Authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

2001/0252(COD) - 15/11/2019 - Follow-up document

The Commission presents a report on the national and European Medicines Agency experience regarding the list of medicines for human use subject to additional monitoring.

Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and Directive 2001/83/EC on the Community code relating to medicinal products for human use provide the EU legal framework for pharmacovigilance for medicinal products for human use. The provisions on pharmacovigilance were amended in 2010 and 2012.

Additional monitoring

The 2010 revision introduced additional monitoring for certain medicines and a mandatory scope of new biological medicines or those containing a new active substance. The medicines which are subject to additional monitoring are identified by the inclusion of a ‘black symbol’ (a black inverted triangle) in the product information. In 2012, the mandatory scope was extended to include medicines with certain post authorisation obligations.

This report is based on a joint report of the Heads of Medicines Agencies (HMA) and EMA and gives an overview of the experience in the three years after the introduction of the black triangle in 2013.

Main findings

The report noted, *inter alia*, that:

- both more time and more communication are needed to raise the awareness of AM [additional monitoring], as well as the need for adverse drug reaction (ADR) reporting in general. The EMA survey results suggest that knowledge of AM is higher in some groups than others and that these data could be used to target the messaging and intensity of communications;

- the EudraVigilance analysis investigating the effect of additional monitoring status on reporting of ADRs was not conclusive and the known disparate influences on ADR reporting raise doubts as to whether a longer period and larger product sample would enable the detection of an impact of AM on ADR reporting and signal detection, if such an effects exists;

- the inclusion of imposed post authorisation safety study (PASS) as a mandatory trigger for additional monitoring leads to large numbers of established products being included in the list and is of limited value;

- additional monitoring status being at product level combined with the inclusion of imposed PASS as a mandatory trigger for additional monitoring were highlighted as major issues with the additional monitoring concept. This is because of the resulting misunderstanding among patients and health care professionals, due to situations when several products containing the same active substance have different AM status. Most examples of this inconsistency could be resolved by removing imposed PASS as a mandatory trigger of additional monitoring status;

- the Pharmacovigilance Risk Assessment Committee (PRAC) would support reconsideration of the scope of additional monitoring, particularly the mandatory inclusion of products subject to imposed PASS.

Recommendations

On the basis of these findings, the report made the following recommendations.

Recommendation 1

Member States and EMA are encouraged to continue promoting ADR reporting and sharing their experience to further develop best practices.

Recommendation 2

The evidence does not allow a conclusion on the impact of additional monitoring on the reporting or detection of adverse events. It is recommended to continue to monitor the impact to strengthen the evidence base for future review of the scheme.

Recommendation 3

Competent authorities are invited to continue to collect data regarding the implementation of additional monitoring to allow at a later stage further assessment of the understanding of additional monitoring and its impact with respect to medicines with the same active substance, as well as experience concerning medicines with an imposed PASS.