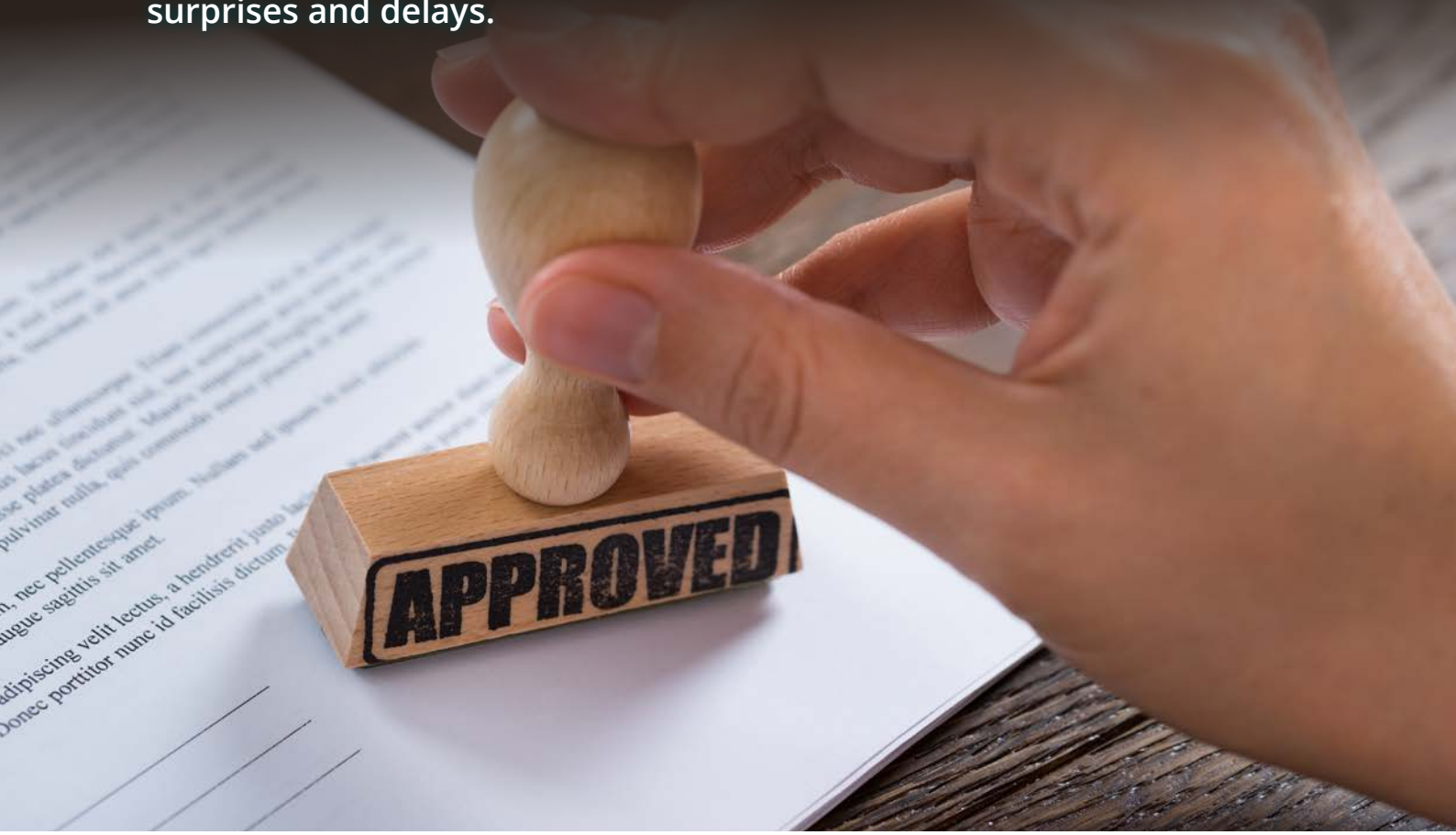
ANIMAL HEALTH INVESTMENT Europe

Expert Insight: Key EU regulatory considerations for the early stages of development of innovative products

Moving from a scientific development to an authorised product ready for marketing requires skills, hard work and good regulatory advice. Very early in the process, you should consider the regulatory aspects of your future product to avoid unpleasant surprises and delays.



Produced in collaboration with: Cyton Biosciences a knoell company · Central VetPharma CONSULTANCY

Questions and Answers

IS THE PRODUCT CLASSIFIED AS A MEDICINE, A FEED ADDITIVE OR SOMETHING ELSE?

There are marked differences between veterinary medicinal products, biocides, and feed additives in terms of data requirements, authorisation procedures, manufacturing requirements, and distribution categories.

In the EU legislation, a veterinary medicinal product (VMP) is defined by claim or by function as any substance presented for treating or preventing disease in animals; or any substance which may be used in animals to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis. In contrast, feed additives are products used in animal nutrition for purposes of improving the quality of feed and the quality of food from animal origin, or to improve the animals' performance and health. Biocidal products have their own EU regulation, while medical devices for veterinary use are not included in the EU legislation and hence have no requirement for CE-marking.

Information on borderline products can be found on CMDv's website for the Borderline Working Group (hma.eu>Veterinary Medicines>CMDv>About CMDv>Working Groups>Borderline).

WHICH AUTHORITY TO CONTACT?

In the EU, the applicant must choose one of four routes leading to a marketing authorization for a VMP. The Centralised route includes all member states and the procedure is coordinated by the European Medicines Agency (EMA). This route is mandatory for VMPs that are developed by certain biotechnological processes, e.g. recombinant DNA technology, controlled expression of genes coding for biologically active proteins, hybridoma and monoclonal antibody methods, and for VMPs that are performance enhancers. Novel or innovative VMPs are also accepted in the centralised route, but this is optional, not mandatory. The other routes are led by a National Competent Authority (NCA) chosen by the Applicant, and include those other EU-member states that the Applicant wishes to include. These routes are mandatory for VMPs containing older active substances, i.e. approved before 2004 in EU, but they can also be used for new or novel VMPs. Most NCAs and EMA are willing to advise Applicants prior to submission of an application.

WILL MRLS NEED TO BE ESTABLISHED?

If your product is intended for a food-producing animal species, all ingredients must be evaluated for food safety. Maximum Residue Limits (MRLs) are established for active ingredients and pharmacologically active excipients, but active substances of immunologicals (e.g. vaccine) are exempted. The MRL-application is submitted to EMA and contains a large amount of data. Already established MRLs can be freely used by everybody and are found in table 1 (allowed substances) of the annex to Commission Regulation (EU) No 37/2010. Be aware that many MRLs are only valid for some animal species and may contain other restrictions that must be obeyed, or the Applicant must seek to extend the MRL. For non-pharmacologically active excipients, there is also a possibility to apply for an "Out-of-Scope" status to avoid the costly MRL application.

Questions and Answers

IS THERE EXISTING GUIDANCE FOR THE PRODUCT TYPE – WHERE TO FIND GUIDANCE DOCUMENTS?

Scientific and regulatory guidelines for VMPs are published on EMA's website and comprise guidance for the quality, safety, residues, efficacy, immunologicals, and novel veterinary medicines. In addition, "globally" applicable guidelines are issued by the V-ICH, and these guidelines are fully applicable in the EU. For very novel products, the ADVENT group in EMA publishes specific items for discussion e.g. related to monoclonal antibodies. Sometimes guidance on a specific topic exists on the human side, which may be used as a frame for the development, but regulatory advice is often needed to adjust the requirements to the veterinary side. To the extent that the European Pharmacopoeia contains monographs that are relevant for the product, these must also be taken into consideration.

WILL IT NEED ITF CONSULTATION?

The Innovation Task Force (ITF) in EMA draws on the scientific expertise of all NCAs and EMA and offers briefing meetings, free of charge, where scientific, technical and regulatory issues can be discussed informally. It encourages future Applicants, particularly those which are SMEs or are within academia, to engage with the regulators early on to assist both the innovators in finding the appropriate road to market, and to flag to the EU regulatory network what regulatory challenges are emerging with the development of new technologies. Only truly novel and innovative ideas/approaches will be accepted for an ITF meeting.

WILL MUMS CLASSIFICATION APPLY?

MUMS means Minor Use Minor Species, and it refers to a number of incentives for VMPs for treatment of minor animal species and uncommon diseases in major animal species in order to increase the availability of authorised veterinary medicines in EU. The Minor Species are all species other than the major ones; cattle, swine, sheep, chicken, dogs, cats, and salmon. Minor Use in a major species is when a VMP addresses an indication for treatment of diseases that occur infrequently or occur in limited geographical areas. The incentives can be both financial, e.g. fee reductions, or a reduction in the data requirements, e.g. fewer or smaller studies needed in the dossier. The request for classification as MUMS is sent to EMA free of charge. The actual data reduction is case-by-case and early regulatory advice or consultancy is an advantage.

Questions and Answers

IS THE COMPANY AN SME?

In the EU, several incentives are put in place to encourage the innovation coming from Small and Medium-sized Enterprises (SMEs). In the VMP field, free scientific advice can be obtained by EMA, assistance with dossier structure, translations, reduced and delayed fees, increased Agency support and other very beneficial measures are available for SMEs. The application for SME-status contains information on internal structure, ownership and financial situation of the company, and is free of charge.

IS YOUR PRODUCT A GMO?

For Genetically Modified Organisms (GMOs) in the EU, there are additional requirements for handling, testing, and for marketing authorisation procedures in particular for the environmental safety of the product. The GMOs must be handled under the legislation for either "contained use" or "deliberate release" prior to a marketing authorisation. During the marketing authorisation procedure, the environmental agencies of EU are involved in the assessment. All GMOs must be authorised via the centralised route and specific data are required in the application dossier.

About our collaborators:

Cyton Biosciences
a knoell company

Cyton is a full-service consultancy providing specialist multi-disciplinary technical expertise in quality, safety and efficacy, as well as regulatory affairs, for the animal health industry. Our broad client base gives us a wealth of varied experience and an appreciation of every client's uniqueness. Whether your product is a pharmaceutical, an immunological or a novel therapy that does not fit within the current regulatory framework, Cyton has the experience with innovative products to negotiate any regulatory challenges.

Central VetPharma CONSULTANCY

Central VetPharma Consultancy is led by Anja Holm, the former chair of EMA's veterinary committee, CVMP, from 2010 - 2016. She provides in-depth scientific and regulatory advice to companies developing veterinary medicines for the European market. Benefit from 20 years of inside experience with regulatory authorities, marketing applications, scientific advice, maximum residue limits (MRLs), use of scientific guidelines, and the EU legislation.