

L'accès aux médicaments innovants en Europe

SRBGE Bruxelles

13 Octobre 2007

Daniel Brasseur

Past Chair CHMP at EMEA



Les commentaires de l'orateur n'engagent que sa personne et d'aucune manière l'Agence européenne du Médicament.

Daniel Brasseur n'a pas déclaré de conflit d'intérêt en relation avec sa participation à la présente réunion. Sa déclaration peut être consultée au site de l' EMEA:

http://www.emea.europa.eu/pdfs/general/contacts/dbrasseur_DI.pdf

Plan

Les efforts de l'Europe

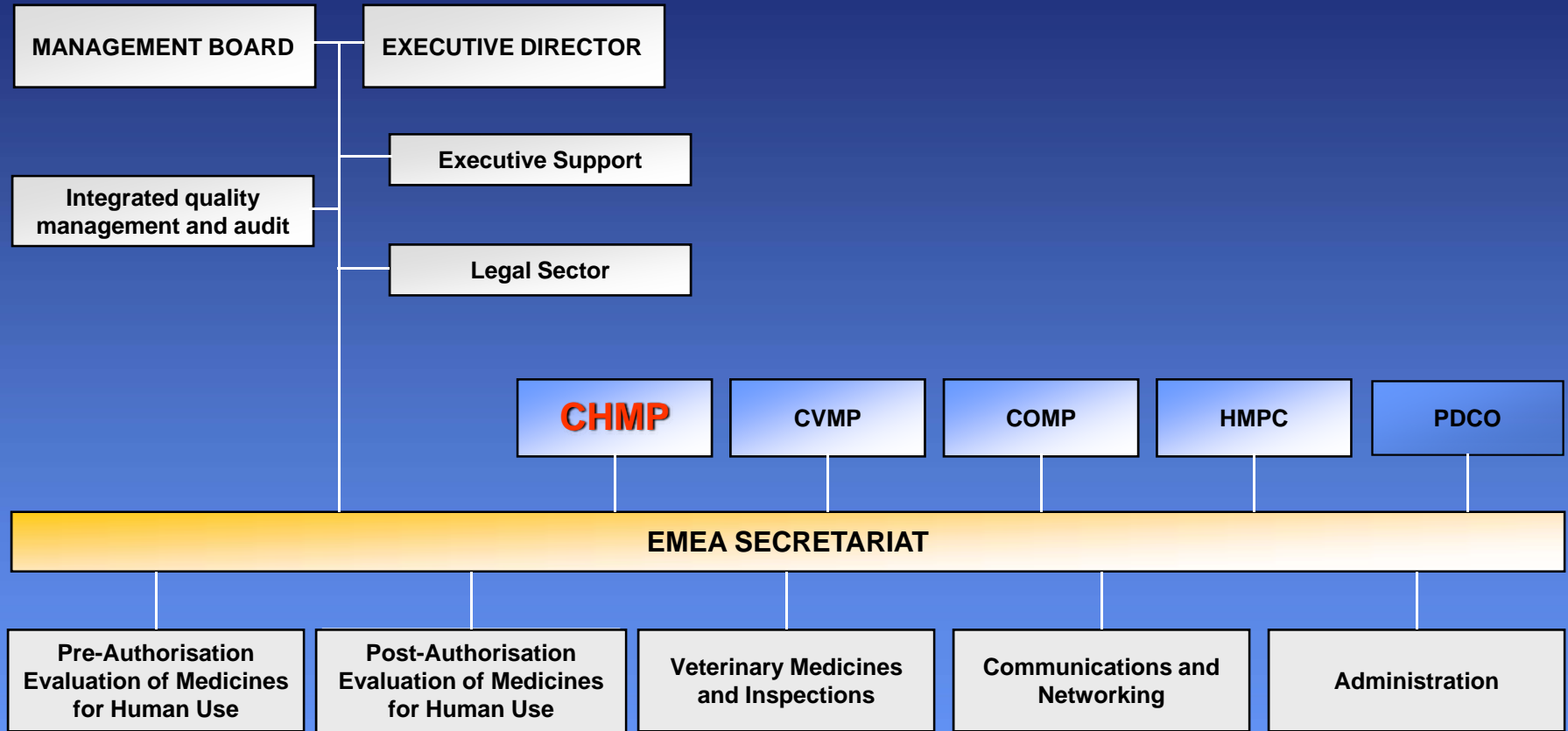
1. Améliorations récentes de l'accès aux Médicaments innovants
2. Corrections progressives de Disparités flagrantes
3. Préparatifs en cours pour faciliter les Thérapies nouvelles

L'Agence européenne du Médicament

EMA, Londres depuis 1995



Structure de l'EMA



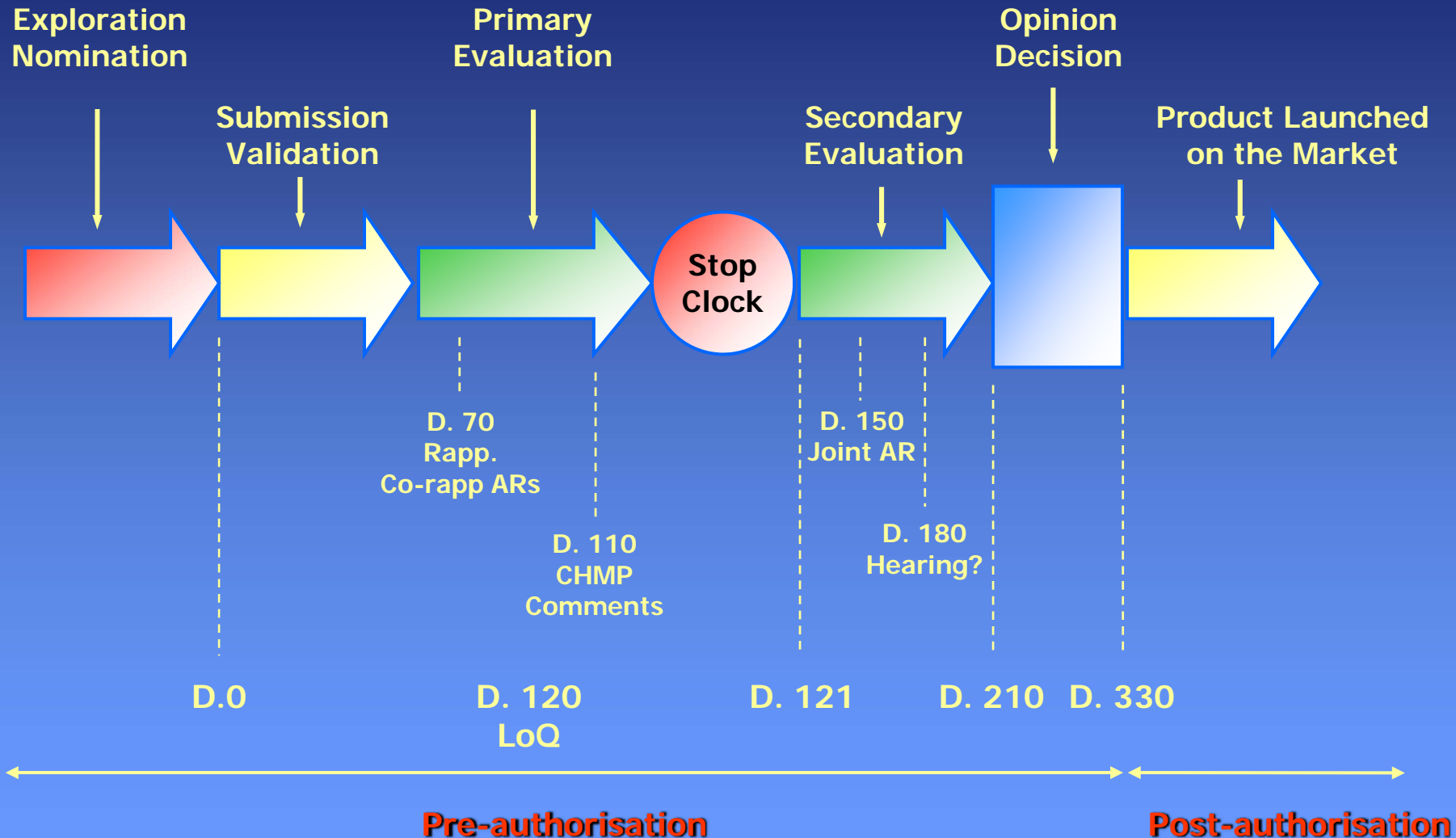
CHMP - Committee for Human Medicinal Products

1 représentant par Etat Membre
1 membre de la Norvège et Islande
(EEA- EFTA states)
5 Membres cooptés

Chair: Dr. Eric Abadie
Vice Chair: Ph T. Salmonson

Chaque membre a 1 suppléant- tous
2 nommés par l'Autorité Nationale

Overview of Centralised Evaluation Procedure



Les Groupes de Travail du CHMP

CHMP Working Parties (WP)

Quality WP

Safety WP

Efficacy WP

Biotechnology WP

Pharmaco-vigilance WP

Vaccine WP

Blood Products WP

Scientific Advice WP

Pharmaco-genetic WP

Gene Therapy WP

Cell based Therapy WP

WP on comparability of
biotechnology products

Scientific Advisory Groups

- Infectious agents
- Diagnostic agents
- Oncology
- Diabetes
- CNS – Psychiatry
- Cardio-Vascular

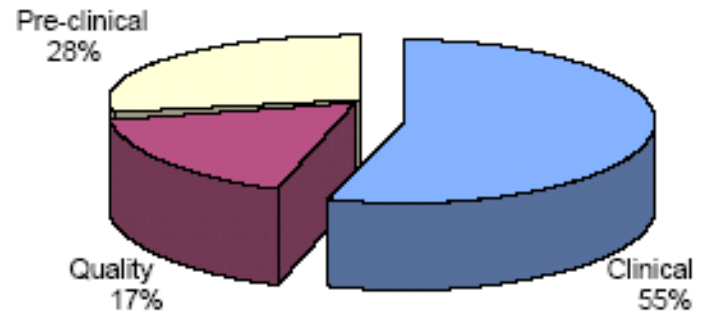
Plan

Les efforts de l'Europe

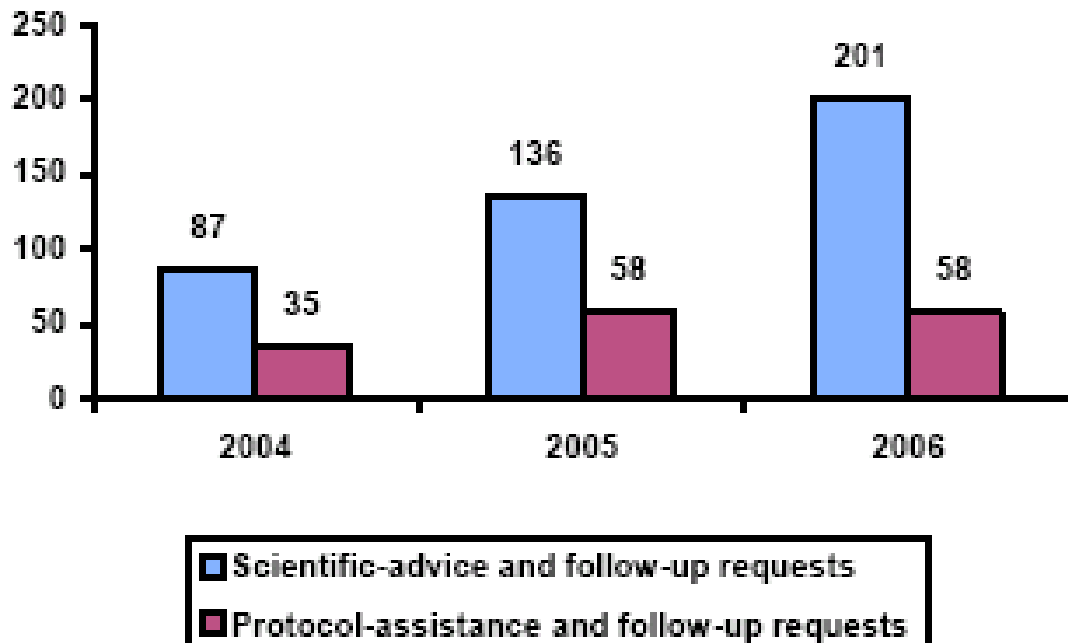
- 1. Améliorations récentes de l'accès aux Médicaments innovants**
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Avis Scientifiques

Scientific-advice requests by topic, 2006

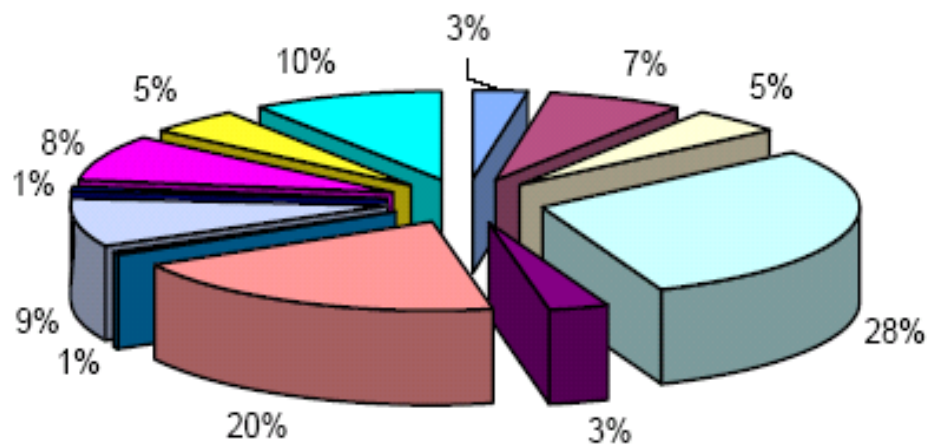


Scientific-advice and protocol-requests received



Avis Scientifiques

Scientific-advice requests by therapeutic area 2006



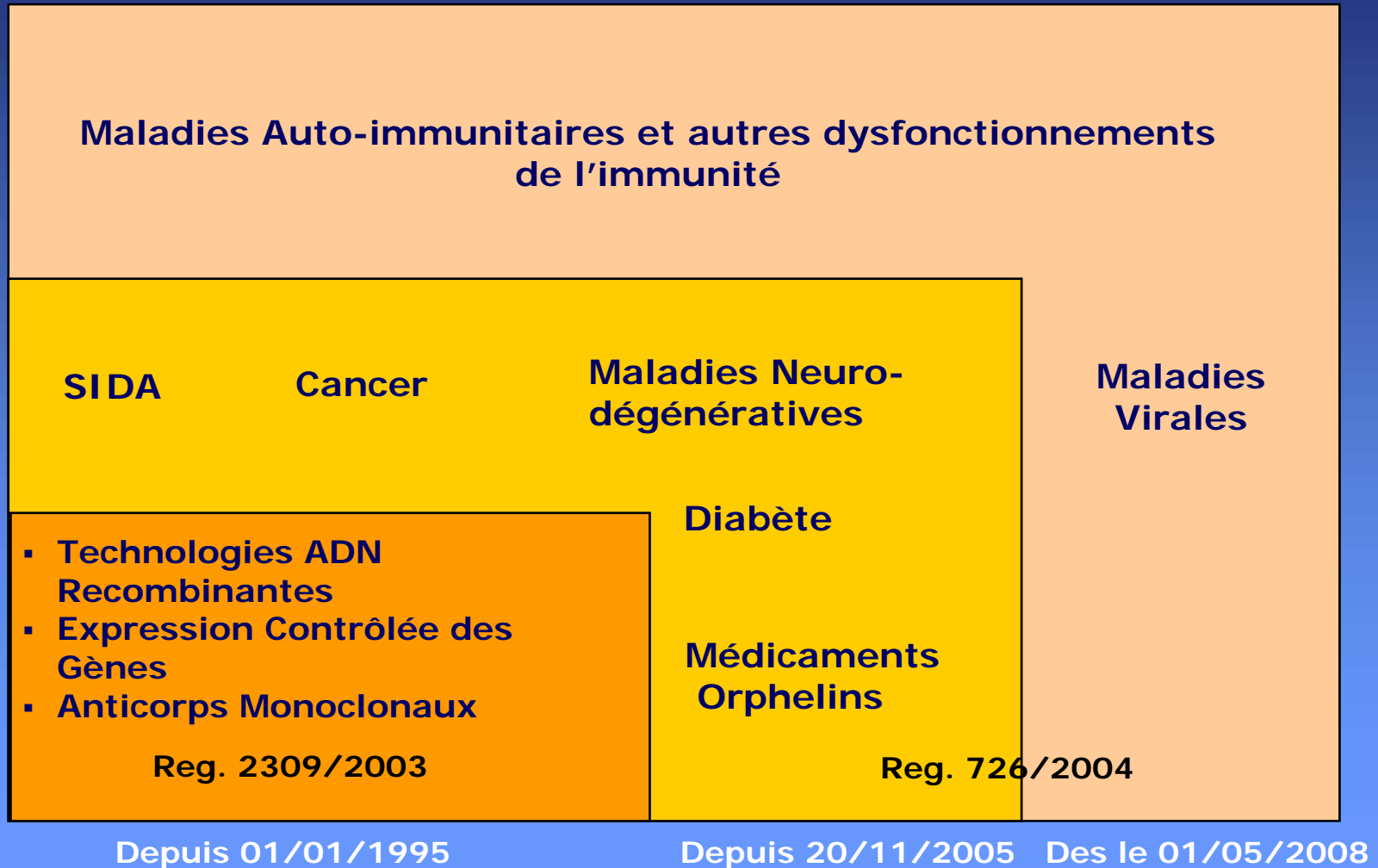
- | | |
|--|---|
| ■ Dermatologicals | ■ Musculo-skeletal system |
| ■ Respiratory system | ■ Anti-neoplastic and immunomodulating agents |
| ■ Various | ■ Nervous system |
| ■ Genito-urinary system and sex hormones | ■ General anti-infectives for systemic use |
| ■ Sensory organs | ■ Cardiovascular system |
| ■ Blood and blood-forming organs | ■ Alimentary tract and metabolism |

En quoi le Système européen a-t-il progressé?

Le Règlement étend sensiblement le champ des activités et de responsabilités de l'Agence a de nouveaux domaines thérapeutiques essentiels

Aperçu de l'Evaluation du Comité

Champ des activités nouvelles



Mise en œuvre de la nouvelle Législation

Le *nouveau* Règlement prévoit en situations déterminées

- une évaluation accélérée
- une mise sur le marché conditionnelle
- un usage compassionnel entre la fin des essais cliniques et la commercialisation

de manière à donner aux patients un accès plus précoce aux médicaments innovants

Mise en œuvre de la nouvelle Législation

Le *nouveau* Règlement prévoit également des outils de gestion du risque

- sous forme de plan de réduction des risques au sein de groupes de patients vulnérables
- un droit d'inspection des systèmes de pharmacovigilance

de manière à donner aux patients davantage de garanties sur la surveillance active de ces produits nouveaux

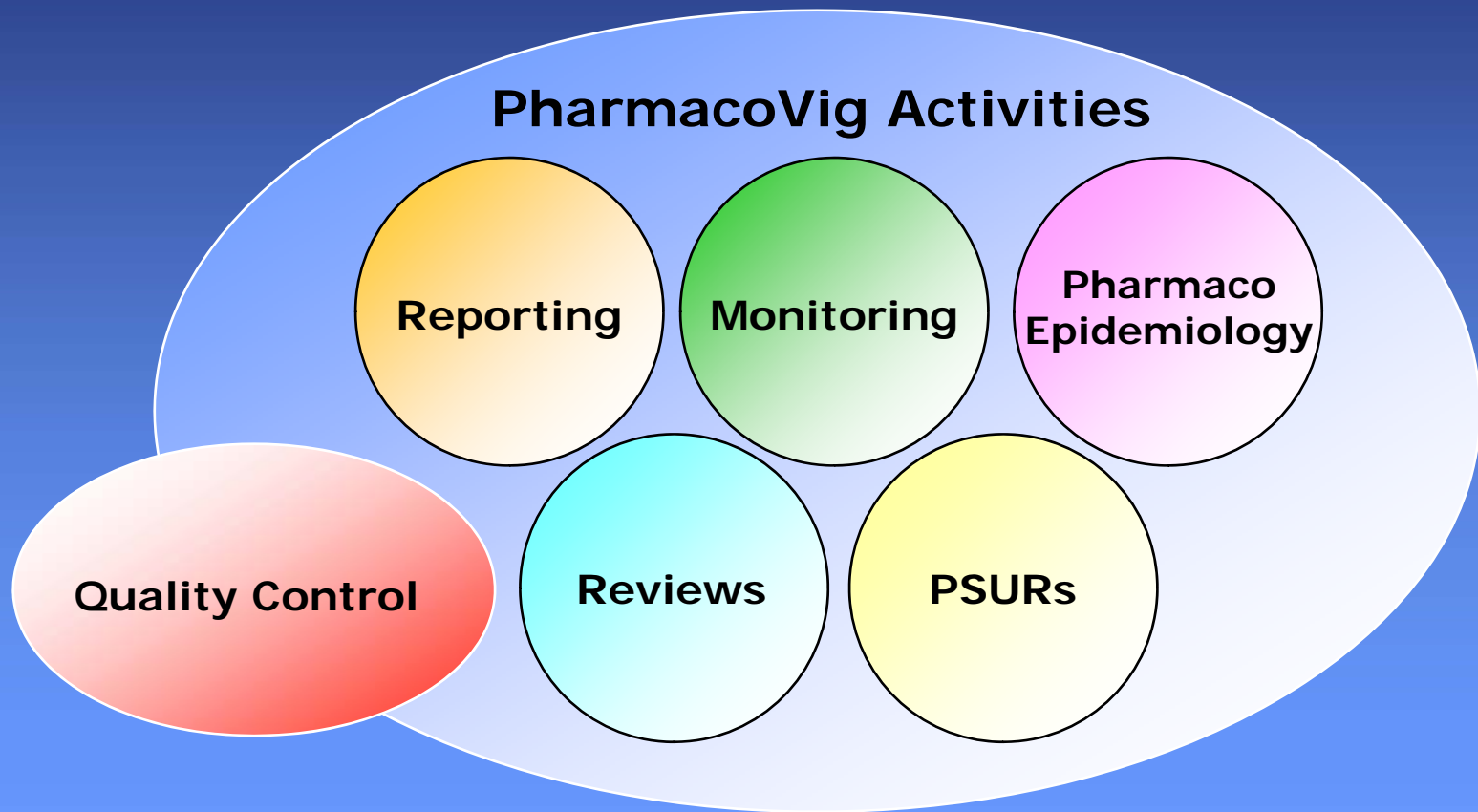
**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
(CHMP)**

**GUIDELINE ON RISK MANAGEMENT SYSTEMS FOR MEDICINAL
PRODUCTS FOR HUMAN USE**

DRAFT AGREED BY PhVWP	26 July 2005
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	27 July 2005
END OF CONSULTATION (DEADLINE FOR COMMENTS)	5 October 2005
ADOPTION BY CHMP	14 November 2005
DATE FOR COMING INTO EFFECT	20 November 2005

PhVig – Risk Management System

Company-related

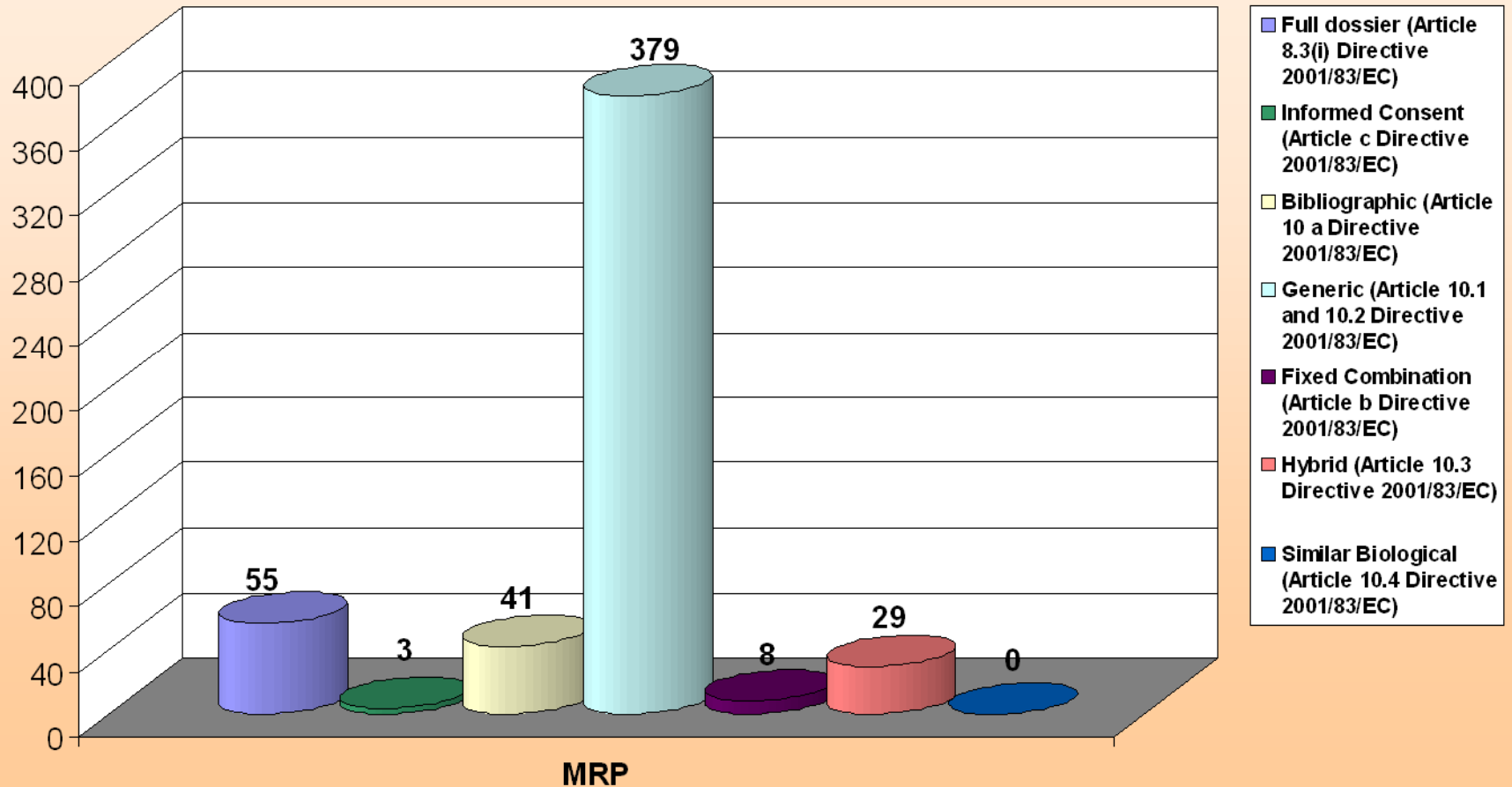


CMDh

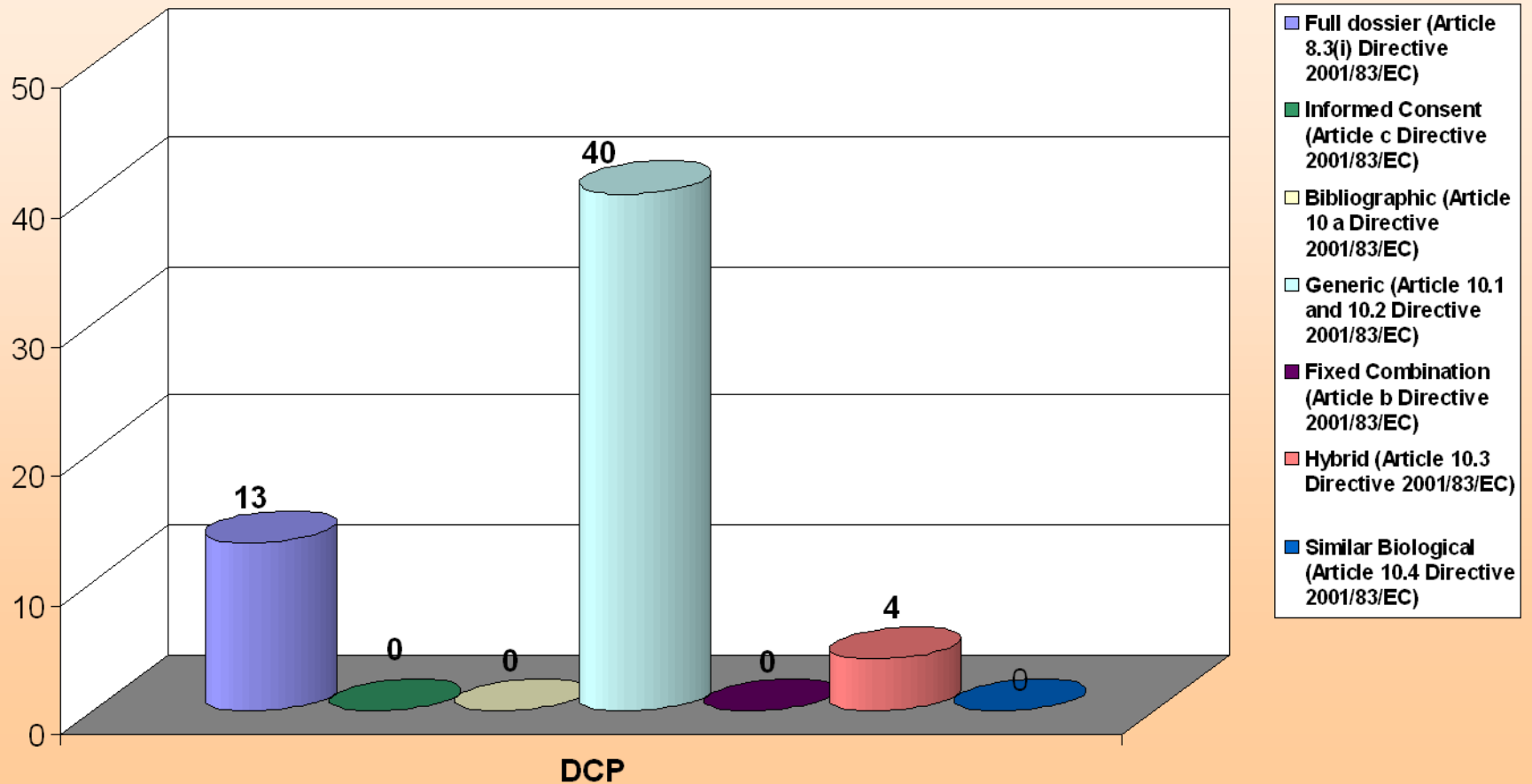
Creation d'un Comité de concertation
pour régler les difficultés engendrées
par la libre circulation des produits,
ou principe de reconnaissance mutuelle



Mutual Recognition New Applications finalised in 2006 (tot: 535)



Decentralised New Applications finalised in 2006 (tot: 57)



Plan

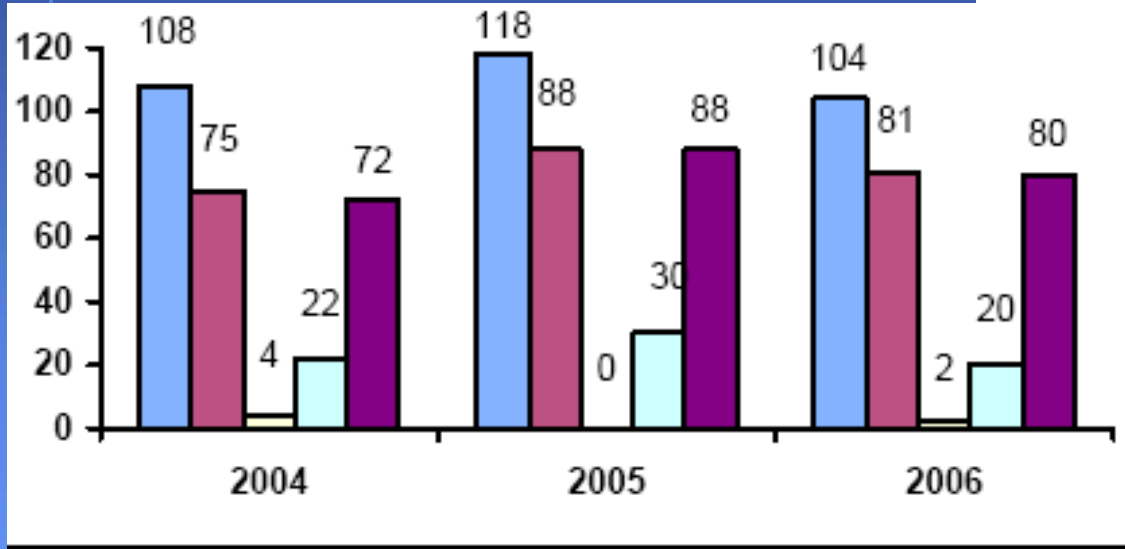
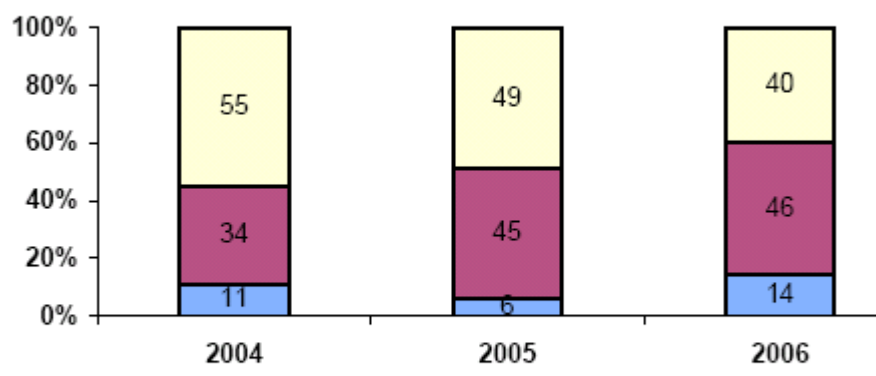
Les efforts de l'Europe

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Désignation Orpheline

Prévalence < 5/10 000

Designated orphan medicinal products for the treatment of children and adults, 2004-2006



■ Medical conditions affecting adults only
■ Medical conditions affecting both children and adults
■ Medical conditions affecting children only

■ Submitted
■ Positive opinions
■ Negative opinions
■ Withdrawals
■ Commission decisions

Pédiatrie

Le Règlement « De Meilleurs Médicaments pour les Enfants »



Situation de fait au sein de l'EU

Les enfants représentent / reçoivent:

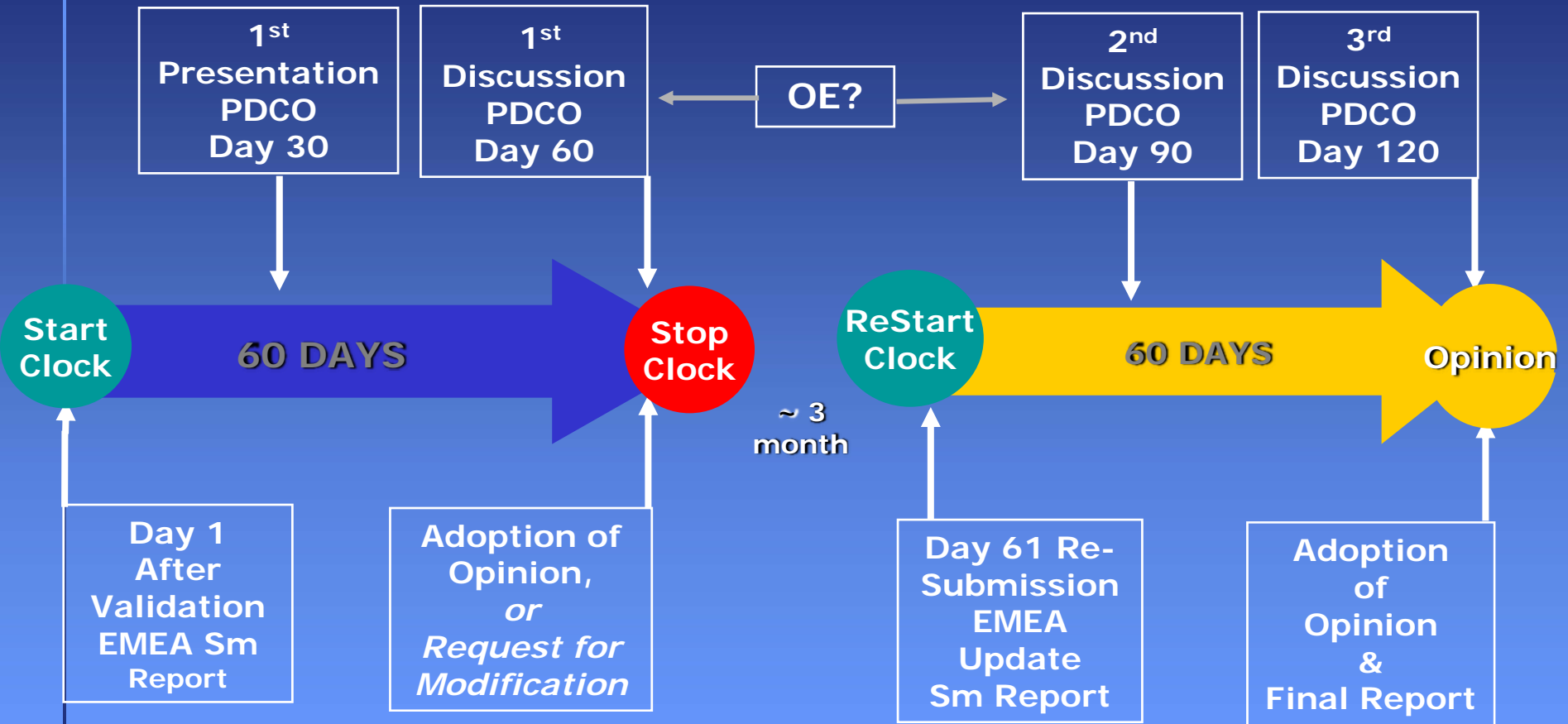
1. 20% de toutes les prescriptions
2. 7% de tous les essais cliniques
3. 72% de leurs médicaments n'ont jamais été testés dans leurs tranches d'âge
4. 90% ne l'ont pas été en ISU
5. 30% ne l'ont pas été en pratique de ville

Nouveaux produits soumis a l'Agence

Médicaments encore brevetés

- Obligation de soumettre un plan investigation pédiatrique (PIP) avant la mise sur le marche du produit adulte, et a l'occasion de toute variation...
- Récompense: 6 mois d'extension du brevet de protection

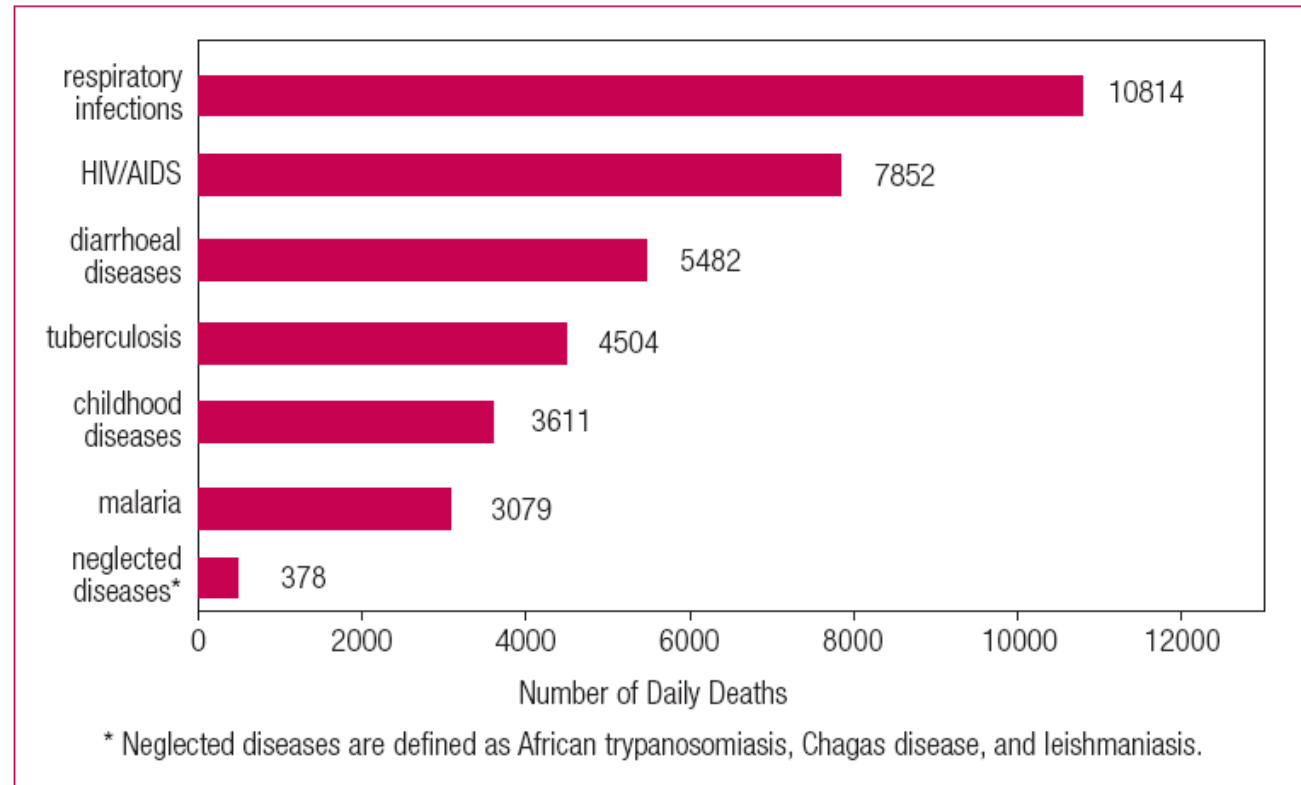
OVERVIEW PIP PROCEDURE



OE= oral explanation

Maladies Négligées

FIGURE 16. GLOBAL DAILY DEATHS PER MAJOR COMMUNICABLE DISEASES



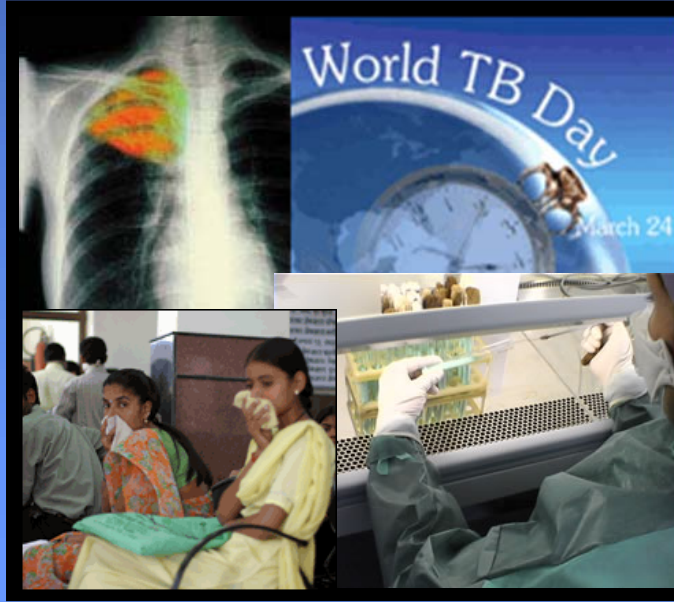
Source: World Health Report 2003, WHO.

Art 58 Regulation (EC) 726/2004 : CHMP Scientific Opinion in cooperation with WHO

- Access to essential medicines for countries lacking the regulatory capacity for assessing new medicinal products for their markets
 - Developing countries often rely on medicinal product that have a marketing authorisation in a development country
 - Many products needed by developing countries have no marketing authorisation in a developed country, e.g. for diseases that have no, or too low prevalence in developed countries to be economically viable
- The CHMP Scientific Opinion in cooperation with WHO is part of the EU response to the need to protect public health and to give scientific assistance to non-member countries, whilst at the same time allowing rapid access to important medicinal products



Malaria



Tuberculosis



AIDS/HIV

Plan

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London, 14 November 2005
Doc. Ref. EMEA/397403/2005

DRAFT

**EMEA PANDEMIC INFLUENZA
CRISIS MANAGEMENT PLAN FOR
THE EVALUATION AND MAINTENANCE OF
PANDEMIC INFLUENZA VACCINES AND ANTIVIRALS**

ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	14 November 2005
END OF CONSULTATION (DEADLINE FOR COMMENTS)	27 January 2006

Comments should be provided to Patrick.celis@emea.eu.int or by fax +44 20 7418 8545

Note	Annex I to this Plan (<i>EMEA Pandemic Influenza Process map</i>) is also released for consultation. The associated Work Instructions referred to in this Annex are available on request.
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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel: (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.eu.int <http://www.emea.eu.int>

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London, 24 July 2006
Doc. Ref. EMEA/CHMP/VWP/263499/2006

**COMMITTEE FOR HUMAN MEDICINAL PRODUCTS
(CHMP)**

<DRAFT>

**GUIDELINE ON DOSSIER STRUCTURE AND CONTENT OF MARKETING
AUTHORISATION APPLICATIONS FOR INFLUENZA VACCINES DERIVED FROM
STRAINS WITH A PANDEMIC POTENTIAL FOR USE OUTSIDE OF THE CORE
DOSSIER CONTEXT**

DRAFT AGREED BY VACCINE WORKING PARTY	July 2006
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	July 2006
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 September 2006
AGREED BY <WORKING PARTY>	<month year>
ADOPTION BY <COMMITTEE>	<day month year>
DATE FOR COMING INTO EFFECT	<day month year>

Comments should be provided using this [template](#) to Patrick.Celis@emea.eu.int
Fax +44 20 7418 8545

KEYWORDS	Avian influenza vaccines for human use; Strains with pandemic potential; Quality, Non-clinical and Clinical requirements
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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel: (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
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Influenza



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 16.11.2005
COM(2005) 567 final

2005/0227 (COD)

Advanced Therapies

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

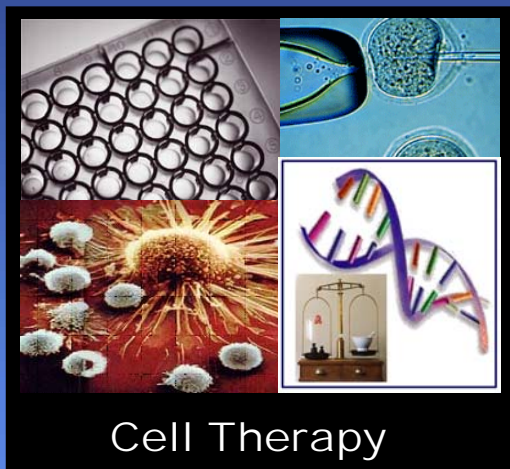
on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004

31.5.2007: Council approval in 1st reading

25.4.2007: Vote in the European Parliament

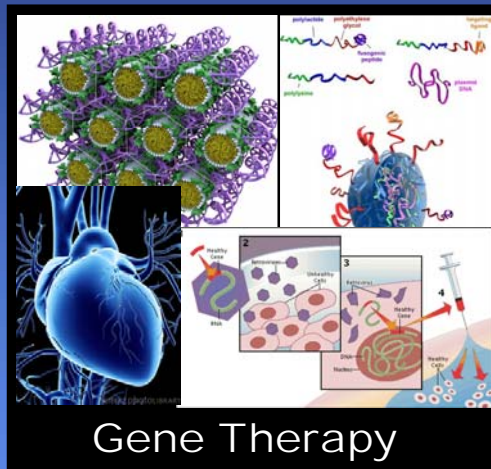
Advanced Therapies

The proposal covers all advanced therapy products



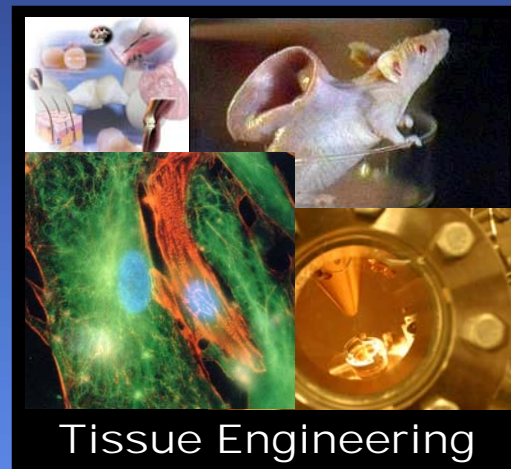
Cell Therapy

Somatic cell therapy medicinal products



Gene Therapy

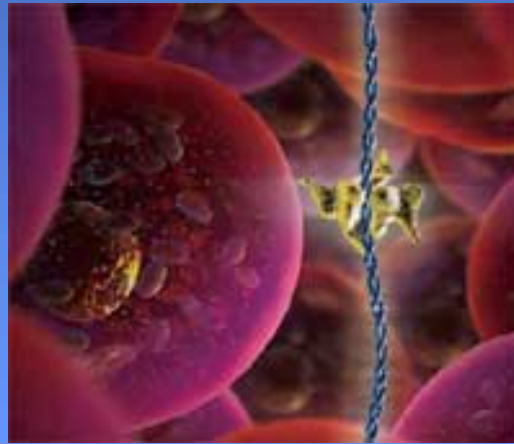
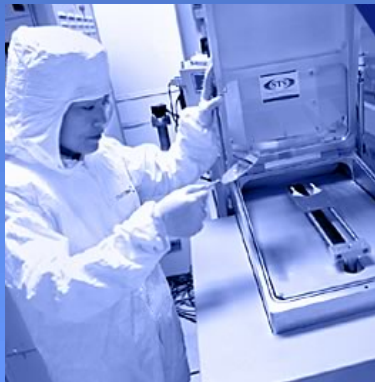
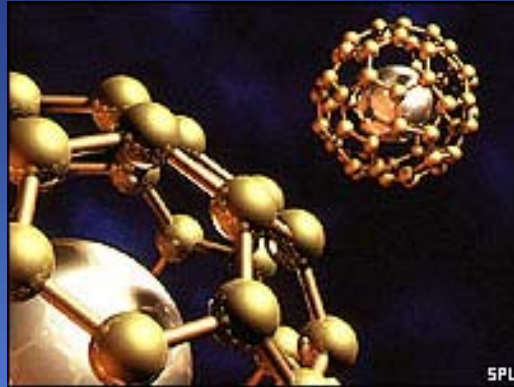
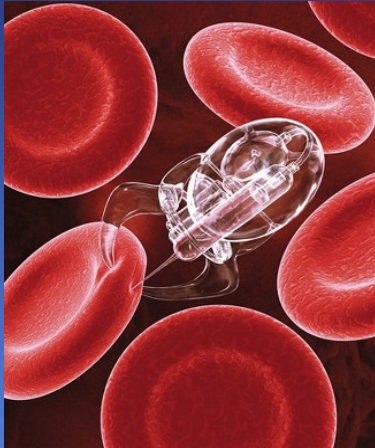
Gene therapy medicinal products



Tissue Engineering

Tissue engineered products

Nanotechnologies



Significant new technologies emerged...

Protein chips

Transgenic animals

Proteomics

Bio-informatics

Pharmacogenomics

Chem-informatics



Molecular modelling

Functional genomics

In silico experimentation

Conclusions

- Le système européen
 - n'intervient pas dans le prix du médicament
 - prend progressivement en charge les thérapies innovantes,
 - pour faciliter leur développement et
 - permettre leur arrivée rapide sur le marché,mais
 - s'appuie sur le réseau d'experts des Etats-membres pour l'enregistrement
 - et pour la gestion de risque

Message Routing

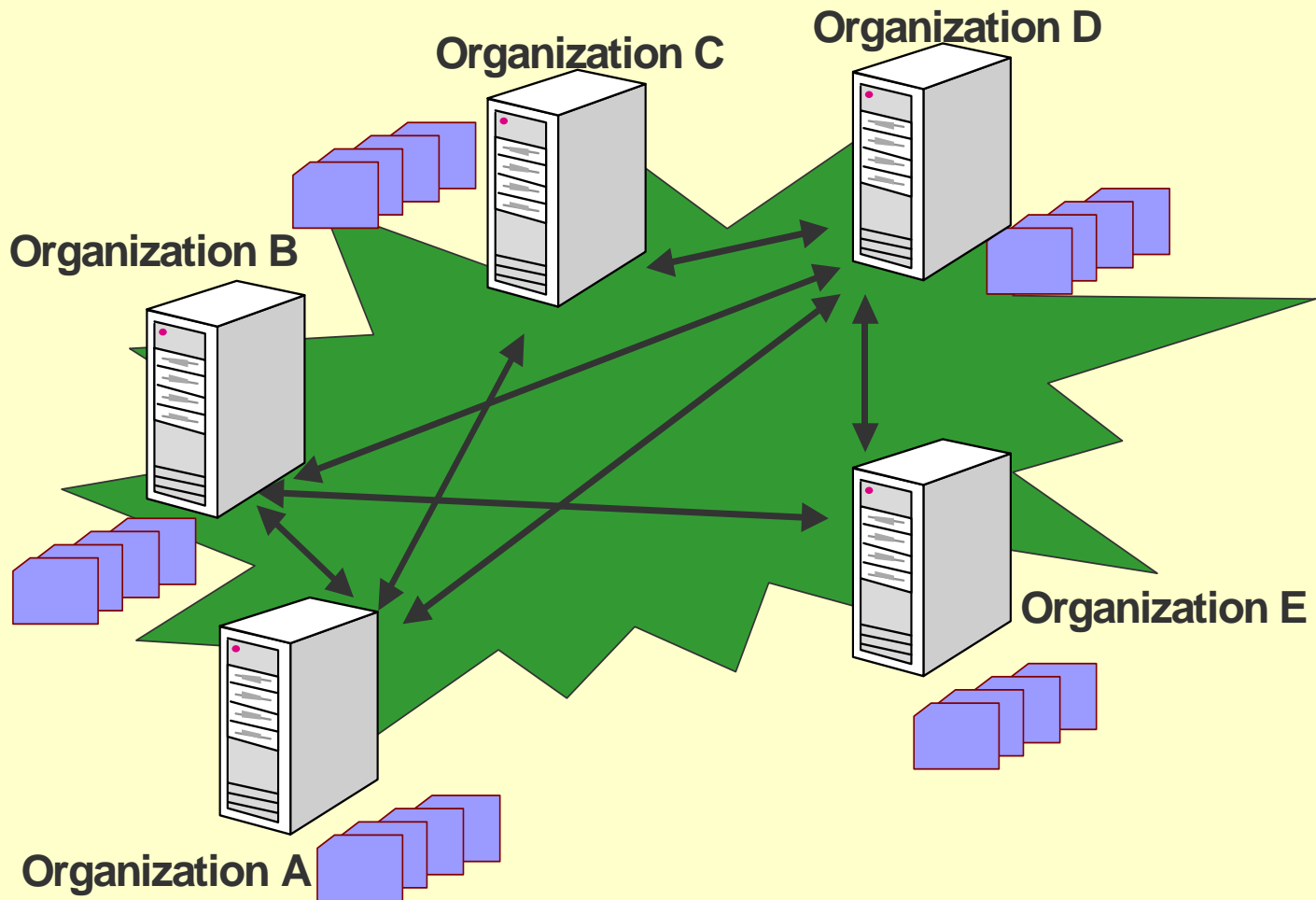
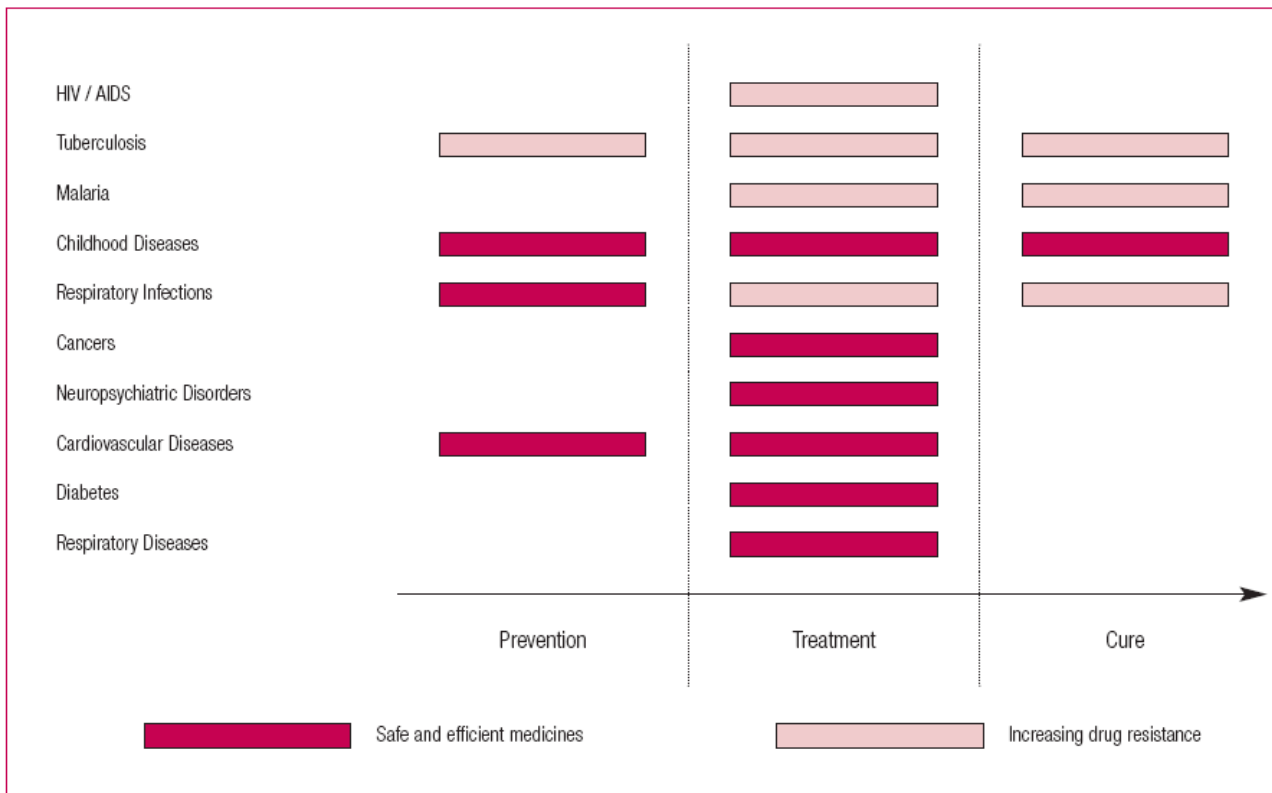


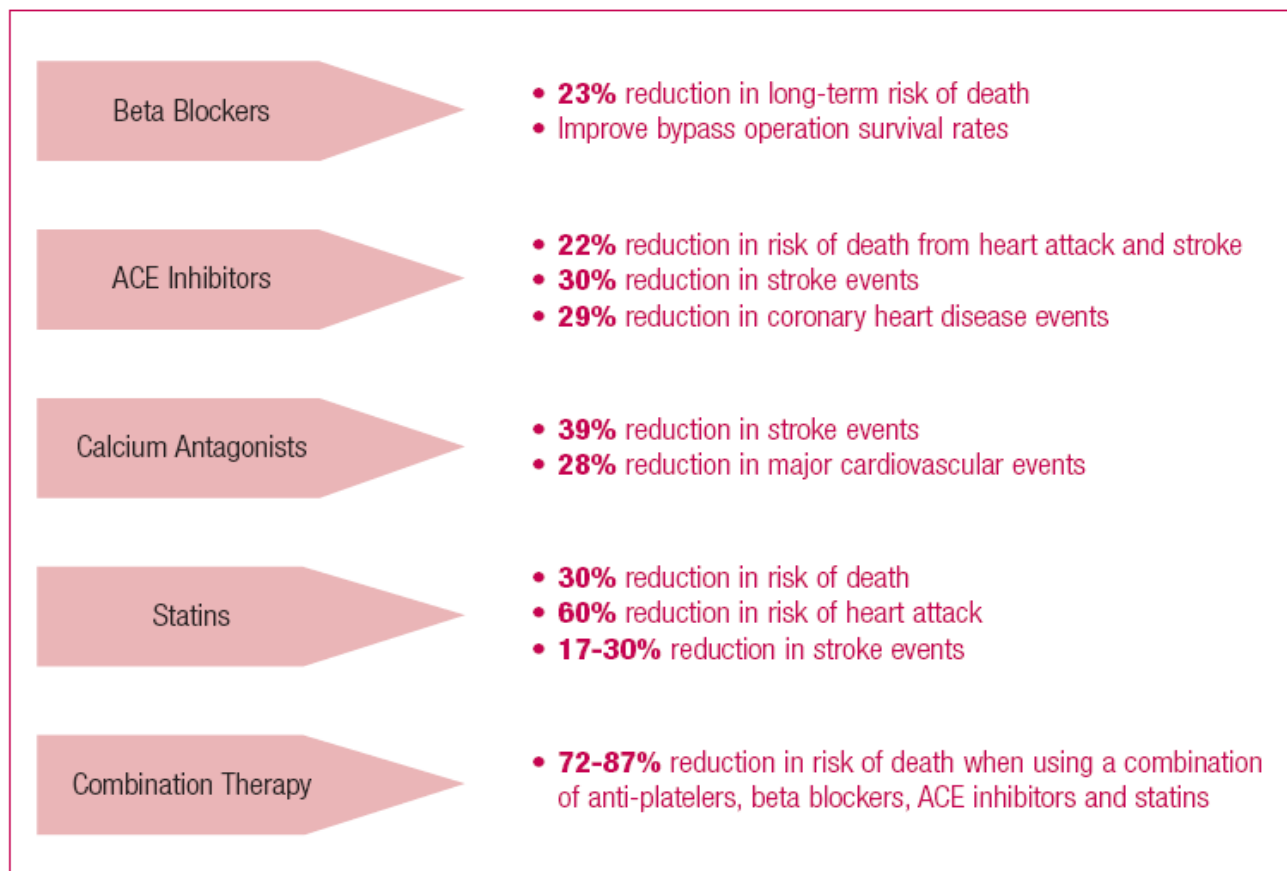


FIGURE 2. THE STATUS OF CURRENT MEDICINES: CONTINUOUS NEED FOR MEDICINES INNOVATION



Source: Various WHO and industry sources

FIGURE 3. BENEFITS OF SELECTED MEDICINES IN THE TREATMENT OF CARDIOVASCULAR DISEASES



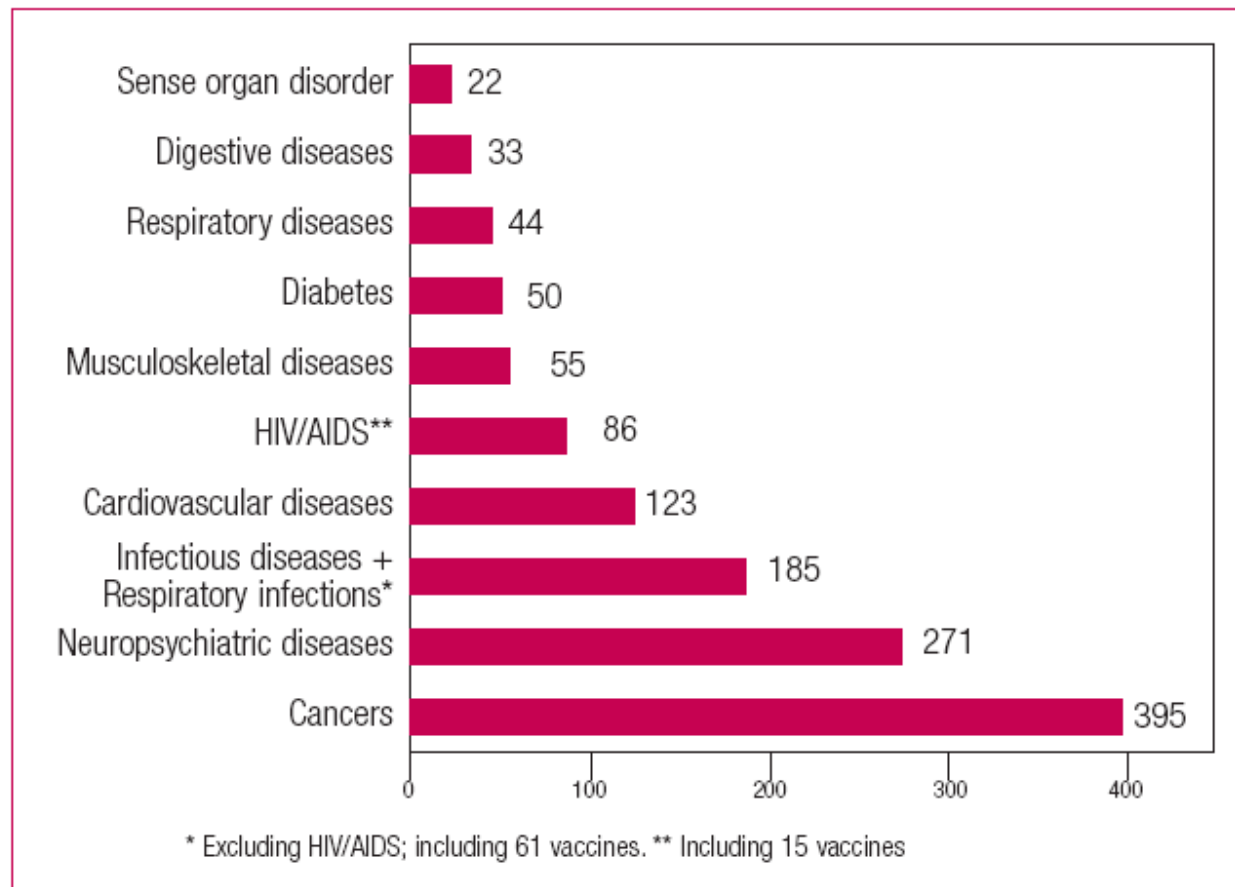
Source: adapted from NERA, *The human And Economic Value of Pharmaceutical Innovation and Opportunities for the NHS. A Report for the ABPI. May 2004*; Blood Pressure Lowering Treatment Trialists' Collaboration, *Effects of ACE inhibitors, calcium antagonists, and other blood-pressure drugs: results of prospectively designed overviews of randomized trials. The Lancet, Vol. 256, 2000.*

Box 9. EUROPE'S NEGATIVE PRECEDENT: CONTROL OVER HEALTHCARE INFRASTRUCTURE LIMITS ACCESS TO INNOVATION

- More than 2.5 million asthmatics in Germany receive no proper treatment.
- Despite cardiovascular diseases being Europe's major cause of death, in Germany 74 percent, in the UK 77 percent and in Italy 83 percent of all eligible patients do not receive up-to-date treatment for high cholesterol.
- In France, less than 50 percent of multiple sclerosis patients eligible for treatment with beta interferons actually receive it.
- In the UK, in 1997 only one in fourteen breast cancer patients, clinically eligible for the newest type of medication, received it.

Schöffski O., Diffusion of Medicines in Europe. University of Erlangen-Nuremberg, 2002

FIGURE 14. NUMBER OF COMPOUNDS IN DEVELOPMENT BY MAJOR DISEASE CATEGORIES



Source: PhRMA, Medicines in Development Surveys 2003/2004.