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

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The committee adopted the report by Rosemarie MÜLLER (PES, D) amending the Council's common position under the 2nd reading of the codecision procedure. It reinstated a number of Parliament's key amendments from 1st reading which had not been incorporated by the Council: - whereas the Council was stipulating that any extension of the centralised authorisation procedure should be the subject of a proposal, to be decided by the Council acting by a qualified majority, MEPs said that the current list of four indications in the annex should be extended automatically four years after the regulation's entry into force so that the centralised authorisation procedure would apply to all new active substances in medicinal products intended for human use; - whereas the Council's common position sought to provide data protection for a longer period for medicines approved under the centralised procedure, the committee said that medicinal products for human use authorised under this procedure should benefit from only an eight-year period of data protection and a ten-year period of marketing protection. Under certain circumstances, this latter period could be extended to a maximum of 11 years (known as the 8 + 2 + 1 compromise); - the Agency's management board should consist of one representative from each Member State, two representatives from the Commission, two representatives from Parliament and two representatives each from patients' and doctors' organisations, whereas the Council wanted only the Member States and the Commission to be represented; - for the purposes of authorising medicinal products for human use, clinical trials carried out in a developing country should not be recognised, unless the product concerned is primarily geared to the domestic market in that country; - the Agency's tasks should include ensuring that patient leaflets are easily readable. The committee also adopted a number of amendments aimed at ensuring the transparency of the Agency's decision-making, by making information publicly accessible. Finally, it called for particular incentives for research into paediatric medicinal products. MEPs said that medicinal products already long established for adult use should be tested for subsequent use by children and the database on medicinal products should also include information about which medicinal products were specifically authorised for children.