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Mr. Peter Arlett
European Commission, DG Enterprise and Industry, Pharmaceuticals
EUROPEAN COMMISSION, BREY 10/118
B - 1049 Bruxelles

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Dear Mr. Arlett

Submission of ICSRs and SUSARs

With reference to the public consultation: An Assessment of the Community System of Pharmacovigilance Lif would like to draw the attention to the submission rules for the above mentioned reports, which are very time consuming and very costly for the industry.

According to the current volume 9, the draft volume 9a and the clinical trial directive, MAHs have to submit Individual Case Safety Reports (ICSR) and SUSARS to National Competent Authorities according to very complicated reporting rules. In addition all unlisted reactions from third countries and all SUSARs must be submitted to EMEA.

As a result MAH and Competent Authorities must test and validate e-submission with more than 25 trading partners, which is very costly. In addition the reporting rules both for both types of reports are very complicated as it is up to the national authorities to define the rules. The rules for marketed products depend on the approval procedure and the rules for investigational medicinal products on the conduct of trials in the concerned member state.

If all electronic reporting is allowed to be done to the Eudravigilance system at EMEA, it would save industry a huge amount of the resources, spend on e-submission.

Direct reporting to the Eudravigilance system should not be a problem for authorities, as all cases are to be found in the EudraVigilance Database Management System. As a matter of fact waivers for direct submission of some of the reportable cases (typically all non-domestic cases) are given to a large extend today based on the fact that authorities can find the reports in the EudraVigilance system, e.g. Italy, Norway, Finland, Holland, Cyprus, Czech republic, Slovakia and Hungary.

With regard to cases submitted directly to authorities, these could either be made available to the MAH in the EudraVigilance Database Management System or simply be faxed or e-mailed to companies. Companies will be prepared to assist safety surveillance in the EudraVigilance system by translating them into English and forwarding them electronically to EMEA.

Please consider this change of procedure which after Lifs opinion would ensure the following:

- Post marketing case received directly by companies would be available for signal detection in the EudraVigilance system within 15 days from receipt (not being delayed by indirect submission via national competent authorities).
- Translation into English would result in better surveillance, as all information would be in a language understandable for everybody rather than in 20 different languages.
- Compliance would be easy to ensure.
- A huge amount of resources for both Authorities and companies would be saved.

Yours sincerely

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