Cyton Biosciences

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Bringing a Veterinary Drug from the USA to Europe:

Key Considerations

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At Cyton, we frequently work with companies who have products that are either in development for, or are already sold in markets outside Europe. Where companies wish additionally to obtain registrations in Europe, there are key areas where the approach and considerations are quite different to those in the USA. Here is a brief outline of some of them.

Regional Harmonisation and the European Union

- In Europe, all countries which are members of the European Union (EU) – the EU Member States – are regulated by the same laws for veterinary drugs, and the EU includes the biggest markets of Europe, such as Germany, France and Spain.
- At the time of writing this checklist, there are 28 EU Member States, but this number changes over time; soon there will be 27, when the UK leaves the EU in what has become known as "Brexit" (more information about Brexit can be found here).
- The laws governing VMPs in the EU also apply to the EEA countries, which include several smaller countries in Europe that are not full members of the EU.
- Critically, those countries in Europe which are not in the EU or EEA, such as Switzerland, Turkey and, following Brexit, the UK, are governed by different laws and the requirements for veterinary drug registration may be different.

Terminology

- What is termed a veterinary drug in the USA is correctly referred to as a Veterinary Medicinal Product (VMP) in the EU
- Some animal health products which are not classified as veterinary drugs in the USA are classified as VMPs in the EU:
    - Veterinary biologics are regulated by the United States Department of Agriculture (USDA) but are regulated as medicines (VMPs) in the EU
    - Pesticide products which are applied to animals, such as flea and tick spot-ons, are regulated by the Environmental Protection Agency (EPA) in the USA, whereas they are treated as medicines (VMPs) in the EU
- Conversely, there are some US veterinary drugs, such as certain anticoccidials, which are termed "feed additives" in the EU and are regulated in a different way to other veterinary drugs.

Strategy

- Define this: what will be your authorisation route – MRP, DCP, NP, CP?
    - A National Procedure (NP) is an application to one country only for a single MA. It is not possible to make more than one national application for the same product in the EU;

  - A Decentralised Procedure (DCP) involves several countries, where one 'takes the lead' in the dossier assessment and management of the procedure. This results in separate Marketing Authorisations (MAs – product licences) which are nevertheless legally linked;
  - A Mutual Recognition Procedure (MRP) is similar to a DCP, involving several countries and resulting in separate MAs, but an MRP requires an existing product, already approved in the EU through a NP;
  - A Centralised Procedure (CP) goes through the European Medicines Agency (EMA) and results in one Marketing Authorisation (product licence) valid in all Member States of the EU. Not all products are eligible to use the CP.
- Does the route depend on your target market, or on the nature of your product?
- You may not have a choice (e.g. GMOs, DNA vaccines….)
- Check if the agency you've chosen has capacity when you need to submit.
- Will any meeting with the authority be involved? If a novel product, is a meeting with a separate working group required - e.g. Innovation Task Force (ITF)?
- If studies involving GMOs to be undertaken in EU, this is overseen and regulated separately: account for this.

The Dossier

- Veterinary dossiers follow a different format to human dossiers in the EU (not CTD)
- The section numbers and contents are different to those used in a US dossier
- The dossier should be complete at time of submission!
- There is no possibility of phased submission
  - No possibility of re-submitting sections repeatedly until the authority accepts them
  - Questions and responses are at set points in the review timetable
  - There may not be a possibility to extend as long as you need if your data aren't adequate
  - Make sure your technical personnel will be available when the questions need to be answered!
  - If the reviewers disagree and there is a referral, do you have the data and strategy to defend your product at an Oral Explanation / oral hearing?
- Data requirements are different in a variety of ways - consider a dossier gap analysis.
- Don't assume your pivotal studies will be accepted in the EU even if they are accepted in the US. If possible, get Scientific Advice in early stages when access to US and EU markets.

For food-producing species

- Does the product have or need an established Maximum Residue Limit (MRL)
  - for your target species?
- Will you need to carry out an Environmental Impact Assessment (EIA / ERA)?

Pharmacovigilance (PV)

- The requirements for monitoring and reporting adverse events associated with veterinary drugs in the EU are more stringent than in the US

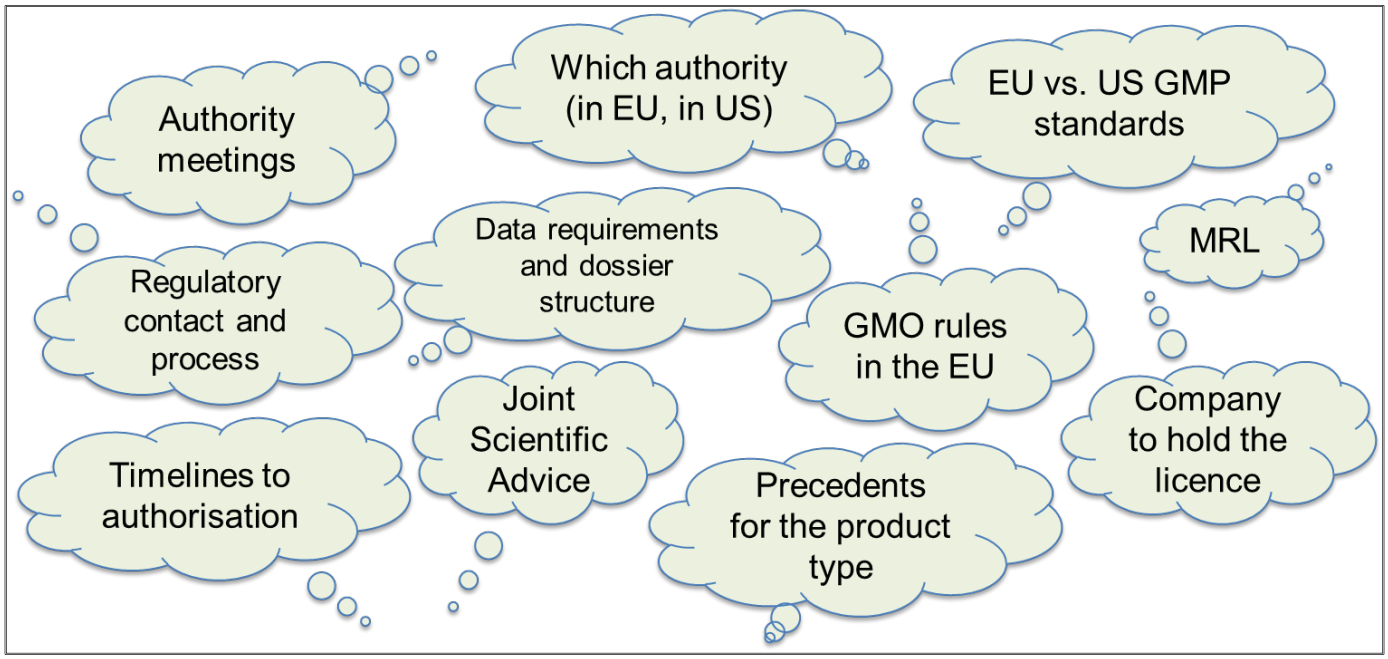
- The systems in place at a company for PV must be accepted by the regulators before a marketing authorisation is approved in the EU.
- The Qualified Person for Pharmacovigilance (QPPV) must be located in the EU (for more information on Cyton's PV services, follow this link)
- Inspections of the PV system take place after a company has placed a product on the market in the EU

Packaging

- Have you thought about how you will manage your product's livery with multiple languages?
- There may be other national requirements by Member State: safety warnings, symbols, etc.
- Can your target markets be split into logical 'regions'?

Other issues

- Manufacturing sites located outside of the EU need to have GMP certification by an EU Competent Authority
- Are there similar products already on the EU market?
- The EU may not see your product as necessary (applies especially if there are any safety issues, and/or alternatives already marketed)
- Could you submit a reduced data package in accordance with the Minor Use, Minor Species (MUMS) initiative?
    - You may be able to get an assessment fee reduction, for MUMS or as a Small or Medium-sized Enterprise (SME).



We are always happy to talk to potential clients about their projects. Feel free to contact us via enquiries@cyton.com, or call our main office number at +44(0)117 973 9036.