



PRESS RELEASE

Industry raises some concerns over PRACTicalities of pharmacovigilance hearings

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The infrastructure for holding public hearings under the EU pharmacovigilance legislation's Urgent Union Procedure is not yet in place, but industry is nonetheless concerned about how this will work in practice. At TOPRA's Annual European Medicines Agency Review of the Year and Outlook for 2013, companies pressed EMA officials for more information on the procedure during an update on PRAC (Pharmacovigilance Risk Assessment Committee) activities.

When asked by delegates how such hearings would be conducted and what they could do to prepare for this eventuality, PRAC Chair June Raine said that a lot of preparatory work was ongoing but due to budgetary constraints, the hearings were not imminent. The EMA's Peter Arlett, Head, Pharmacovigilance and Risk Management, Patient Health Protection, added that the Management Board would be discussing how the procedure might work at its March 2013 meeting, and that one or two hearings could be expected next year. Dr Arlett also foresees some kind of guidance – at least in draft form – becoming available next year.

Although it has yet to handle a referral under the Urgent Union Procedure (a so-called Article 107 referral), the committee has received six non-urgent 'Article 31' referrals, which are triggered when the interest of the EU is involved following concerns relating to the quality, safety or efficacy of a medicine or a class of medicines. For example, it is reviewing possible cardiovascular risks associated with diclofenac under an Article 31 referral initiated at the request of the UK MHRA.

As for its other activities, PRAC has seen a steady flow of new safety signals in each of the four meetings it has held since its inaugural meeting in July 2012. Dr Raine noted that risk management plan submissions were increasing particularly fast, and at the most recent meeting held from 26-29 November, there were 21 PSURs – the first time PSUR assessments were on the PRAC agenda. Overall, there has been 'an exponential increase in activity' in PRAC, she said.

Besides getting the Article 107 procedures up and running, the next big step is to appoint representatives from patient organisations. Dr Raine explained that the committee requires a breadth of expertise and 'we have a gap that needs to be filled'.

NOTES FOR EDITORS

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