



The third TOPRA Annual Veterinary Symposium looked at challenges across a range of veterinary-related topics, including urgent disease threats in the EU, the harmonisation of data requirements, consumer and environmental safety and data protection, and projects under review to improve the regulatory framework

# The 3rd TOPRA Annual **Veterinary** **Symposium** 2008

*Reviewed by Rick Clayton, Technical Director, IFAH-Europe*

In October 2008, delegates from the industry and regulatory authorities gathered in Budapest, Hungary, to hear the latest developments related to the regulatory control of veterinary medicines. Of particular interest, in view of the risks to society posed by avian influenza and blue tongue disease in ruminants, was how the system can help address urgent animal disease threats in the EU.

The symposium was opened by **Gábor Kulcsár**, recently appointed head of the **Directorate of Veterinary Medicinal Products** in Hungary. In his opening remarks Dr Kulcsár noted the potential effect of European legislation on local manufacturers since the accession of Hungary to the EU, and the pragmatic approach taken by the Hungarian authorities to avoid essential medicines being withdrawn from the market.

A key topic for discussion within the regulatory world is how the European regulatory network, comprising the national agencies and the EMEA, will adapt and restructure to face the future challenges. Therefore the opening key-note presentation was eagerly anticipated, as it discussed 'Challenges identified by the Heads of Medicines Agencies Strategy document and how they are being addressed', delivered by **Patrick Dehaumont**, head of the **French National Agency for Veterinary Medicinal Products**, in his capacity as co-chair of the Heads of Medicines Agencies Benchmarking Working Group.

The first session of the symposium, chaired by **Declan O'Brien**, Managing Director of IFAH-Europe and Chairman of the **European Technology Platform for Global Animal Health**, addressed the question of urgent disease threats in the EU. Declan introduced two speakers to tackle this topic. Firstly, **Klaus Depner** from the **Health and Consumer Directorate of the European Commission** reviewed how DG SANCO was approaching the policy challenges of preparing Europe against disease threats. Control relies on eradication of the disease and in recent years policymakers have placed an increased emphasis on vaccination as an important part of any disease control strategy.

Secondly, **David Mackay**, head of the **EMEA Veterinary Medicines and Inspection Unit**, examined the role of the EMEA in the Community Animal Health Policy and what it could do to help respond to these urgent disease threats. Of particular interest were the major transboundary diseases of foot-and-mouth,



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Avian influenza and Bluetongue. He noted that the current situation for authorisation of epizootic vaccines is not optimal for industry, regulators or Chief Veterinary Officers, and the EMEA had made some proposals to improve the situation in the short term. However in the long term a review of the veterinary legislation is needed. He stressed that the ultimate success of the measures proposed will require the engagement of all stakeholders.

The second session of the symposium, chaired by David Mackay, examined two topics concerning the gradual evolution of harmonised data requirements in the EU. The evolution of the data requirements via the much anticipated release of a revised Annex I to Directive 2001/82 as amended was critically appraised by **Raymond Harding** of **Cyton Biosciences**. Then the arbitration and referrals procedure, seen as a main driver to forced harmonisation, was reviewed from two perspectives; firstly **Esther Werner**, chair of the **Committee for mutual recognition and decentralised procedures**, described the progress made by this committee in resolving objections from member states during the mutual recognition and decentralised procedures. Secondly, **Melanie Leivers**, from the **EMEA**, reviewed the experience gained from referrals to the CVMP, and the precedents and principles these scientific opinions had set.

Turning to the area of safety issues, two hot topics were included in the third session. Of great interest to the veterinary medicines sector is the progress through the European Co-decision procedure of a new Regulation to govern the establishment of maximum residue limits for veterinary medicines. The symposium audience were delighted to receive an update from the main architect of the draft Regulation within the **Enterprise and Industry Directorate of the European Commission, Martin Terberger**. He reported that the European Parliament's first reading had been completed in June 2008, and that the Council was now working towards a common

position. The European institutions were engaging in tripartite discussions to ensure the co-decision procedure is completed as quickly as possible, and within the current parliamentary term. A more candid view of the co-decision procedure was then given by **Rick Clayton**, Technical Director of **IFAH-Europe**. He explained the timelines of the procedure and examined some of the critical amendments proposed by the European Parliament, and how these were managed.

The second hot topic in the safety arena is the question of environmental risk assessments, particularly for generic products. The current legal interpretation of the veterinary Directive on this point, and the current guidance to applicants, was presented by **Kornelia Grein**, Head of **Sector for Safety** within the veterinary unit of the **EMEA**. This was followed by a panel discussion looking at the implications for the protection of data generated by applicants. **Irene Antypas**, from the Brussels law firm **Ashurst**, was invited to join this panel to respond to questions of legal interpretation.

The final session of the day looked at two important initiatives aimed at improving the regulatory environment for veterinary medicinal products. The first initiative is a joint project between IFAH-Europe and the CMDv to look at ways of rationalising the packaging and labelling requirements, and of maximising the opportunities within the legislation, to improve the availability of veterinary medicines in small markets. The topic was introduced by **Veena Singh**, **Pfizer Animal Health**, who described the main proposals that had been developed and the background behind them. **Christophe Debruyne**, of **Belgium's Federal Agency for medicines and health**, followed this with a review of the main areas where Member States found agreement, and the main contentious areas of the proposals.

The symposium concluded with an update from Melanie Leivers, EMEA, on the review of the variation's Regulations.