Comments on the 'Strategy to Better Protect Public Health by Strengthening and Rationalising EU Pharmacovigilance'

Public consultation on legislative proposals d.d. 5 December 2007

Dr. Peter Arlett
DG Enterprise and Industry
Bruxelles

Dr. Pim van der Giessen
Netherlands Medicines Evaluation Board
The Hague

Sir,
Thank you for the opportunity to give some considerations regarding the concept paper.

Main points of comment

Section 3.2.6.
Regarding the point of basis of patient reporting it is proposed to make a reporting form part of the patient information leaflet for intensively monitored drugs with reports addressed directly to the Marketing Authorisation holder.
In The Netherlands the Netherlands Pharmacovigilance Centre Lareb has extensive experience with reporting by patient and published several papers about it. A evaluation of thee years of experience with reporting by patients is in press with *Drug Safety.*
We have on this point the following suggestions:

- Paper reporting can best be done through a website form.
  Our research has shown that the Internet is available for a fast majority of drug user, including elder people. The advantage is that you get structured and complete responses. E-reporting facilitates the possibility to ask for additional information (including the permission to go the treating physician of the patient involved) if needed.

- The report should be send to the same National Centre as other reports.
  It is a key point in accepting reports from patients that they are treated for logistical and methodological reasons in the same way as other reports. 'It is about the message, not about the sender'.
  Sending the report to a national centre could reporters give more confidence that their concern is take seriously.
  It is our conclusion after four years of experience with patient reports that they are not abundant in number and that their content is generally serious and of acceptable qualitity.

- 'For all other drugs reporting via web-sites, directly to the national authority'.
  The word 'directly' should be deleted.
  In several countries reporting – this is for example the case in France - is done to national or regional centre that are not the national authority themselves.

Other points to consider

Section 2, first phrases and
You give a definition of pharmacovigilance which differ from the WHO definition. It is important to use international accepted standard definition (see: 'The need for Definition in Pharmacovigilance' in *Drug Safety* 2007;30(10):825-830).

Annex 1, Directive 2001/83/EC Article 1(11)
For the same reason the definition of Adverse reaction should stay as it is.

> *The proposed changes make the definition different from the internal accepted definition and include for example toxicology!*

Annex 1, Directive 2001/83/EC Article 1(15)
'A pharmacoepidemiological study or a clinical trial' could be replace by 'any study'.

General
Little is said about transparency. It should be made absolutely clear that Risk Managements Plans and Eudravigilance information will be public available at a easily accessible way.

Literature

1. Grootheest AC van, Graaf L de, Jong-van den Berg LTW de. Consumer adverse drug reaction reporting: a new step in pharmacovigilance? Drug Saf 2003;26:211-7.

2. Grootheest AC van, Passier JL, Puijenbroek EP van. Meldingen van bijwerkingen rechtstreeks door patiënten: gunstige ervaringen van het eerste jaar. Ned Tijdschr Geneeskd 2005;149(10):529-33.

3. Grootheest Kees van, Lolkje de Jong – van den Berg. Patients' role in reporting adverse drug reactions. Expert Opin Drug Saf 2004;3:363-8.

Prof. dr. A.C. van Grootheest MD
Netherlands Pharmacovigilance Centre Lareb
University of Groningen