



Evaluation of the European Medicines Agency (EMA)

Findings, conclusions and recommendations

Conference on outcomes of the assessment of the European
Medicines Agency

30 June 2010, London

Agenda

1. Scope, research methodology and tools of the evaluation
2. Evaluation results
 1. Effectiveness
 2. Efficiency
 3. Long-term effectiveness on EU citizens
 4. Impact on EU internal market
 5. Impact on other stakeholders
3. Conclusion and recommendations

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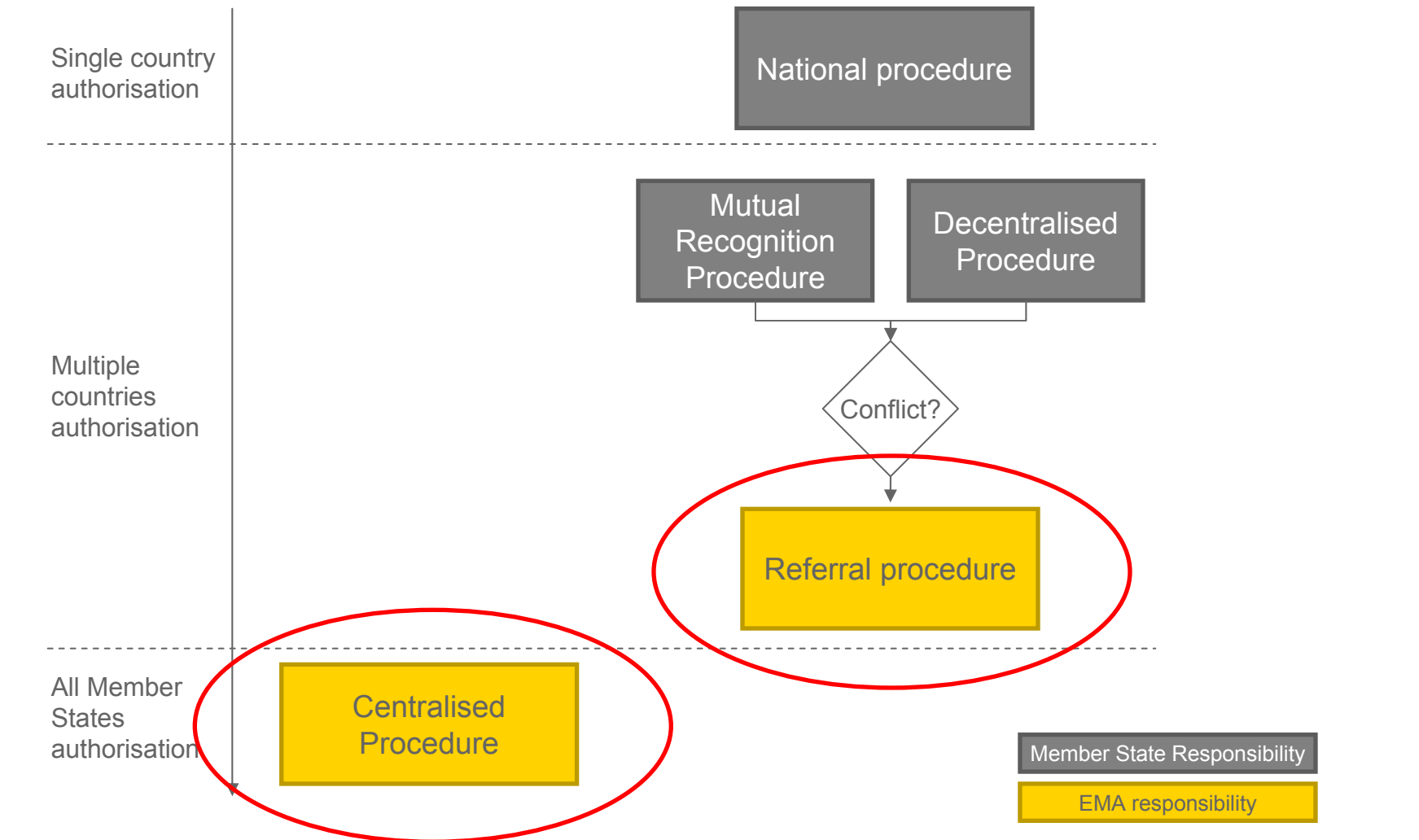
3. Conclusion and recommendations

An ambitious evaluation scope...

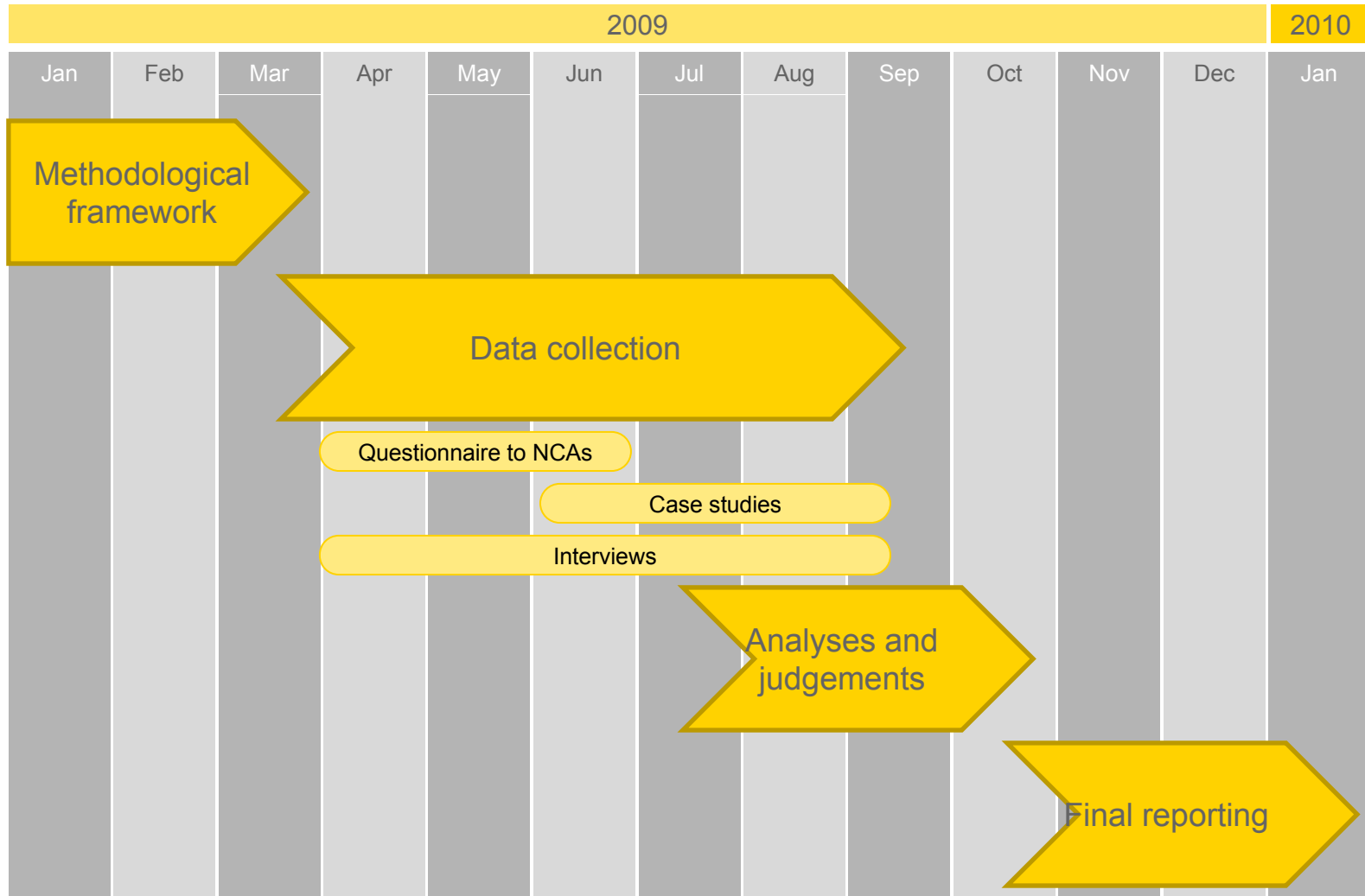
- ▶ Following evaluation questions have been answered:

Evaluation theme	Evaluation question
Effectiveness	To what extent has the EMA, as a part of the European medicines network, contributed to an effective system for authorisation of human and veterinary medicinal products for the EU?
Efficiency	To what extent has the EMA, as a part of the European medicines network, contributed to an efficient system of authorising human and veterinary medicinal products for the EU?
Long-term effectiveness on EU Citizens	To what extent has the EMA achieved its mandate to protect public and animal health by providing the EU citizens with human and veterinary medicinal products fulfilling the basic requirements for quality, safety and efficacy?
Impacts on the EU internal market	To what extent has the EMA contributed to an effectively operating internal market for human and veterinary medicinal products?
Coordination and added value to other stakeholders	To what extent has the EMA gained trust and provided added value to other stakeholders ?

... focusing on the centralised European authorisation system



A one-year evaluation process



A large data collection plan involving all types of stakeholders

Tools	Objectives	Implementation modalities	Coverage	Limits
Direct observation	To get a better understanding of interactions between participants	Attending EMA committees and working	CHMP, Pharmacovigilance WP, CMDh	Limited coverage
Questionnaire to NCAs	To have a comprehensive view of NCAs perception regarding the EMA	Test of the questionnaire with 2 NCAs, submitted to 44 NCAs	40 answers (91% return rate)	Insufficient feedbacks on quantitative data
Interviews	To get feedbacks from all types of stakeholders	Face-to-face and phone interviews (1.5 – 2 hours)	EMA Secretariat (16), Industry (13), Patients & consumers (3), Healthcare professionals (4), others (10)	Difficulties to reach some companies
6 Case studies	To conduct in-depth analyses of MS involvement	Selection criteria: large/small NCA, new/old MS, level of involvement	France, Sweden, United Kingdom, Portugal, Estonia, Hungary	Subject to MS specificities

6 case studies to get in-depth knowledge of NCAs involvement

- MHRA: Human / VMD: Veterinary
- Ministry departments
- Staff: 1 002 / 149
- Funding: fees and government funding
- Nr. of interviewees: 6 / 4

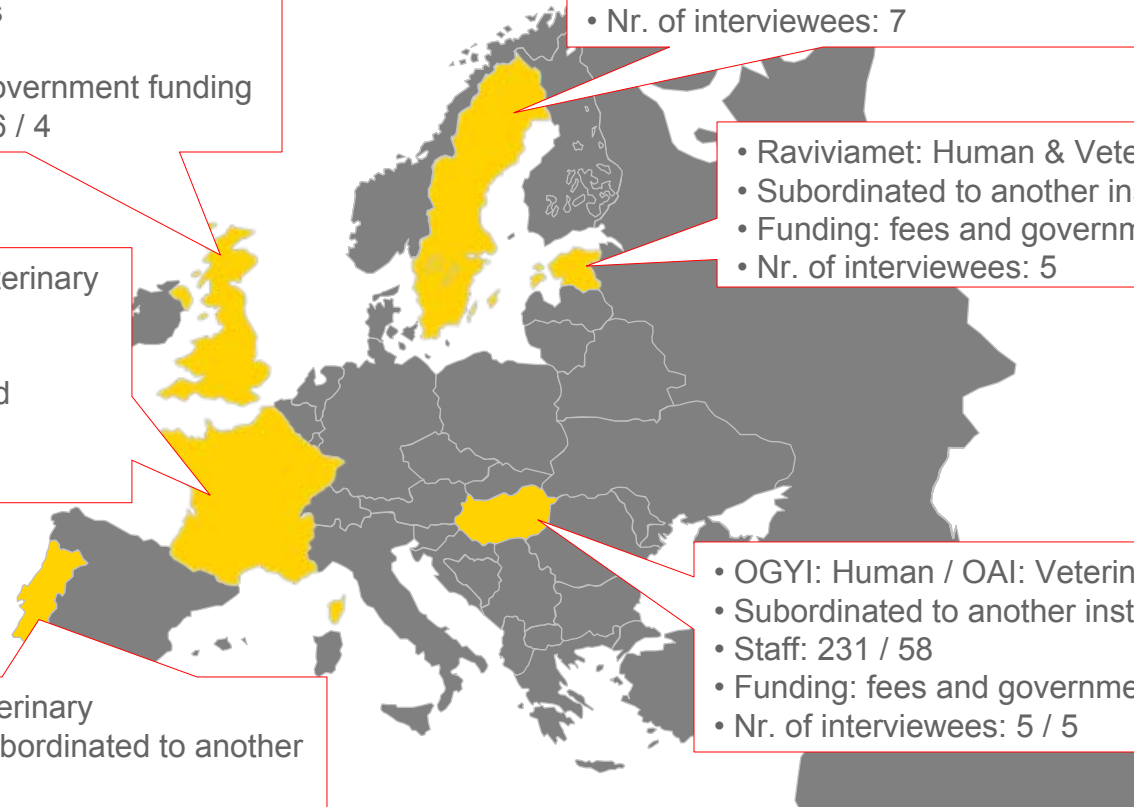
- MPA: Human & Veterinary medicines
- Independent public body
- Staff: 543
- Funding: fees and government funding
- Nr. of interviewees: 7

- Raviviamet: Human & Veterinary medicines
- Subordinated to another institution
- Funding: fees and government funding
- Nr. of interviewees: 5

- OGYI: Human / OAI: Veterinary
- Subordinated to another institution
- Staff: 231 / 58
- Funding: fees and government funding
- Nr. of interviewees: 5 / 5

- Infarmed: Human / DGV: Veterinary
- Independent public body / Subordinated to another institution
- Staff: 327 / 16
- Funding: dedicated tax, fees / government funding
- Nr. of interviewees: 4 / 4

- AFSSAPS: Human / ANMV: Veterinary
- Independent public bodies
- Staff: 1 025 / 90
- Funding: fees, dedicated tax and government funding
- Nr. of interviewees: 2 / 6



45 interviews with key stakeholders

Target group	Entity	Nr. of interviews
EU officials	DG Budget, European Parliament	2
EMA Secretariat	Heads of Units, Heads of Sectors	16
Pharmaceutical companies	Human / Veterinary Big / Medium / SME Patented / Generics General / Paediatric / Orphan / Biosimilar	10
Pharmaceutical industry representative organisations	EFPIA (Pharma), EGA (Generic), IFAH (Veterinary), LEEM	4
Patient and consumer organisations	IAPO, EURORDIS, BEUC	3
Healthcare professionals organisations	UEMO, EFN, FOV	3
National pricing & reimbursement bodies / HTA bodies	EUnet HTA, ESIP	2
Non-European Agencies	FDA, PMDA (Japan)	2
International organisations	ECDC, EFSA	2
Comparable European Agency	EPO	1

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Effectiveness

The EMA is delivering an increasing number of highly valued opinions for centrally authorised products

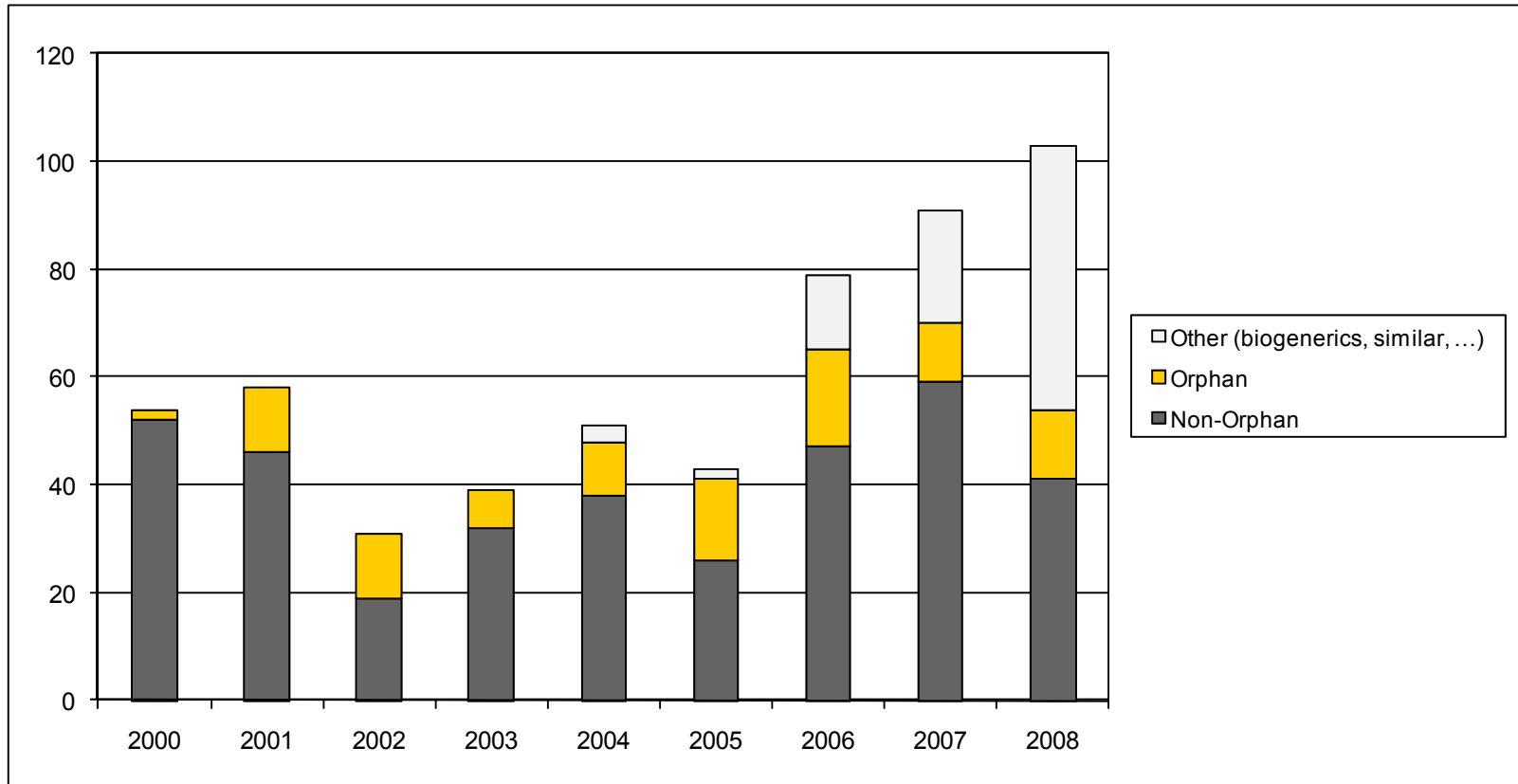
- ▶ The European authorisation system provides with **complete, clear and highly valued opinions within tight regulatory deadlines** (119 initial applications in 2008).
- ▶ **Best available experts in Europe contribute to the assessments**, contingent on the absence of conflict of interests.
 - ▶ Although the expertise coverage of MS representatives in Committees is not always sufficient, the system encourages the contribution of NCAs experts, at several stages of application's life cycle.
- ▶ **Increased interactions between the stakeholders** (industry, patients and assessment experts) have been developed. This increases mutual understandings and therefore contributes to the improvement of the quality of the applications and their assessment reports.

EMA and NCAs should **encourage more experts** at the NCA level to be exposed to European procedures, so as to foster harmonisation in evaluation practices and increase the number of knowledgeable experts that could be solicited for any given assessment.

Effectiveness

Since, 2005 the number of initial applications for human medicines per year has doubled

Initial evaluation applications by type of application for human medicinal products going through the centralised procedure

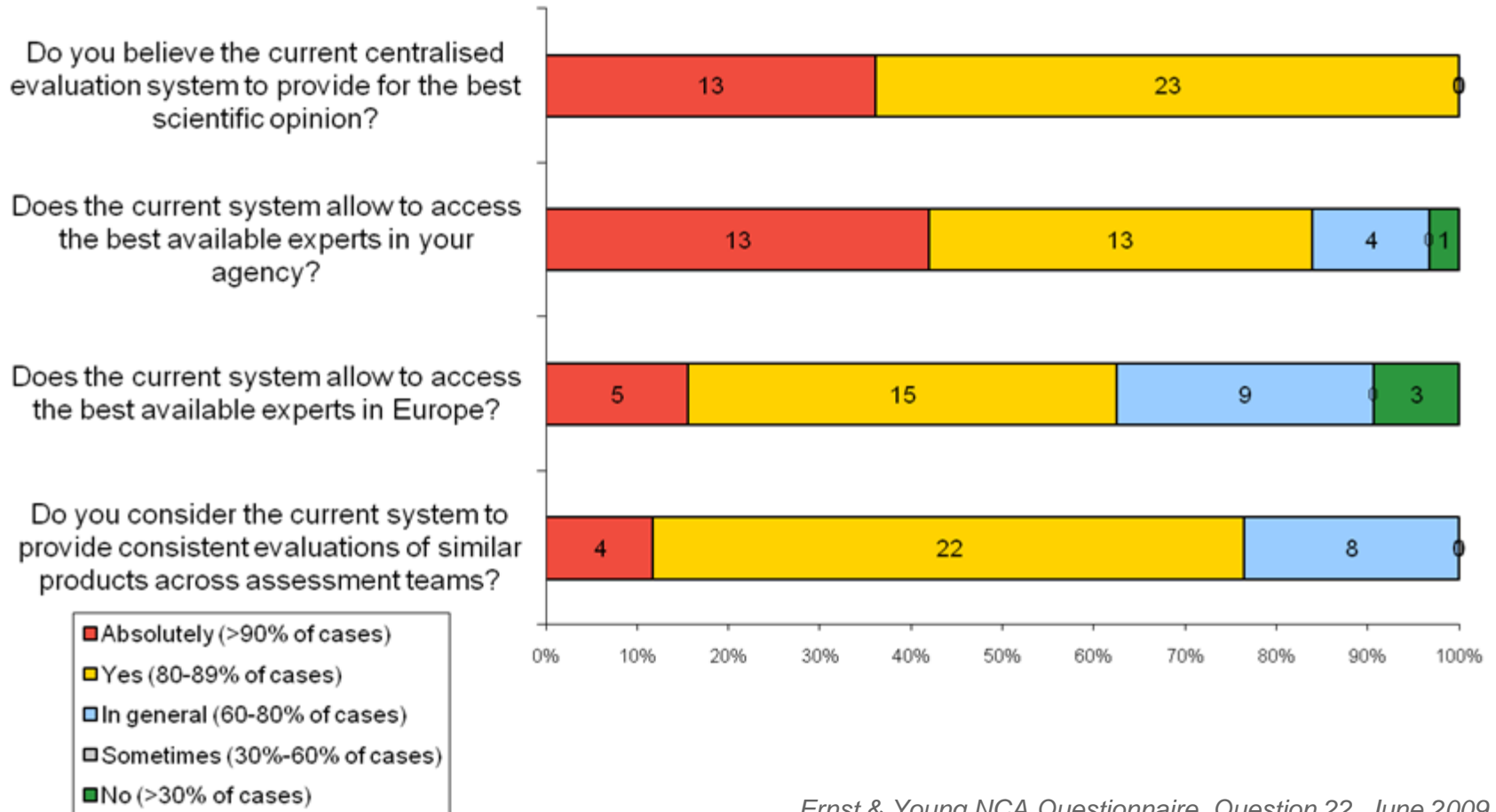


EMA annual reports

Effectiveness

An highly valued authorisation system by NCAs

General evaluation of the authorisation system



Ernst & Young NCA Questionnaire, Question 22, June 2009

Effectiveness

The organisation of *EMA committees* requires some adjustments to face an increasing workload

- ▶ The **participation of the 30 representatives** (27 MS + EEA-EFTA countries) to the opinion-making Committees is in line with political prerequisites considering the sensitiveness of these Committees' mandates but also ensures an equal access to information for all Member States.
 - ▶ The **main committees are overwhelmed with work** and their agendas could hardly be extended.
 - ▶ The **consistency between the 35 entities** (Committees, WP, SAG, etc.) is a permanent challenge. The consistency is still ensured by specific procedures and management tools, however a risk of overlap exists and has been identified for example between PDCO and CHMP, CAT and CHMP or pharmacovigilance WP and CHMP.
- ▶ PDCO, CAT and HMPC could evolve towards an **expert model** to improve the reactivity of the opinion process.
 - ▶ The creation of **additional temporary targeted pre-committees for referrals and for generic products** may decrease the CHMP and CVMP workload.

Effectiveness

The *EMA Secretariat* strongly contributes to the effectiveness of the system

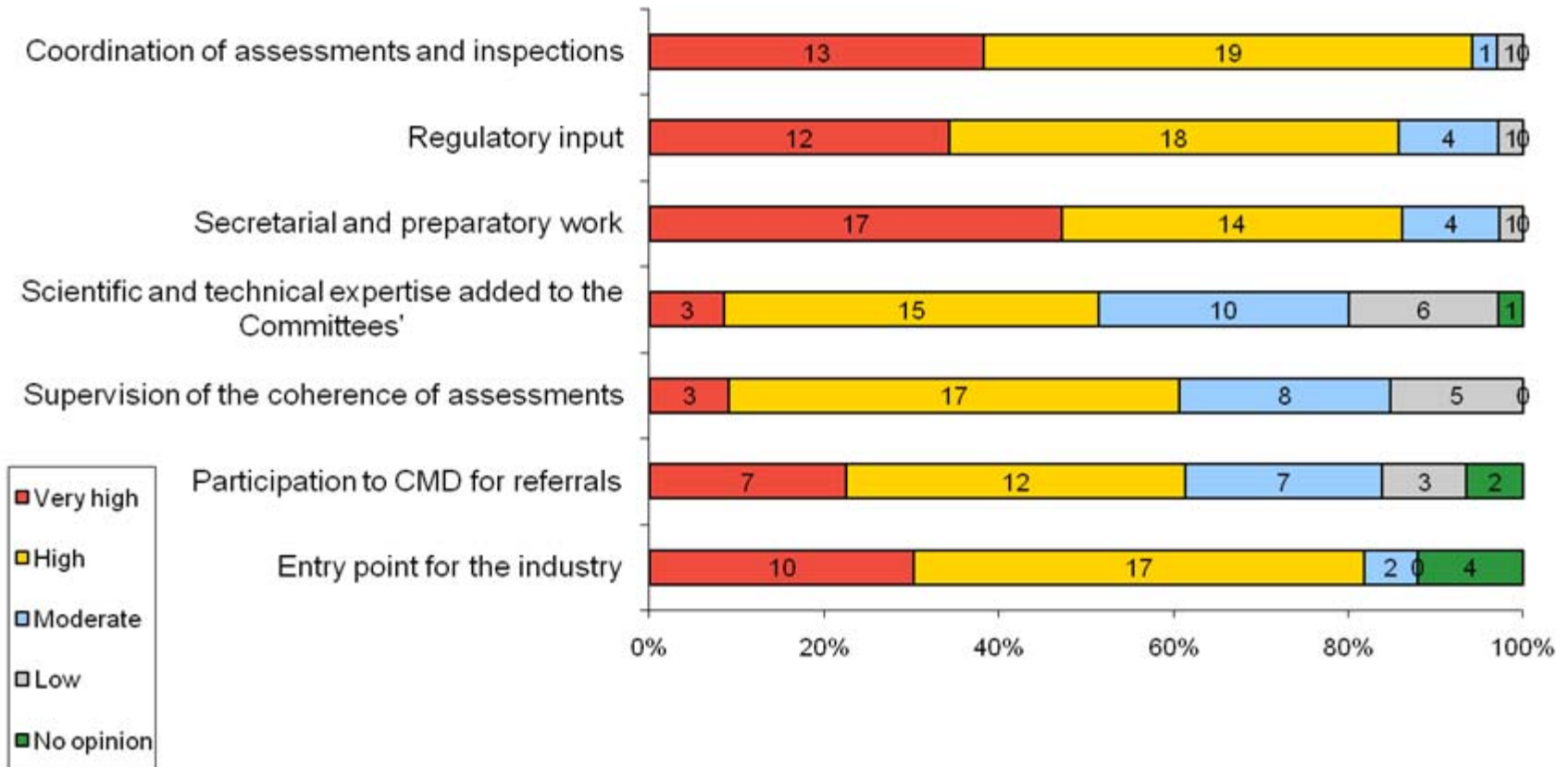
- ▶ The EMA Secretariat (469 staff, 182,9M€ budget) appears to be a **learning organisation** that shows a permanent willingness to develop an on going improvement process.
- ▶ The attractiveness of the centralised procedure together with the EU enlargement and the new regulations have led to an **increased workload and an enlarged scope of responsibility** for the EMA over the past ten years.
- ▶ However, the external stakeholders fear the development of **bureaucracy and rigidity that are challenging the ratio scientific assessment / formalisation in particular for the most complex new entities.**

- ▶ The EMA Secretariat should strengthen its ability to monitor consistency of EMA outputs.
- ▶ The EMA Secretariat should alleviate the administrative burden for scientific assessors when the scientific complexity of a dossier justifies it.

Effectiveness

NCAs recognise and appreciate the support of the EMA Secretariat

In which fields and to what extent does the EMA Secretariat provide input?



Ernst & Young NCA Questionnaire, Question 21.2, June 2009

Effectiveness

EMA answer to address the recent and future contextual challenges

- ▶ The Agency is continuously **addressing innovative scientific topics** (e.g. biomarkers, gene therapy) in order to smoothly conduct the changes requested by the permanent research advances.
- ▶ However, the **shortage of scientific workforce** will certainly be a critical concern in the future. A coordinated effort at EU level may attenuate this deficiency.

On a prospective point of view, **specific Veterinary challenges** should be considered as independent fields with highly specific issues that can no longer be solved through mirror solutions of human initiatives:

- ▶ launch a reflection on the necessity for amending the veterinary regulation on specific aspects: ecotoxicity assessments, generics;
- ▶ launch a reflection on the appropriateness of market exclusivity or other incentives for MUMS products.

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Efficiency

EMA activities are efficiently managed

- ▶ The EMA is composed of:
 - ▶ the EMA Secretariat and
 - ▶ a network of 44 National Competent Authorities.
- ▶ Its functioning is based on **a volunteer contribution of NCAs.**

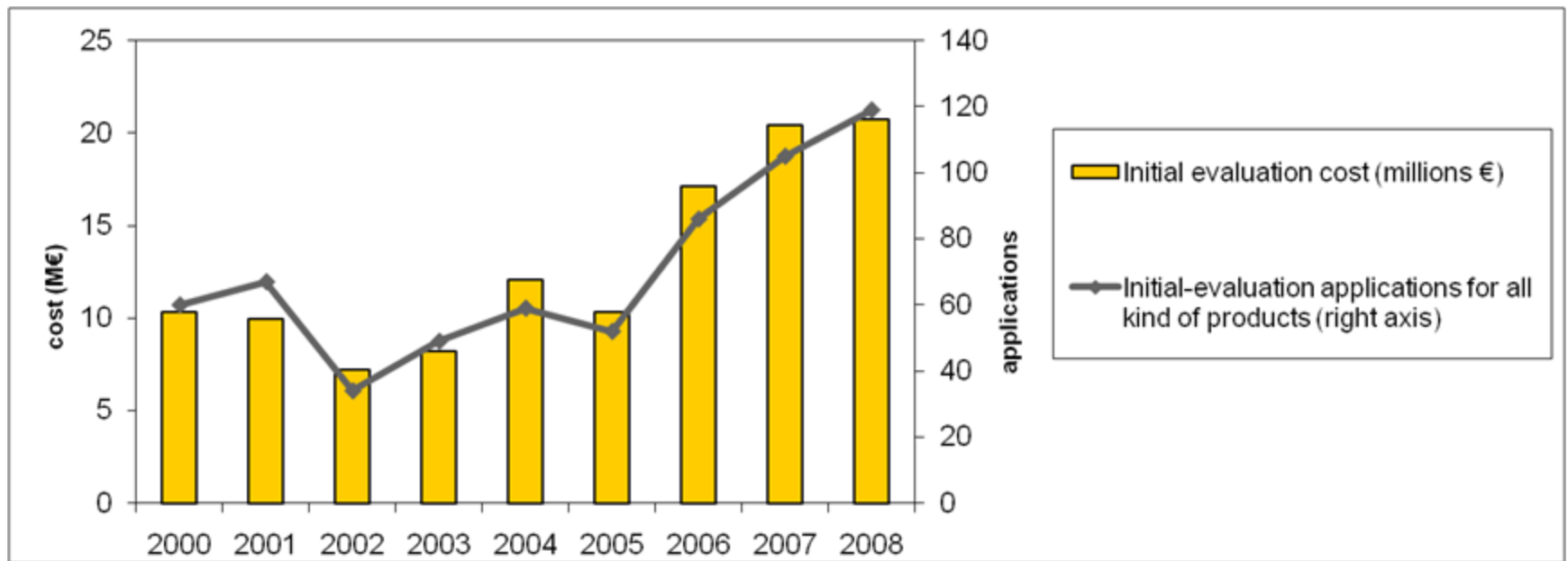
- ▶ **The operational efficiency of the EMA has improved over the period 2000-2008.**
 - ▶ The EMA Secretariat as well as EMA support services have gained in efficiency since 2000
 - ▶ Cost optimisation is an on-going process within EMA Secretariat and participates in maintaining the costs.

- ▶ **A clear opinion on the total cost of the system is not possible at this stage.** Most of the NCAs have no insight into their own costs, neither the costs of the national procedures, nor the costs of their contribution to the EMA.
 - ▶ An on going study aims at identifying the real costs incurred at national level.

Efficiency

EMA evaluation activities are efficiently managed

- ▶ The **EMA core activity has doubled** (from 60 initial applications for human and veterinary medicines in 2000 to 119 initial applications in 2008). The EMA budget has followed the same trend (led by industry fees that represent on average 66% of EMA resources)
- ▶ Although the system has become more and more complex (enlargement, extended scope of the regulation, etc.), **the quality of the work has been maintained.**



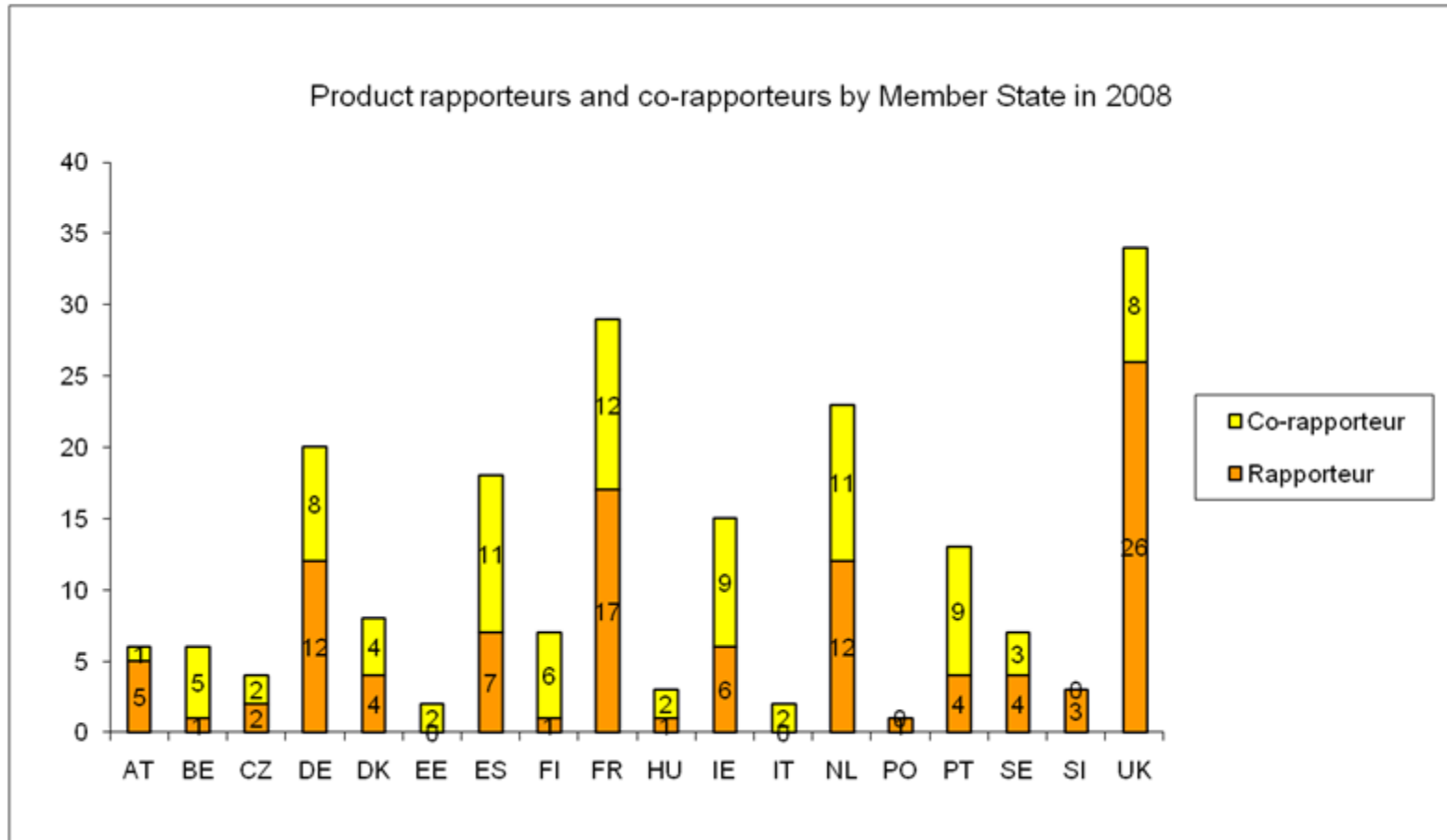
Ernst & Young evaluation report, from EMA Activity Based budget & Annual reports, January 2010

Efficiency

Several types of involvement of NCAs in the EMA have be considered

- ▶ **The involvement of the NCAs in EMA activities varies**, depending mainly on their size, type of expertise and financing model:
 - ▶ Large agencies dedicate up to full-time experts to EMA activities;
 - ▶ Some medium Member States agencies are highly involved despite limited resources;
 - ▶ Small agencies may not be able to ensure proper involvement in EMA activities (e.g. some small NCAs are even rarely taking part in the CVMP meetings).
- ▶ All agencies consider that their involvement in EMA activities is **of high scientific interest, also to the benefit of national procedures.**

Seven Member States are taking 75% of rapporteurships and co rapporteurships of the CHMP



Ernst & Young evaluation report, from EMA statistics produced for HMA, January 2010

Efficiency

NCAs network involvement

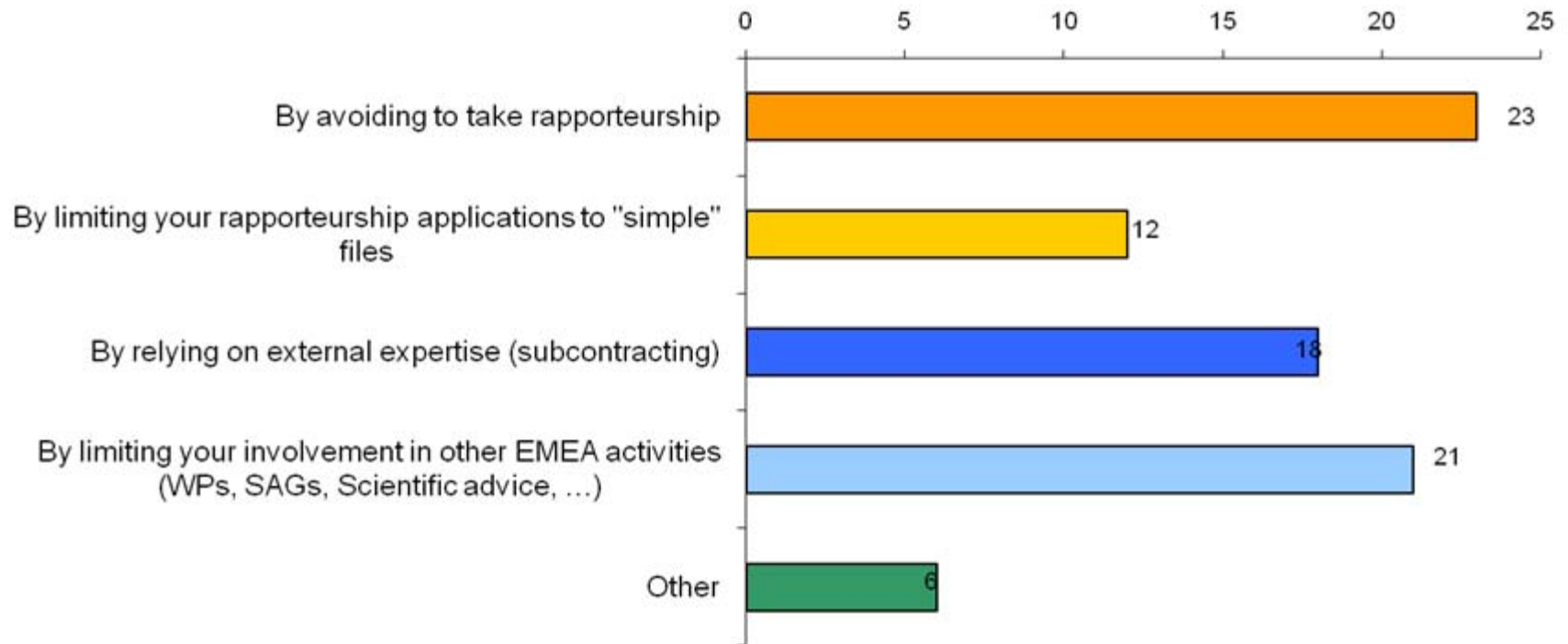
- ▶ NCAs are of the opinion that **their contribution to centralised applications is mainly covered by the compensation paid by the EMA.**
- ▶ However, despite some differences based on their internal resources, all **NCAs are facing an increasing lack of resources** that impact directly their level and type of involvement in EMA activities.
- ▶ In this context, **the maintenance of the voluntary system still provides the flexibility required** and the great majority of NCAs do not plan to reconsider their involvement in EMA activities, identified as a priority for national agencies. However, **its sustainability is not ensured.**

- ▶ The compensation system should be clarified and a **funding system identified for non-paid activities.**
- ▶ The EMA should make a better use of the experts in the network by promoting **multinational assessment teams.** This should include removing administrative burdens and allowing the EMA to directly compensate each contributing NCA in proportion to its involvement in the assessment.

Efficiency

Lack of national resources impacts strongly the involvement in EMA activities

How NCAs deal with the lack of resources they face?



Ernst & Young NCA Questionnaire, Question 12.3.4, June 2009

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Long-term effectiveness on EU citizens

The EMA contributes to the development of medicinal products of major therapeutic interest

- ▶ **Orphan medicines** activities have proved successful in promoting research, development and introduction of new medicines for orphan diseases
 - ▶ The Committee for Orphan Medicinal Products (COMP, 2000, operating since April 2001) is often referred to as a “success story”.
 - ▶ However “orphan” veterinary medicines for “Minor Use - Minor Species” (MUMS) status has not enjoyed the same success.
- ▶ The **Committee for Advanced Therapies** (CAT, 2008, operating since January 2009) addresses the specific issues raised by new type of biological medicines.
- ▶ EMA completes its activities on medicinal products of major therapeutic interest through 7 SAGs, widely recognized by stakeholders

- ▶ **COMP** should be considered as a “opinion-making committee” using a “member-state model” for modus operandi.
- ▶ **CAT** is a “Pre-committee” that may evolved towards an “Expert model” for modus operandi.

Long-term effectiveness on EU citizens

EMA constant efforts into supporting European citizens and animals, including specific populations

- ▶ **Paediatric regulation** is intended to ensure that safer and more innovative drugs were made available to children patients.
 - ▶ Paediatric Committee (PDCO) was created in 2006 to assess the content of paediatric investigation plans
 - ▶ Submitting a Paediatric Investigation Plan (PIP) to PDCO before engaging in the development of a medicine intended for children is compulsory.
- ▶ Principal limitation regarding PIP is precisely the **risk of incoherence** between the opinions produced by the PDCO, the CHMP Scientific Advice and later by the CHMP itself.

- ▶ **Coordination between PDCO, CHMP and SAWP** should thus be enhanced to complete EMA efforts regarding specific patient populations.
- ▶ PDCO should evolve towards a Pre-committee model to reinforce consistency of the whole system.
- ▶ The EMA should explore the potential impact of recent scientific evolutions such as the impact of personalised medicine concepts (e.g. smaller and more well-defined patient population using pharmacogenomics and biomarkers).

Long-term effectiveness on EU citizens

Right level of safety before and after marketing authorisation of products through guidelines and post-authorisation activities (1/2)

- ▶ **Guidelines contribute to harmonisation** and access to medicinal products with a satisfactory level of efficacy, quality and safety
- ▶ EMA guidelines are considered **useful and valuable** both by the industry, for enhancement of product development's predictability and by evaluators, for harmonisation of assessment practices.
- ▶ The guideline production process is efficient but may benefit from more fruitful interactions with stakeholders.
- ▶ EMA role in **post-authorisation activities** for centralised products such as inspections is well recognised (regular increased of EMA-coordinated inspection number in good coordination with NCAs).

Implement **minor improvements to guidelines preparation process**:

- ▶ Making the guidelines preparation process more transparent,
- ▶ Clarifying guidelines by presenting case studies & underlining major changes
- ▶ Proposing trainings or annual updates,
- ▶ Monitoring new guidelines impact on other guidelines.

Long-term effectiveness on EU citizens

Right level of safety before and after marketing authorisation of products through guidelines and post-authorisation activities (2/2)

- ▶ Pharmacovigilance has received a lot of attention recently, and is undergoing **major changes** at the EMA level. Specific difficulties have been identified both at the data collection, storage and analysis level.
- ▶ Huge efforts have already been invested in the conception and realisation of **EudraVigilance database**. However EudraVigilance remains a complex system to manipulate for the end-users, either the NCAs or the industry.

- ▶ EMA should keep the lead on harmonising pharmacovigilance procedures and tools at European level.
- ▶ Constant efforts should be put into **streamlining all tools contributing to Pharmacovigilance**, including EudraPharm and EudraVigilance.

Long-term effectiveness on EU citizens

Although EMA generally has a very positive and increased impact on EU citizens, it may fail to communicate with them properly.

- ▶ EMA dedicates resources and uses suitable mechanisms to inform healthcare professionals and patients, but some of those could be improved: transparency measures, website, etc.
- ▶ The EMA generally suffers from a **lack of visibility** both from the patients' and the healthcare professionals' point of view (EMA exposure to media is low).
- ▶ **EMA communication strategy is heavily dependent on its networks**, especially NCAs, their involvement in EMA communication strategy being crucial.

- ▶ EMA should pursue its efforts to provide clearer, more coherent and targeted messages
- ▶ Propose a **communication adjusted for each public type** concerned
- ▶ **Strengthen the role of NCAs in the communication strategy** through a coordinated action among healthcare agencies
- ▶ Improve EPAR to better suit the HTA uses, increase the awareness of EPARs' information for healthcare professionals
- ▶ Fine-tune the SPC for the understanding of healthcare professionals
- ▶ Improve the user friendliness of the website

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Impact on EU internal market

EMA offers the opportunity for access to medicinal products for all citizens through a relatively affordable marketing authorisation procedure

- ▶ The human pharmaceutical industry consider **EMA fees to be fair and appropriate** to the evaluation work done with the notable exception of Scientific Advice.
- ▶ Independently of the fees level, **EMA fee structure is complex**, as resulting from consecutives regulations.
- ▶ The **veterinary pharmaceutical industry is more dependent on EMA fees rates**, as the centralised procedure may prove less attractive because of more fragmented and species-specific markets.
- ▶ MUMS medicines do not benefit from the same incentives as Orphan medicines do, limiting the improvement of veterinary medicines coverage.

- ▶ Facilitate the **understanding of fee structure** by providing support to industrials in navigating EMA fee system & helping them estimate, through a multi-choice web interface.
- ▶ **Simplify fee structure keeping the fairness of fees** as an important goal.

Impact on EU internal market

EMA contributes to the harmonisation of European marketing procedures (1/2)

- ▶ Scientific Advice (SA) is considered helpful by all stakeholders with a steady increase of the number of applications as an indication for success.
 - ▶ SA use and quality is recognised especially for helping industry to get better prepared and provide the right data
 - ▶ The recent introduction of a new procedure for SA has been welcomed, as it has helped reducing timelines and simplifying the process.
- ▶ However SA may not be as predictive of CHMP opinions as the industry would have expected, raising the **issue of SA consistency with committees' opinions**.
- ▶ Both companies and NCAs have regretted the **high level of formalisation of SA** potentially hindering the discussion.

Make the Scientific Advice **a more streamlined and easily accessed procedure** through:

- ▶ streamlining the pre-submission process;
- ▶ facilitating communication with the industry, maybe by making an entry point more available throughout the procedure (and not providing only written responses);
- ▶ launching a reflexion on fees, especially for Veterinary products.

Impact on EU internal market

EMA contributes to the harmonisation of European marketing procedures (2/2)

- ▶ Most stakeholders recognize that EMA already stands as an **example in terms of transparency**, and that recent efforts in this regard have proved extremely fruitful.
- ▶ This commitment does not go without a higher level of resource needs, and should be further strengthened by the recent proposal for a consistent **Transparency Policy for EMA**.
- ▶ Transparency policy aims at applying a more proactive approach towards transparency in the daily operation of the EMA, further strengthening interaction with NCAs and external stakeholders.

Transparency of Rapporteurship appointment procedures should be strengthened:

- ▶ assessment of candidates carried out by independent authority on the predetermined criteria;
- ▶ details of conflict of interests of candidate made public;
- ▶ names of appointees and reasons for decisions made public;
- ▶ appointment process to be audited.

Impact on EU internal market

EMA supports SMEs and their ability to innovate

EMA Service	Applicable type of product	Reduction
Scientific Advice	All except Orphan medicines & MUMS	90% fee reduction to the total applicable fee
	Orphan medicines	100% fee reduction to the total applicable fee
	MUMS	100% fee reduction to the total applicable fee
Pre-authorisation Inspections	All	90% fee reduction and deferral
Application for Marketing Authorisation	All except Orphan medicines and Advance therapy medicinal products	Deferral and conditional fee exemption
	Orphan medicines	100% fee reduction to the total applicable fee
	Advanced therapy medicinal products	50% fee reduction to the total applicable fee
Scientific Services	All	90% fee reduction
Establishment of MRL for veterinary medicinal products	All veterinary medicinal products	90% fee reduction
Administrative services (excluding parallel distribution)	All	100% fee exemption
Post-authorisation inspections	All	90% fee reduction
Post authorisation activities including annual fees during the 1st year after MA	Orphan medicines	100% fee exemption to the total applicable fee
	Advanced therapy medicinal products	50% fee reduction to the total applicable fee

Impact on EU internal market

EMA supports the entry of generic medicines and biosimilars in the market

- ▶ Human medicines
 - ▶ The number of centralised applications for human use (generics and biosimilars) significantly increased since the introduction of generics at EU level: they represented roughly **half of the applications for centralised procedure in 2008**.
 - ▶ The number of positive opinions issued on generics does not precisely mirror that evolution: 10 out of 66 applications for generics in 2008.
- ▶ Veterinary medicines
 - ▶ Generic medicinal products mainly go through DCP & MRP, impacting EMA through referrals mostly, generating **dramatic increase in referrals workload**.
 - ▶ The fact that veterinary products apply to different species, in different national breeding contexts leads to a lack of harmonisation of Reference Products in the EU.

Consider a dedicated committee responsible for assessing generics while still leaving the final decision in CHMP (respectively, CVMP) hands to significantly lighten their work.

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Impact on other stakeholders

EMA collaboration with HTA, pricing and reimbursement bodies

- ▶ Although stakeholders acknowledge that scientific assessment performed by the EMA and decision on the medicine reimbursement is not directly linked, EMA outputs is recognised as a **key step in a global process leading to pricing and reimbursement**.
- ▶ HTA, pricing and reimbursement bodies acknowledge EMAs' efforts as well as the constructive collaboration in place and wish to **further develop this mutual understanding to reach increased consistency** within the whole drug evaluation and marketing process.

Particular areas of improvement for the EMA in relation to this cooperation are:

- ▶ the transfer of useful and needed information under the appropriate format;
- ▶ collection and share of relative effectiveness data.

Impact on other stakeholders

EMA contribution to the harmonisation of authorisation procedures at international level

- ▶ All stakeholders clearly acknowledge the role of the EMA as a **recognised actor at international level** as well as a great contributor in the harmonisation of authorisation procedures:
 - ▶ within international organisations (ICH, VICH, WHO, OIE);
 - ▶ with its major international partner, the FDA, and other international medicine agencies such as PMDA in Japan;
 - ▶ with other European agencies and in particular around overlapping topics such as infectious diseases and vaccines with the ECDC or EFSA;
 - ▶ with health authorities in developing countries through issuing certificates of medicinal products.

A remaining area for harmonisation between FDA and EMA has been suggested to be the clinical trial phases where FDA performs centralised procedures where Europe processes through national agencies

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The EMA, a successful European story...

- ▶ Since its creation in 1993, the EMA has made considerable progress in setting up and maintaining an effective European authorisation system for human and veterinary medicinal products. **In a quite limited timeframe, the EMA has gained great consideration from all stakeholders.**
- ▶ With regards to its mandate, the EMA has proved **effective in protecting public and animal health** by providing the EU citizens with human and veterinary medicinal products fulfilling the requirements for quality, safety and efficacy.
- ▶ These achievements have been possible thanks to an **effective and efficient organisation** of the stakeholders involved in the marketing authorisation process.
- ▶ The European Medicines Agency, as a whole including the contribution of 44 National Competent Authorities throughout the 27 EU Member States and the 3 EEA-EFTA countries and the EMA Secretariat, is the **archetype of an effective community model with concrete and regular outputs.**

... facing increasing challenges

- ▶ EMA faces **difficulties to cope with this increasing workload**. The system has achieved its maximum capacity, especially when considering the workload of the main opinion-making committees (CHMP and CVMP).
- ▶ EMA will have to face **novel challenges** in the years to come, including
 - ▶ scientific (e.g. the emergence of novel technologies like biomarkers, pharmacogenomics and theranostic),
 - ▶ contextual (e.g. aging of population that may in the long-term lead to the need a specific focus on geriatric products)
 - ▶ and organizational challenges (e.g. some stakeholders argue in favour of including clinical trials under the scope of EMA competencies).
- ▶ One may trust the EMA to adapt to these new challenges as successfully as it has dealt with the previous ones, if its **organisation is appropriately altered in order to ensure the sustainability of the system**.

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