Pharmacovigilance: transparency and efficiency of the system. Regulation

2012/0023(COD) - 12/07/2012 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Linda McAVAN (S&D, UK) on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards pharmacovigilance.

The committee recommends that the European Parliament's position in first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

List of products: the list of products subject to additional monitoring should only include products subject to the most serious conditions and safety concerns, as otherwise the list becomes too long and loses meaning. It should automatically include all new products containing new active substances, as well as all new biosimilars, for the first five years.

Fees: in order to ensure full implementation of the new provisions related to pharmacovigilance the European Medicines Agency must be empowered to charge fees to marketing authorisation holders for the fulfilment of the pharmacovigilance tasks.

Consequently, the Commission should be empowered to adopt a delegated act in order to supplement the provisions in Article 67(3) as regards services provided by the Agency or the coordination group with respect to pharmacovigilance.

The power to adopt the delegated acts shall be conferred on the Commission for a period of 5 years from 1 July 2012. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it.