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Sent: 22 January 2008 13:11

To: ARLETT Peter (ENTR)

Cc: bsickmueller@bpi.de

Subject: Public consultation on Proposal: " Strategy to better protect Public Health/Pharmacovigilance"

Comment on the Proposal of the EU.-Commission, Final 5-12-2007, entitled "Strategy to better protect Public Health by strengthening and rationalising EU Pharmacovigilance"

Dear Peter,

may I take the opportunity to make use of the offered public consultation procedure:

in reading the new proposal of Dec, 5th 2007, I may contribute one general remark:

from my 20 years experience in vigilance procedures the impression has grown that improved safety has been almost result of improved attention of all stakeholders. Especially the intensified activities of the MAHs to complete their safety documentation and elevate the level of experience of their staff can help to better recognize risks and medical causes of effects.

We all do not suffer from to small numbers of cases of adverse reactions, but from precise information concerning the exposure, the circumstances and the individual factors, contributing to the final symptom.

The rule is simple: shit in - shit out.

What we should consider is how to improve the original information deriving from the treating doctors and hospitals.

It is completely meaningless to amplify the number of recorded events without having a tool to follow-up the

details of a case (I know many documents of ICSR from the MHRA, which are completely meaningless due to the high number of reported substances being "suspect". All you can do with them is to store them and fill-up your file.)

New rules of reporting should therefore comprise more medical knowledge instead of more general bureau-crazy.

The existing filter of local medical evaluation with the focus on reporting of severe cases only, is certainly an advantage. Any central authority concerned with safety duties should be kept free of irrelevant matter.

The focus of an improved safety tool should be directed on the primary information coming from those people, who are in place and who may be capable to comment in a medical sense of causality.

Any other approach may rise numbers of cases and help to fill data bases, but will not really enhance our problem of being to late and to simple in our vigilance efforts with respect to the very severe and serious cases.

I wish you and your team a big success and a good year 2008!

Dr. med. WOLFGANG MATTHIES

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