PHARMIG
Verband der pharmazeutischen Industrie Österreichs

PHARMIG contribution to the European Commission's public consultation paper on

„Better Regulation of Pharmaceuticals: Towards a simpler, clearer and more flexible framework on variations"

PHARMIG, the Association of the Austrian pharmaceutical industry welcomes the European Commission's efforts to invite interested parties to give their opinions on the present public consultation paper "Better Regulation of Pharmaceuticals: Towards a simpler, clearer and more flexible framework on variations".

Regarding the changes to medicinal products ("Variations") as one of the crucial factors in the constant development of the pharmaceutical industry's high tech products, Pharmig considers the present document as a positive attempt to provide a simpler, clearer and more flexible environment for the implementation of variations. However, we regard the below-mentioned annotations as important to be further discussed:

Article 11 and Article 15 (6): Pharmig would prefer to substitute the notion "accordingly" in subparagraph 5, with the relevant article.

Article 12-16: The abbreviation DCP (decentralised procedure) should be added to the headlines of the mentioned articles.

Article 14(3) & Article 15(3): For a better workflow, we would appreciate if the Assessment Report and the Draft Decision would be submitted not only to the other Relevant Authorities, but also to the Marketing Authorisation Holder. This would simplify future acting of the Marketing Authorisation Holder.

Article 16 (1) & Article 16 (2): It is questionable if the procedures stressed in article 16 (1) are not contradictory to "Do & Tell Variations" (art.12). Additionally, it remains unclear what the possibilities of the MAH will be, if such variations have already been implemented and further action has been done by the MAH. Such possibilities are not laid down in article 16 (1). In addition to that, the rather general notion used in article 16 (1) "best endeavour" should be specified.

Article 21 (1) a: As described above (Article 16 (1) and Article 16 (2)) the advantage of "Do & tell Variations" is questionable. A disagreement by a relevant authority might affect a "Do & Tell Variation" already implemented up to 14 months before (time frame as laid down in Article 21 (1) b). In addition, further variations may have been built on that variation which is no in agreement with an authorities´ opinion.

Article 24 (5): Pharmig would appreciate a specification of the notion of "within the period laid down in paragraph 3 …".

Annex III: In the present "Variation Guideline" not only "Conditions" are defined, but also the "Documentation" is defined. In order to provide harmonisation of documentation requirements within the European Community, it seems to be useful to add the requested "documentation" requirements.

Variation No. 2 (Change in the name of the medicinal product): It remains unclear which "relevant authority" is meant. To conduct the change in the name of the medicinal product, a positive decision of the "Trade name authority" is a prerequisite. The provision that the acceptability of the new name by the concerned Member State(s) is finalized and positive contradicts the classification of this variation. In addition the procedure to obtain a positive opinion from a concerned Member State authority is not described and no time lines are given

Variation No. 10 (Minor change in the manufacturing process of the active substance): It is not comprehensible why, as set out in Condition 1, (no change in the qualitative and quantitative impurity profile or in physico-chemical properties) a Variation Type I B is required. We consider a Type IA or a Type IA $_{IN}$ as sufficient.

Ad Public Consultation Paper:

7. Key Item 5: Type IB by default:

- It is necessary to determine the notion "substantial potential" in order to clarify the conditions under which a competent authority may re-classify the submission.
- If several competent authorities are involved, which opinion prevails if divergent views exist?
- What happens, if the competent authority exceeds the 30-days period?

Miscellaneous:

- Guideline Variation No. 13b: Condition 5 is listed, but in fact deleted.
- Guideline Variation No. 38a: Condition 5 is listed, but in fact deleted.