HealthforAnimals Statement on Article 118 of the new EU Veterinary Medicines Legislation

In November 2018, the European Union (EU) passed new veterinary medicines legislation. Article 118 states that prohibitions, restrictions and use limitations for antimicrobials in the EU could also apply to livestock farmers in other countries exporting to the EU. Despite assurances, it is difficult to see how Article 118 could be implemented in a way that complies with World Trade Organization (WTO) rules and does not erect new international trade barriers.

HealthforAnimals supports global, multilateral efforts to reduce the need for antibiotics and combat antimicrobial resistance. Approaches that do not meet WTO rules could undermine these efforts and put international trade at risk. We urge the EU to address the following concerns raised by important stakeholders (see annex for more details). The EU imported over €30 billion in animal products in 2017. Clarity on Article 118 is urgently needed to ensure this smooth, free-flow of trade is not put at risk.

Concerns and questions

1. **WTO compatibility:** One of the core pillars of the WTO SPS Agreement is that a risk assessment must be performed before any trade measure, like Article 118, is put in place. The WTO Appellate body has defined this as a "*process characterized by systematic, disciplined, and objective enquiry and analysis*" and that there is a "*rational or objective relationship between the SPS measure and the scientific evidence."* The EU has not done a risk assessment to evaluate whether/how antimicrobial organisms can spread in the EU through consumption of imported animal products nor whether Article 118 would address it. Questions: Will the EU perform risk assessment on the impact/use of products outside its territory and how will it do this? Will health/agriculture authorities of other countries be involved?

2. **Disease control:** The European Commission, using the advice of its scientific agencies, will create categories of antibiotics and designate if they can be used in the EU in animals. This is appropriate and the prerogative of the EU. Applying these same rules to exporters in third countries is dangerous though. Disease pressures and resistance levels are different in each country. The EU should not take away a nation's ability to decide which antibiotics are appropriate for their producers. This can harm the health of their animals. Question: What happens if the EU decides that a product cannot be used (or used in a certain way) but the national authorities of a third country designate that product essential to limit disease?

3. **Impact on production and trade:** Full application of Article 118 could likely lead to two production streams in non-EU countries – one for export and one for internal consumption. This will increase production costs. Question: Who will carry these costs? Will there be enforcement, inspections, certification, etc.?

4. **International engagement:** There is a lot of uncertainty about Article 118, and most stakeholders are unclear how it could be legally and practically implemented. The Commission has said it will "*proactively engage with non-EU countries to inform them*". Question: Will the engagement happen prior to finalization of implementation measures? What level of detail will be provided and in which organizations?

5. **Undermining global efforts:** The WHO Global Action Plan on AMR states measures to address resistance "*must take into account national and regional priorities.*" Article 118 essentially requires exporters to adopt the EU priorities instead of their own. This undermines trust in important multilateral processes in OIE, Codex, WHO and FAO, and risks AMR becoming a divisive trade issue instead of a global, collaborative effort. Question: How does Article 118 align with the recommended approach by WHO and other IGOs?

Annex 1: External Stakeholder Concerns

Below are questions and concerns that have been raised by governments, veterinarians, farm groups, and others about Article 118 of the new EU veterinary medicine legislation. This shows significant uncertainty about implementation around the world. Engagement and dialogue is urgently needed to ensure the €30 billion in animal products imported into the EU each year is not at risk.

Concerns from Argentina, Australia, Brazil, Canada, Colombia and USA

Argentina, Australia, Brazil, Canada, Colombia and USA, raised questions and concerns about Article 118 in the December 2018 WTO report to the Codex (found here on pages 8-11). Major points include:

- **Argentina**: *"The proposed text…would require exporters of animals and animal products to meet EU standards concerning the use of certain antimicrobial medicinal products, as well as specific usage provisions, as a condition for maintaining access to the EU market, despite the differences in the prevailing sanitary conditions."*
- **Argentina**: *"The European Union would be applying a reciprocity approach that lacked scientific basis, preventing access to the EU market for animal products from third countries where antimicrobial medicinal products were subject to different usage authorization standards"*
- **USA**: *"EU restrictions would require other Members to adopt essentially the same comprehensive EU regulatory programme, without taking into consideration different conditions present in their territories….these restrictions would undermine multilateral efforts to combat AMR "*
- **Canada**: *"Canada expressed concerns that the EU proposed approach would likely have an unnecessary restrictive impact on international trade and that it would undermine the ongoing multilateral efforts to combat [AMR]"*
- **Brazil:** *"Brazil regretted that the European Union had moved forward with a proposal that might prohibit exporting companies to engage in trade with the European Union if their national governments authorized the use of certain veterinary antimicrobial drugs under different conditions than those permitted by the European Union, or if the exporters did not comply with certain EU requirements…It was unclear how the EU proposed legislation would converge with the international criteria for maximum residue levels (MRLs) already established in accordance with a scientific risk assessment."*
- ***Australia: "****The application of risk measures to prevent and reduce AMR should be based on internationally agreed standards and supported by scientific data. Australia also stressed the importance of retaining access to effective antimicrobials to protect animal health and to avoid adverse animal welfare outcomes. Australia strongly discouraged regional and individual countries' efforts to introduce AMR-related risk management measures inconsistent with agreed standards and not supported by science that could distort trade."*

Letter to the Commission – Concerns from trading nations

In July 2018, Politico Europe published a letter that six exporting nations (Argentina, Brazil, Canada, Chile, Japan and the USA) sent to the European Commission outlining concerns about Article 118. Major points include:

- ***"****We are concerned with the likelihood that certain amendments, if adopted, may have a significant impact on international trade,"*
- *"We request that the EU take into account that different regulatory regimes may use different policy levers to achieve similar public policy goals"*
- *"We would also request that the EU consider whether these proposals could lead unintentionally to increase resistance to antimicrobial or impact on the welfare of animals for example if producers were to base decisions regarding antibiotic use on their ability to export to the EU rather than on the best veterinary decision based on specific regional considerations."*
- *"International trade concerns should not dictate the choice of best antimicrobial treatment"*
- *"we would also encourage the EU to consider the negative animal welfare effects that could result"*

Media Reports – Legal questions and veterinary concerns

Legal: Brendan McGivern, an international trade lawyer and former head of dispute settlement at the Canadian Mission to the WTO, published an op-ed in The Hill citing several WTO legal issues with Article 118:

"…This new provision, made under the guise of protecting antibiotics from overuse or misuse, is not supported by scientific evidence, as required by the WTO. ….Like other WTO member governments, the EU has both the right and the responsibility to protect the health of its citizens. However, it must do so within the agreed framework of WTO rules…..The EU cannot apply a blanket presumption prohibiting the importation of animals or animal products from countries where antibiotics are permitted under conditions different from those of the EU. Under the WTO treaty, food safety rules must be based on science rather than presumptions…"

In addition, Mr. McGivern highlighted that the legislation could "*pave the way for new tariffs or other trade rows…sets a legal and trade precedent…and opens the EU to the possibility of a legal challenge in the WTO."*

Veterinary: Dr. Paula Parker, President of the Australian Veterinary Association, published an opinion piece in Euronews, highlighting concerns from Australia veterinarians about the legislation and Article 118:

"…But new EU rules could create unnecessary pressure by insisting that veterinary medicines cannot be used any differently outside of the bloc if farmers want to export their produce to European countries – even if it is legally compliant with their native regulations."

"The bill, …. ignores any regional disease threats or environmental conditions that might require certain nationally-approved treatments. Instead, veterinarians and farmers would be held to EU standards the world over if they wanted to trade with Europe…"

"…Decisions, then, about the health and welfare of Australian animals should not be dictated by Brussels, and farmers and veterinarians should not be put in the position of potentially having to select an inferior therapy to maintain market access…"

"…Not only is it therefore unnecessary for the EU to intervene in the use of veterinary medicines outside of Europe, it is thoroughly counter-productive to global trade and animal wellbeing. It implies that our existing systems are not rigorous enough to satisfy European standards despite offering Australian consumers sufficient levels of food safety…"