From: Saad Shakir [saad.shakir@dsru.org]
Sent: 01 February 2008 16:01
To: ARLETT Peter (ENTR)
Subject: Commission Consultation on Pharmacovigilance

Dear Peter
I think that the legislative proposals are generally positive with regards to enhancing pharmacovigilance to protect public health. I have a few comments which or your colleagues may find useful.

1. I agree with and support the proposal in 3.2.4 for the rationalisation of risk management planning. I suggest that risk management plans in their entireties be placed in the public domain. This will encourage scientific debate and in the long term enhances risk management. Any drawbacks are insignificant when compared with this undoubted advantage.
2. I support 3.2.7 to link PSURs with Risk Management Plans. I suggest commissioning an external independent study to examine the benefits (which I think are very few) of PSURs for long established products and the thousands of generic products.
3. With regard to 3.2.9 (key safety information), the principle is excellent, the application will ensure that critical key safely messages stand out from background noise or less important information. However, prior to implementation, work is needed to decide what the key messages are. For example are they serious ADRs (how many to include) and the levels of certainty of their drug relatedness. Naturally there will be some tensions, for example one imagines that industry will push for elevating the thresholds, while some patients_ advocacy groups will want them to be very low. Another important group are events where actions by patients or doctors, e.g. reducing the dose or stopping the drug, will prevent a worse outcome.
4. I suggest that the definition of post-authorisation study be: a pharmacoepidemiological or a drug utilisation study or a clinical trial with an authorised medicinal product conducted with the aims of identifying, characterising or quantifying safety hazards or confirming the safety profiles of medicinal products.
5. I support the introduction of the period of intensive monitoring of new medicines (and new indications, populations, etc.). Intensive monitoring systems such as events monitoring are integral part of pharmacovigilance during the

intensive period. I suggest that they should be recommended and included in the proposals.

Overall, as I said above, the proposals are positive; I wish you luck in the next stages of the complex process. Please do not hesitate to ask me to help in way that serves public health.

Best wishes.

Saad

Professor Saad Shakir
Director - Drug Safety Research Unit, Southampton, UK
saad.shakir@dsru.org