REPORT ON EFPIA INFO DAY - 22 OCTOBER 1999

The sixth EFPIA Info day organised by EFPIA with the collaboration of the EMEA and the CPMP was held in London on 22 October 1999, under the chairmanship of S. Heppell, Chairman of the EMEA Management Board, and B. Ager, the EFPIA Director-General. About 350 delegates attended this event, including a large number of industry representatives, EMEA staff, CPMP members as well as two Commission representatives.

Decentralised Procedure

The first session addressed the performance of the decentralised procedure. H. Wahlroos, the current Chair of the Head of Agencies, underlined the constant improvements in the handling of this procedure, detailing the greatest challenges faced by the mutual recognition procedure: elimination of the "national policies", ensuring the smooth operation of the system, promoting harmonised, high-quality assessment work and reducing the withdrawal rate of applications. The work achieved this year by the Mutual Recognition Facilitation Group was presented by the previous and the current Chairs, with a particular emphasis on the number of applications, the Product Index, and the various documents prepared recently by this group.

The latest EFPIA survey findings showed a high level of satisfaction with regard to automatic validation. Some key critical points such as unexpected specific national requests, serious public health issues, and the time periods to obtain national marketing authorisations still need further improvement.

Centralised Procedure

In this session, chaired by M. Teeling and J.-P. Osselaere, EFPIA and EMEA confirmed their commitment to continue working together on the joint survey on the performance of the centralised procedure. Overall, EFPIA findings of 1999 were even better than those of 1998. For the first time, companies reported an early identification of potential problems (before submission). This was corroborated by the rate of "non approvable" dossiers at the time of the CPMP conclusions (Day 120). Moreover, the length and complexity of the phase from opinion to decision were still a critical issue for pharmaceutical companies. The EMEA results showed that the quality of the initial dossier, as well as the expert reports and the companies' written responses showed slightly less satisfactory ratings than in the previous years. Remaining problems identified during the validation phase, as well as poor quality of initial translations, were also pointed out.

For the first time, the joint performance indicators survey was extended to withdrawals. Surprisingly, most pharmaceutical companies which withdrew their applications were satisfied with the procedure (55%) as well as with transparency, dialogue and advice from Rapporteurs, Co-Rapporteurs (82%) and the EMEA (91%). Companies mainly complained about the way their requests for an extension of the timeframe to respond to CPMP list of questions were handled. An in-depth EMEA analysis on withdrawals demonstrated that the main therapeutic classes concerned were antineoplastic drugs, blood products and medicinal products for conditions of the nervous system. Major objections were related to clinical efficacy, essentially for methodological reasons.

It was remarked that CPMP scientific advice had rarely been used for these products, both for completed applications or withdrawals. Pharmaceutical companies were encouraged to use this service more frequently, in order to overcome potential problems later on in the process.

Community Referrals

In the following session chaired by M. Teeling and D. Gilbert, discussions were held on the difficulties of handling Community referrals with special regard to pharmacovigilance issues where several products are concerned. *Inter alia*, it was suggested that competent authorities envisage two levels of action: rapid measures or more in-depth analyses, depending on the potential threat to public health and the level of imputability.

Evolution and Future

F. Sauer and Y. Juillet addressed the targets for the future and elaborated on past, current and future work in connection with the EU enlargement. F. Sauer welcomed the imminent adoption of the Orphan drugs regulation. He particularly advised companies to systematically use pre-submission meetings, as well as CPMP scientific advice.

From a regulatory side, several significant points with regard to the review of the rules governing medicinal products in the EU were made by P. Brunet, from the EU Commission, DG Enterprises, responsible for pharmaceuticals. With respect to the evolution of scientific standards, the potential consequences of the current trend of basing scientific assessments mainly on active control trials were addressed by G. Picot.

Throughout the day, the key goals of the EFPIA Regulation 2000 project, such as the need for globally competitive performance, transparency and protection of innovative data, were stressed.

The Chairman of the EMEA Management Board, S. Heppell and the EFPIA Director-General, B. Ager, concluded the day by welcoming the fruitful discussions, stressing the need for industry and authorities to keep on working constructively, and reaffirming clearly that the only criteria for the assessment of medicinal products are quality, safety and efficacy.

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