



Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

Deputy Director General

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WSAVA Position Statement on Regulatory Harmonisation

Dear Dr Ryan

The World Organisation for Animal Health (OIE) acknowledges and supports the World Small Animal Veterinary Association (WSAVA) Position Statement of July 2019 on Regulatory Harmonisation as in:

"There are recognized regional inequities in the availability of veterinary medicines for both companion and food production animals globally, and this results in differing abilities of the animal health sector to provide appropriate animal care – both preventatively and therapeutically – and negatively impacts on animal welfare. While this is a multi-factorial issue, at the root of availability of licensed veterinary medicines is the regulatory approval process that grants a product market access. Regardless of region and/or country, the regulatory approval processes all have similar outcomes objectives – ensuring the availability of safe, effective veterinary medicines of high and consistent quality. Despite this common goal, the approval process is duplicated in various regions and/or countries, often requiring duplication of data generation even when the data already exists and has been demonstrated to be scientifically sound. This duplication of process often presents an unnecessary regulatory hurdle that undermines broader availability of licensed veterinary medicines and places animal welfare at risk. Regulatory convergence & harmonization between regions and/or countries should be explored and enacted where and if this would not undermine safe and effective veterinary medicines use."

The access to veterinary medicinal products including antimicrobials is of great interest to the OIE Member Countries not only to control animal diseases, but also to ensure animal welfare.

Harmonised regulatory approval processes are key to market access. The OIE is therefore engaged with partners to support harmonisation of approval processes.

The OIE is also strongly committed to supporting its 182 Member Countries in the implementation of the responsible and prudent use standards¹ and the recommendations published in the OIE List of Antimicrobials of Veterinary Importance² on the use of certain human and veterinary important classes.

These elements are critical to improve access and keep veterinary medicines available and efficient.

Your sincerely,

Matthew Stone

Cc: Dr Matthew Stone

¹ https://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_antibio_use.htm;

https://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_antibio_resp_prudent_use.htm

² https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_OIE_List_antimicrobials_July2019.pdf