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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use **(first reading)** - Adoption of the legislative act - Statement

Commission statement

"The Commission recalls its position that when adapting existing Commission empowerments to Article 290 and 291 TFEU it is not an appropriate legislative technique to provide for transitional provisions that would state that Commission acts adopted previously under those empowerments will continue to apply unless and until repealed. In the Commission's view such provisions state the obvious and would not be coherent with other legislative acts and are liable to induce legal uncertainty at a broader level.

The Commission regrets that only part of the existing regulatory procedure with scrutiny empowerments in Directive 2001/83 and Regulation 1901/2006 will be aligned in this instrument, while the rest of the empowerments remain to be aligned in the context of the negotiations on the Omnibus alignment proposal (COM(2016) 799). In the Commission's view the full alignment should have taken place in one of the two instruments."