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Reasoned opinion from EuropharmForum
Remarks concerning the EU Commission's consultation on pharmacovigilance

1. It must be ensured that a re-structuring of the European directives does not undermine the existing, well-functioning systems of the EU Member States. This is especially important insofar as the role of health professionals – for example pharmacists – is concerned. The consultation does not cover the role of these health professionals in detail, but only mentions them a few times.
   Some Member States possess well-functioning rapid-alert systems and procedures for market withdrawal that include active participation of health professionals and their own pharmacovigilance institutions. This has proven to give an enormous amount of added value to the minimum legal standards envisaged by the European directives.
   It must be ensured that these proven and reliable systems can be operated also under the new conditions. This is also required by the principle of subsidiarity.

2. It must be taken into account that not only new (prescription-only) medicines may show adverse reactions, but also new and existing OTC medicines. Concerning these medicines, pharmacists and their institutions are the most important control instance. **It is important that pharmacovigilance also covers OTC medicines**, but these are currently not sufficiently covered by the consultation text.

3. A specific remark concerning temporary suspensions (p. 29, Annex 1, Chapter 6, Art. 101k): It is very essential that maximum time limits are mandatory to notify competent authorities in those Member States where the medical product in question is also marketed. Experience shows that these notifications are transferred to the EMEA, but not to authorities of other Member States in due course.
   A solution for this could be **re-structuring of the notification process**. The Member State who reports an incident should notify the EMEA, which then would notify the other Member States on its own. It would be important to ensure that these notifications are proceeded without delay, for example by stating exact dates and short time limits.

4. The database to which Art. 123 paragraph 4 relates is currently managed on an annual basis. It would be much more sensible if this **database**, which shall be run by EMEA in the future, **contained updated data on a daily basis** and would also be **accessible for all European members of the pharmacovigilance process**. Moreover, the database should not only cover drugs, which are prohibited, but also drugs whose authorisation is temporarily suspended.