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From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a Regulation of the European Parliament and of the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use (Text with EEA relevance) **(first reading)** - Adoption of the legislative act **(LA + S)** = Statements

Statement by the European Commission

In the light of the decision of the Council to significantly decrease the fee income of the European Medicines Agency (EMA) from the fee for pharmacovigilance referrals referred to in Article 6 of the legal proposal on "Fees payable to the European Medicines Agency (EMA) for the conduct of pharmacovigilance activities in respect of medicinal products for human use" (COM(2013) 472 final of 26.6.2013), the EMA will not be able to cover its estimated costs foreseen in the financial statement that accompanied the legal proposal. Therefore, the Commission, in cooperation with the EMA, will re-examine the activities performed and services provided by the EMA in this context, including payments to the delegates of the relevant committees, in order to achieve the necessary cost savings and cater for this estimated lack of revenue.

The Commission notes that the above mentioned Council position is without prejudice to the future review of the EMA fees.

Statement by Germany and Denmark regarding the
Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

Germany and Denmark expressly welcome the announcement of the European Commission to carry out a review of all fees payable to the European Medicines Agency (EMA) as soon as the Regulation on pharmacovigilance fees is adopted. In the context of this review, Germany and Danmark would welcome a task review and an expense evaluation of the EMA in order to achieve the highest possible efficiency of the activities of the EMA.