

Session 3: Topics specific to veterinary medicinal products (VMPs)

Brigitte Boenisch, IFAH Europe

**Outcomes of the evaluation of the European Medicines Agency – the
future sustainability of the system, 30 June 2010, London**



Veterinary dimensions to the European Medicines Network

Specifics

- Additional dimensions of safety: for the consumer (food), for the user, for the animal
- Market is very small (ca. 2.5% of human) and fragmented (e.g. species)
- “Patient” of defined economic value, no reimbursement schemes
- Product availability is highly variable across EU:
 - difficulty of extending aged marketing authorisations
 - cost of goods for country-specific labelling

Veterinary dimensions to the European Medicines Network (cont'd)

Regulatory system

- CP – restricted access
- MRP/DCP, existing national MAs: national differences, inconsistencies - referrals
- Complexity of regulatory system – administrative burden, inefficiencies
- Resources a compelling issue
- Post-authorisation framework: fair and equitable regulatory environment proportionate to needs of veterinary medicine sector

Supporting the product development pipeline

- Efficient and predictable regulatory framework, adapted to respond to challenges of the future (new technologies, emerging diseases, communication to public)
- Strong support for early involvement into guideline development and increased dialogue between regulators and sponsor during product development
- Possibility for phased filing with a view to further reducing time to market
- Improved data protection for innovation

Supporting the product development pipeline (cont'd)

- Consistent, high quality scientific assessment
- Systematic methodology for benefit/risk assessment adapted to veterinary medicines
 - ⇒ Requires access to the best European expertise
 - ⇒ Accelerate access for new products
 - ⇒ Fill therapeutic gaps (minor uses, minor species)
- Pan-European market access facilitated by single procedure & rationalised labelling requirements

IFAH-Europe strategic objectives

- Protect and stimulate innovation
- Reduce time and cost to market
- Reduce administrative burden
- Level playing field – make the system fair to all
- True single market for ALL veterinary medicines with an efficient regulatory system

The “Euro Schnitzel” Concept

- There is a single market for food in Europe
 - No true single market for veterinary medicines
 - A schnitzel from Austria can be eaten anywhere in EU
- It makes no sense to authorise a veterinary product in country A and not in country B, if the food from A can be freely eaten in B



1-1-1 Concept



How do we get the single market for all VMPs?

Based on concepts already enshrined in EU legislation and using a single simplified procedure:

- quality, safety and efficacy described in one single EU dossier as the basis for granting marketing authorisations,
- one single assessment of the dossier employing the best expertise,
- resulting in one decision for marketing authorisation.

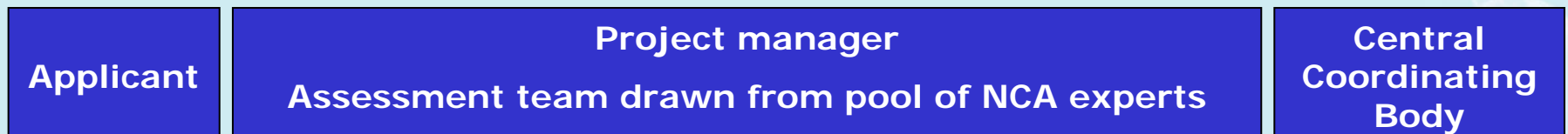
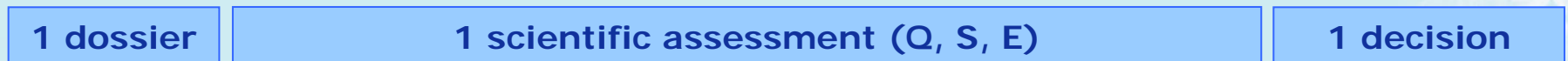
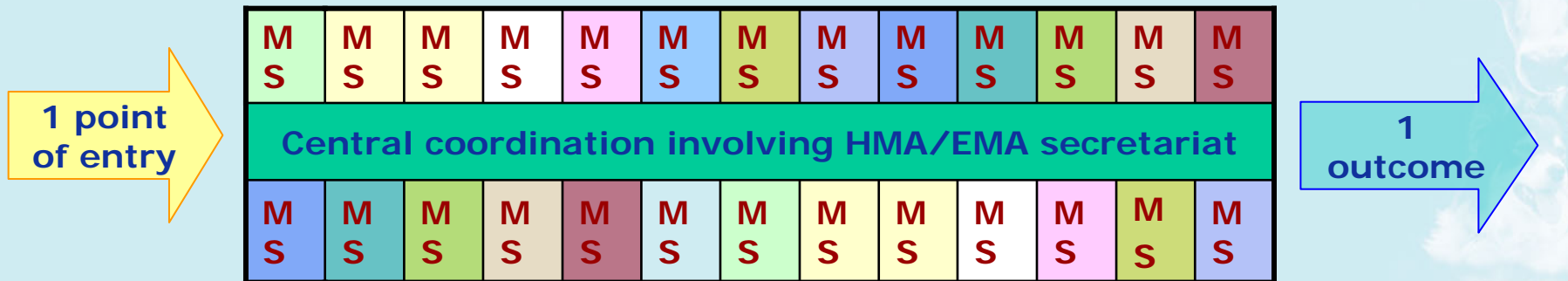
The one, one, one (1-1-1) concept
applied to all VMPs

The future



One single regulatory procedure for all products

National competent authorities are the backbone of the system



Future agency committee architecture in support of VMPs



Requires legal change

- One single Central Coordinating Body (CCB) to organise and oversee all work, to adopt decisions (structure evolved from today's Standing Committee, CMDv and CVMP)
- One representative per Member State with the competence to make decisions and chaired by the European Commission
- Joint responsibility for the efficient running of procedures and assigning the [multinational] team of NCA experts to do the scientific assessment
- Transposes scientific opinion into formal adoption of a decision and issues marketing authorisation (MA)
- Creates sub-committees and appoints expert committees ("Expert Model", on as needed basis)
- Administratively supported by a central secretariat

The central secretariat

- activities and responsibilities



To a large part already in place

- Receipt and validation of applications; appointing a national language manager (from NCAs) if requested
- Receipt of fees for the single assessment and issuance of European marketing authorisation (MA)
- Assisting the CCB in putting together the [multi-national] scientific assessment teams from NCA
- Regulatory management of the scientific assessment process; ensuring consistency of output
- Coordination of PV, inspections, secretariat to WGs, management of databases etc.
- Training of assessors, QA, communication

The [multinational] scientific assessment team



Concepts could be realised within existing legal framework

- Appointed by Central Coordinating Body
- Virtual assessment teams comprising the best scientific expertise
- Appropriately qualified experts coming from accredited national competent agencies
- Harmonised standard of assessment, applied to all scientific evaluations (pre- and post-approval)
- For referral/arbitration a second independent assessment team will be appointed – no more referrals if implementation of 1-1-1 concept
- Efficient use of resources, neither duplication nor inconsistencies

Agency committees for VMPs: E&Y proposals relevant already today

- Opinion-making committee (CVMP) to delegate work to “Pre-committees” to relieve workload (e.g. for MUMS, referral work etc.)
- “Pre-committees” to follow the “expert model”, drawing the best expertise from the NCAs and allowing for efficient working processes
- High quality scientific evaluation and methodology for risk/benefit assessment, consistent outputs (role of Secretariat)

The way forward

“The veterinary system needs its own specific organisation and regulation and no longer being a mirror legislation of the human legislation.”

Ernst & Young EMA Evaluation Report, January 2010

**Maximise upcoming opportunity
for veterinary legislative reform**

➤ **Differentiate as necessary**



Impact of veterinary reform on the human sector

- Concepts for veterinary reform follow general European policy goals for medicines
- Scientific assessment already requires specific technical expertise and different approaches – assessment criteria identical
- Some differences in registration procedures should be manageable - dedicated resources normally deal with the veterinary files & increased efficiency expected

Basic approach to medicines regulation remains fully aligned between both sectors

Conclusion



Thank you

