From: Joop van Oene
To: SANCO PHARMACEUTICALS D5
Subject: PCPD/12/01 - Public Consultation on paediatric report

To: European Commission, Health and Consumers Directorate-General
Health systems and products

Medicinal products – authorisation, EMA

Dear Sir/Madam,

This response is to the European Commission's General Report 'Experience acquired' and 'Lessons learnt' which was submitted for public consultation.

For your understanding I should add that I have been working in pharmaceutical drug research for over 25 years as clinical research associate/clinical study manager/clinical program manager.

What surprised me most in your report is that it does not limit itself to apparent facts but that it brings biased opinions and takes political stands. I strongly feel that these must be adapted in order to avoid serious misunderstanding of the reasons why in the past far too little information – I fully agree with that conclusion – was obtained on drug action in children.

Your report appears to put all the blame for this on the pharmaceutical industry whereas I know from my own experience that not the industry but rather general views of ethics committees and regulatory authorities prevented initiatives of research physicians - whether asked for this by pharma companies or acting entirely on their own initiative – from performing almost any research activity in children. In the 1990's and way into the first decade of the present century the general view on drug research was that this should be done with adult persons only, healthy individuals first and patients later in the development, but that it was merely "unethical" to propose doing such investigations in childern being one of the labeled categories of vulnerable subjects!

This general view completely changed, and was even converted into its opposite, somewhere around 2005 when the FDA all of a sudden decided that, because no data were obtained on drug effects in children, experiments showing these effects should be demanded from drug research companies. The implicit message was that FDA had completely changed their minds and that they felt it was now ethical to do such experiments in children just because the expected knowledge benefits were supposed to overrule the negative aspects of doing experiments in low-age groups.

What resulted is a system in which gathering specific data in children of various age categorieson the action of any and all new drugs has become mandatory, even if it comes to new drugs in Alzheimer's disease, whereas 15 years ago the development of new drugs for e.g. special types of childhood epilepsy was hardly possible because of the above cited ethical prejudices.

My conclusion from all this is that avoiding to mention the above paradigm shift in ethical concepts as at least one of the contributing factors to the paucity of drug data in children, must be considered a serious historic omission. I would therefore urgently recommend you do pay due attention to this in the final version of your document.

With best regards,

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