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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 on veterinary medicinal products and repealing Directive 2001/82/EC **(first reading)** - Adoption of the legislative act - Statements

Statement by the Commission

The new EU Regulation on veterinary medicinal products requires Member States to collect and report data on sales and use of antimicrobials used in animals. The Commission considers this information essential to identify possible risk factors for development and spread of antimicrobial resistance (AMR), monitor trends in antimicrobial consumption, target relevant policy measures and assess their implementation. Although the implementation of this legal requirement is foreseen through a gradual (stepwise) approach, it may require substantial input in terms of administrative, human and financial resources.

The European One Health Action Plan against AMR recognises that in order to deliver long-lasting results and create the necessary impetus, it is important that the EU legislation related to AMR (including, inter alia, on the use of veterinary medicines) is adequately implemented. In this context, the Commission has committed in that Action Plan to engage in supporting Member States in the implementation of EU rules, including by providing technical support through the Structural Reform Support Service (SRSS) for designing and implementing policies against AMR.

Furthermore, the Commission will explore the possibilities for supporting this data collection in Member States in line with its proposals made in the context of the future EU Multiannual Financial Framework.

Statement by the Czech Republic

The Czech Republic can agree that the update of the existing Directive 2001/82/EC would be beneficial in the case of full and reasonable adherence to the objectives and principles as declared by the European Commission prior the beginning of negotiations of the draft regulation on veterinary medicinal products.

The Czech Republic also strongly supports the objective to contain the risks related to antimicrobial resistance. However, the failure of the new legislation to enforce compliance with the EU standards, inter alia, with respect to restricted conditions for use of antimicrobials, by the 3rd countries, weakens significantly the EU political message with respect to commitments to fight against the antimicrobial resistance and in the same time, renders the EU producers uncompetitive with their 3rd countries counterparts. In addition, the required room for flexibility for the Member States to ensure availability of suitable alternatives to antimicrobials in particular on the small markets, and risks related to future availability of old, legacy, veterinary medicinal products, present another key issues related to the new regulation.

The proposal according to the Czech Republic opinion will increase administrative and associated financial burdens both for the public budgets and for private enterprises. It is becoming apparent that the implementation of the regulation will be more costly than originally expected. This new regulation will also decrease the flexibility and - in the consequence – the innovation, what can cause lack of availability of the veterinary medicinal product on the Czech market.

The text also contains apparent mistakes that can have an impact on the safety of consumer.

The Czech Republic regrets to express that via the approval of this regulation we miss the opportunity to meet the principles as were originally declared and intended to be reached.

The Czech Republic therefore keeps the position from the COREPER after the trilogue (June 2018) and abstains from the voting.

Statement by Germany

Deutschland nimmt zu den Artikeln 73 bis 81 in der Textfassung des vorliegenden Dokuments PE-CONS 45/18 wie folgt Stellung:

Das finale Dokument PE-CONS 45/18 zum Vorschlag für eine Verordnung des Europäischen Parlaments und des Rates über Tierarzneimittel stellt grundsätzlich ein ausgewogenes Gesamtergebnis dar, in dem in vielen wichtigen Punkten eine Einigung erzielt werden konnte. Gleichwohl ist Deutschland besorgt, dass bei der Pharmakovigilanz von Tierarzneimitteln der Schwerpunkt auf dem Signalmanagement des Zulassungsinhabers liegt und die derzeit geltenden Regelungen nicht fortgeschrieben werden. Dies betrifft insbesondere

- den Wegfall der periodischen Sicherheitsberichte,

- die Verlängerung der Meldefrist für schwerwiegende unerwünschte Arzneimittelwirkungen und

- die mangelnde Differenzierung im Hinblick auf den Schweregrad bei unerwünschten Arzneimittelwirkungen.

Da jedoch in den Beratungen insgesamt Verbesserungen erreicht wurden, hindern die aus Sicht Deutschlands bestehenden Bedenken nicht die Zustimmung zum finalen Kompromisspapier.