

# BENCHMARKING OF EUROPEAN MEDICINES AGENCIES

## 1 Executive Summary

- 1.1 Benchmarking is a well established methodology for internal performance improvement through comparison of good practice which is widely used in the public and private sector. Benchmarking of European Medicines Agencies (BEMA) was the first attempt of the European Medicines Network to collectively embark on such a programme of internal self improvement and mutual learning. This is an account of the first cycle of BEMA visits. As well as an explanation of the aims and genesis of BEMA, it contains both an overview and a detailed analysis of the data base derived from the Peer review visits. It also contains an explanation and an evaluation of the BEMA methodology.
- 1.2 The concept of BEMA was first discussed at the Heads of Agencies meeting in Rome in November 2003. Following a presentation by the UK and Germany at the first Heads of Agency of the Irish Presidency (Dublin, January 2004), the Heads decided to establish a Steering Group to further the approach to benchmarking. Building on previous initiatives (such as the PERF) it was tailored to the needs of the EU25 and policy goals as set out, inter alia, in the Lisbon European Council Conclusions on competitiveness and economic growth and the G10 Medicines initiative.
- 1.3 In the Steering Group, the UK and Germany were joined by Italy, Spain, Finland, the Czech Republic and the EMEA in the task of developing and coordinating the first benchmarking project involving the entire human and veterinary medicines agencies in the EU/EEA Network. Specific veterinary input was provided by Ireland and, later, France.
- 1.4 The Group defined its mission as:

*To contribute to the development of a world class regulatory system for medicinal products based on a Network of agencies operating to best practice standards.*
- 1.5 The first key task was developing a questionnaire, on which each Agency could conduct an internal self assessment and on which a subsequent peer review could be based, which covered all aspects of the Network's performance, not just the regulatory and safety aspects of the role but also the management processes which underpin it. A rating system, designed to illustrate the maturity of the systems in place in each Agency was devised. A training programme was developed and the EMEA developed and coordinated a peer review visit programme. This schedule contained twenty nine visits to thirty five different agencies between June 2005 and May 2006.

- 1.6 There were inevitable difficulties in maintaining consistency of approach with this number of visits and individual assessors but, without undermining the integrity of the data gathering exercise, these were resolved through better training and guidance. An anonymous database was also constructed to contain all of the data and to provide a learning tool for the Network and a whole and individual agencies
- 1.7 With the completion of the Peer Review visit programme the Steering Group could begin its remaining tasks, an analysis of the information gathered and an initial consideration of the learning points from the project. The key findings from each of the four sections of the questionnaire (Organisation and Management, Pre and Post authorisation, Pharmacovigilance and Inspection and Market Surveillance) illustrate many of the strong points of the Network and also the areas where there is potential for improvement.
- 1.8 Turning first to Organisation and Management issues, it is clear that there is a formal stable approach to many aspects of the management of national agencies. The approach to strategic planning and resource management seems to be effective but there is a clear indication from the findings that only the most mature Agencies have addressed corporate governance issues (from ensuring continuity of service in case of a major incident through to the establishment of systems to minimise risks from bad publicity, financial mismanagement etc). Stakeholder engagement also seems to be in an advanced state in many Agencies but there is still a variable approach to how transparent Agencies are and what systems they have in place.
- 1.9 In terms of Pre- and Post- authorisation activities, particular strengths lie in the expertise of the assessment staff. The importance of employing appropriately qualified staff and ensuring that they maintain their expertise was clearly understood. IT support for the assessment process was also identified as an important issue. Documenting systems, a key to maintaining quality of consistency of operations and of decisions making, is an area where more work needs to be done. Recognising the recent introduction of the approach, the analysis of the database revealed that there are still concerns over the adoption of the new processes to implement the new legislation on risk management planning is an area of development.
- 1.10 In relation to pharmacovigilance, the review of the database gives an assurance that systems to gather and analyse adverse drug reactions are stable and formalised. Areas for potential improvement might include a greater emphasis on capturing the impact of regulatory action and internal review of pharmacovigilance action. Where this is done, it is done on an ad hoc basis and systems are not fully documented.
- 1.11 In relation to inspection and market surveillance, SOPs are developed in most of the agencies and operating procedures are usually integrated

into quality assurance systems. Planning of activities, reporting and supervision of inspections, recruitment and maintenance of staff competency could benefit of a strengthened and more harmonised approach.

- 1.12 The detailed findings will be of use at both Community and national level. A Community approach is needed to ensure that best practice is shared – whether this is done through the HMA, the Commission or the committees and working parties of the EMEA. Nationally, the learning points could come from the detailed analysis in the Report, the database and in the on-going internal improvement plans engendered by the benchmarking process.
- 1.13 Agencies and assessors were sent a feedback survey at the end of the project by the BEMA SG. At an organisational level, many indications were given of improvements identified as a result of the exercise. At the level of peer review assessors there was also recognition of the professional growth experienced by quality professionals which is of benefit to their Agencies.
- 1.14 In line with the Steering Group's Terms of Reference, a reflections paper will be produced, considering what has been learnt and options for the future. This will include a consideration of the costs of the BEMA exercise.
- 1.15 Commitment and support was shown by the Heads of Medicines Agencies throughout the project. Tribute is also paid to the hard work and dedication of the teams of assessors who made the benchmarking exercise a reality.

*The main body of the Final Report is published on the HMA website.*

*December 06.*