Europe

Flexicam comments

EU legal expert Elisabethann Wright, of law firm Hogan & Hartson, spoke on generic authorizations at Animal Pharm's generics conference in Amsterdam. Commenting on the recent EC approval of Omnipharm's Flexicam (meloxicam), she says:

"The EC recently granted the first central authorization of a generic veterinary medicinal product to Omnipharm's Flexicam, a generic of the Boehringer Ingelheim product Metacam, after a positive CVMP opinion in February (Animal Pharm No 584, p 6).

"The effect of the authorization of Flexicam was to deprive Metacam of part of the 10-year protection period which the European Medicines Agency (EMEA) regulation provides for centrally authorized products.

"However, the commission apparently based its calculation of the protection period to which Metacam was entitled, not on the period granted under the EMEA regulation, but rather on a period linked to a previous national authorization.

"There is no reference in the original EMEA regulation to approval of generic products according to the centralized procedure. The new EMEA regulation permits approval of generic versions of products 'authorized by the community' by the competent national authorities of the EU Member States.

"In the absence of any specific guidance from the regulation, the commission appears to have adopted the approach that it had the power to centrally authorize a product on the basis of a previous national authorization, rather than on the basis of an authorization previously granted in accordance with the centralized procedure.

"If, in the present case, the 1.5 mg oral suspension for dogs was previously approved at national level this may, or may not, have been justifiable. If it was not then the commission's approach raises questions as to its perception of what is covered by a global authorization.

"Moreover, if the commission were permitted to approve generics on the basis of prior national authorizations, the question arises as to whether it considers itself entitled to approve the same products that competent national authorities can approve provided they are generic products.

"Nothing in the EMEA regulation permits the commission to reduce the 10-year protection period that is granted to a centrally authorized product, such as Metacam. However, this is the effect of the commission's approach in the present case.

"If this constitutes a policy decision on the part of the commission as regards future applications for approval of generic versions of centrally authorized reference products, this raises concerns as regards the data and market protection periods that the EMEA regulation grants to centrally authorized products, not only as regards veterinary medicinal products but also as regards human medicinal products." ●

Animal Health – just another niche market?

The current limited generic penetration in the animal health market presents good opportunities for big pharmaceutical companies wishing to expand their range, delegates heard at Animal Pharm's Animal Health Generics conference, held in Amsterdam on July 10th-11th.

Speaking at the conference, business advisor Ms Jean Hoffman, president of consultancy Q Street Advisors, said that, at a time when human pharma brand companies are using anti-generic tactics, the ability to evaluate patent minefields is a core generic competence.

She also emphasized the need for speed and forward planning in the increasingly competitive landscape of animal health generics.

Ms Hoffman compared the animal health generics market to that of the human generics market in the US twenty years ago. She urged the need for product development and evaluation of process patents in active pharmaceutical ingredients (API) manufacture to begin seven to 10 years prior to loss of exclusivity in major markets.

However, internal pipelines are "dry" – weak in both new brand launches and generic R&D, she said.

Ms Hoffman believes that India and China are key regions to watch – India providing lower cost science and technical talent in addition to R&D; China increasingly supplying Indian companies with APIs and intermediates.

In three to five years, Ms Hoffman predicts that these markets will be producing finished dose-form pharmaceuticals.

However, she said APIs are the more expensive and most critical part of regulatory approval, with the auditing of suppliers to safeguard compliance presenting an area of particular risk.

In Europe, Ms Hoffman said fewer launches and slower growth in the human pharma market will urge companies to expand into the animal health "niche."

Ms Hoffman ended her presentation with the prediction of a "more competitive landscape" in which aggressive business development and launching on loss of exclusivity will be demanded. These trends will increase demand for generics, she said.

Returning to her theme of speed, she concluded that it is better to be first than to provide better quality – as long as the quality is sufficient for approval.

Speaking on the second day of the conference, Edward John Allera, attorney with Buchanan Ingersoll PC, agreed with Ms Hoffman, citing two key causes of delay of launches – the inertia of the Food and Drug Administration and the failure of API manufacturers to comply with current legislation. ●