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Date: 4 January 2008
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Subject:

Austrian response to the

- **Public Consultation Paper – Better regulation of Pharmaceuticals: towards a simpler, clearer and more flexible framework on variations and the Draft Commission Regulation concerning the examination of amendments to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products**

Dear Mr. Rossignol,
Dear Nicolas,

As mentioned already in our first comments last year on the proposal for a review of the Variation Regulation Austria welcomes this Commission initiative, and we want to take the opportunity to comment on the draft proposal.

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

Key Item 1: Purely National Authorisations *(Chapter II)*:

We agreed already within the Public consultation on the "co-decision" part with the concept on a harmonised approach for maintaining a MA independent of the licensing procedure, but with the need to simplify the procedures. Currently we are recognising that there is a reduction of administrative burden for the industry, but not for the national competent authorities. With the implementation of the EU-classification and timelines for variation at national level in Austria we will have additional workload and will need more resources, not only for assessment but also for the administration. We look forward agreeing on more simple practical arrangements, including really simple notification procedures.

Key Item 2: ICH

We welcome this reasonable concept, hopefully it will encourage companies to submit such Type II variations. In addition we only want to mention that even now – without the revision of the Variaiton Regulation – it is already possible for companies to submit a Type II variation for "Design space". The

use of a guideline as tool to align with ICH-develoments is flexible and welcome.

Key Item 3: "Do and Tell procedure":

On the basis of our experience with the selfresponsibility of MAH in selfmanaging certain changes we agree with the "Do & Tell" procedure. The possibility of providing several Type IA variations within a 12-month period as an annual report is also acceptable, but the annual report has to be provided for each Marketing authorisation separatly. We are prepared to discuss a simple procedure for administering the information provided in an annual report, but again – per MA – because currently our whole maintainance system of the dossier for a particular medicinal product is based on an individual update of each dossier. This is also the reason why we are not in favour of grouping of variations.

Key Item 4: Worksharing

We endorse a legal provision for worksharing wholeheartedly as worksharing is an important tool in the future in order to reduce duplication of work and to perform all the necessary assessments. All member states have to participate in this worksharing activities, to trust in the results of the worksharing and implement accordingly. Support by all Heads of Agencies is needed.
But the current proposal for worksharing is rather complex. Already gained experience with current ongoing Worksharing projects should be used and further improved. At EU-level we do not only have experience with the PMF-procedure coordinated by the EMEA, but also some experience with the Paediatric worksharing project – coordinated by the member states at the level of the CMD. Therefore the coordination by EMEA – as proposed in the draft – should be questioned. In any case the assessment work has to be done by the National Competent Authorities.

We are not in line with the principle of "Downgrading", especially not for an Extension. An Extension is a change listed in Annex I and fulfills the relevant conditions laid down therein. This procedure cannot be handeled via a variation procedure within one and the same Marketing Authorisation. An Extension is a new self-standing Marketing Authorisation, which usually is granted with it´s own MA-number additional to the already existing MA.

Key Item 5: Type IB by default:

The principle that a non-classified variation is a minor one and not a major one is fully acceptable, and in line with the current pure national legal provisions of our Austrian legislation. But the whole purpose of "classification procedure" for a non-classified variation at the level of the EMEA has to be questioned. Why should a Marketing Authorisation Holder apply for that?
A non-classified variation is Type IB by default. We have the so called safeguard clause in the legislation, therefore it is possible for NCAs to reclassify a variation.

We would propose that in case there is no agreement between the MAH and the MSs it would make sense to introduce a kind of arbitration procedure at the level of the CMD or EMEA. This would also lead to a consistent interpretation of the Regulation.

Further the possibility for a "volunteer upgrade" of a non-listed variation to a Type II should be provided for a Marketing Authorisation Holder within the legislation. The current proposal of the guideline on the classification on the variations has to be updated in respect of additional mandatory Type II variations. Currently only 5 different possibilities for Type II-Variations are mentioned in the guideline.

Transitional period:

Clear and detailed instructions for the transitional period are missing. As Austria is one of the member states which has to prepare for the switch from the pure national variation procedures to variation

procedures according to the EU-classification and timelines, we are in favour of a longer transitional period – we propose 2 years, especially for Chapter II. Perhaps the timelines can be differentiated according to the different Chapters.
Further an advice is needed whether the time period for unchanged medicinal products – after the variation is granted- can be placed on the market – is to be handeled at pure national level in the national law, or whether their will be a common provision in the Regulation. Currently in Austria for this so called "stock-problem" a transitional period of 12 months is in place.

Grouping of variations:

We are not in favour of grouping of variations as mentioned already, because currently our whole maintainance system of the dossier for a particular medicinal product is based on an individual update of each dossier.
Grouping of variations would lead to an unbearable additional workload for the NCAs and would only facilitate life of the industry. Especially the proposal of a "three-dimensional grouped variation" is not acceptable. Several – even - minor changes to several MAs owned by the same MAH cannot be seen as one variation.
Under certain circumstances we perhaps can agree on certain "two-dimensional grouped variations". For example we can agree that several variations which lead to the revision of the SPC, PL and/or labelling shall be considered as part of the same variation.

Structure of the draft legal proposal:

- Concerning the structure of the draft legal proposal – we are very much in favour to have a single regulatory text, covering changes to all types of marketing authorisations.
- To separate the classification of variations within a guideline, which can be updated much more easily, is acceptable, but the legal status of this guideline has to be clarified. It cannot be possible that this guideline is – like all the other guidelines – soft law, without being legally binding.
  We are fully aware that the guideline as such is currently not part of the public consultation, but we want to raise the general comment, that since the guideline should cover Type IA, IB and II-variations – a lot of work has to be done in order to define Type-II variations.
- Concerning timelines – it has to be guaranteed that the guideline is ready before the Variation Regulation is coming into force. Who will be involved in the elaboration of the guideline? We assume that especially from the BWP a lot of comments on the guideline are expected.
- Concerning the Annexes to the Regulation – we don´t have comments on Annex I – Extensions of MAs, but we do have problems with Annex II - "grouping of variations", as elucidated above. Annex III – we agree with the concept of an annual report, but the concrete content of this Annex III has to be further clarified.

Looking forward to discuss the issue further
Kind regards

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