HPRA Veterinary Medicines Information Day, 13 June 2018

Meeting Report: Pascale Canning, Regulatory & Communications Executive, Cyton Biosciences Ltd

Last week's HPRA Veterinary Information Day provided an opportunity for stakeholders from diverse backgrounds to catch up in a relaxed atmosphere with, amongst other topics, recent developments in the HPRA's internal work, news and interpretations from the latest draft of the new veterinary regulation for the EU, and of course some insights to the Brexit process - with an Irish perspective.

The first session dealt with the new veterinary regulation (NVR), and included presentations by professionals from the Irish Department of Agriculture, Food and the Marine (DAFM) as well as HPRA colleagues. There was an interesting overview of the rationale behind the review of Directive 2001/82/EC, having been carried out with four key criteria in mind: protection of human and animal health, functioning of the single market, availability of medicines, and reduction of administrative burden. It seems as though, after the best part of a decade in the making, the end is now in sight for agreement on the new Regulation, which will bring noticeable changes to the regulatory work within companies and the competent authorities. In terms of veterinary practice, further restrictions on the use of antimicrobials are foreseen, whereas changes to the cascade system will give veterinarians better ability to source appropriate treatments if there is no immediately applicable authorised product available. Regulatory burden is likely to be reduced in some areas: for example the requirement for MA renewals has been removed unless safety issues are identified, and PSURs will soon become a thing of the past. The new regulation also includes an article relating to internet retailing of veterinary medicines, which until now has not been addressed in the EU legislation.

Session 2, relating to Brexit preparedness opened with some statistics pointing to the importance of Ireland as a key regulatory authority for taking on Community procedures work which can no longer be processed by the UK VMD (over 25% of the RMS-ships already transferred from the UK were received by Ireland). HPRA availability to act as RMS in new procedures over the coming months was also highlighted. The subsequent presentation highlighted the complexity of medicines supply chains and batch release arrangements, particularly for operations working across the UK and Ireland, with some clarifications and FAQs. The issue of joint labelling for products on the UK and Irish markets was also addressed, with some reassurance that the HPRA will aim to be as pragmatic as possible on this issue, to the benefit of MAH / manufacturer companies and consumers alike.

In the afternoon, the third session looked at performance indicators for the HPRA - which, happily, pointed towards a broadly satisfied public. Hiccups resulting from implementation of a new IT system at the agency were notable in the statistics presented on meeting timelines for the various procedures, but following the IT implementation, the HPRA's performance has recovered to its previous standard. There was an overview of the HPRA's strategic plan to 2020, with some detail of how this translates into everyday actions at the agency, and a review of how the aims are being and will be met. The final session 3 presentation looked at placing clinical trials in Ireland and the administrative processes and costs involved in this.

The last session was a mix of topics, including: the review of Annex 1 of the EU GMP Guidelines for Medicinal Products for Human and Veterinary Use (referring to sterile products) and the changes that can be expected as a result when the new Annex 1 comes into force; an insight into pharmacovigilance inspections as carried out by the HPRA, and what can be expected from them; and a review of statistics relating to veterinary antimicrobial use in Ireland. Overall, the day was an opportunity to take in key messages relating to important regulatory changes that are on the horizon, together with an informative overview of how the HPRA engages with stakeholders in specific areas of its official remit.

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