AGES
Österreichische Agentur für Gesundheit
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Sent by e-mail to
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Date: January 23, 2008
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Subject: Austrian response to the PUBLIC CONSULTATION ON LEGISLATIVE PROPOSALS – *STRATEGY TO BETTER PROTECT PUBLIC HEALTH BY STRENGTHENING AND RATIONALISING EU PHARMACOVIGILANCE*

Dear Mr. Arlett,

We want to structure our comments in that way that we respond to the Key Items outlined in the Public Consultation Paper.

3.2.1. Fast robust EU decision-making on safety issues by rationalising the existing EU referral procedures and reinforcing the committee structure

We welcome the concept of establishing a committee responsible for pharmacovigilance issues which replaces the existing Pharmacovigilance Working Party. The relationship between the CHMP and this committee should be clearly defined and this description should contain clear responsibilities and duties for each committee. For example which committee would be the responsible one in the light of Art 107 Directive 2001/83/EC. This also includes the clear determination of the legal status of decisions by the "pharmacovigilance committee".

Referring to the sentence on page number 4 *"This means that products can be authorised earlier in their development and this is of crucial benefit to patients with unmet medical needs"* we think, that safety issues are an import point in the marketing authorisation procedure and are against a shift of pivotal data from a pre- to a post-authorisation timepoint.

3.2.3. Simplify informing the authorities about the company pharmacovigilance system

We welcome the idea of a "Pharmacovigilance System Master File" in order to minimize the number of variations triggered by changes to the "Detailed Description of the Pharmacovigilance System" as part of each dossier.

Nevertheless we are of the opinion that the "Detailed Description of the Pharmacovigilance System" should be subject to assessment by NCAs (or alternatively by the RMS, EMEA – depending on the procedure).

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We therefore propose that "Pharmacovigilance System Master Files" and regular updates (e.g. once yearly) should be submitted to the competent authority (this could either be the EMEA, the Reference Member State in case of an MRP or DCP procedure or the NCA in case of a purely national authorisation). Any dossier submitted thereafter might then refer to the "Master Files" of the applicant.

The administrative burden for industry and regulators should be revisited and changes incorporated via the amendment of the "Variation Regulation", since currently any change to a company system has to be submitted via a variation procedure.

3.2.5. Codify oversight of non-interventional safety studies

We fully agree with this proposal. Clear guiding principles for non interventional safety studies would be very helpful specifically for Austria, where most non-interventional studies would fall under the single-nation option.

3.2.6. Simplify and make proportional reporting of single serious adverse drug reaction (ADR) case reports

We agree that all serious 3rd country reports should go to the EU Eudravigilance database only.
We disagree with the proposal that all EU domestic reports should only be submitted to Eudravigilance directly and thereby only reach the Member State indirectly where they occurred. We insist that all EU domestic reports should go in parallel to Eudravigilance and to the Member State where they occurred. Our reasoning is that any possibility of a delay in the assessment is not in the interest of public health and has to be avoided. As a National Authority it is vital for us to react as quickly as possible to all reports of serious events which occurred in Austria.

To refer to the point *"the EMEA to take on new tasks, clearly defined in scope, for scanning of the scientific literature and entering case reports from the literature on Eudravigilance, rather than the duplication currently conducted by the industry"* it is unclear to us, who should do the work. Is it done by staff of the EMEA or by experts of the MS and if it is done by experts of the MS who is responsible for the funding and is the report of the scientific literature scanning also reported to the MAH? Does the responsibility for the screening of purely local literature rest with the MAH?

We endorse the idea of "consumer or patient reporting" but still find unresolved questions:
We think that consumers should only send their reports to the NCAs. We believe that, if for example a patient from Spain reports to a MAH in Estonia, it might be difficult for the MAH in Estonia to translate and assess the report in time. MAHs would be required to handle reports in all European languages, which makes this part of the "consumer or patient reporting system" un-practicable and would lead to unnecessary delay of assessing the report by the NCAs and possibly to a decrease in overall report quality. Moreover, difficulties in communication could cause problems in the identification of the concerned product and raise follow-up and traceability issues for received reports. Moreover, it seems questionable whether patients will notice the difference of adverse events related to products under intense monitoring which are reportable to the MAH and those related other products which are reportable to their NCAs.

3.2.7 Simplify and make proportional to risk periodic safety update report submission by industry (PSURs)

In our opinion there is no clear definition of an "old established product". If this term contains all products no longer covered by the data protection we recommend to extend this period for PSURs. In

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principle, also depending on the nature of the product, ten years are too short to monitor "long-term safety issues" (take NSAIDs as an example).
Moreover it is unclear to us if only the originator or also the MAH of any generic product would fall under this exclusion.

We recommend keeping the existing legal system of PSURs.

3.2.8. Strengthen medicines safety transparency and communication

As mentioned under Point 3.2.1 we welcome the concept of establishing a committee responsible for pharmacovigilance issues and moreover the provisions of transparency and communication as laid down in this proposal. We would recommend publishing the assessment reports of this "pharmacovigilance committee".

3.2.9 Clearer safety warnings in product information to improve the safe use of medicines

We welcome a reasonable concept of making the Patient Information Leaflet more user-friendly for patients with the idea of making important safety warnings visible at first sight.

However, instead of repeating this essential information twice in the Patient Information Leaflet (text and box) we would recommend to work on readability and clarity of the document instead.

Section 1
Eudravigilance and recording and reporting of adverse reactions

Art 101d point 3:

We agree with the idea that individual adverse reaction reports held on the Eudravigilance database should be forwarded to the public on request but to reduce the burden for the CAs this data should only be provided by the EMEA. In our experience applicants usually ask more than one CA and thus might receive different answers. Some NCA do not give any answer others provide the applicant with all requested data, further, the interpretation of datasets might vary. To prevent divergence and to harmonise this system the EMEA – as the holder of the "source database"the "voice" to answer these requests.

Art 101f point 3:

We do not agree with the provision that no PSUR should be required, unless this is a specific condition of the marketing authorisation, for generics, well-established use, informed consent, homeopathic or traditional use registered herbal medicinal products.

In the case of generics whose introduction to the market reduces the number of patients treated with the originator the monitored group of patients would gradually shrink, which cannot be the intention of this proposal.
Another question is what would happen if the originator withdraws his product for reasons other than safety issues. In this case the CA would have to change the specific condition of the marketing authorisation concerning the PSUR.

We think that this system is not practicable and moreover reduces the amount of monitored patients.

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Section 2
Post-authorisation safety studies

Art 101h lit j)

We are in line with the principle that the abstract is made public via the European medicines safety web. However we are unclear on whether the word "after" agreement with the MAH has the meaning that the committee is only allowed to publish this abstract with the agreement of the MAH. We think that the word "agreement" should be replaced by the word "information".

Looking forward to discuss the issue further

Yours sincerely

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