ICU
MANAGEMENT & PRACTICE

ICU Volume 5 - Issue 3 - Autumn 2005 - Europe

Interview with Peter Arlett: Proposing a Medicinal Products Regulation

Interviewee

Peter Arlett

Principal Administrator at the Pharmaceuticals

Unit, DG Enterprise and Industry

Correspondence

peter.arlett@cec.eu.int

Peter Arlett's responsibilities include amongst others medicines for children, the safety of medicines, orphan medicines and international relations. In this interview with Helicia Herman, he describes thedevelopment of a draft regulation by the Commission on medicinal products for paediatric use.

How was the Idea Initiated?

The Commission, along with the Council and the Parliament, were made aware of the public health issue relating to medicines for children through dialogue and correspondence from patient organisations, doctor organisations and individuals affected by the issue. Moreover a Council resolution in December 2000 invited the Commission to find solutions to the issue of inadequate medicines for children. There were also calls from the European Parliament for a proposal.

At this time the French Government had the Presidency of the European Union. The French Medical profession had raised the issue previously with the French Department of Health and the French Presidency had therefore put the issue on the agenda for the Presidency. If there is political pressure in this way, the Commission is then under pressure to react. In general, if an issue is brought to the attention of a national government, it is during that country's EU Presidency that they have the most power to initiate European action.

Ideas may therefore stem from local, national or European groups. If the Commission needs to prioritise its work, it prioritises demands from European groups. This is simply because inviting national associations is not always easy to accomplish logistically and budget resources for organising meetings with possibly 25 national associations are limited. Moreover European groups such as those from industry associations in the pharmaceutical sector are usually well organised.

How did the Commission Progress the Idea?

The Commission researched the problem and potential solutions intensively. Part of the research included study of how other regions are tackling this issue and how regulation has dealt with similar but distinct problems, such as how to stimulate the development and authorisation of medicines for rare diseases (orphan medicines).

Because of the complexity of healthcare delivery and the pharmaceutical sector, the Commission conducted a detailed assessment of the social, economic and environmental impacts of its proposal on the different stakeholders involved (e.g. children and their families, healthcare workers, the pharmaceutical industry and those that pay for medicines). The results of the 'Extended Impact Assessment' (EIA) show that the proposal will lead to the availability of more and better medicines for children and that the pharmaceutical industry will benefit through increased innovation.

How are Responsibilities Assigned?

When a request for action or a question arrives with the Commission, for example with the Secretariat General, it is sent to whichever Directorate General (DG) has the most relevance. The Secretariat General has a horizontaloverview of all activities of the Commission and usually the responsible DG is clearly defined.

Within the DG there are coordinating units who direct the matter to the attention of the responsible person in the unit.

In case of a competence overlapping between two DGs, one is assigned as responsible and the other is consulted (and hence informed) on all matters. Difficulties can arise when the European Commission has low competence on a topic, for example on delivery of healthcare.

In this case the request is responded to by the Commission, but the scope for action is limited. initiators of requests can correspond directly with theresponsible DG; contact details are available on the Europa-server (http://europa.eu.int/comm/index_en.htm). All DGs have their own website, including a description of their policy field.

Who Participates and How?

This proposal was the subject of an extended impact assessment (EIA) of the overall proposal and the specific measures included. An EIA assesses the economic, social and environmental effects of the proposal on the key stakeholder groups. The Commission's EIA is principally based on an independent, externally contracted study. The EIA also draws on experience with the existing EU pharmaceutical market and regulatory framework, experience with legislation on paediatric medicines in the US, experience with orphan medicines in the EU, extensive consultation with stakeholders, the published literature and other available data.

The Commission consulted extensively on the issue of medicines for children and on its proposals for a draft paediatric regulation.

This consultation included:

• Workshops and roundtable meetings

• Stakeholder interviews during the EIA (including the externally contracted study)

• Public consultation

In the course of conducting the EIA Study, interviews took place with representatives of the following organisations: Association of the British Pharmaceutical Industry (ABPI, United Kingdom) Aventis Pharma AOK Health Insurance (AOK Krankenkassenverband, Germany) BLISS (United Kingdom) British Medical Association, General Practitioners Committee (BMA, United Kingdom) Dutch Medicines Evaluation Board (College ter Beoordeling van

Geneesmiddelen (CBG), The Netherlands)

Dutch Healthcare Insurance Board (College voor Zorgverzekeringen (CVZ), The Netherlands) Confederation of European Specialist in Paediatrics (CESP)

Direzione Generale dei Farmaci e dei Dispositivi Medici (Italy)

European Agency for the Evaluation of Medicinal Products (EMEA)

European Federation of Pharmaceutical Industries and Associations (EFPIA)

European Generic Medicines Association (EGA)

European Network for Drug Investigation in Children (ENDIC)

European Organisation for Rare Diseases (Eurordis)

European Society of Clinical Pharmacy (ESCP)

Medicines and Healthcare products Regulatory Agency (MHRA, United Kingdom)

This kind of list is not necessarily definitive. In the present case the list was compiled through research and by talking to people in the field. To a certain extent it was created by word of mouth. Another party may show interest in the matter and could be added to the list at any point. Budget constraints at some point may force the Commission to restrict invitations to participate in face to face meetings, however. In that case, once again the Commission would prioritise European over national groups, or organisations over individuals.

The Commission's public consultation was split in two. Between 28th February 2002 and 30th April 2002, the public consultation focussed on the key elements to be included in a regulation. Between 8th March 2004 and 9th April 2004, public consultation was based on the draft legislative text. For the latter part of the consultation, the consultation document was placed prominently on the Commission website and sent by e-mail to key stakeholder organisations.

How Quickly was a Draft Completed?

The Council resolution of December 2000 was the true start of the Commission's preparatory work. The Commission formally adopted the proposed regulation on medicinal products for children in September 2004. Three and a half years were spent researching the issue together with possible solutions, conducting the EIA, consulting stakeholders, and drafting the regulation and supporting documents (in the 20 official languages of the EU).

What Happens if Commissioners Disagree?

At the end of the process to prepare a legislative proposal, the Commission as a whole (meaning all Commissioners) vote on the draft. All internal disagreements need to be resolved before the Commission decides on a proposal. The discussions between the DGs are very formalised and overseen by the Secretariat General. For all initiatives (legislative or others) there is an Interservice-consultation at service level. DGs who are interested may comment on the matter.

The controversial issues are usually resolved in meetings between the heads of cabinets, who meet before the "college" of Commissioners schedules the issue on its agenda. Uncontroversial decisions can be taken by written procedure. If controversial issues still remain after the discussions between the heads of cabinets, the Commissioners discuss the matter during the "college" meeting. A decision can be taken with a simple majority. All decisions, once taken, are considered as unanimous, meaning that all Commissioners must defend it in public. Externally the Commission therefore acts with one voice.

Thank you very much for this interview.

Published on : Thu, 20 Oct 2011