Regulation of veterinary medicinal products within the European Union is based on harmonised legislation established at European Community level. This legislative framework covers the manufacture, authorisation (also referred to as registration or licensing), placing on the market and subsequent monitoring and maintenance of products throughout their lifecycle.

Regulation is operated by means of a European Medicines Regulatory Network that includes both national regulatory authorities, the European Medicines Agency (EMEA) and the European Commission. The system operates on the principle of subsidiarity whereby national authorities retain competence for those products that they authorise on a national basis but pool competence for those products authorised by the Commission at community level or when an authorisation is mutually recognised in more than one Member State.

EU Legislation defines in Directive 2001/82/EC, as amended, a set of common standards that a medicinal product must meet before it can be sold in the Community, irrespective of the way in which the product is brought to market. The legislation offers a choice of routes to authorisation, depending in part on the type of product (novel, biotech, generic etc.) and in part on the wishes of the applicant in terms of the geographical extent of the target market (national, regional, Community). This leads to a regulatory system based on harmonised standards that is flexible, but also complex.

The legislation requires a manufacturing authorisation certifying that the product is manufactured in compliance with Good Manufacturing Practice (GMP) and a marketing authorisation to place the product on the market. Following authorisation, products are monitored by a combination of pharmacovigilance (monitoring adverse drug reactions), sampling and testing of products on the market, and regular inspections of manufacturing sites. The regulatory network has now operated for over 20 years. The presentation will review the lessons learnt in terms of how to maximise the benefit from a networking model and how these lessons might be useful for the future development of medicines regulation in other regions of the world.