MUMS Medicinal Products; Availability and Market Share Expansion

For the veterinary medicines industry, it can be attractive to expand the market for any veterinary medicinal product to include sectors of minor use and minor species; the so-called MUMS. For the veterinary practitioner and the animal owners, increased availability of approved medicines makes a lot of sense in daily life with alleviating animal diseases. If there is an approved product for the indication in the specific species, off-label use of other products is not allowed, which logically directs the user to the correctly authorised medicines.

In the EU, the EMA's MUMS policy seeks to improve the availability of veterinary medicinal products and to minimise the implications for animal welfare and for public health from the lack of veterinary medicines. A MUMS policy has been in place since September 2009, intending to stimulate the development of new veterinary medicines for minor species and for rare diseases in major species that would otherwise not be developed in the current market conditions. The availability of safe and effective veterinary medicinal products for MUMS/limited market is expected to improve animal welfare, animal health and, in some cases, public health. The regulatory network provides two types of assistance for products indicated for MUMS/limited market: reduced data requirements, and financial incentives for applications. Currently the legal basis is EU Regulation 726/2004, art. 79, which is not very firm, but with the new EU Regulation on veterinary medicines, which will likely come into force in 2022, the legal base for MUMS-products and incentives will be much more solid.

The classification as MUMS can be given to any product, irrespective of the intended route of licensing, and the benefits for the applicants comprise certain reduced data requirements for product authorisation or extension and for MRLs, financial incentives under specific conditions, and a greater level of advice and assistance from the regulatory system.

Which veterinary medicinal products can be classified as MUMS? A minor species has nothing to do with the size of the animal, but with the size of the market sector for this species. In other words, minor species are all animal species except: cattle, sheep (meat animals), pigs, chickens (including laying hens) and salmon, which are the major species. However, there are situations where products may be indicated for a minor species, but the market is not considered limited, e.g. anthelmintic products for horses.

A minor use is defined as a treatment or prevention of diseases that occur infrequently or in limited geographical areas, i.e. a smaller market sector, typically in a major species. In the EU, the CVMP in EMA decides the classification using a case-by-case approach after application, i.e. with no fixed cut-off limits, which is different from the MUMS designation in the USA, where the applicant must justify an expected low number of treated animals. In the EU, the applicant is asked to clarify the prevalence of the disease or condition in the EU, including the geographical distribution, and to specify if other products or treatments already exist for this disease or condition. In addition, an estimate of the market size or return on investment is requested. There is no fee for a MUMS classification.

The opportunities for reduced data requirements compared to the standard dossier are described in new updated guidelines from November 2017 and concern quality, safety and residues, efficacy, and immunologicals. The extent of data reduction depends on the nature of the

Product description/ATCvet name	Target species	Classification (reclassification) / financial incentives	Date
Immunological	Sheep	MUMS/no	6/02/2017 / 12/04/2017
Genito urinary system and sex hormones	Rabbits (does)	MUMS/no	16/03/2017
Immunological	Rabbits	MUMS/no	16/03/2017
Cardiovascular system	Cats	not MUMS	16/02/2017
Alimentary tract and metabolism	Horses	MUMS/no	16/02/2017
Cardiovascular system	Dogs	MUMS/no	19/01/2017
Cardiovascular system	Cats	MUMS/yes	19/01/2017
Immunological	Sea Bass	MUMS/yes	19/01/2017
Immunological	Sea Bass	MUMS/no	19/01/2017
Immunological	Horses	MUMS/no	19/01/2017
Cardiovascular system	Dogs	MUMS/no	19/01/2017
Antiparasitic products, insecticides and repellents	Dogs	MUMS/no	08/12/2016
Immunological	Dogs	MUMS/no	10/11/2016
Cardiovascular system	Cats	MUMS/no	10/11/2016

product and the indication. There is obviously more scope for reductions if the product is already authorised for a major species or belongs to a well-known class of substances. In contrast, reductions will most likely be limited for new or novel therapeutic products or a first-in-class authorisation for a veterinary medicine.

For maximum residue limits, new rules of extrapolation of MRL-values from major to minor species and between certain foodstuffs give very good support to the applicant to expand the usefulness of any existing product with a very small effort. Sometimes requiring neither data, nor fee!

For products with indications for food-producing animals and where no alternative product is authorised, options for financial incentives, e.g. reduced fees for centralised applications, extension dossiers, and scientific advice. When a product receives a MUMS classification, limited information is published on the EMA website, e.g. pharmaceutical or immunological, species concerned, and the therapeutic field. A MUMS status is valid for five years and renewable.

One of the most valuable incentives for small or inexperienced applicants is the greater level of advice and assistance provided by the regulators. If a company is registered as a SME (small and medium-sized enterprise) and develops an innovative MUMS product for food-producing species, scientific advice can be given by CVMP completely free. This and other opportunities, e.g. for meeting with the EMA project manager, for very early consultation with the innovation task force in EMA, etc., show the willingness from the authorities to play their part in improving the availability of veterinary medicines for animals in the EU.

In the USA, there is also a MUMS scheme in operation with the intention to ease the way for products that would otherwise not be developed. The system is slightly different and uses other parameters than the EU system, but once you have a MUMS designation, a request for a fee waiver or reduction can be sent to the FDA. This may reduce the heavy burden of the normal annual fee, which can be around 75,000 USD. In addition, the product may obtain exclusive marketing rights for a period of seven years after approval.

Both for large and experienced companies and for smaller, newly established companies, the option to expand an existing product from a major species to one or more minor species could be a very useful exercise, reaching out for new parts of the market and new customers. But also for specific products aimed only at a minor species or a minor indication in a major species, a MUMS classification could be useful – and not prohibitive in resource demands – for business development, and of course for animal health and welfare.

Extrapolation from major to minor species:

Category	Existing MRLs	Extrapolation to
Ruminant	Cattle (meat)	All other ruminants (meat) except sheep
	Sheep (meat)	All other ruminants (meat) except cattle
	Cattle and sheep (meat)	All ruminants (meat)
	Cattle milk	All ruminant milk
Monogastric	Pigs	All monogastric mammals
Birds	Chicken and eggs	Poultry and poultry eggs
Fish	Salmonidae	All fin fish
Other	Either cattle, sheep or pigs	Horses, rabbits
	If identical MRL in ruminants and monogastrics	All mammals
	If identical MRLs in cattle (or sheep), pigs and chicken	All food producing animals (except fish)

Extrapolation of MRL from major to minor species

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