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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004 **(first reading)** - Adoption of the legislative act = Statement

Statement by Denmark

Denmark supports the proposal on amendments to the Commission proposal for a Regulation of the European Parliament and of the Council laying down transitional rules for the packaging and labelling of veterinary medicinal products authorized in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004. Denmark finds it very important that the issues relating to packaging and labelling are resolved swiftly with transitional measures such as the measures proposed.

However, Denmark is still concerned that Article 106(1) of Regulation 2019/6 could lead to an unintentional increase in the use of antimicrobials in Denmark and would have preferred if the proposal had also addressed this issue. According to paragraph 1 of Article 106, veterinarians are no longer allowed to deviate from the dosage and the duration of treatment stated in the Summary of Product Characteristics (SPC). Denmark is concerned that veterinarians will be forced to use unnecessarily high amounts of antimicrobials by not being allowed to reduce the duration of treatment stated in the Summaries of Product Characteristic (SPC), even when clinical effect can be

achieved by a shorter duration of treatment. An increase in the consumption of antibiotics would be incompatible with the reduction targets in the Farm to Fork-strategy.

The Commission has referred to updating of SPC's as the solution to this issue. However, according to the Danish Medicines Agency it is up to the marketing authorization holder to decide which dosage and duration treatment regime they wish to have covered by the SPC – as long as the safety and efficacy is confirmed by the supporting documentation. Furthermore, if there is evidence to support a need to change the SPC for the above reasons, it is still up to the marketing authorization holder to decide, whether they wish to change the marketing authorization or alternatively deregister the medicinal product, which can lead to supply problems and risk of animal health and welfare. Therefore, until the marketing authorizations have been updated, and for products where the marketing authorizations will not be updated to a sufficient extent, to mitigate these consequences, there is a need for an alternative solution.

Denmark therefore urges the Commission to assist Member States in finding a solution that decreases antibiotic consumption all over the EU.