

**BENCHMARKING OF EUROPEAN
MEDICINES AGENCIES
(BEMA)**

**REPORT ON THE OUTCOME OF THE
1ST CYCLE**

**Presented by Germany and the United
Kingdom on behalf of the BEMA
Steering Group**

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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.

Key Performance Indicators of the BEMA project

KPI 1:	Describe how objectives or targets are set for the different processes of the organisation, and they are reported publicly
KPI 2:	Describe how the organisation identifies different stakeholders’ (other regulatory bodies, patients/public, healthcare professionals, animal owners, vets and consumers and industry) needs and expectations on a continual basis.
KPI 3:	Documented systems are in place to ensure that risks to the functions, finance, reputation and business processes of the NCA are identified and effectively managed. (internal risk management).
KPI 4:	Appropriate measures are in place to protect confidential information from security threats, maintain the physical security of buildings and property and to protect staff.
KPI 5:	The capability and capacity of performing pre- and post-authorisation activities with high quality is demonstrated.
KPI 6:	The full range of high-level, internationally recognised, regulatory and scientific expertise to fulfil the chosen regulatory functions is available within the organisation and from appropriate external sources.
KPI 7:	The organisation has the capacity to receive, validate, use and archive fully electronic applications and data submissions using robust modern information management systems.
KPI 8:	There is routine access to reliable systems for use in signal detection/evaluation, preferably in house.
KPI 9:	The organisation has the ability to produce consistently high quality risk pharmacovigilance assessments to deadlines.

KPI 10: The organisation has the capability of leading EU wide co-ordination of regulatory action and communication of drug safety issues.

KPI 11: There are appropriate GXP standards in place and compliance with these is monitored and enforced

KPI 12: There is a documented system for ensuring the removal of non-compliant medicinal products from the market

2 Introduction and background

Introduction

2.1 This report is presented by the Benchmarking of European Medicines Agencies Steering Group and is an analysis of the first BEMA cycle. The main aim of the report is to present the findings derived from the peer review data. It examines the key findings, areas of strength and areas where improvement might be made, across the four components – Organisation, Pre and Post Authorisation, Pharmacovigilance and Inspections and Market Surveillance – covered by the BEMA questionnaire. A more detailed analysis of the findings is also contained in Appendix 2 to the Report. The report also provides a commentary on the evolution of BEMA and the development of the methodology and performance indicators, with some observations how these might be improved.

Background

2.2 Heads of Medicines Agencies (HMA) first discussed a proposal for a benchmarking initiative in Rome in November 2003. Benchmarking had been used as a successful management tool in 2003 as part of the Pan-European Forum (PERF) in view of the EU enlargement. HMA endorsed a formal proposal in Dublin in January 2004, following a joint presentation by the UK and Germany. At the meeting in Dublin, Italy, Spain, Finland, Czech Republic and the EMEA volunteered to join the UK and Germany to form a Steering Group (BEMA-SG) to further develop the benchmarking approach, taking into account the strategic goals set in Lisbon Council and the subsequent elaboration by the G10 Medicines and the experience obtained in PERF.

2.3 The BEMA SG developed the initial questionnaire of performance indicators and the basic methodology, comprising elements of self-assessment and peer review. As HMA considered the issue further, it became apparent that a joint human and veterinary approach would extend the benefits across the medicines sector and bring about economies of scale in the collection of best practices. Representatives from the veterinary agencies of Ireland and France joined the BEMA-SG and HMA subsequently agreed a joint approach. The HMA Management Group has also monitored the progress of BEMA and has discussed the exercise a number of times during the development and implementation stages.

2.4 The BEMA methodology was expanded throughout the development stages, and a body of working instructions, standard operating procedures and an assessors' manual were developed for use in carrying out different aspects of BEMA. The methodology is discussed in more detail in Chapter 4.

2.5 Once the methodology had been agreed the work began within Agencies with the period for self assessment and was concluded in May 05. The Peer Review programme was devised and begun in June 2005, finishing in May 2006. Twenty nine Peer review visits took place, involving the participation of 82 assessors. The Schedule is attached at Annex B. The BEMA SG took delivery

of the database of results and begun a process of interpreting the data with a view to the preparation of this Report in August 06.

3 Aim of BEMA and Terms of Reference of the BEMA SG

- 3.1 The following aim of BEMA was agreed by HMA, taking into account the conclusions of the Lisbon European Council 2000 and recommendations of the G10 Medicines Group:

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.

- 3.2 In discussing the Aims and Terms of Reference, the BEMA-SG recognised the need to avoid duplication of existing work, and to build on the work already undertaken. The PERF benchmarking exercise was a valuable building block for the BEMA initiative. The PERF exercise generated confidence in benchmarking as means to share best practices and strengthen the Network of EU medicines agencies. The BEMA exercise tailored much of the methodology used in the PERF exercise.
- 3.3 The Commission's review of competent authorities' pharmacovigilance resources, the work being done by the Commission on public health benchmarks for the pharmaceutical industry, and the Joint Audit Programme for inspections were other relevant activities in the spirit of the Lisbon Council.
- 3.4 Further information on the Lisbon European Council 2000, the G10 Medicines Group and PERF can be found in Appendix 1.
- 3.5 The purpose of BEMA is to enable the gathering of information on best practices, with a view to introducing improvement measures within agencies. BEMA is not designed for direct comparison of, 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. Neither is it an audit designed to identify non-compliance. The most valuable part of the BEMA exercise is that it is a form of self-assessment enhanced by ad-hoc consultancy carried out by colleagues from other agencies that are fulfilling national responsibilities under EC legislation.
- 3.6 The following Terms of Reference were agreed for the BEMA-SG:
- To develop and agree on a number of high level indicators supported by specific performance indicators to achieve the best practice standards
 - To define procedures and methodology for self assessment and assessment
 - To co-ordinate information gathering activity
 - To validate outcomes through peer review
 - To interpret information gathered
 - To make recommendations to Heads of Agencies for an approach to continuous quality improvement, and EU wide improvement for the future

- 3.7 In carrying out the 1st benchmarking cycle, the BEMA initiative has contributed to the main focus of recommendation 1 in the G10 Report - developing a series of benchmarking performance indicators in the medicines regulatory environment.

4 Summary of Methodology and Discussion of Learning Points

4.1 The BEMA SG was tasked with developing a series of performance indicators to encompass all regulatory functions, taking into account new legislation and responsibilities. The basic methodology for BEMA was agreed by HMA in Dublin in May 2004. The final list of performance indicators was agreed in Reykjavik in February 2005.

BEMA Questionnaire

4.2 The questionnaire comprises 12 Key Performance Indicators (KPI) and 44 Specific Performance Indicators (SPI) across the following four areas of business:

- Organisation/Management
- Pre and post authorisation
- Pharmacovigilance
- Inspections and Market Surveillance

4.3 Each performance indicator is complemented by a description of the types of evidence that might be used to support the score. The full list of the KPIs and SPIs is attached at Annex C.

The Assessment

4.4 The assessment included two main aspects: self assessment and peer review. Agencies were asked to forward a profile of their organisation to inform the planning for the peer review visits. The BEMA SG circulated a prototype profile supplied by Finland to assist in this process.

Self-assessment

4.5 The assessment process includes elements of self-assessment and peer review. All agencies were invited to complete an internal self-assessment using the agreed performance indicators by 31st May 05. This had two advantages – it provided a foundation on which to introduce internal improvement plans in agencies, and also prepared the agencies for the subsequent peer review visit. Agencies were encouraged to retain on file the various documents used during the self-assessment, to expedite discussions with the visiting assessors. Discussions at HMA and in the BEMA SG underlined the usefulness of the self assessment and many Agencies would appear to have built it into their on-going management systems, planning to repeat it outside the BEMA “cycle”.

Peer Review

4.6 The agreed system involves the formation of teams of three assessors chosen from a pool of volunteers taken from agencies across the Network. At the end of the 1st cycle of BEMA, there were 82 assessors available to carry out visits or assist in self assessment at national level. In the end, some 52 assessors

participated in peer review visits. Criteria for the selection of peer review teams were agreed by HMA in Reykjavik in February 2005. The EMEA's Integrated Quality Management Team agreed to co-ordinate selection of teams using the criteria and design the visits programme. It was necessary to ensure, as much as possible, that peer review teams contained the necessary skills and expertise (including language skills) to effectively gather the evidence required during the visit. This was largely achieved (for example, 90% of lead assessors met the criteria agreed by HMA). The peer review process ended in May 2006.

Training of Assessors

4.7 Five training events, hosted by the EMEA but with the involvement and input of the BEMA SG, were held for assessors. The aim of these events was to explain the concepts and methodology of BEMA and allow the assessors the opportunity to practice the techniques required. This training was useful for the preparation of both the self assessment and the participation in peer review.

Scoring system

4.8 The options for scoring were assessed by the BEMA SG and HMA and the chosen system was based on the ISO method, which involves assigning 'maturity levels' to each process or system. There are 5 levels of maturity:

- No formal approach
- Reactive approach
- Stable formal system approach
- Continual improvement emphasized
- Best-in-class performance

4.9 It was decided to allow the allocation of half scores, to allow 10 possible scores to be allocated to each indicator.

Data anonymisation

4.10 HMA agreed a process to ensure the anonymity of information gathered during the course of peer review visits and the process was subsequently reflected in an agreed protocol. The peer review team leader and the visited institution were responsible for anonymising the data, and a keyholder was appointed, through which all peer review reports were sent. The reports were retained by the keyholder and sent in batches to avoid detection against the agreed schedule. Codes were assigned to each report by the keyholder to allow the agency subject of the report to be traced by the EMEA via the keyholder if necessary (ie to correct errors).

Confidentiality and Code of conduct

4.11 In addition to the steps outlined above for the anonymisation of the peer review results, a Code of Conduct for assessors was developed by the BEMA SG and endorsed by HMA in February 2005. It was designed to encourage a consistent

approach to peer review by assessors and to contribute to confidence building between the peer review teams and the visited agency.

Database of peer review results

4.12 Following an examination of all possible options, HMA agreed that the functionality of the PERF database might be replicated for the BEMA exercise, to create an anonymous database for storing the peer review reports. The database lists the anonymous reports for each visit under each performance indicator heading. The database allows simple searches and queries to take place on sight. The complete database can be circulated as a PDF document to agencies as necessary.

Discussion of the methodology and Questionnaire

4.13 During the course of the 1st cycle of visits it became apparent that certain aspects of the methodology and questionnaire could be improved for future rounds of visits. This was inevitable for such a new and challenging exercise. There were a number of sources of information on improvements to BEMA. The BEMA SG monitored the implementation programme and shared its own experiences to highlight areas for improvement. Several Heads of Agency also pointed out where there was the potential to improve the methodology. Finally, improvements were identified in the anonymous feedback provided by assessors and agencies via a brief feedback survey conducted by the BEMA SG (described in Chapter 7).

4.14 The purpose of these improvements are twofold – to increase the accuracy of individual assessments, and to increase the consistency of assessments across the board.

BEMA Questionnaire

4.15 The wording of a number of performance indicators and the description of the evidence required could be improved to introduce greater clarity to what is being asked. Some of the performance indicators – particularly in the pharmacovigilance section – tend to produce yes/no answers, rather than a useful description of the findings. These could be amended to encourage more discussion and exploration of the findings.

BEMA Methodology

4.16 The methodology of BEMA could also be improved to introduce greater consistency in assessment. HMA is aware that there was a tendency in the early stages of peer review to allocate relatively high scores. It appears that these became progressively lower during the course of the 11 month 1st cycle as further guidance was issued by the BEMA SG via the EMEA. This raises a number of important learning points – particularly in the training and selection of peer review assessors. There may be benefits in introducing an element of professionalism into the training of assessors – perhaps by using a smaller

pool of highly trained 'expert' assessors. A system of accreditation may also be advantageous.

Database of results

- 4.17 There may also be scope to improve the efficiency of submitting data to the EMEA and the functionality of the database of results. A direct access portal based system would simplify the process greatly, allowing peer review team leaders to deposit the reports directly (with necessary confidentiality safeguards). It would also allow agencies themselves to access the database directly.
- 4.18 These issues are explored further in a reflections paper but are included here in summary, as an indication of the potential limitations to the 1st cycle of results. Given that BEMA was an exercise in identifying good practice, as well as areas for improvement, the database, notwithstanding the learning points above and the potential inconsistencies in assessment, provides a valuable snapshot of the overall strengths and weaknesses of the Network as a whole. For this reason, the BEMA-SG places great emphasis on the narrative aspect of the report, considering that the written description of the findings is of greater value to agencies than any quantitative analysis.

5 Analysis of Peer Review Findings

5.1 The Terms of Reference of the BEMA SG included the task of the interpretation of the information gathered. The SG devised an approach to this task which focussed on a structured approach to the analysis of the descriptions of the findings in the four components (of Organisation, Pre - and Post-Authorisation, Pharmacovigilance and Inspections). This is found at n Appendix 2 to this Report.

5.2 The work was divided up amongst the Steering Group members, working as small “virtual” teams set out below. A simple template was designed which allowed each team to analyse the KPIs and SPIs in such a way as to explain the purpose of the KPI and SPI, summarise the findings, consider their implications and then draw some general conclusions about the characteristics possessed by the most mature systems possessed.

- Organisation: EMEA and Finland
- Pre and Post Authorisation: Czech Republic and Germany (PEI)
- Pharmacovigilance; UK and Italy
- Inspection / Market Surveillance France and Germany (BfARM)

5.3 There were four advantages to this approach:

- It proved to be the most effective way of analysing a large amount of data (the database running to some 255 pages) and allowing there to be sufficient homogeneity between the analyses of the different Components.
- Difficulties covered elsewhere in this Report, such as the earlier inconsistency in the maturity rating, were smoothed over by this approach as the BEMA SG was able to devote as much time to the analysis of the findings as to a cruder quantitative analysis.
- It was easier to draw conclusions from the analysis which related the Network as a whole and also to make recommendations for improvements which Agencies might consider building into their own internal improvement plans.
- An element of internal peer review and quality assurance was provided by the team work approach as devised.

6 Key Findings

6.1 The key findings of the peer review visits are set out in this Chapter. It provides an overview of the strengths of the Network as a whole and of individual agencies and should be read in conjunction with the more detailed analysis in the Appendix. Clearly, both this Chapter and the Appendix are an interpretation of the data gathered during the peer review visits. This Chapter also goes on to consider in brief to what use data of this sort might be put.

Organisation/Management

6.2 Taken as a whole, the results indicate that a stable formal approach is the dominant level of maturity for this section.

6.3 With the exception of some recently established organisations, most Agencies have a stable formal system for strategic planning, setting objectives, measuring against indicators, publishing plans and annual reports. In Agencies where a more mature management system has developed over time, sustained improvement trends in fields such as business risk management, business continuity planning, stronger investment in people with staff motivation/job satisfaction surveys and subsequent action are present. These are important aspects of the management of public service organisations as they all contribute to continuity and professionalism of service. A key to this would appear to be an increasingly effective, all encompassing quality management system in order to ensure that the risks to the functions, finance, reputation and business processes are properly better managed.

6.4 In relation to interaction with stakeholders and partners, the results suggest there is a need to establish standards for the appropriate levels of transparency towards partners and to establish what should be published and what should be considered confidential. There is also a need to formalize the interaction with stakeholders

6.5 The peer review findings highlighted a number of tools in operation in the Network to manage and standardise the process of stakeholder engagement. For example, systems to ensure consistency in replies to queries from the public (e.g. by means of an electronic database with effective search function) are recommended. Other examples include user-friendly websites, e-discussion boards, voice over internet systems and other technically achievable means to reduce costs and enhance participation and communication with stakeholders and partners.

6.6 One SPI aimed to gauge how effectively Agencies participated in the operation of the Network (from contributing to its strategic direction, through to ensuring that all appropriate internal and external stakeholders were properly engaged). It seems that the reasons and decision making behind participation in meetings at the EU level is well documented and documented in many Agencies. It is systematic and based on available resources. There is a continuing issue of the accessibility and capacity of feedback channels and degree of

transparency to the stakeholders/interested parties in many Agencies although strong examples of best practice can be identified.

Pre and post authorisation

- 6.7 Pre - and post- authorisation activities through the whole European Network can be characterized as stable formal system. The overall median score was 3 and the levels of maturity were supported by robust data obtained by BEMA visits. From reports included in the BEMA database is clear that a great emphasis is placed on qualification and continuous education of experts involved in authorisation processes. Importance of IT systems is understood and investment is evident. However, processes are not always fully documented and document control does not fulfil requirements of quality standards.
- 6.8 Two main opportunities for improvement have been identified. One of them is providing EMEA scientific advice (SPI 6.5) although it may be caused by a lack of available experts. The second one has risen from SPI 6.6 (ability of assessors to devise/assess/advise on risk management plans) as this activity is quite new and processes have not been fully implemented.

Pharmacovigilance

- 6.9 A stable formal approach is the dominant characteristic of pharmacovigilance activities across the Network. There was an overall median score of 3 for this component of the report. Median Scores of 3.5 were evident for KPI 8 and SPI 8.1 and SPI 8.2 (covering access to systems for use in signal detection/evaluation, and the ADR reporting systems and databases). According to the report, these and SPI 9.4 (contribution to the EU pharmacovigilance system) were the most mature systems – all receiving a median score of 3.5. Three best in class scores were allocated to SPI 9.4.
- 6.10 At least a stable formal approach was apparent for a majority of agencies for the remaining indicators in the pharmacovigilance section besides the final two in this section – SPI 10.4 (systems for capturing regulatory action) and SPI 10.5 (systems for monitoring and reviewing pharmacovigilance processes). Some agencies make use of appropriate databases for capturing regulatory impact (ie sales and prescribing information) although this was mostly on an ad-hoc basis and without documented procedures. For SPI 10.5 most agencies use internal audits and some external resources (ie ISO, BEMA and PERF) to review processes, although on the whole there appeared to be a lack of systematic approaches.

Inspection and Market surveillance

- 6.11 Transposition and Implementation of GXP rules are taken efficiently on board by the whole Network to give a good level of confidence.
- 6.12 SOPs are developed in most of the agencies as far as they are concerned. Operating procedures of the inspection services are usually integrated in a

quality assurance system. However different organisations and administrative structures may be competent on these issues, depending on the administrative organisations in place.

- 6.13 Planning of activities, reporting and supervision of inspections, recruitment and maintenance of staff competency could benefit of a strengthened and more harmonised approach. Particular attention could be usefully paid to the qualification process of inspectors and to the development of communication about corrective actions engaged on the basis of defective results of inspection.

Discussion

- 6.14 The outcome of the 1st cycle of BEMA visits indicates that at least a stable formal approach is dominant for a majority of agencies against a majority of performance indicators.
- 6.15 There are three main ways in which the opportunities for improvement can be realised – the BEMA SG would support the use of all three of them:
- 6.16 Individual agencies can use the results of BEMA as an indication of how well they are performing against the Network as a whole in order to identify areas for improvement. The characteristics of the highest performing agencies can be used to direct agencies to areas of the database that might be beneficial. The database contains valuable information and ideas on how to operate within the Network, and it should prove useful to agencies in their continuous improvement and strategic planning.
- 6.17 The feedback survey suggests that the self-assessment process was at least as rewarding to agencies as peer review. In view of this, it is suggested that the internal self assessment could be built into similar performance improvement or strategic planning activities, regardless of the future of BEMA. It is clear that the information from the database can feed into any future self-assessment. .
- 6.18 At the level of the Network, it might be appropriate to invite the scientific, regulatory and management committees of the EMEA/HMA (PWP, HMA, HMA-MG, EMEA MB, IWG) to develop informal standards and performance minima using the characteristics identified in the main body of this report. It is clear from the analysis of results that some areas are lacking the levels of maturity of others, and it may be sensible to prioritise those that require short to medium term action.

7 Feedback Survey on the 1st Cycle

Purpose

7.1 Just as every other management system and tool is subject to continual improvement, there is a need for improvement of the benchmarking criteria and methodology used for BEMA, taking care however that results obtained in the series of assessments conducted in 2005 and 2006 are comparable to the future BEMA visits. The analysis provided here is based on the replies from a written survey organised by the Steering Group in June. The replies confirm comments received by letters or during the training events.

Methodology

7.2 To enable the BEMA Steering Group to formulate improvements to the Heads of Medicines Agencies feedback was collected from Agencies and BEMA assessors during BEMA seminars in the course of the first BEMA round and by use of questionnaires at the end of the first benchmarking cycle.

7.3 Whereas the first type of feedback served continual improvement – without changing the indicator questions – throughout the BEMA visit period in 2006, the final feedback will be used to add justifications for improvement proposals that might touch as well the total number of indicators, the wording, the examples provided and the logistics (e.g. duration of an assessment visit in function of the number of regulatory processes and their complexity).

7.4 The surveys were electronically sent out to all 35 Agencies and BEMA assessors on the mailing lists used for the logistical arrangement of visits and invitations to seminars. Questionnaires prepared by the Steering Group were specific for Agency or Assessor reply (see Annex D).

Response rate

7.5 The response rate is also an indicator for the commitment of both the organisations involved and the assessors. From the Agencies assessed 23 replies were received (about 65% of agencies) and from the 53 assessors, who conducted at least one visit, 27 questionnaires were received (52%), which is reasonable considering that the survey took place over 3 weeks during June/July 06.

Results

7.6 The replies by the 27 assessors indicate that 18 of them took more than once part in a BEMA visit (see question 1). The participation of 2 assessors in 4 visits, of one in 5 visits and another one in 7 visits is a reinforcing factor for the methodology. Such assessors form the core assessment team of BEMA. All assessors took part in the BEMA training, attending at least one seminar. It should be noted that 82 assessors took part in at least one training seminar and that not all participated in BEMA visits. Their participation served the self-

assessment at the organisation itself and contributed to a better understanding of the same questions used for both types of assessments.

7.7 From the comments received during the questionnaire it is clear that further improvement and harmonisation of understanding is desired. The detailed descriptions in the current BEMA database for each indicator will contribute to a better understanding and provide the “examples of problems identified in real situations”.

7.8 The tabled results are self-explaining, but some might benefit from the following additional reflections:

- The question related to sufficient time for the assessment was YES by 83% of the replying organisations, but 37% of the BEMA assessors found that there was not sufficient time. Indeed many of the assessors continued to work on the assessment in the evening, which is an invisible part of the assessment visit for the assessed organisation. The lack of time became also visible by the delays in providing the cleaned, quality controlled databases to the key holder at the HMA secretariat.
- In the case of difficulty in interpretation of one or more performance indicators, which are visible for both parties at the same time, the replies by the assessed organisations and the assessors (53% and 55%) mutually reinforce each other. The issue/lack of clarity is by both parties the same for indicators 7 (capacity to receive, validate, use and archive electronic submissions), 7.1 (documented systems for submitting accurate information to Eudract), 8.2 (database of ADRs enabling reliable system generated signal detection), 8.3 (access to query tools to allow characterisation of ADR data to support signal evaluation), 8.5 (access to epidemiological databases), 10.2 (systems to support communication of urgent drug safety signals), 10.4 (systems for capturing regulatory impact) and 11 (appropriate GXP standards in place), which require therefore most attention during a revision for improvement. For improvement of future training events specific comments from the assessors might be considered.
- A similar concurrence in opinion exists about the perceived duplication of questions. The detailed list provided might lead to proposals to merge certain indicators, which would shorten the questionnaire and assessment, addressing in this way partially the shortage of time felt by 37% of the BEMA assessors.
- The suggestions for improvement indicate that there is a need for more training in the methodology of a benchmarking assessment, which is based on the audit/inspection methodology with opening and closing meeting, as indicated in the BEMA manual and during the training. The need for evidence besides interview is also clear from comments. This is raising the question of the profile of the assessor, which was agreed upon by the Heads of Medicines Agencies and the requirements were documented in the training manual, whereas for each assessor the profile was provided to the team responsible for the composition and logistics of the visits.

- Although immediate corrections of rating misunderstandings were not possible as was the case in PERF due to the protocol to ensure that data and their source remained anonymous, also for the team responsible for training, logistics and data entry, it is reassuring to see that 70% of the organisations assessed and 78% of the assessors find the rating system useful. Improved training in the understanding of the indicator questions and rating scale and reading of the descriptions in the current database might be helpful for the 17% of the replying organisations and 15% of the replying assessors, who are of the opinion that the rating is not helpful.
- Two thirds (66%) of the 23 replying organisations didn't notice disagreements regarding the rating system and 56% of the assessors didn't report any disagreements. It is striking that between assessors, part of one team, the disagreement rate is 0%-4%, whereas there is more disagreement between the assessed organisation and the assessors (between 14%-22%). In a number of cases the Agencies found that the rating was "too high" or "higher" than the self-assessment rating and in a limited number the rating was considered "too low". It is in such a case that an explanation by the assessors can be helpful to understand the reason for the lower score.

Summary

7.9 The feedback indicates that the majority of the participants, whether organisations assessed or BEMA assessors, found that BEMA was enriching, providing additional experience and has a catalyst function to implement better management systems and better practices. In this way it certainly contributes to the development of a world-class regulatory system.

8 Conclusion

- 8.1 The origins of BEMA can be traced back to the Lisbon European Council 2000, the conclusions of which described the need for a new open method of coordination as a means of spreading best practice and achieving greater convergence towards EU goals. This was further elaborated in the report of July 2003 by the G10 Medicines Group, and the concept of developing indicators in the field of medicines regulation was subsequently recommended in the Commission's response to that Report.
- 8.2 The BEMA SG was charged with developing proposals for consideration by HMA to address this aim. The following Terms of Reference were agreed for the BEMA SG:
- To develop and agree on a number of high level indicators supported by specific performance indicators to achieve the best practice standards
 - To define procedures and methodology for self assessment and assessment
 - To co-ordinate information gathering activity
 - To validate outcomes through peer review
 - To interpret information gathered
 - To make recommendations to Heads of Agencies for an approach to continuous quality improvement, and EU wide improvement for the future
- 8.3 This Report explains how BEMA has met its Terms of Reference and supported the first cycle of benchmarking of the current state of the Agencies in the Network as a whole. It provides a full and detailed interpretation of the information gathered for the benefit of the Network.
- 8.4 The key findings, the detailed analysis and the methodology (as well as the analysis of its strengths and weaknesses) will be the basis for the delivery of the final element of the work of the BEMA SG which is "to make recommendations to Heads of Agencies for an approach to continuous quality improvement, and EU wide improvement for the future". The Group is preparing a further Reflections paper for HMA.
- 8.5 The BEMA SG would like to express its gratitude to Heads and Agency staff for their participation in the first cycle of visits. The contribution of resources and the openness with which they approached the process was essential for the completion of the project.