

## Commission welcomes agreement by Member States on Pharmaceuticals Reform

***Today, the EU Health Ministers reached an agreement with qualified majority on the proposals by the European Commission to modernise the current pharmaceutical legislation in Europe. These proposals consist of a package of proposals for three legislative acts: a Regulation on the European Medicines Evaluation Agency and its marketing authorisation procedure and two Directives on human medicines and on veterinary medicines respectively. Erkki Liikanen, European Commissioner for Enterprise said: "with today's agreement, we have taken an important step towards ensuring that Europe gets a more robust, modern, effective and competitive regulatory framework for pharmaceuticals. Despite the fact that the Member States on some issues did not follow our proposal, this is a well balanced compromise. We are now looking forward to discussing these issues with the European Parliament with a view to hopefully formally adopt this regulatory package by the end of the year."***

At today's meeting of the Health Council, the Member States focused their discussions on two points of particular importance, namely the scope of the mandatory centralised marketing authorisation procedure and the so-called data protection scheme. These two issues have been, from the very beginning of the Council discussions, the more sensitive ones.

Regarding the scope of the mandatory centralised marketing authorisation scheme, the Member States agreed that this should cover medicines for the treatment of cancer, aids, neuro-degenerative diseases and diabetes. In addition, the Member States agreed that the industry would have the choice between the centralised procedure and a de-centralised marketing authorisation procedure (at Member State level coupled with a scheme of mutual recognition) for medicines for other types of diseases. The Commission had initially proposed that all medicines containing new substances would be covered by the centralised procedure.

Erkki Liikanen said: "the reinforcement of the centralised procedure will help speed up the marketing authorisations in Europe. This will mean faster access to market for the pharmaceutical industry and quicker access to newer and better medicines for patients for these types of illnesses. This is a genuine win-win situation."

Regarding the period of data protection for medicines, authorised under the mandatory centralised procedure, the Member States agreed that this should be ten years with the possibility to extend this by one year if the producer can demonstrate that the medicine in question can be used for a new treatment. For medicines authorised under the de-centralised procedure or under the optional centralised procedure, the period would also be ten years with the possibility of generic medicines to launch their application for marketing authorisation two years before the expiry of this ten years period. Erkki Liikanen said: "this agreement represents a good balance between keeping the necessary incentives for innovation in Europe whilst ensuring a better access for Europe's patients to generic medicines".