



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New Challenges for EMA and National Competent Authorities

Update from the EMA

12th DGRA Annual Congress, 15 June 2010, Bonn

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In this Presentation

- Outcome of the public consultation on the EMA Road Map to 2015
- Optimizing project management and scientific assessment
 - EMA reorganisation
 - Update on the organisation of the work of the CHMP Working Parties (WPs) and Scientific Advisory Groups (SAGs)



The EMA Road Map to 2015



EMA Road Map to 2015: A Quick Overview (1/8)

- Is a continuation of the Road Map to 2010 project, building on current achievements, but also taking due account of the Agency's business drivers
- Provides the Agency's vision on how it should further develop itself as a public health Agency
- Encompasses the Agency's longer term strategy for both human and veterinary medicines
- Should be consistent with and complementary to strategic directions provided by the European Commission and Heads of Medicines Agencies (HMA)



EMA Road Map to 2015: A Quick Overview (2/8)

- Recognises the important contribution by the National Competent Authorities (NCAs) through the provision of high-quality scientific resources for the evaluation and supervision of medicinal products
- Will be complemented with a document “From Vision to Reality” and a multi-annual work programme



EMA Road Map to 2015: A Quick Overview (3/8)

Identified business drivers:

- Efficient operation of the Agency's core business
- Addressing public health needs
- New and emerging science
- Impact of increasing globalisation
- Regulatory model
- Ensuring patient safety
- Demands for more transparency and openness



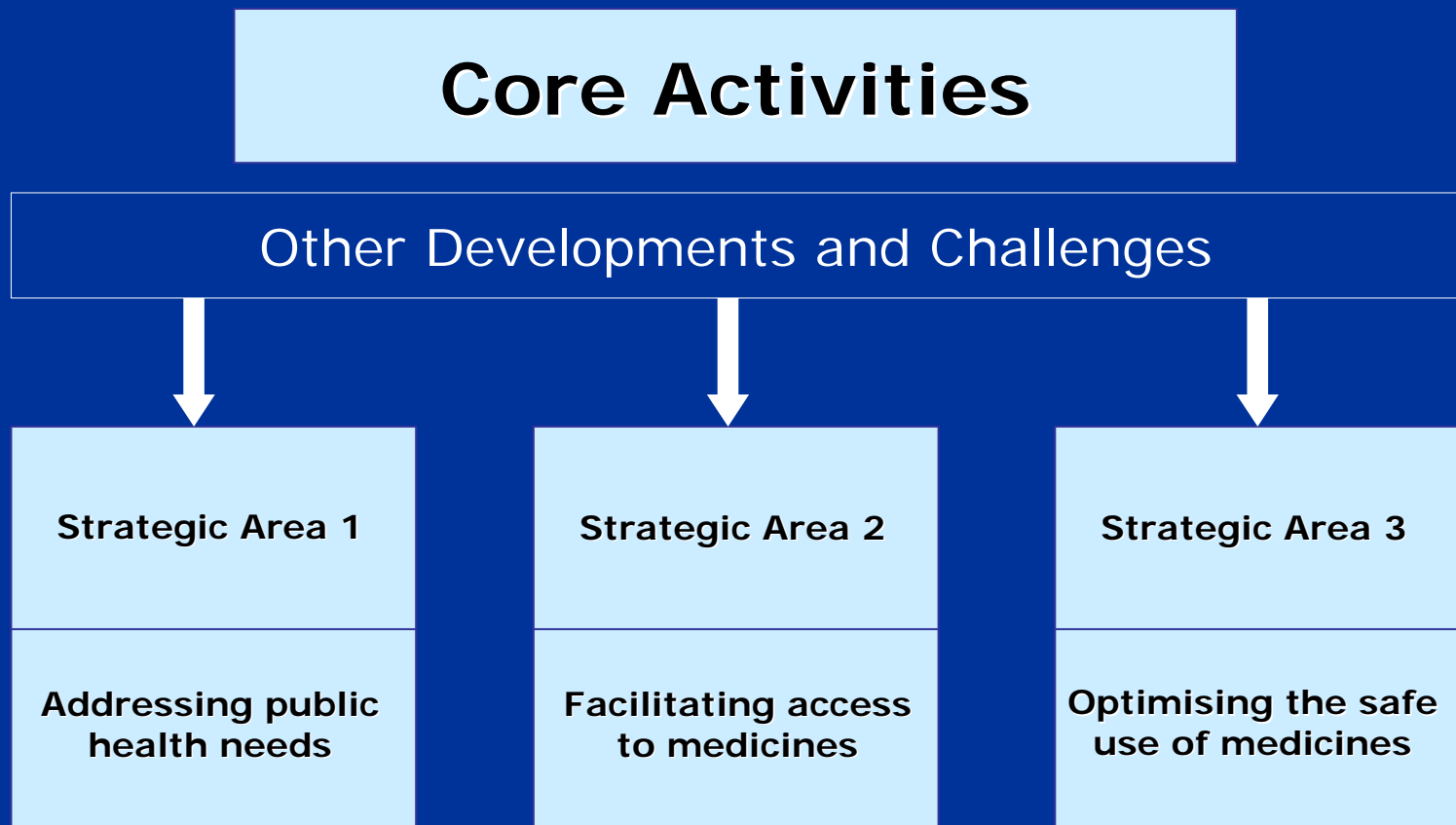
EMA Road Map to 2015: A Quick Overview (4/8)

Core activities:

- 1st priority
- In line with current and upcoming Community legislation
- Further strengthen efficiency
- Focus on increasing the quality of the outcome of the work
- Details in “From Vision to Reality” document



EMA Road Map to 2015: A Quick Overview (5/8)





EMA Road Map to 2015: A Quick Overview (6/8) – Strategic Area 1

Objectives	Impact/Result Indicators
Stimulate medicine development in areas of unmet medical needs/neglected and rare diseases, and for all types of medicines for veterinary use.	<p>Increase in the number of scientific advice requests for medicines for unmet medical needs/neglected and rare diseases, and for all types of medicines for veterinary use.</p> <p>Increase in the use of specific procedures such as Article 58 procedures (under Regulation (EC) N° 726/2004).</p>
Facilitate new approaches to medicine development.	Existing model for medicines regulation is adapted to enable integration of new and emerging science.
Apply a more proactive approach to public health threats where medicines are implicated.	Effective preparedness mechanisms which take due account of learnings from previous public health threats/crisis situations are available.



EMA Road Map to 2015: A Quick Overview (7/8) – Strategic Area 2

Objectives	Impact/Result Indicators
Address the high attrition rate during the medicine development process.	<p>Increase in the number of successful marketing authorisation applications for which scientific advice has been sought and adhered to.</p> <p>Scientific information on failed medicine development processes is made available to the scientific community.</p>
Reinforce the benefit/risk balance assessment model.	<p>Increased inclusion of quantitative elements, alongside an improved elaboration of the rationale for the decision/opinion in the benefit/risk considerations, for subsequent publication in the European Public Assessment Reports (EPARs) (medicines for human use).</p> <p>Systematic reference in all EPARs to the concept of benefit/risk assessment applied during the scientific review (medicines for veterinary use).</p>
Continue to improve the quality and the regulatory and scientific consistency of the outcome of the scientific review.	<p>Structured external surveys performed by the Agency's stakeholders on the outcome of the scientific reviews demonstrate an increase in the quality and the consistency.</p>



EMA Road Map to 2015: A Quick Overview (8/8) – Strategic Area 3

Objectives	Impact/Result Indicators
Strengthen the evidence base in the post-authorisation phase to enable better regulatory decision-making.	A regulatory model which facilitates the post-authorisation collection of data on benefits and risks of medicinal products is put at the disposal of the Regulatory System.
Enhance patient safety by avoiding unnecessary risks to patients as a result of the use of medicines.	A revised risk management concept, which targets both novel pharmacovigilance methodologies as well as a risk minimisation toolbox better adapted to reduce harm, is available.
Become a reference point on information for medicines evaluated by the Agency.	A high-quality, informative and targeted set of information on medicines, falling within the sphere of the Agency's responsibilities, is proactively put at the disposal of the EU Regulatory System Network at the moment of licensing/updating of the marketing authorisation.
Improve the decision-making process by taking due account of patient experience, hence contributing to the rational use of medicines.	Conclusions from outcome research projects analysing the impact of the regulatory decisions on public health are used to provide input in future regulatory policy decision-making.



EMA Road Map to 2015: Outcome of Public Consultation (1/4)

- 71 contributions have been received (from EU Institutions, Member States' Competent Authorities, European Industry Associations, European HCP Organisations, Academia / Learned Societies, International Organisations, HTA Bodies, individual pharmaceutical companies, etc.)
- Feedback is very positive, with overall support for the Agency's vision for the next 5 years, including the objectives and priorities as well as the choice of the strategic areas



EMA Road Map to 2015: Outcome of Public Consultation (2/4)

- Main general comments relate to:
 - Specific groups asking for their needs to be better recognised (OTC medicines, generics and biosimilars)
 - The need to recognise pharmaceutical industry as a stakeholder
 - Specific groups advocating greater involvement (academia)
 - Requests for the Agency's sphere of involvement to be widened (clinical trials, complementary and alternative medicines, contrast agents) or more emphasis to be put on specific population needs (elderly, women)



EMA Road Map to 2015: Outcome of Public Consultation (3/4)

- Main general comments relate to (cont'd):
 - Core business not to be affected
 - Concerns about the implementation of the Vision as well as the sustainability of the current system
 - Current proposals for involvement with HTA Bodies as well as the concepts for earlier access to market to be further developed



EMA Road Map to 2015: Outcome of Public Consultation (4/4)

- Next steps:
 - All individual contributions to be published on EMA website shortly
 - Review of all individual contributions is still ongoing
 - Road Map will be redrafted in August taking into account comments made
 - From Vision to Reality document is being drafted (comments from public consultation will be taken into account)
 - Further involvement of stakeholders is likely (dedicated meeting 4th Quarter 2010 is being considered)
 - Finalisation is still scheduled for the December 2010 Management Board meeting



Optimizing Project Management and Scientific Assessment



EMA Reorganisation: Rationale

- New responsibilities for the EMA over the past years leading to
 - More Scientific Committees and increased cross-relationships
 - Increase in procedures and more complex procedures
 - Increase in Staff to deal with the new responsibilities
- Future legislative proposals will bring further responsibilities
- EMA reply
 - Agency-wide process improvements started in 2006
 - In 2007 increased focus on how to further optimise the functioning of the Agency leading to a reorganisation in 2009



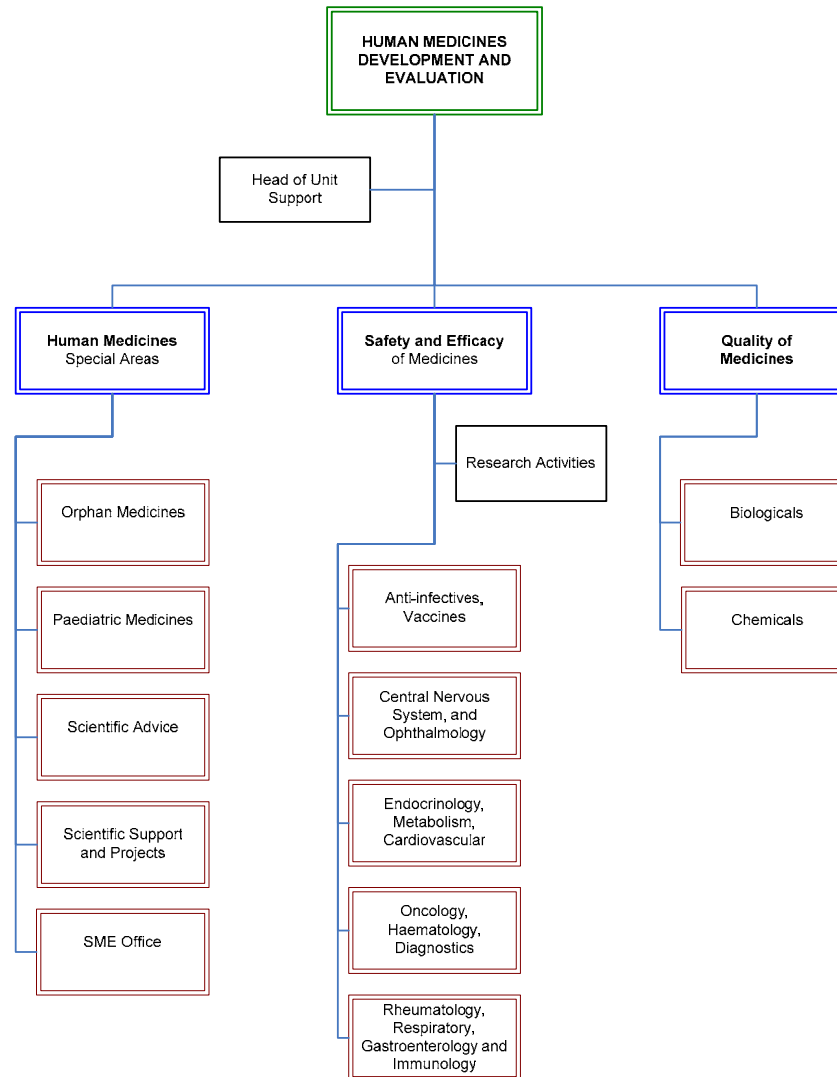
EMA Reorganisation: Key Changes (1/2)

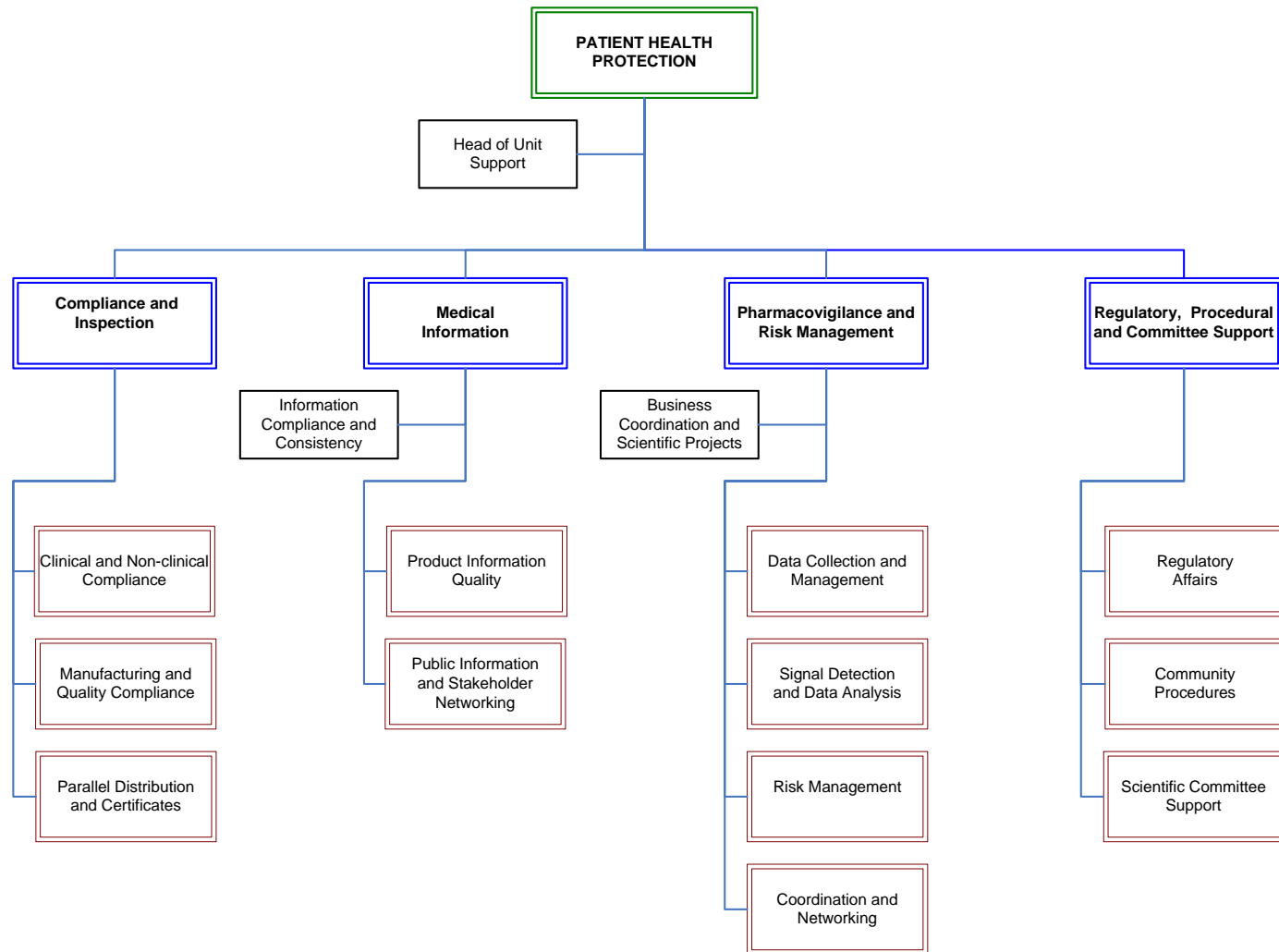
- Organisational changes
 - Bringing life-cycle management of medicines for human use in 1 Unit, covering the various steps from provision of advice during R&D up to post-authorisation changes
 - Creating a Unit contributing to patient health protection from the multiple perspectives of pharmacovigilance risk and crisis management including “crisis” procedures, inspections, regulatory compliance, referral procedures
 - Creating a dedicated Sector for the management of product data and documentation related to applications for the whole Agency
 - Rationalisation of services within the other Units



EMA Reorganisation: Key Changes (2/2)

- Managerial changes
 - Revising the roles and responsibilities of EMA management and introducing a 4th layer of management (Section Heads)
 - Revising the Agency's governance structure
- Operational changes
 - Maintaining the Product Team concept but further refining its operation
 - Introducing the concept of Product Oversight meetings





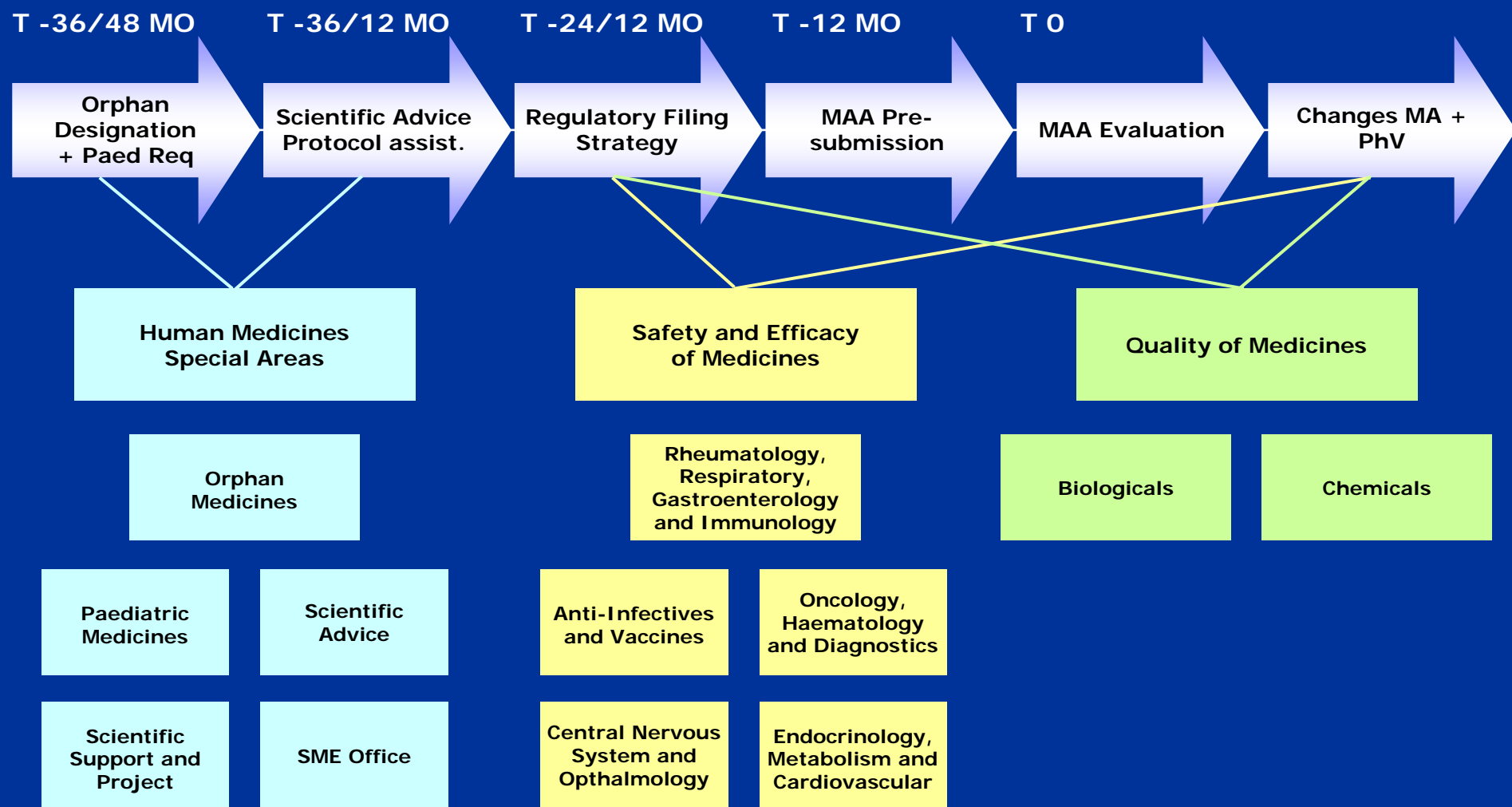


EMA Reorganisation: Further Work

- Full implementation of the reorganisation is ongoing with emphasis on
 - Detailed allocation of the roles and responsibilities within the Product Team concept for the various EMA activities (using the RACI methodology)
 - Identification of dedicated Process Owners
- Review of already implemented aspects of the reorganisation in order to introduce further improvements
 - Concept of Product Oversight meetings

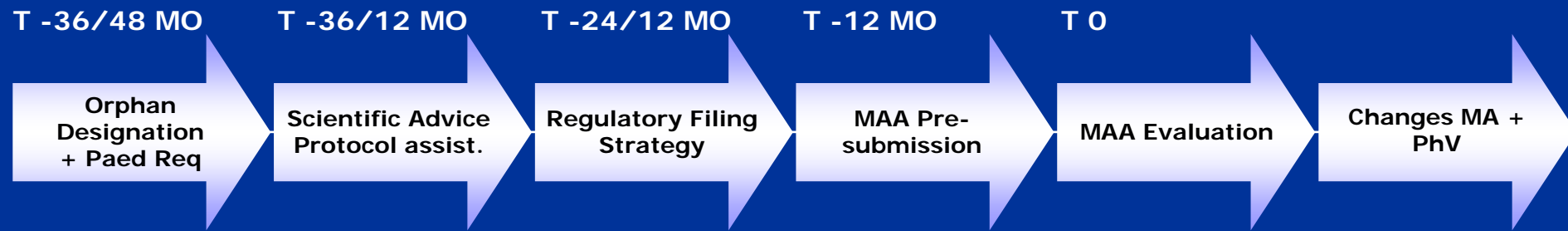


Human Medicines Development and Evaluation





Patient Health Protection



Pharmacovigilance and Risk Management

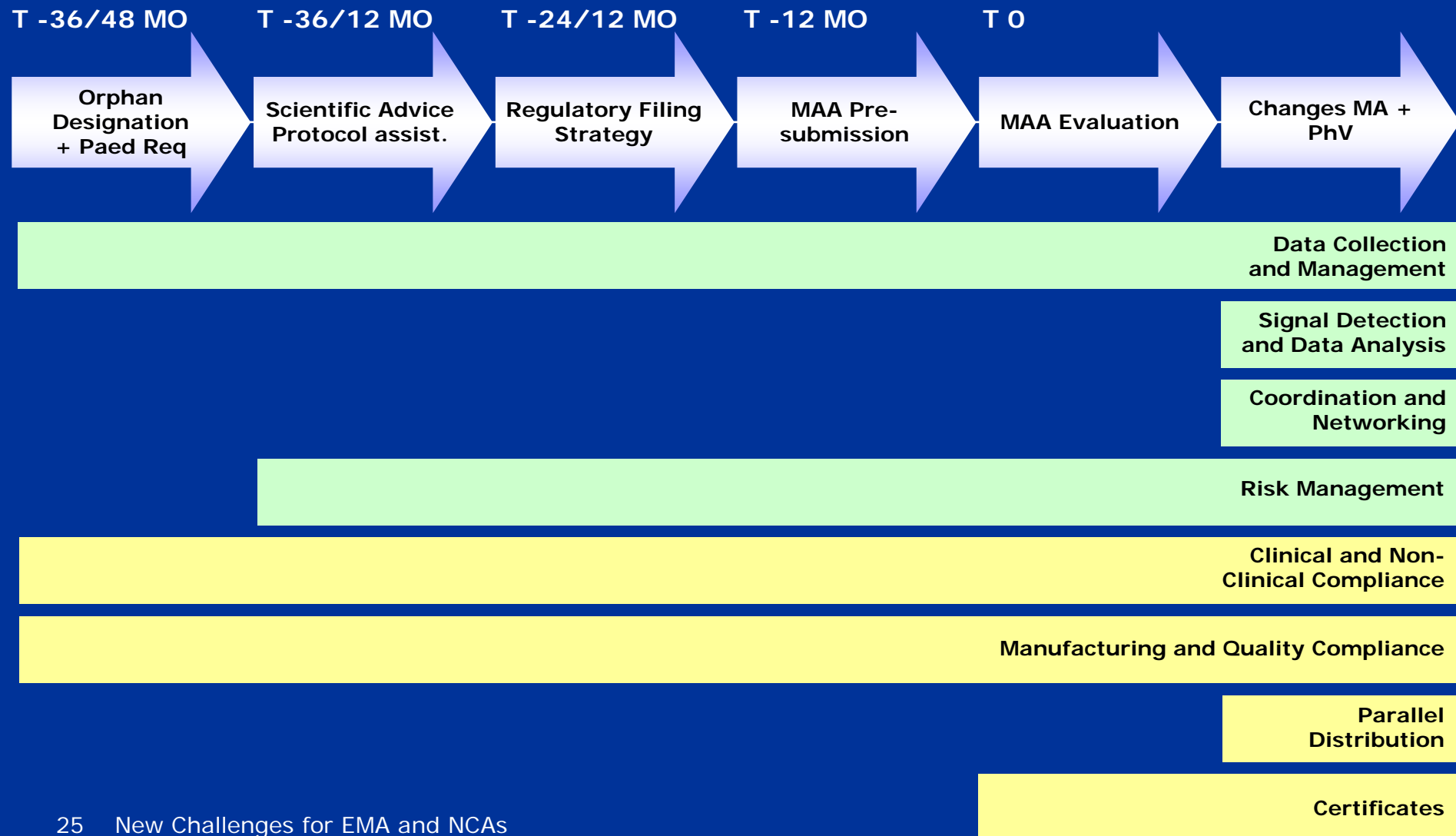
Compliance and Inspections

Medical Information

Regulatory, Procedural and Committee Support

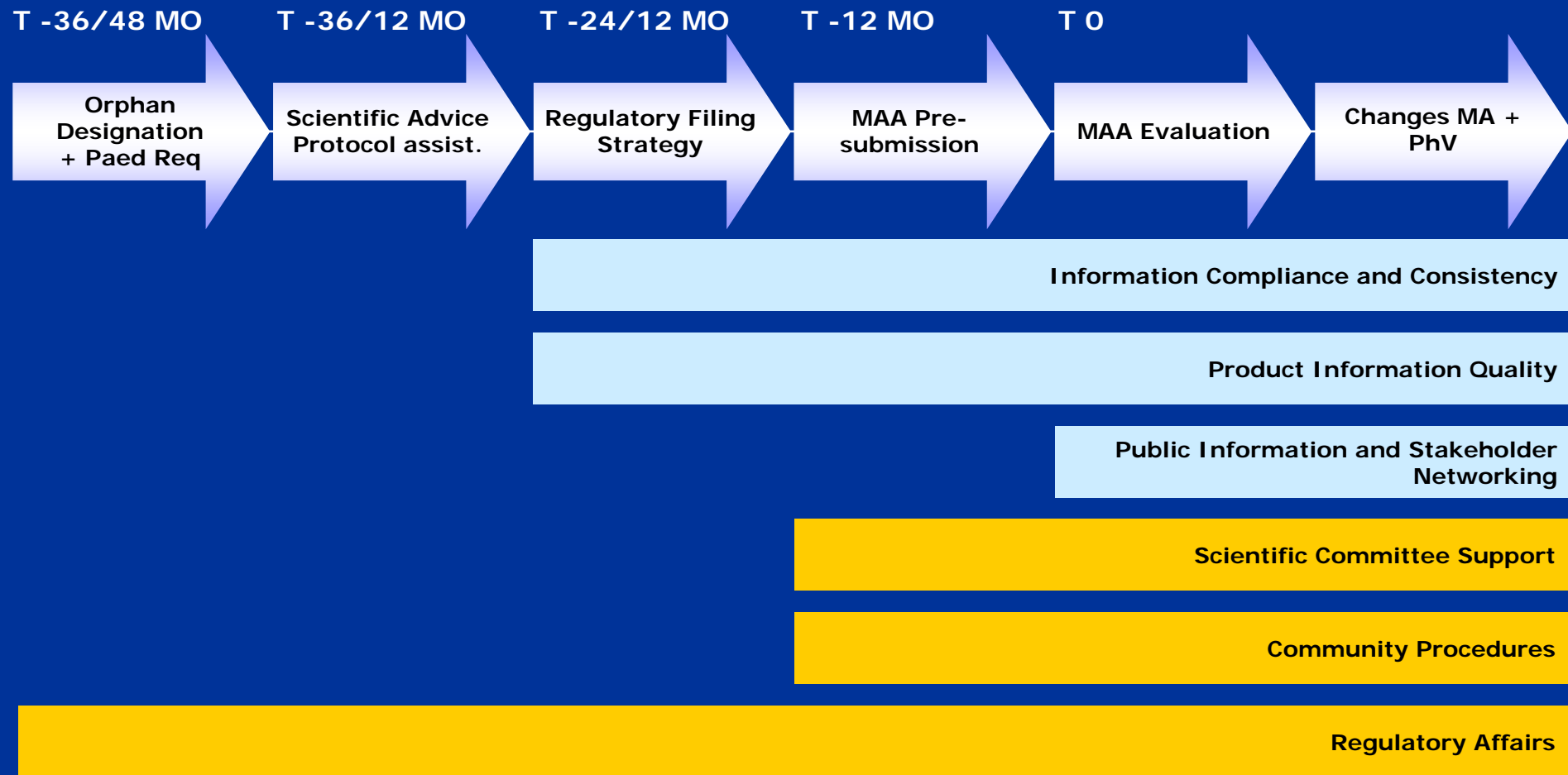


Patient Health Protection





Patient Health Protection





Update on CHMP Working Parties: Background (1/2)

- Legal basis: Article 56(2) of Regulation (EC)No 726/2004
- Key role in strengthening the EU Regulatory Network by
 - Developing regulatory guidelines
 - Contributing to scientific advice
 - Contributing to specific aspects of dossier evaluation (at CHMP request)



Update on CHMP Working Parties: Background (2/2)

- Some WPs were put in place several years ago (BWP, EWP, QWP, SWP, ad-hoc BPWP)
- Others were subsequently set-up: SAWP, BMWP, CPWP, GTWP, PgWP and VWP
- However, complexity and workload of the system (including the creation of new Committees) have increased considerably



Update on CHMP Working Parties: WPs Review Project (1/7)

- Need to review the structure, composition and mandate of the CHMP WPs to
 - Improve efficiency
 - Avoid overlapping and unnecessary competition
 - State clearly the role of each stakeholder
- PhVWP and the 2 EMA fora on interaction with the civil society representatives are excluded from this scope
- Reflection Paper adopted at the May 2010 CHMP meeting



Update on CHMP Working Parties: WPs Review Project (2/7)

- Legislation mentions standing and temporary WPs
- Two main types of WPs have been identified
 - With transversal competences
 - With more specific competence linked to a particular kind of product / therapeutic class
- In addition, Drafting Groups (DGs) can be established when a process for reviewing or developing a particular guideline is adopted and the topic doesn't fit with any of the existing WPs



Update on CHMP Working Parties: WPs Review Project (3/7)





Update on CHMP Working Parties: WPs Review Project (4/7)

EWP

Temporary WP (Therapeutic)

CVWP
OWP
IDWP
CNSWP

Temporary WP

BSWP
PKWP

Drafting Groups

Endocrinology
Rheumat/Immunol
Respiratory
Gastroenterology



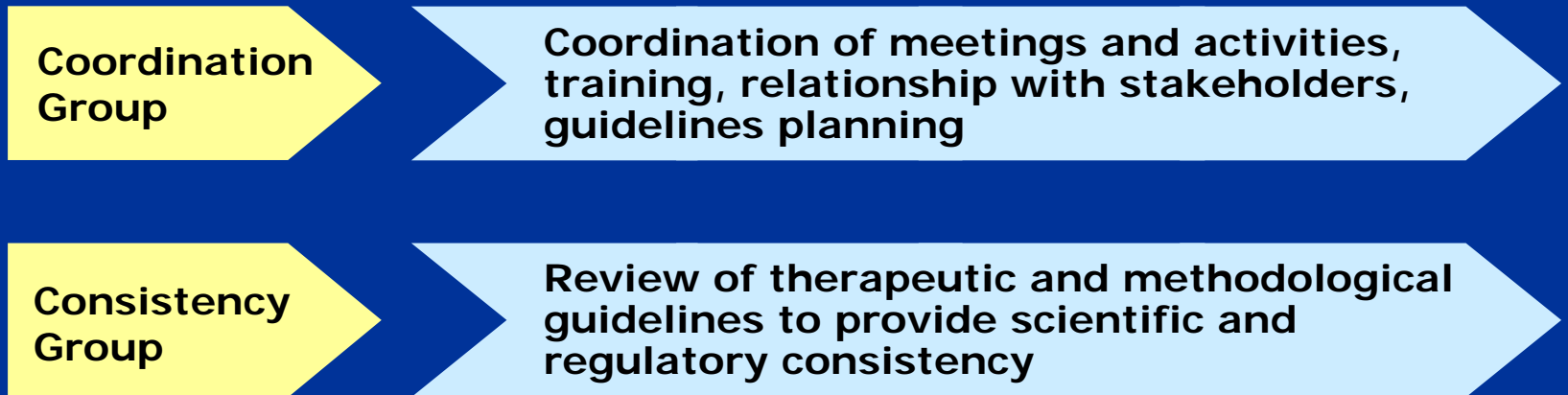
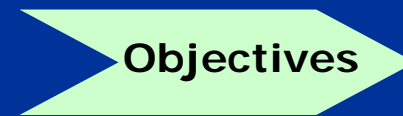
Update on CHMP Working Parties: WPs Review Project (5/7)

- Composition of WPs and DGs
 - Assessors from NCAs, \pm half of them senior assessors with accredited experience in the assessment of medicinal products and drafting of guidelines (remainder to be less experienced assessors to ensure continuity in the future)
 - Chair to be one of the senior assessors
 - For standing WPs 1 member per NCA and for temporary WPs composition to be based only on competence and expertise



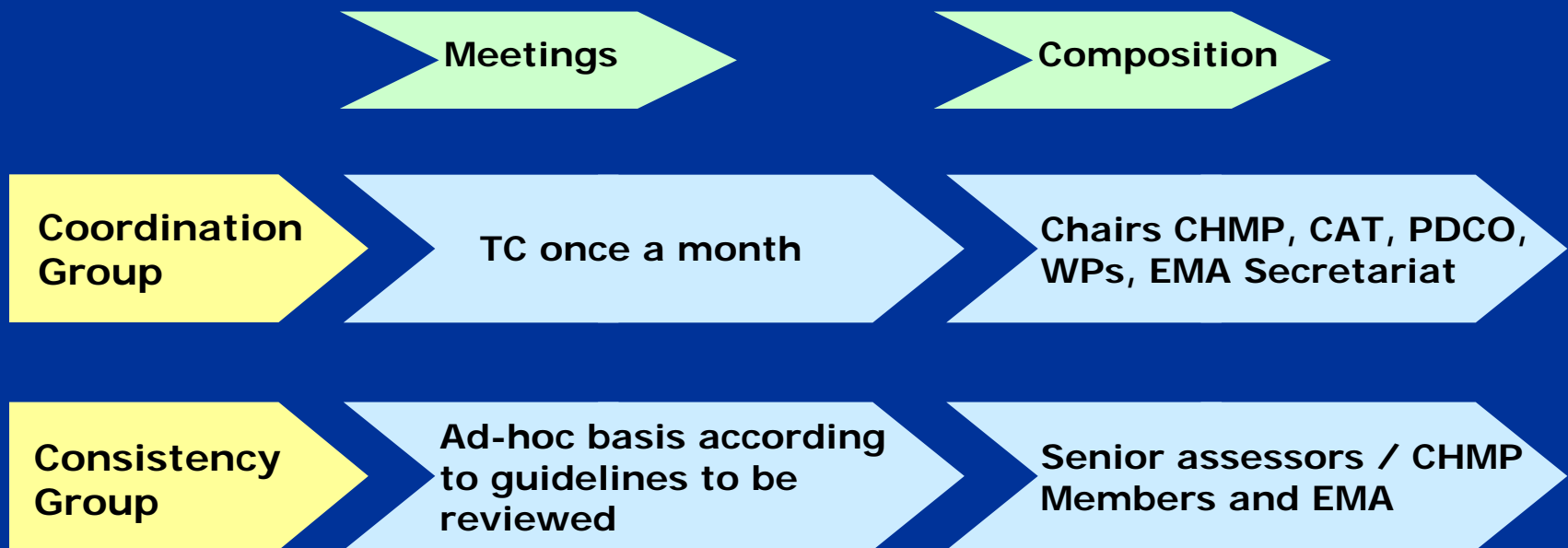
Update on CHMP Working Parties: WPs Review Project (6/7)

- In addition, Consistency and Coordination Group to be established





Update on CHMP Working Parties: WPs Review Project (7/7)



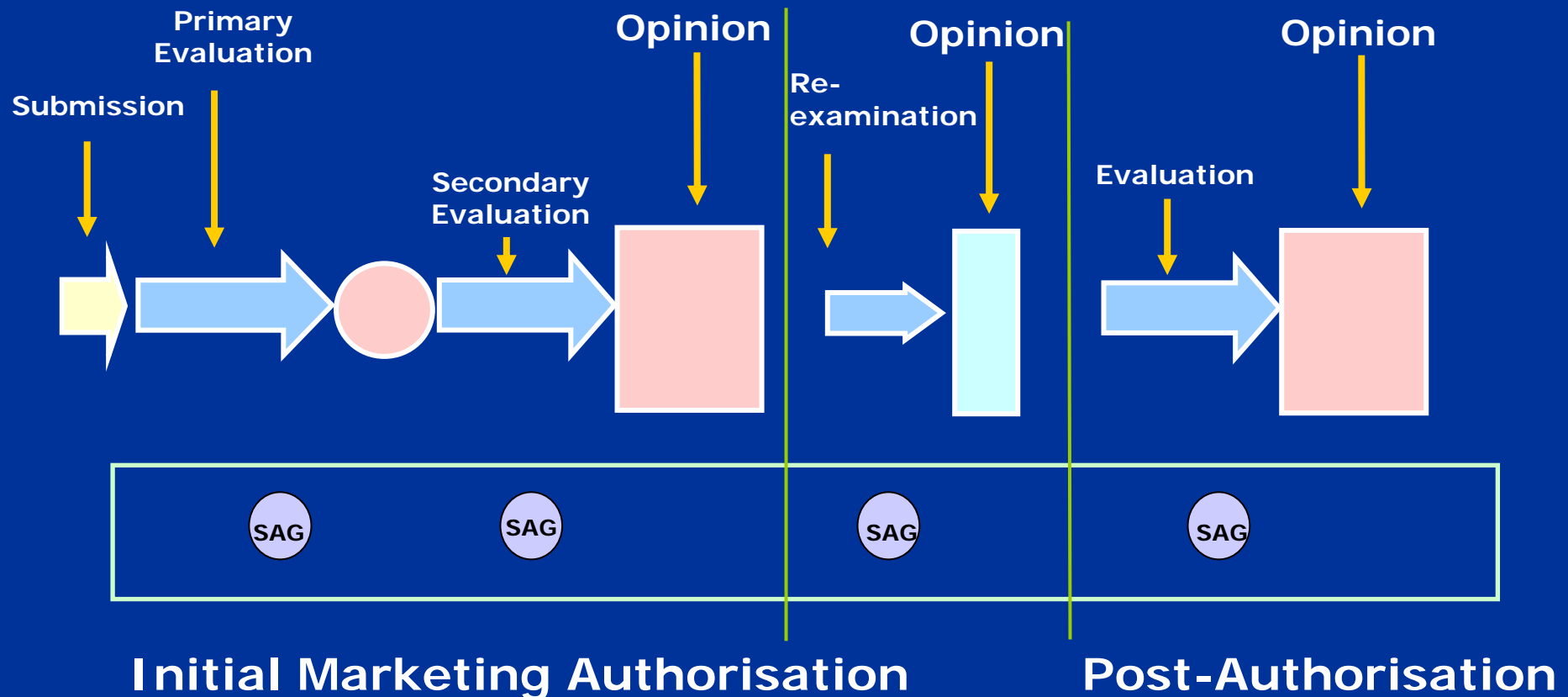


Update on SAGs: SAGs and the CHMP

- SAGs are created by the CHMP to deliver answers, on a consultative basis, to specific questions addressed to them by the Committee
- The CHMP, while taking into account the position expressed by the SAG, remains responsible for its final Opinion



Update on SAGs: SAG Activity During the Scientific Review Process





Update on SAGs: EMA (Advisory Groups) versus FDA (Advisory Committees)

- Many similarities
 - Overall concept, structure, experts
- Key differences
 - FDA: public (recorded, transcript, media)
 - EMA: not public (but reflected in EPAR)
 - FDA: longer timelines (e.g. disclosability guidance requires sponsors backgrounder to be submitted 48 business days prior to the meeting)
 - EMA: more flexible, shorter timeframe



Update on SAGs: SAGs Review Project

- Agreed Action Plan
 - Review of handling of conflicts of interests
 - Optimisation of SAG meetings frequency
 - Increase in number of Core Members and possibility to invite additional experts as well as patient representatives
 - Attendance by applicants of (Co)-Rapporteurs' presentations
 - CNS SAG to be split into Neurology SAG and Psychology SAG
 - When to use SAGs and B/R assessment by SAGs



Update on SAGs: SAGs Review Project

- In conclusion
 - SAGs deliver independent, non-binding advice to the CHMP
 - SAGs ensure support and feedback from a broad range of scientific and professional expertise available in Europe
 - SAGs are a flexible and valuable instrument to optimise the regulatory decision-making process
 - Action Plan is in progress