



TOPRA/EMA meeting: Medicines legislation within the European regulatory network London, December 3-4, 2007

Scientific Advice

Reviewed by

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The procedures for Scientific Advice (and also Protocol Assistance) were looked at from the perspective of the EMA, a national competent authority (BfArM) and the pharmaceutical industry.

Bruno Flamion (EMA) provided an update of experiences with Scientific Advice and Protocol Assistance procedures from 2007. The number of these procedures has increased year on year, with

the biggest increases over the last three years, with almost 300 such procedures during 2007 (compared with approximately 100 in 2004). He expressed the key achievements for the year for these procedures: the increased number of advices given, more frank exchanges with sponsors and the publication of new guidelines (<http://www.emea.europa.eu/pdfs/human/sciadvice/22553207en.pdf>). He also expressed an opinion that the quality of the content of the advice given had been generally improved and was leading to better CHMP decisions.

This was contrasted with the perceptions of "outsiders" who had expressed concerns about the uncertain effects of advice given on CHMP decisions, the quality of the advice, low numbers of meetings with sponsors and the time taken for the procedures. The quality of advice is being improved by involving more experts in difficult

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cases, although the resource implications of this were acknowledged. Since September two peer-reviewers are being used. The various therapeutic assessor groups and working parties are also being involved more in the process.

The effect of Scientific Advice on the CHMP decisions is being improved by the discussion of critical issues at CHMP meetings, involving the CHMP peer-reviewers and the attendance of CHMP and EWP chairpersons at SAWP meetings. The value of discussion meetings as part of the process was considered, together with the factors that influence the decision to hold such meetings (eg, major disagreement with the sponsor, potential therapeutic breakthrough, orphan status and lack of guidelines). The benefits of EMEA-FDA parallel advice were explored taking into consideration the differences in the processes and limited experience to date and the fact that it is seen as particularly sponsor-driven.

Peter Bachmann (BfArM) gave a perspective of national Scientific Advice as experienced by BfArM, which has conducted approximately 250-300 Scientific Advice procedures per year since 2004. In Germany the national competent authorities are legally obliged to provide advice. The objectives of national advice were explored together with the critical time points in the development life of a product. Pipeline meetings are followed by Scientific Advice meetings prior to Phase I, again prior to Phase II and always prior to Phase III. Finally pre-submission meetings are held before filing the Marketing Authorisation Application (MAA).

The differences between "central" and "national" Scientific Advice were discussed, the main difference identified was the emphasis on the "application" in the national procedure, whereas the Centralised Procedure is more focused on "pure science". The value of the national procedure to the competent authority was discussed both in terms of equipping the assessors and establishing good communications with the applicants' key experts. The importance of transparency was stressed, especially between the central and national advice being sought. In conclusion, the manner in which the national and central advice procedures complement each other was expressed.

Finally **Axel Breitstadt (MSD)** gave the industry position on Scientific Advice. He set out what is expected in terms of the benefits to the development programme as well as what is covered and details of the procedure. Some of the advantages of national advice discussed were the inclusion of "regulatory" advice in addition to Scientific Advice, more flexibility in terms of timelines and holding face-to-face meetings and scope of discussions. Again, national advice was perceived as being complementary to central advice. Recent changes in the framework and performance of the procedure were presented, touching on the expected increase in use as a result of the Paediatric Regulation. The benefits and problems associated with parallel EMEA-FDA scientific advice were also discussed.

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