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DANISH MEDICINES AGENCY

The European Commission
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Comments of the Danish Medicines Agency on Strategy to Better Protect Public Health by Strengthening and Rationalising EU Pharmacovigilance: Detailed proposals for legislative changes

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The Danish Medicines Agency welcomes the draft legislative proposal on pharmacovigilance and appreciates the opportunity to comment on it.

The Danish Medicines Agency agrees with the initiative of the Commission to rationalise and strengthen EU pharmacovigilance. Overall, we are supportive of changes to the provisions concerning pharmacovigilance that supports the aim of the initiative.

We believe that the draft legislative proposal presents many interesting and good initiatives and we look forward to further discussions with the Commission and Member States later in the process.

However, the draft legislative proposal needs clarification, including some definitions, and gives rise to some concerns and questions.

A few important comments are set out just below and are followed by a list of other issues that should be considered.

National accountability and responsibility

The Danish Medicines Agency supports the initiatives to create a more efficient and effective pharmacovigilance system for all medicinal products in the EU regardless of their route of authorisation. The improved pharmacovigilance system shall ensure that all relevant data and information are available to all competent authorities and, when relevant and possible, include work sharing and rationalisation.

However, improvement of the pharmacovigilance system should not take place at the cost of national accountability or responsibility. It is important that national competent authorities retain national responsibility in pharmacovigilance and that the pharmacovigilance system does not become anonymous thereby making it difficult for the national competent authorities to communicate with the public.

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Committee on Pharmacovigilance

With regard to the introduction of a new Committee on Pharmacovigilance it could seem that both the CHMP and the Committee on Pharmacovigilance should be responsible for evaluating the benefit-risk balance of medicinal products. It should be clarified that the CHMP is responsible for the evaluation of the benefit-risk balance and good communication between the two committees should be ensured.

The tasks and responsibilities of the new Committee on Pharmacovigilance should be clearly defined to avoid any overlap with those of the CHMP.

Furthermore, we believe that it would be favourable to the system if it would be possible to maintain one body responsible for pharmacovigilance of all medicinal products regardless of the route of authorisation.

Definitions of adverse reactions and abuse of medicinal products

The Danish Medicines Agency would like to raise a question with regard to the proposals to amend the definition of "adverse reaction" and to repeal the definitions of "unexpected adverse reaction" and "abuse of medicinal products" as the current definitions are well founded and internationally accepted. The proposed definition of "adverse reaction" may make it difficult for the public to understand the concept of "adverse reactions" which would impair some of the other initiatives of the draft legislative proposal.

List of intensively monitored medicinal products and new information in the product information

The Danish Medicines Agency has reservations as to the value of the list and the new product information as we are concerned that they may deter some patients from taking the medicinal products.

Furthermore, we are concerned that the new information in the product information could represent a trend to supply more and more information on the safety of the medicinal products than on the efficacy of the products. We wonder if such a trend is desirable.

We would appreciate that those initiatives be further elucidated.

Other issues to be considered

- A definition of medication error is lacking.
- We wonder about the proposal to change the reasons for refusing, suspending etc. a marketing authorisation and for prohibiting the supply for a medicinal product or its withdrawal.
- It could be considered if the Pharmacovigilance System Master File belongs in a framework similar to that of the Good Manufacturing Practice without a direct link to the marketing authorisation.

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- With regard to the non-interventional post-authorisation safety study it seems unclear if the definition of a "non-interventional study" in the Clinical Trials Directive might overlap with this draft proposal. There is a need for a clear distinction between the two directives and for a definition of "non-interventional post-authorisation safety study".
- Clarification is required on the relationship between risk management systems and risk management plans/programmes.
- With regard to the pharmacovigilance inspections, clarification is needed as to inspection and reporting requirements for national competent Authorities and the possibilities for work sharing.
- The scope of the pharmacovigilance referral should be clarified and we question the added value of the public hearing that are part of the process. The US experience with public hearings could inform this issue.
- We support the risk-based approach to PSURs introduced by the draft proposal and the efforts to ensure work sharing of the assessment of PSURs, but we have concerns about the means to achieve them.

We are of course at your disposal, should you wish more detailed comments.

Yours sincerely,

. Jytte Lyngvig

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