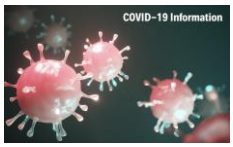

News Flash 10 **14 April 2020**

Recap of recent EU Publications

1. **Regulatory guidance for human medicines: EMA - Commission Q&A (10 April)**

The European Commission, EMA and the European medicines regulatory network have developed a question and answer guidance document on regulatory expectations for medicinal products for human use during the COVID-19 pandemic: https://www.ema.europa.eu/en/news/guidance-regulatory-requirements-context-covid-19-pandemic.

It includes information on legal and regulatory guidance on 1/ MAs/MAs procedures, 2/ manufacturing and importation of Finish Product and Active pharmaceutical ingredients with an Exceptional Change Management Process (ECMP) being introduced, 3/ quality variations and 4 / product information and labelling.

This document is a living document which will be updated, as required. The need for any further updates, will need to be prioritised on the basis of public needs.

2. **Supply Guidance: Commission Guidelines (8 April)**

European Commission adopted supply guidelines to protect public health and preserve the integrity of the single market, whilst ensuring that Europe has the supply of affordable medicines it needs during the COVID-19 outbreak. They focus on the rational supply, allocation and use of medicines to treat COVID-19 patients. They also cover any medicine at risk of shortage due to the COVID-19 pandemic. The guidelines are addressed to the EU Member States

A special section is dedicated to vet meds ensuring they will be used in a controlled manner and in full cooperation with competent national authorities:

> *e. Considering the use of magistral preparations or veterinary medicines*
> Magistral preparations should be used to replace unavailable medicines. In case of critical shortages of essential authorised human medicines, using equivalent medicines (the same active substance, strength and pharmaceutical form) authorised for veterinary use should also be considered. Substitution should always be carefully assessed and authorised by the appropriate national authority taking into account the possible specificities of the veterinary sector. Special attention should be given to ensure appropriate dosing and additional reporting of adverse reactions. Where regular sources are exhausted, essential medicines should be allowed to be sourced outside the EU/EEA under the supervision of national authorities or the European Medicines Agency.

3. **Covid-19 and food: Commission Q&A (8 April)**

DG Santé published a new Q&A on Coivd-19 and food. For the time being in English only. Reminder: EFSA's statement is that there is no evidence that food is a soured or a transmission route.