EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Fee system of the European Medicines Agency

Ensuring long-term sustainability

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On behalf of the Project Team

Scope of the presentation

- To present the reasons for changing the current fee system
- To propose a model which takes account the objectives identified by the EMA
- To discuss the objectives for a future fee system

Drivers for change

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1. Result of Ernst & Young Evaluation on fees
2. Fee regulation requires evaluation of its implementation
3. Recent and anticipated changes in legislative and regulatory environment

1. Result of Ernst & Young Evaluation on fees

- Stakeholders recognise the economic interest of centralised procedure
- Overall the fees compare favourably with other regulatory agencies
- EMA's income is vulnerability due to its high dependency on fees from applications

1. Result of Ernst & Young Evaluation on fees *(cont.)*

- Stakeholders consider that:
  - Fee structure could be simplified
  - Certain applicants and product groups require special attention
- Sustainability of resources from the European network questioned as certain procedures are currently non-fee attracting

2. Fee regulation requires evaluation of implementation

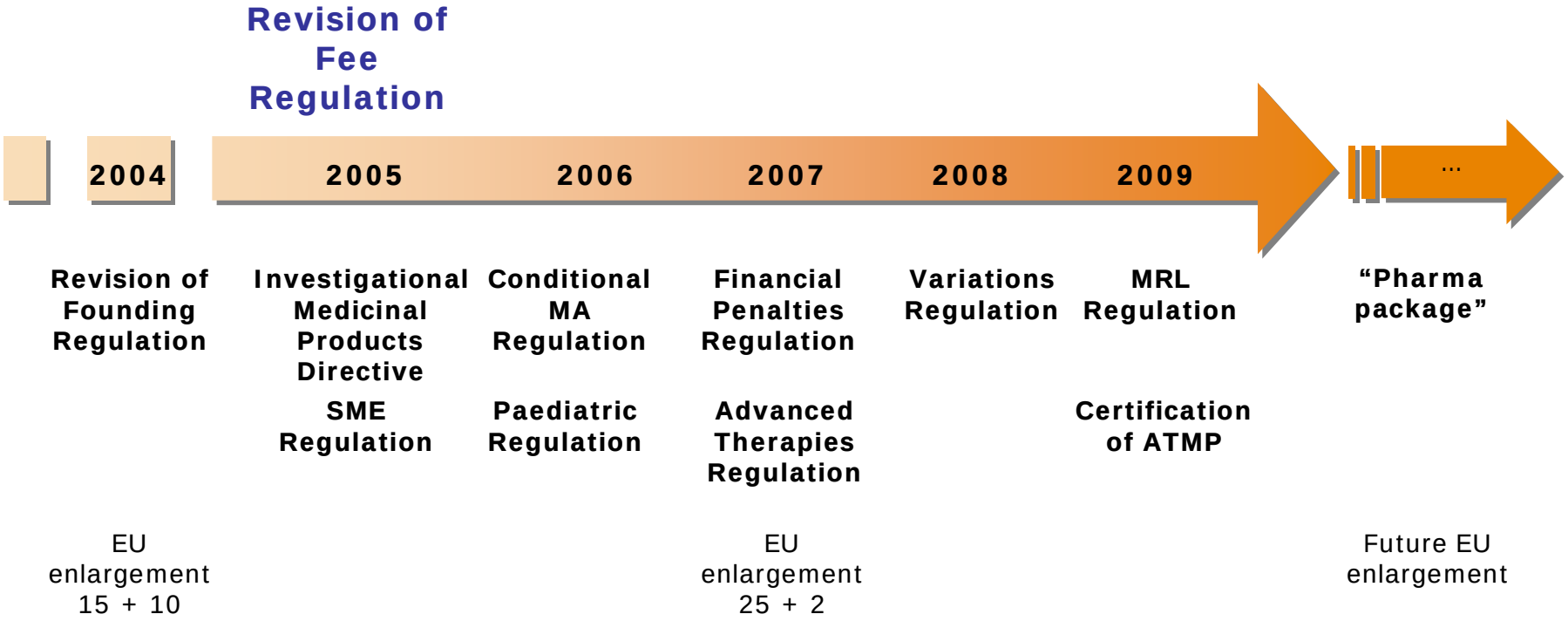
The 3rd paragraph of Article 12 states:

"By 24 November 2010, the Commission shall present a report on its [the Fee Regulations] *implementation to the Council ..."*

3. Recent and anticipated changes in legislative and regulatory environment

- New tasks resulting from changes in pharmaceutical legislation since 2005
- Legislative proposals under discussion include introduction of new types of fees

3. Recent and anticipated changes in legislative and regulatory environment *(cont.)*

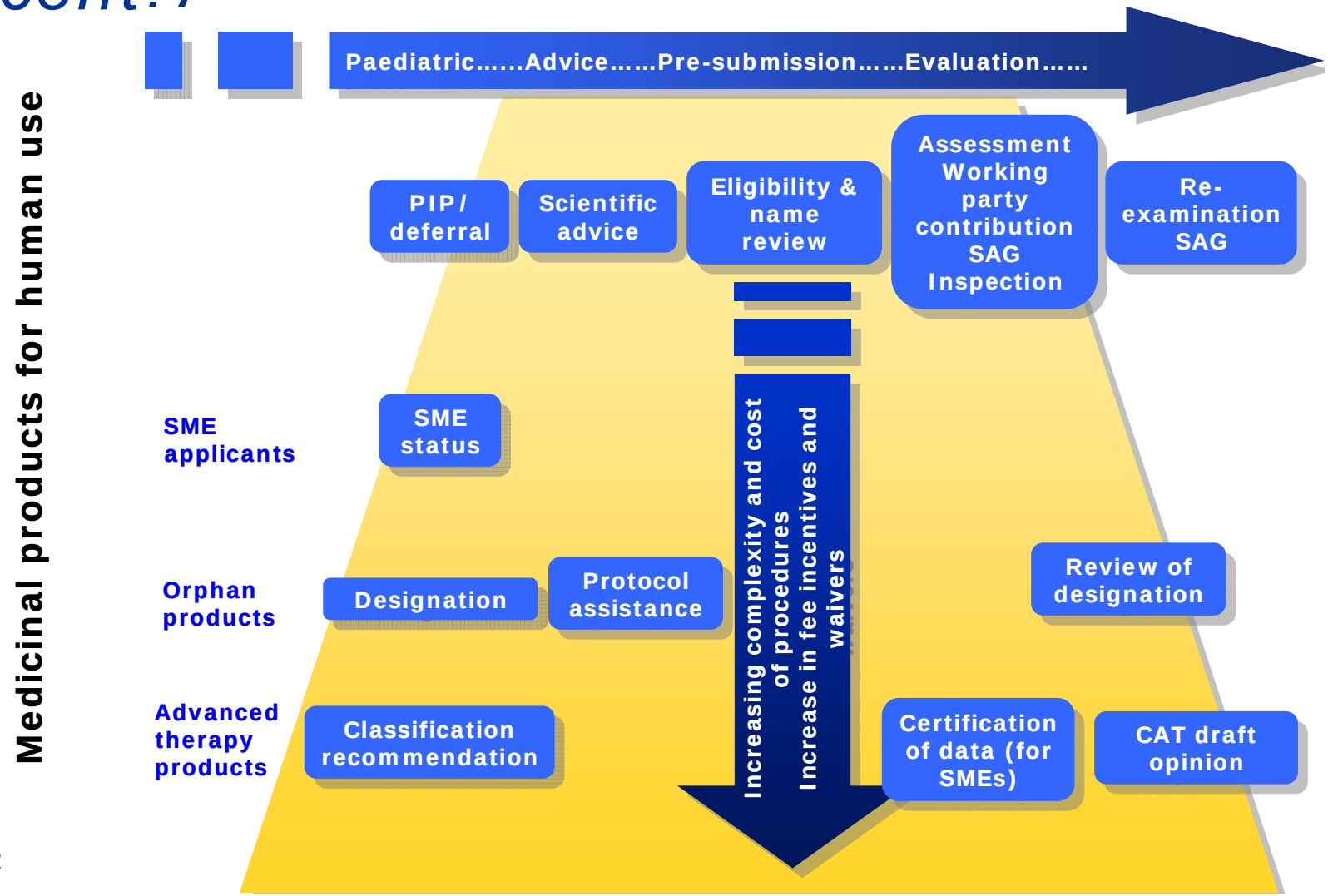


EMA’s reflection on current fee system

EMA's reflection on current fee system

- Overall fees and EU contribution finance EMA's activities
- Balance between fee and level of service for certain activities no longer provided
- Complexity of fees has increased over the years leading to high administrative burden for the pharmaceutical industry, NCAs and EMA (currently 131 different types of fees)
- Limited flexibility in introducing and adapting fees to a changing legislative and regulatory environment

EMA's reflection on current fee system *(cont.)*



Model – overall concept

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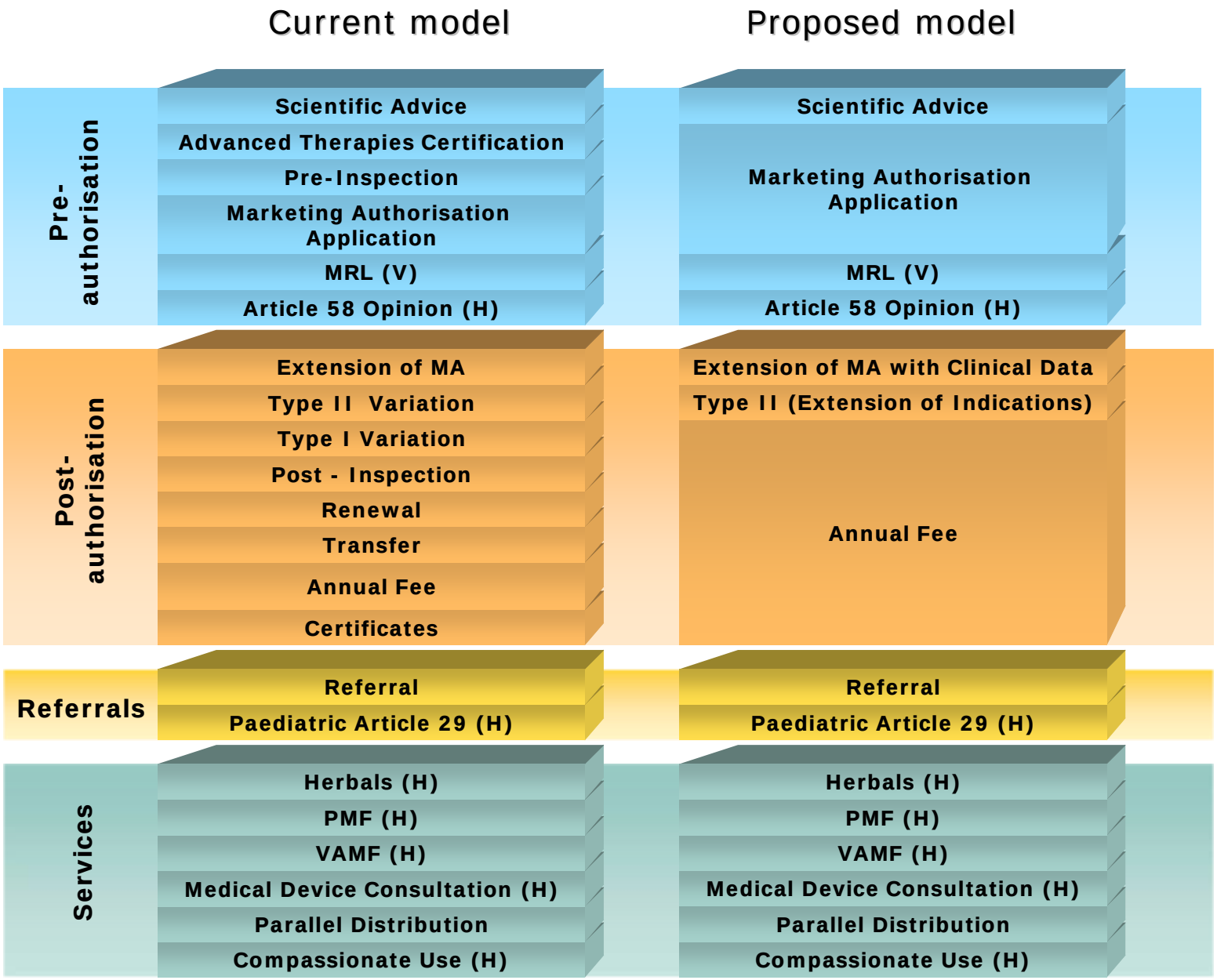
- To allow compensation for services provided by the NCAs, including for those that are currently not remunerated
- To maintain lower fee levels and incentives for certain types of applicants and products
- To allow cost of future additional activities to be incorporated
- To simplify the EMA's fee structure


Current model
Proposed model
Pre-authorisation
Scientific Advice
Advanced Therapies Certification
Pre-Inspection
Marketing Authorisation Application
MRL (V)
Article 58 Opinion (H)
Scientific Advice
Marketing Authorisation Application
MRL (V)
Article 58 Opinion (H)
Post-authorisation
Extension of MA
Type II Variation
Type I Variation
Post - Inspection
Renewal
Transfer
Annual Fee
Certificates
Extension of MA with Clinical Data
Type II (Extension of Indications)
Annual Fee
Referrals
Referral
Paediatric Article 29 (H)
Referral
Paediatric Article 29 (H)
Services
Herbals (H)
PMF (H)
VAMF (H)
Medical Device Consultation (H)
Parallel Distribution
Compassionate Use (H)
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PMF (H)
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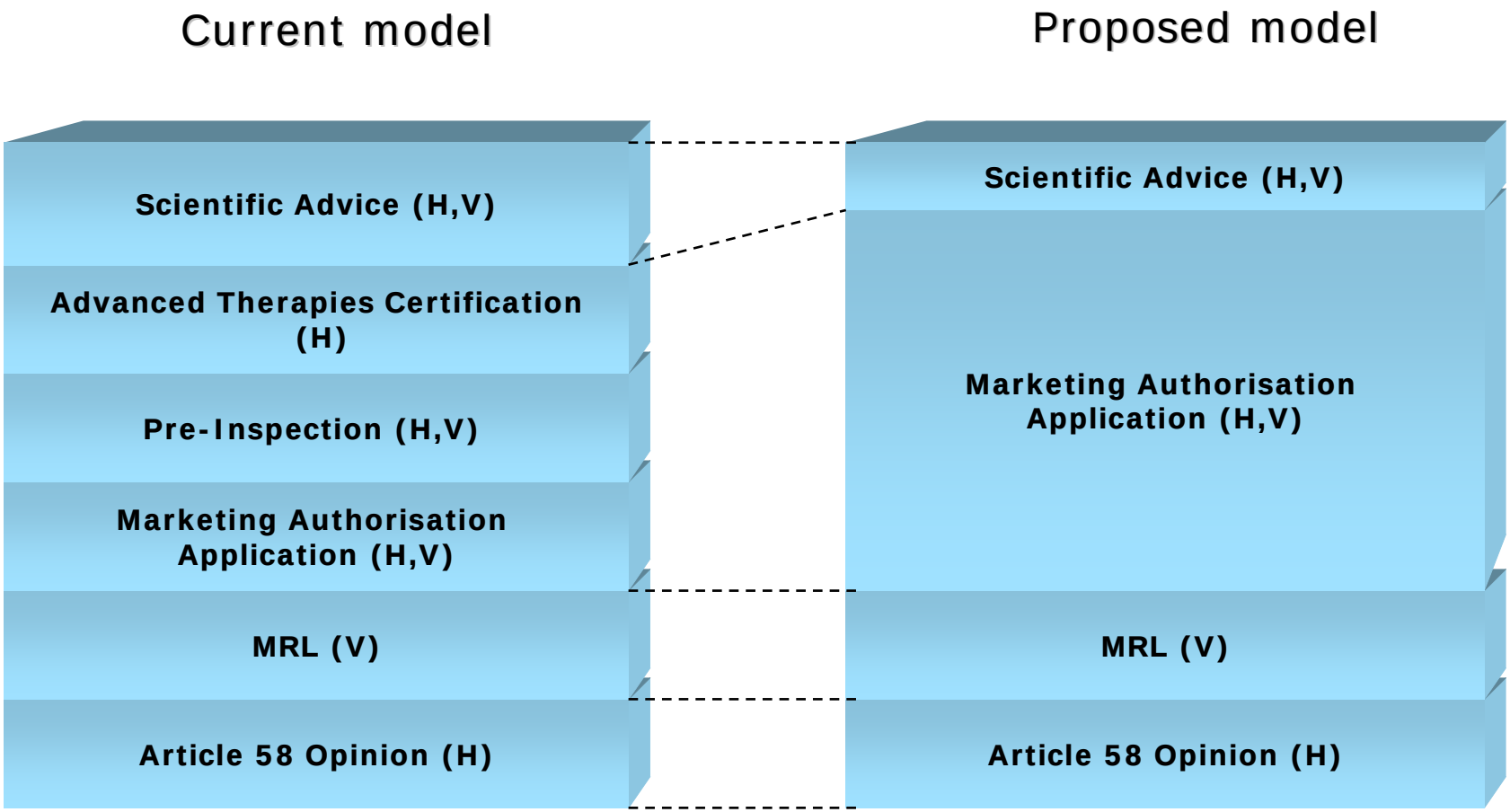
Compassionate Use (H)

Pre-authorisation



Current model

Medicinal products for human use

- Pre-authorisation inspection
- Consecutive pre-authorisation inspection
- Advanced Therapies Certification
- Application for MA (full dossier)
- Additional strength to MAA (full dossier)
- Additional presentation to MAA (full dossier)
- Application for MA (Article 10(4) 2001/83/EC)
- Additional strength to MAA (Article 10(4) ..)
- Additional presentation to MAA (Article 10(4) ..)
- Application for MA (Article 10(1), 10(3), 10c ..)
- Additional strength to MAA (Art. 10(1), 10(3), 10c ..)
- Additional presentation to MAA (Art. 10(1), 10(3), 10c ..)

Veterinary medicines

- Pre-authorisation inspection
- Consecutive pre-authorisation inspection
- Application for MA (Full dossier)
- Additional strength to MAA (full dossier)
- Additional presentation to MAA (full dossier)
- Application for MA (Article 13(4) 2001/82/EC)
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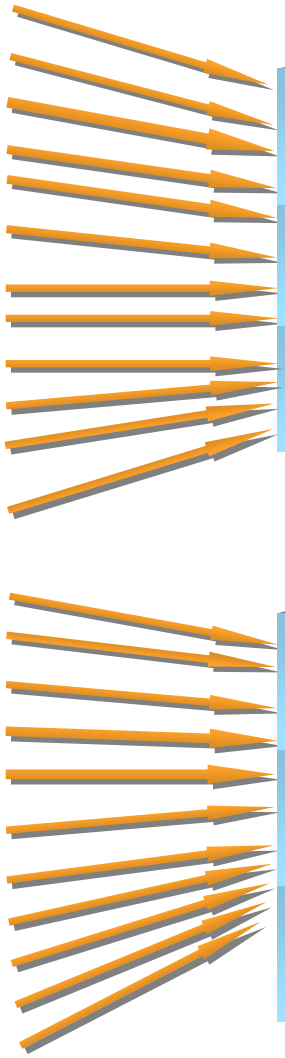

Proposed model

- Application for Marketing Authorisation
  Full dossier
  Medicines for human use
- Application for Marketing Authorisation
  Article 10 (4)
  Medicines for human use
- Application for Marketing Authorisation
  Article 10 (1), 10(3), 10c
  Medicines for human use
- Application for Marketing Authorisation
  Full dossier
  Veterinary medicines
- Application for Marketing Authorisation
  Article 13(4)
  Veterinary medicines
- Application for Marketing Authorisation
  Article 13(1), (3), 13c
  Veterinary medicines

Objectives for a future fee system

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- Ensure sustainability
- Introduce adaptability
- Reduce complexity

Sustainability

- Provide for realistic funding and take account of all EMA public health responsibilities
- Compensate for differences in procedures due to their inherent variability
- Maintain fee system as major source of income for EMA

Adaptability

- Adaptability to a changing environment including ongoing or new pharmaceutical legislation
- Model remains flexible enough to accommodate different product types

Complexity

- Potential 3-fold-reduction in total number of fee types:
  - Administrative simplification for all involved parties
  - Increased transparency
- Simplify fee incentives whilst maintaining overall value of incentives for pharmaceutical industry

In conclusion …

What do we seek to achieve?

- A better system for the partners in the network
- A better system for the pharmaceutical industry
- A better system for the European Medicines Agency

Thank you very much for your attention