Läkemedelspaketet – Förslag till ny läkemedelslagstiftning från Kommissionen
S2008/10685/HS

Kungliga Tekniska högskolan, KTH, har tidigare meddelat att vi inte har några synpunkter på rubricerade remiss. KTH tar härmed tillbaks detta yttrande och avger nedanstående remissyttrande angående Kommissionens ”läkemedelspaket” om patientinformation, säkerhetsövervakning och förfalskade läkemedel. KTH är sammantaget positiva till Kommissionens förslag.

Våra detaljerade synpunkter redovisas nedan. Vi har valt att skriva kommentarerna på engelska eftersom det utskickade förslaget är skrivet på engelska.

**COM(2008)666**

*General comment:*
Active pharmaceutical ingredients are a group of compounds that has to be added to the list of potentially hazardous chemicals ending up in the aquatic environment. Up to now almost 200 pharmaceutical substances have been identified in surface waters in several member countries. With an increasing population and an increasing use and consumption of synthetic chemicals – including pharmaceuticals – the Community needs, in our view, to consider prompt actions towards the aim to protect further pollution of water resources.

*Specific comment:*
Section 1.3.3. Addressing the Environmental Impact should be regarded to express a minimum level of ambition for the current revision of Directive 2001/83/EC.

**COM(2008)663**

*Specific comment 1:*
In Directive 2004/27/EC, amending Directive 2001/83/EC, an article (127b) was introduced requiring that all member states in the EC shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired. The instruction to patients to use these systems is however vague and incomplete (cf. below) and therefore in need of clarification to achieve the goals of these systems. In Directive 2004/27/EC article 54 (j) should be amended as follows:
Specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate, as well as reference to any appropriate collection system in place.

**Specific comment 2:**
In the current proposal Article 100(c) should be amended as follows:

Current text: information on the environmental impact…

Proposed text: information on the environmental risk…

The term “impact” is vague and not in line with the current terminology.

**COM(2008)665**

**Specific comment 1:**
Pharmacovigilance is defined in the Proposal’s General Context (1.2) as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of medicinal products”. An extension of the pharmacovigilance concept to include not only protection of public health but also the environment is motivated:

Explanatory memorandum, General Context (1.2), first sentence.

**Current text:** Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of medicinal products.

**Proposed text:** Pharmacovigilance is defined as the science and activities relating to detection, assessment, understanding and prevention of adverse effects of medical products on patient’s health, public health and the environment.

**Specific comment 2:**
The risk concept in the risk-benefit balance should preferably be defined as risk for patient’s health, public health and the environment, harmonizing the wordings to the Commissions Communication COM(2008) 666, point 1.3.3.

Furthermore, the definition of risk-benefit balance will be identical to the corresponding definition in directive 2004/28/EC of 31 March 2004 (amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products), Article 1, point 20.

Therefore we propose that Directive 2004/27/EC, article 1, point 28 should be amended as follows:

**Current text**
28a. Risk-benefit balance:
An evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined in point 28, first indent.’;

**Proposed text**
28.1. Risk-benefit balance:
An evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined in point 28.

**Specific comment 3:**
Scientifically well-motivated management of environmental risk requires the dissemination of appropriate information about environmental risk and hazard. To achieve this, a classification system needs to be developed and adopted as an EU standard. Such a system should be based on experiences from similar systems already in use under support from the producers.
In Directive 2004/27/EC article 8(3c) should be amended as follows:

<table>
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<tr>
<th>Current text</th>
<th>Proposed text</th>
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<tr>
<td>3c. Evaluation of the potential environmental risks posed by the medicinal product. This impact shall be assessed and, on a case-by-case basis, specific arrangements to limit it shall be envisaged.';</td>
<td>3c. Evaluation of the potential environmental risk and hazard posed by the medicinal product. This impact shall be assessed in accordance with a classification system. Specific arrangements limit the environmental impact shall be envisaged on a case-by-case basis.</td>
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KTHs remissyttrandet har utarbetats av Docent Christina Rudén, skolan för Arkitektur och samhällsbyggnad, avd. för filosofi och teknikhistoria.

Peter Gudmundson