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Comments to

STRATEGY TO BETTER PROTECT PUBLIC HEALTH BY STRENGTHENING AND RATIONALISING EU PHARMACOVIGILANCE

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The following points are discussed

- adverse events
- data management and reporting
- PSUR

and annotated as follows:

1) adverse events

It is proposed to shorten the definition of an adverse reaction to

"Adverse reaction: A response to a medicinal product which is noxious and unintended."

We are not in accordance with that proposal.

The definition of an adverse event shall include

- hints regarding doses and application form normally used

  because the (re-)evaluation of a risk/benefit ratio has to be done in relation to recommended daily dose or application form in contrary to drug misuse;

- a definition of an unexpected adverse event

  because the consequence of e.g. an adaptation of the SPC or other measures to be taken, are related to an ongoing evaluation of the risk/benefit ratio;

- a definition of an abuse

  because it should be clearly distinguished between an abuse and an adverse event related to a recommended use.

2) data management and reporting

It is proposed in Article 101e that

*"2. Marketing authorisation holders shall submit electronically to Eudravigilance, no later than 15-days following the receipt of the report, **all** adverse reactions that occur in the community and all serious adverse reactions that occur outside the community."*

We are not in accordance with that proposal.

There is no need to change the requirements of expedited reporting as stated in VOLUME 9A of The Rules Governing Medicinal Products in the European Union,

because a sound standing revision of the risk/benefit ratio demands a critical evaluation of ICSRs. In addition, a clearly regulated reporting in order to avoid duplication is essential for a feasible pharmacovigilance.

3) PSUR

It is proposed in Article 101f that compilation and submission of periodic safety update reports …

"… shall not apply to products authorised in accordance with articles 10, 10a, 10c, 13t to 16, or 16a to 16i of Directive 2001/83/EC."

We are not in accordance with that proposal.

PSURs shall be prepared for all medicinal products, including those described in articles 10, 10a, 10c, 13t to 16, or 16a to 16i of Directive 2001/83/EC

because a periodically prepared report balancing the risk against the benefit is required to compile a sound standing revision of the risk/benefit ratio for all medicinal products to realise a Good Vigilance Practice. With particular regard to herbal medicinal products there is a lot of published literature of minor scientific quality which makes a periodic critical examination necessary.
As stated in VOLUME 9A PSURs are important pharmacovigilance documents for maintenance of marketing authorisation. They provide an opportunity for Marketing Authorisation Holders to review the safety profile of their products and ensure that the Summary of Product Characteristics (SPC) and Package Leaflet are up to date. They also provide the Competent Authorities with a valuable source of pharmacovigilance data. For these reasons the Competent Authorities place great importance on compliance with periodic reporting.