpose of the Global Conference: to start to establish global

standards for hospital pharmacy. Before and during the conference delegates shared their vision, identified strategic goals and shaped 74 consensus statements. It was a learning experience that looked to the future, in line with her personal vision of international collaboration. "The Basel Statements" are available in print and online from the AJHP and FIP [1, 2].

Mrs Surugue was proud of the response to the survey that provided the evidence base for the discussions: responses were received from 85 nations representing 86% of the world's population. The EAHP Board has discussed how the consensus statements can be carried forward and "think tanks" have been set up in South Africa, The Netherlands and Uruguay.

Dr Vogel, Germany's delegate to the FIP conference, showed us how some of the statements described the present situation, but others were still aspirations. In Germany, a federal country, there are 34 presidents of various pharmacists' associations, and hospital pharmacists are a small part of pharmacy. They are determined to become more patient oriented, part of the clinical team, but have to persuade not only physicians and nurses, but redesign university courses as well as agree the boundaries for community pharmacy. A great struggle is under way to establish national standards in Germany and persuade hospital administrators to see the pharmacy not as a cost but rather a leader in improving quality. Direct reimbursement for services provided would also save money overall. So German hospital pharmacists are using the FIP statements as a way of closing the evidence gap, of showing the authorities that Germany should come in line with global standards.

The audience eagerly shared the situation in their own countries. Australia, Saudi Arabia and Spain already have patient-focused hospital pharmacy but found the statements encouraging. In Belgium, there are not enough hospital pharmacists. Greece and Latvia have a lot to do to introduce these standards.

1. www.ajhp.org/content/vol66/5_Supplement_3/index.dtl
2. www.fip.org/globalhosp