

Benchmarking of European Medicines Agencies

Background and Aim

1. HMA is currently overseeing the implementation of an exercise to identify and share best practices across the network of EU and EEA medicines agencies (human and veterinary). The exercise – known as the Benchmarking of European Medicines Agencies (BEMA) – has the following broad aim:

“To contribute to the development of a world class medicines regulatory system based on a network of agencies operating to best practice standards”.

2. Benchmarking is a generally accepted technique for comparing individual management systems or processes with the aim of learning from one another. It is not an audit designed to identify non-compliance. The most valuable part of the BEMA exercise is that this is a form of ad-hoc consultancy carried out by colleagues from another competent authority who are fulfilling the same responsibilities under legislation in different and complementary ways. It is a recognition that we can learn from one another first and foremost.

3. The specific purpose of the exercise is to enable mutual exchange of information, with a view to introducing improvement measures within agencies. The exercise is not designed for direct comparison or ranking of agencies – a process of anonymisation has been agreed so that none of the information held in the centralised database is attributable to any agency.

Development and data collection

4. The origins of the current exercise lie in the request by the European Commission to the Heads of Medicines Agencies to develop the benchmarking system as a way of ensuring that the regulatory system met stakeholders needs as defined in the G10 Medicines Report. It builds on an earlier PERF (Pan European Regulatory Forum) benchmarking exercise but has been “tailored” to the needs of the 42 national competent authorities for veterinary and human medicines in the European Union.

5. A Steering Group (the Czech Republic, Finland, Italy, the EMEA and France, led by the UK and Germany) was established in January 2004 to develop proposals for the exercise, including a series of performance indicators across four key areas (organisation, pre and post-authorisation, pharmacovigilance, and inspections and market surveillance) and the methodology of how to identify and share the best practices.

6.. The agreed methodology includes elements of both self-assessment and peer review. Self-assessment enables agencies to assess their own strengths and weaknesses in relation to the areas targeted by the performance indicators. The peer review is important as it allows each agency to be visited by teams of assessors (drawn from a pool of volunteers from other agencies) for an independent assessment against the performance indicators. The outcome of each visit is an anonymised report produced by the peer review team and agreed with the visited agency, with an anonymised description of how the agency performs against each indicator. All results are stored on a central database and the information can be accessed by agencies. Much of the

logistical support, which has been invaluable, has been provided by the EMEA. The exercise is likely to be repeated on a regular basis each two to three years.

Experience to date

7. The BEMA experience has proved enormously rewarding at the level of the individual competent authority. The self assessment process identifies gaps in procedure, and areas for self improvement, as well as good practices, in a methodical and uniform way. An additional benefit of the methodology we have established is that the self assessment may also be repeated outside the formal benchmarking cycle to measure internal self improvement on a periodic basis. Peer Review, so valuable because it is performed by colleagues in the same field of operations, provides an additional assurance that the self assessment was properly conducted. In the long term, the information collected during the peer review will be important in setting standards and learning from one another at the level of the network .

Final Report

8. The final report on the operation of the 1st cycle of BEMA will be presented to HMA in late 2006. Although the exact structure of the report is yet to be decided, it is likely to include the following broad headings:

- Introduction and genesis of BEMA
- Main body of report illustrating findings
- Next Steps including communications and lessons learned
- Annex of Key documents

Transparency and openness

9. It is our intention to maintain appropriate levels of transparency towards stakeholder on BEMA, in line with the principles set out in the draft HMA Strategy Paper (also published on this website). We intend to publish an account of the first benchmarking cycle on these pages in late 2006.

Conclusion

10. The BEMA project is part of the Network of Medicines Agencies' response to the challenges faced by regulators today. Its aims and methodology has the full support of HMA. It provides an opportunity for national regulators to assess their own performance and organisational achievements and to learn from one another. We will publish an account of the exercise in late 2006.

Benchmarking of European Medicines Agencies – Steering Group May 06