EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The role of EMA and drug approvals for chronic HBV/HCV

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Science. Medicines. Health.

The mission of the
European Medicines Agency
is to foster scientific excellence in
the evaluation and supervision of
medicines, for the benefit of
public and animal health.

A European agency and medicines system: Why?

- Protect and promote public and animal health
- Pooling of best scientific expertise from across Europe for evaluation of medicines
- Facilitate availability of new medicines to patients
- Same product information to patients and healthcare professionals
- Single market for pharmaceuticals
- Benefits R&D industry
- Platform for discussion of public health issues

A European agency and medicines system: How?

'One system, two routes for approval'

- Centralised European route
- Mutual recognition + decentralised national routes

Agency is the focal point of centralised procedure

One application, one evaluation, one rapid and EU-wide authorisation

No pricing or reimbursement issues

The role of the European Medicines Agency

The Agency is also responsible for:

- Provision of scientific advice on the development of medicines
- Coordination of pharmacovigilance at European level (supervision of the medicines on the market)
- Coordination of the inspection activities
- Provision of information to the public

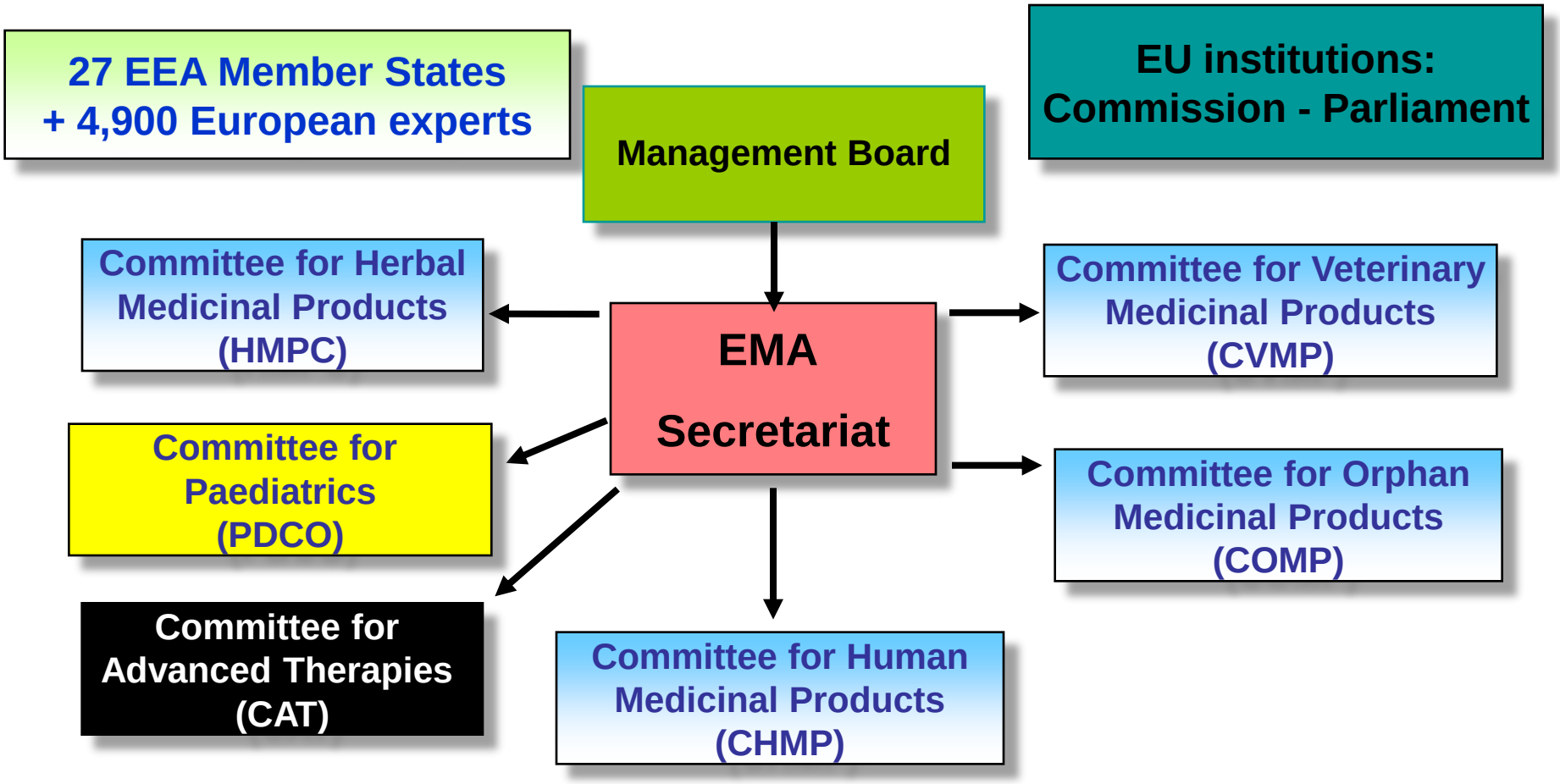
The role of the European Medicines Agency

The Agency is primarily responsible for providing a scientific opinion to the EU institutions about authorisation and surveillance of medicinal products

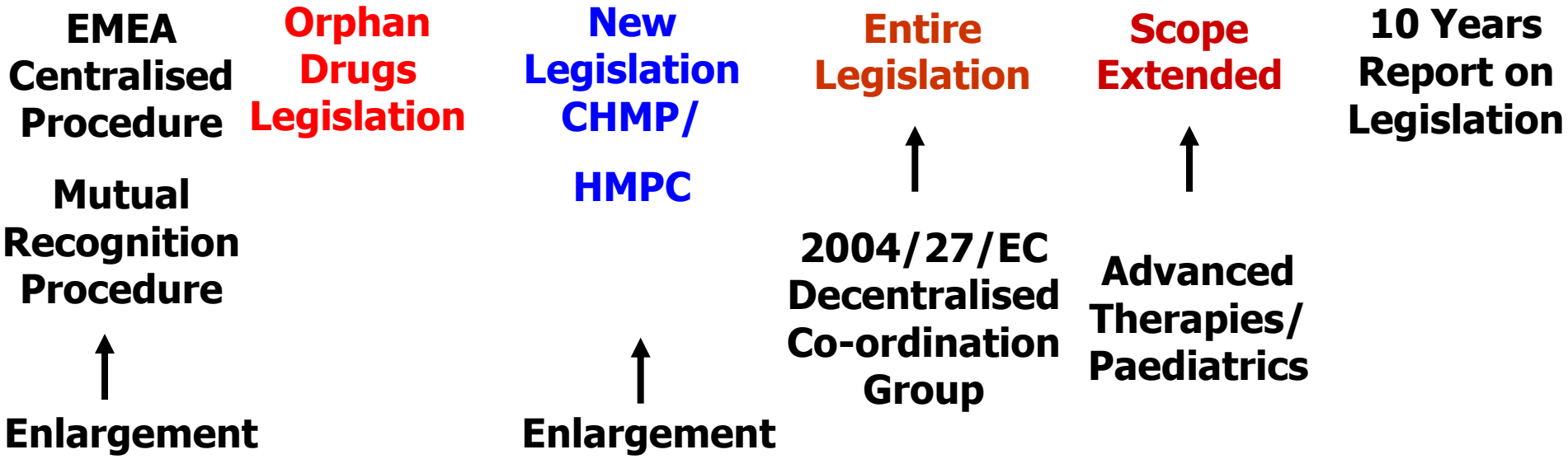
The Agency procedure is compulsory for some types of new drugs:

SINCE 2008 TREATMENT FOR ALL VIRAL DISEASES INCLUDING HEPATITIS IS INCLUDED IN THE MANDATORY SCOPE

How is the European Medicines Agency Organised?



The European Regulatory Environment has changed dramatically since 1995 and will change more in the coming years



Seven Medicinal Products approved centrally for treatment of Chronic Hepatitis B

Zeffix (lamivudine) 29/07/1999

IntronA (interferon alfa-2b) 09/03/2000

Viread (tenofovir disoproxil) 05/02/2002

Pegasys (peginterferon alfa-2a) 20/06/2002

Hepsera (adefovir dipivoxil) 06/03/2003

Baraclude (entecavir) 26/06/2006

Sebivo (telbivudine) 24/04/2007

+ 1 generic Lamivudine 23/10/2009

Four Medicinal Products approved centrally for treatment of Chronic Hepatitis C

Rebetol (ribavarin) 07/05/1999

IntronA (interferon alfa-2b) 09/03/2000

PegIntron/ViraferonPeg (peginterferon alfa-2b) 25/05/2000

Pegasys (peginterferon alfa-2a) 20/06/2002

+ 4 ribavirin generics approved centrally in 2009-2010

Roferon (interferon alfa-2a) for both CHB and CHC and Copegus (ribavarin) for CHC approved by Mutual Recognition Procedure in 2000 and 2002 respectively

Continuous Benefit/Risk monitoring in the post-authorisation phase

- Monitoring of long-term efficacy and resistance data with potential labelling implications (e.g. lamivudine SmPC indication wording revision)

- Monitoring of long-term safety (e.g. interferons growth retardation in children)

- Potential extensions of indication (e.g. inclusion of decompensated patients among the authorised indications)

Paediatric Investigational Plans

- *Three published Opinions for drugs for treatment of Hepatitis B:*

Telbivudine, Peginterferon alfa2a, Tenofovir

- *Seven published Opinions for drugs for treatment of Hepatitis C:*

Peginterferon alfa2b, Peginterferon alfa2a, Boceprevir, Telaprevir, Albinterferon alfa2b, TMC435, ribavarin

Guidance on drug development for Hepatitis

- *Guideline:* Clinical Evaluation of Medicinal Products intended for Treatment of Hepatitis B adopted February 2006

- *Guideline: Clinical evaluation of direct acting antiviral agents intended for treatment of chronic Hepatitis C* adopted May 2009

- Several SA procedures completed in the area of chronic hepatitis treatment

Guidance on drug development for Hepatitis

22 April 2010
EMA/CHMP/EWP/825749/2009
Committee for Medicinal Products for Human Use (CHMP)

Concept paper on the need for revision of the guideline on the clinical development of medicinal products for the treatment of Hepatitis C

Draft Agreed by Efficacy Working Party	April 2010
Adoption by CHMP for release for consultation	22 April 2010
End of consultation (deadline for comments)	31 July 2010

The proposed guideline will replace guideline on the Clinical Evaluation of Direct Acting Antiviral Agents Intended for Treatment of Chronic Hepatitis C (EMEA/CHMP/EWP/30039/2008).

Comments should be provided using this template. The completed comments form should be sent to EWPSecretariat@ema.europa.eu


Thank you for
your attention