# Metacam exclusivity debate: a legal perspective

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**EU legal expert Elisabethann Wright of global law firm Hogan & Hartson's Brussels office comments on the latest twist in exclusivity law, revealed in the CVMP's positive opinion of Flexicam, a generic version of Boehringer Ingelheim's meloxicam-based anti-inflammatory Metacam (Animal Pharm No 584, p 6).**

According to the European Public Assessment Report on Metacam that was prepared by the EMEA, the initial marketing authorization for this product was issued by the European Commission on January 7th 1998. Article 35(3) of Regulation 2309/93, which was in force when the authorization was granted, provided Metacam with 10 years' protection from that date. The positive opinion of the EMEA on Flexicam was issued on January 18th 2006, eight years and two weeks after Metacam was authorized.

The EMEA did not provide any justification for its decision to issue an opinion (and the potential positive European Commission Decision that may follow) while two years of the exclusivity period granted to Metacam under Article 35(3) is still to run.

The answer may lie in Article 89 of Regulation 726/2004, the new EMEA Regulation which has replaced Regulation 2309/93. This Article states that the periods of protection for which the Regulation provides will only be available to those reference products for which Applications for Marketing Authorizations are made after the entry into force of the main elements of the Regulation, ie for applications submitted on or after November 20th 2005.

There is nothing, however, to suggest that the provisions of the Regulation that are of benefit to generic applicants, including the possibility to apply for generic authorization eight years after a reference product has been authorized, will equally be available to generic applicants only after this date. Although it may raise questions of conflict of laws been the old and new Regulations, the actions of the EMEA in the present case suggest that it and the commission consider that the EMEA has a right to consider applications for generic authorization eight years after the reference product has been authorized even if the generic application was made before November 20th 2005.

If this proves to be the case, innovative manufacturers may be justified in considering the approach adopted by the EMEA to be unsporting. It may be difficult, however, to successfully argue that it is illegal. The market protection rights granted to innovative manufacturers, both under the old Regulation and the new Regulation, are not undermined by the EMEA's apparent approach in the present case. The periods of market protection to which they are entitled remain untouched. Moreover, even if a generic product were to be authorized before expiry of the ten years' marketing exclusivity to which its reference product is entitled, it would still not be possible for it to be marketed until this period has expired.

What, however, of the rights and expectations of the innovator? Article 35(3) of the old EMEA Regulation, in force when Metacam was authorized, and the other provisions to which it refers, do not specifically state that Metacam is entitled to 10 years' data protection. They refer only to the fact that it must be authorized in the Community for not less than ten years before a generic application could be made. Nevertheless, the common perception of this term, a perception held by the European Commission as much as by anyone else, has been that this meant that the product was entitled to both 10 years' market exclusivity and 10 years' data exclusivity (running concurrently). It was only with the entry into force of the new legislation in late 2005 that a distinction between periods of data protection and periods of market protection was made. While the approach apparently adopted by the EMEA in the present case does not undermine the 10 years' market exclusivity to which Metacam was entitled, it has, effectively, reduced the 10 years' data protection that common interpretation of the old legislation gave Metacam to eight years. If the EMEA has relied on data related to Metacam in coming to its opinion on Flexicam, it has undermined the 10 years' data exclusivity that Boehringer Ingelheim arguably was legitimately entitled to expect.

It remains to be seen whether the court would support the view that the EMEA has undermined Boehringer Ingelheim's legitimate expectation that the received interpretation of the provisions of the old legislation gave it an entitled to 10 years' data exclusivity. What appears certain, however, is that innovative manufacturers may well know who their generic competitors are somewhat earlier than they had anticipated. ●