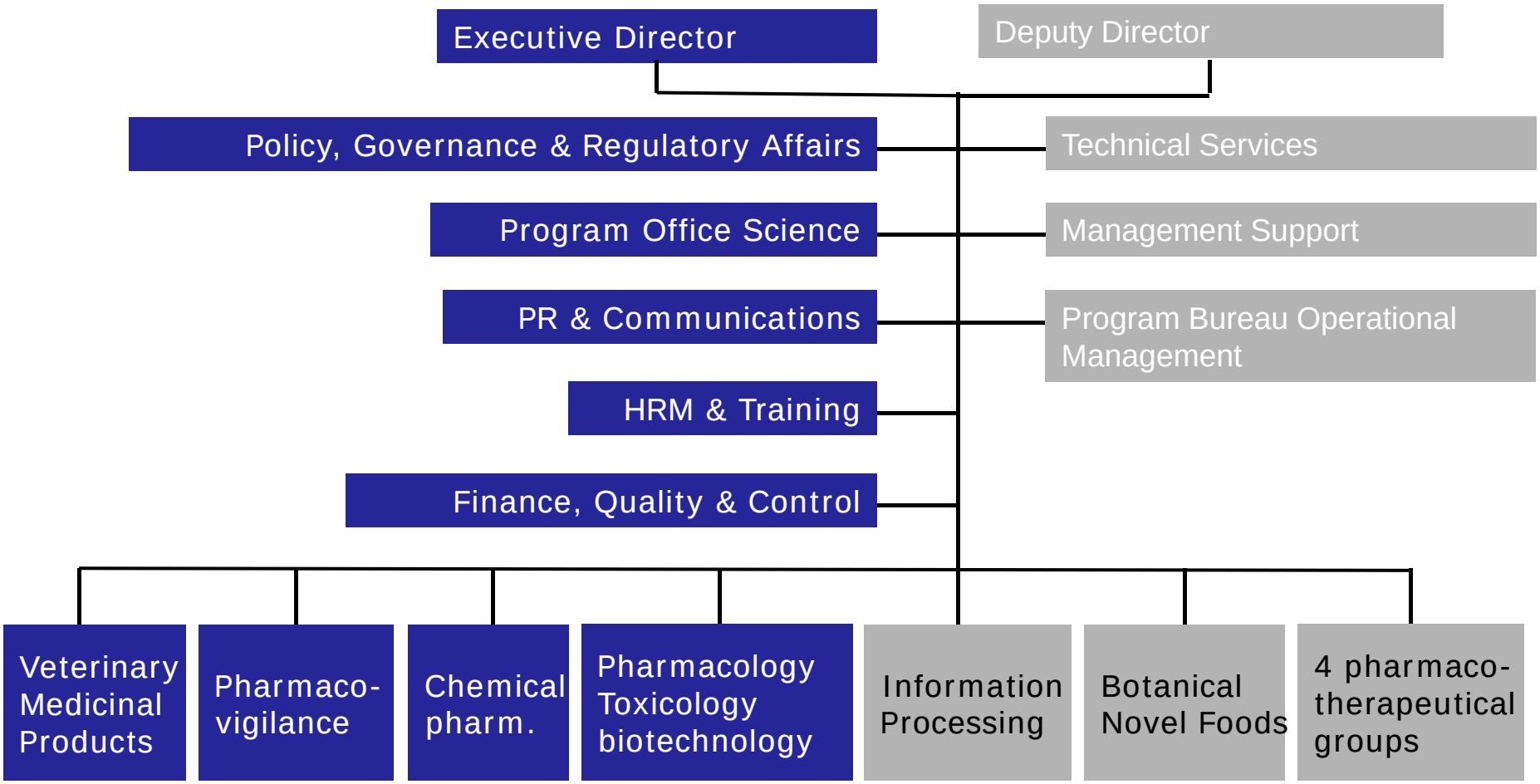
Quality System for Reviewers

An inside look: Medicines Evaluation Board the Netherlands

November 7th, 2012

Short introduction to the Medicines Evaluation Board (MEB)….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HRM & Training
Finance, Quality & Control
Veterinary Medicinal Products
Pharmaco-vigilance
Chemical pharm.
Pharmacology Toxicology biotechnology
Information Processing
Botanical Novel Foods
4 pharmaco-therapeutical groups

Principles of the MEB…

Our Mission

The Medicines Evaluation Board evaluates and monitors the efficacy, the risks and the quality of human and veterinary medicinal products. The MEB also evaluates the safety of novel foods for human consumption.

Our Vision

The Medicines Evaluation Board has unique insight into the development, efficacy, risks, quality and post-marketing surveillance of medicinal products. As this knowledge may also benefit other areas of Dutch healthcare, the MEB proposes to apply its expertise more broadly and to continue developing it. Key priorities include transparency and the provision of information to healthcare professionals and patient organisations.

Ambition

The Medicines Evaluation Board invests in independence, scientific underpinning and patient orientation. In this way, we want to strengthen our role as a 'gate keeper'. Although granting marketing authorisations is and will remain the MEB's core activity, it is also the MEB's ambition to make a significant contribution to innovation and the promotion of public health.

From mission to vision: *Strategic Business Plan 2009-2013*

In the Strategic Business Plan 2009-2013 the MEB identified five strategic objectives:

1. Solve assessment backlogs
2. Continue to develop a scientifically robust, consistent and transparent assessment system
3. Assist and invest to strengthen the medicinal product regulatory chain
4. Strengthen scientific underpinning
5. Knowledge must be translated and disseminated.

How does MEB deal with Quality Management?! : *ISO 9001…*

Weblink: *http://www.cbg-meb.nl/CBG/en/*

Scope of 2012 re-certification…

- Evaluating (risks, efficacy and quality) medicinal products for human use and admitting these to the market;
- Monitoring medicinal products for human use (pharmacovigilance - human);
- Providing scientific advice to the industry and partners in the chain about issues concerning medicinal products for human use;
- Evaluating the safety of novel foods for human use;
- Evaluating, admitting to the market and monitoring medicinal products for veterinary use;
- Evaluating and issuing licences for the preparation and delivery of veterinary medicinal products;
- Evaluating animal feed additives, dietary feeds and bioproteins.

Pre-conditions of maintaining Quality: *some remarks from the audit report*

"*The organisation is very deliberately investing in a number of preconditions that are vital to the provision of quality:*
•*the focus on all stakeholders (patients, health care professionals)*
•*the quality of information*
•*the quality of resources*
•*the quality of staff*"

"*Considerable attention was given in the past year to standardisation and peer reviews*."

"*Standardisation is now a prominent feature in documentation about issues that are submitted for decision-making. Decisions are made by the MEB or the Board. An increasing number of documents, texts of decisions and so on are being standardised and made accessible to employees*."

Practical approach: *Some examples from daily regulatory practice…*

Some key elements of the quality system…

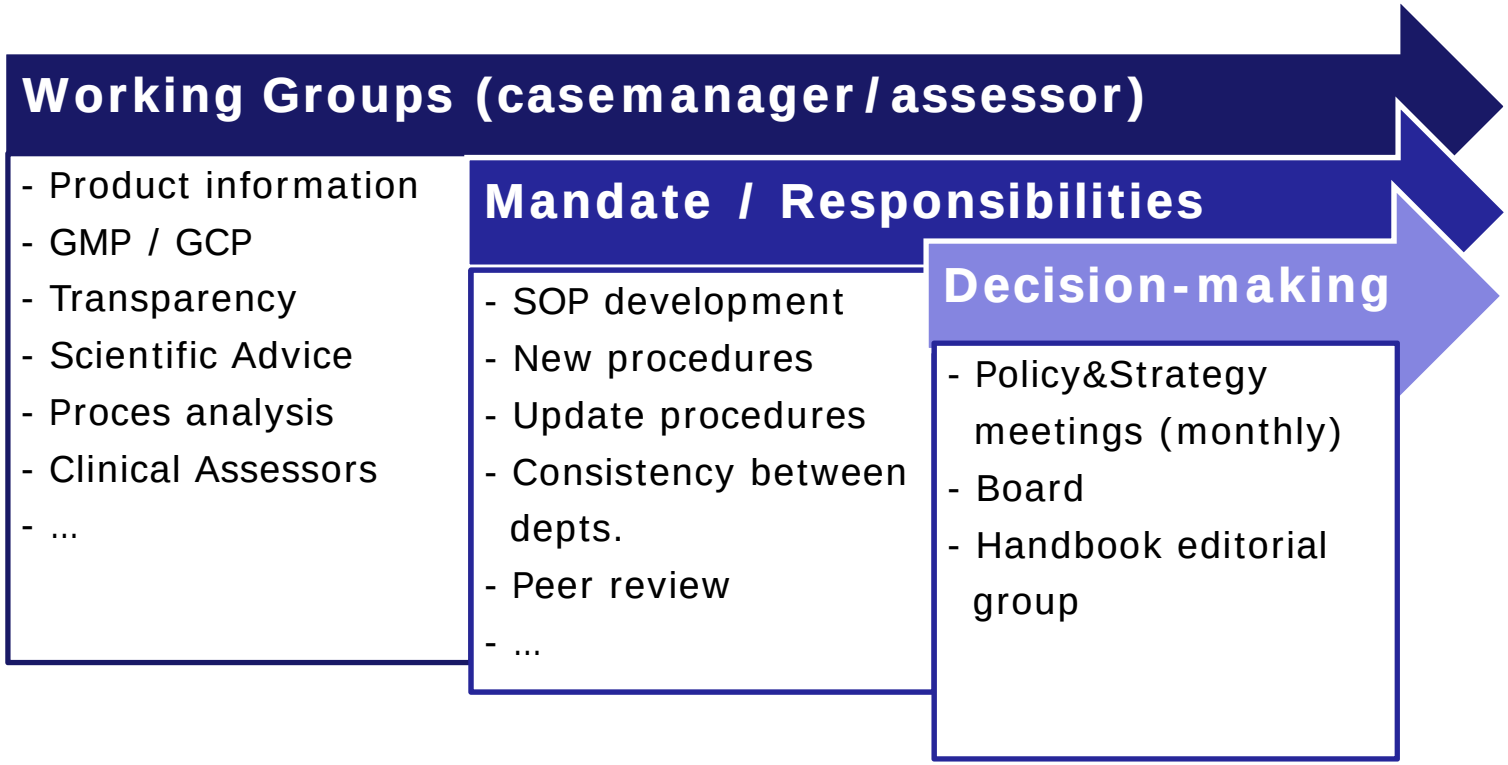
- QM-system operational since 2005, including ISO 9001:2008 certification. Includes the entire organisation/processes.

- Scope amongst others:
  - ✓ QM activities over both management and projects Dedicated QM department (direct contact with top management)
  - ✓ Electronic quality manual in which processes, guidelines, and instructions are mapped and periodically revised.
  - ✓ SOPs in place for content management of the quality manual
  - ✓ Internal audit system, including SOPs, in place
  - ✓ Annual QM-review in place (effectiveness of the system)
  - ✓ Improvement actions centrally recorded and updated
  - ✓ Complaint procedure in place (including online complaint mailbox at the website)

Quality management documentation during product review…

- Learning guide / digital handbook (*content management described in SOP*)
  - ✓ Policy documents
  - ✓ SOPs
  - ✓ Procedural instructions / checklists
  - ✓ Link to meeting minutes/reports
  - ✓ Templates
- Content owner for each section in the learning guide / website (working group)
- Accessible by all MEB employees

Regulatory SOP development and policy consistency: *Internal working groups*



- Dossier subm.
- Validation

- Assessment
- Decision making

Approval / Rejection

Information processing
-Document management system

Therapeutic department
-Validation (SOP/checklist)
-Time-table for procedure (tracking system in place)

Assessment disciplines
-Assessment reports templ
-Guidelines (EU/national)
-Assessors peer review

Decision making
-Board meetings
-Mandated

Timeliness
-2 assessment rounds principle
- Fixed time-table (tracking system in place)

Transparency
-Publication of public assessment reports

How do we check and improve our processes?!

- Internal / external audits
- Complaint procedure (external parties)
- (European) Benchmarking / Peer reviews
- Management Review
- Customer / employees surveys

Subsequently, improvements are planned, performed, checked and reported on by the QM-department.

Focus on all stakeholders: *Some examples…*

Patients	Health care professionals	Pharma / industry
• Meetings patient representatives • Publication labelling / safety information • Initiatives to improve Patient label/information	• Medical practice expert group • Various disciplines within Board • Scientific network	• Scientific advice • Meetings with Industry associations • Surveys (Customer satisfaction)

Take home messages from a regulator:

"Commitment from management is crucial for embedment within organization"

"Consistency in regulatory decision-making is a BIG challenge: both in and over time"

"Identify and understand all your processes – document in a clear and transparent way"

Aimad Torqui
a.torqui@cbg-meb.nl