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Medicinal Products Registration EMEA/FDA/SWISSMEDIC

5 November, 2004

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Regulatory World

EU

USA

Japan

+ Others: EFTA(CH), Canada, Australia, WHO

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Regulatory World (2)

Since 1990 = International Conference on Harmonisation (ICH)

ICH TOPICS AND GUIDELINES

The ICH Topics are divided into four major categories and ICH Topic Codes are assigned according to these categories. The Guidelines deriving from the Topics are frequently referred to using the ICH Codes.

Q	**"Quality"** Topics, i.e., those relating to chemical and pharmaceutical Quality Assurance.
S	**"Safety"** Topics, i.e., those relating to *in vitro* and *in vivo* pre-clinical studies.
E	**"Efficacy"** Topics, i.e., those relating to clinical studies in human subject.
M	**"Multidisciplinary"** Topics, i.e., cross-cutting Topics which do not fit uniquely into one of the above categories.

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International Conference on Harmonisation (2)

Swissmedic implements all ICH Guidelines that have reached step 5

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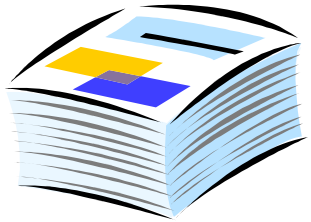
International Conference on Harmonisation (3)



Harmonisation of the Format of the Dossier Common Technical Document (CTD)

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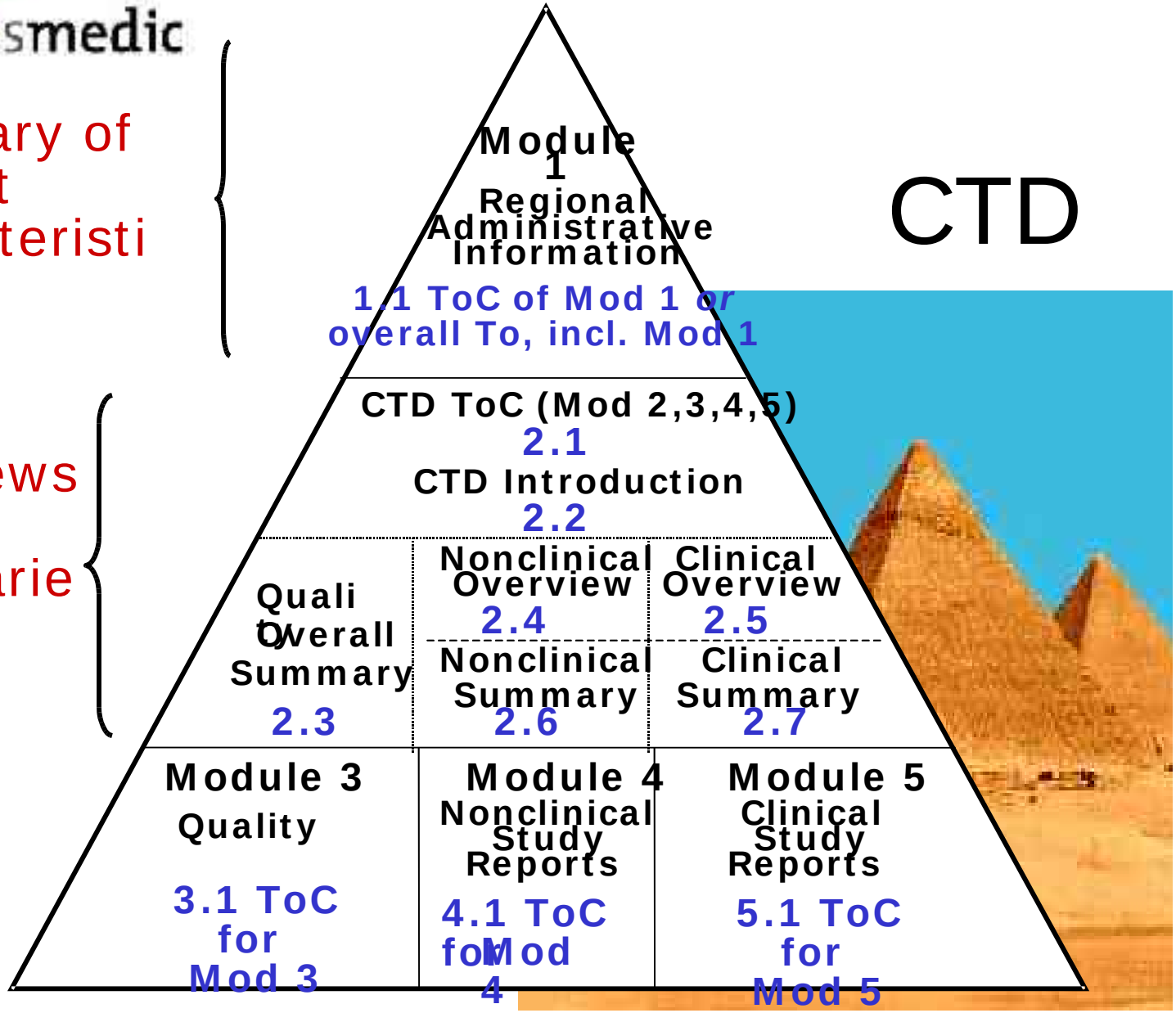
CTD

Summary of Product Characteristics

Overviews and Summaries

Data



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Marketing Authorisation Procedures

- EU (EMEA) -Marketing Authorisation Application (MAA)
- CH (Swissmedic) -MAA
- US (FDA) -New Drug Application (NDA)

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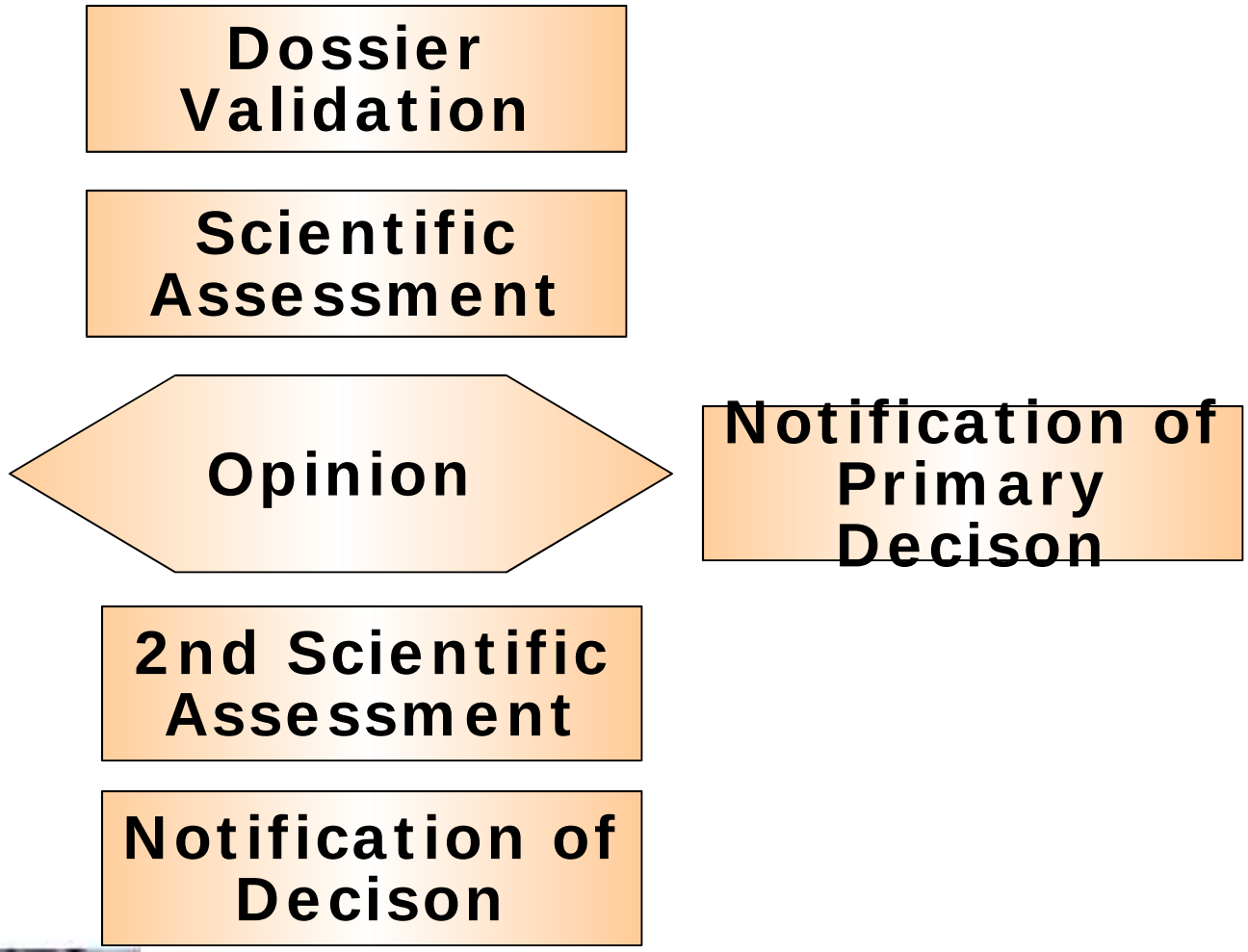
Marketing Authorisation Process



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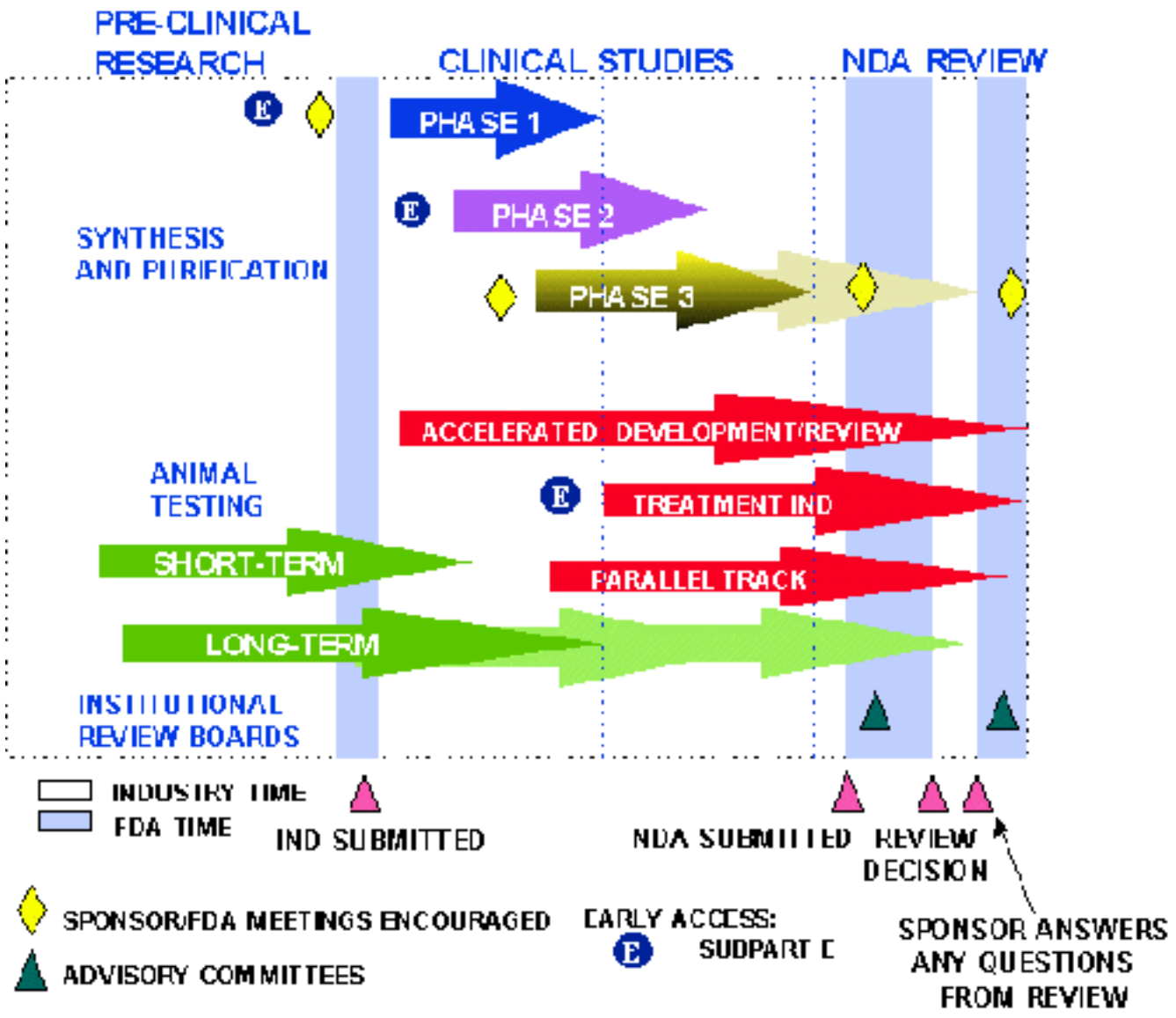
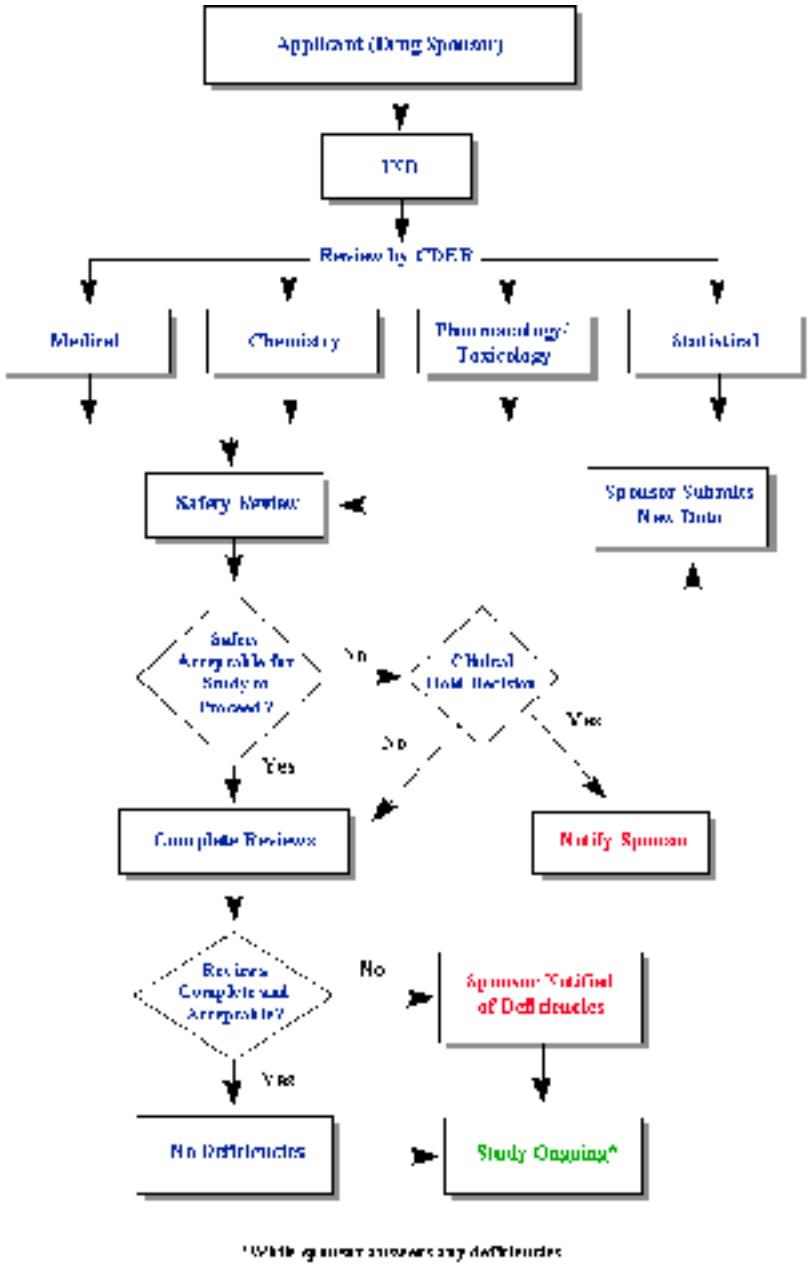
Marketing Authorisation Procedure US/FDA

The New Drug Development Process:
Steps from Test Tube to New Drug Application Review



http://www.fda.gov/cder/handbook/

IND Review Process



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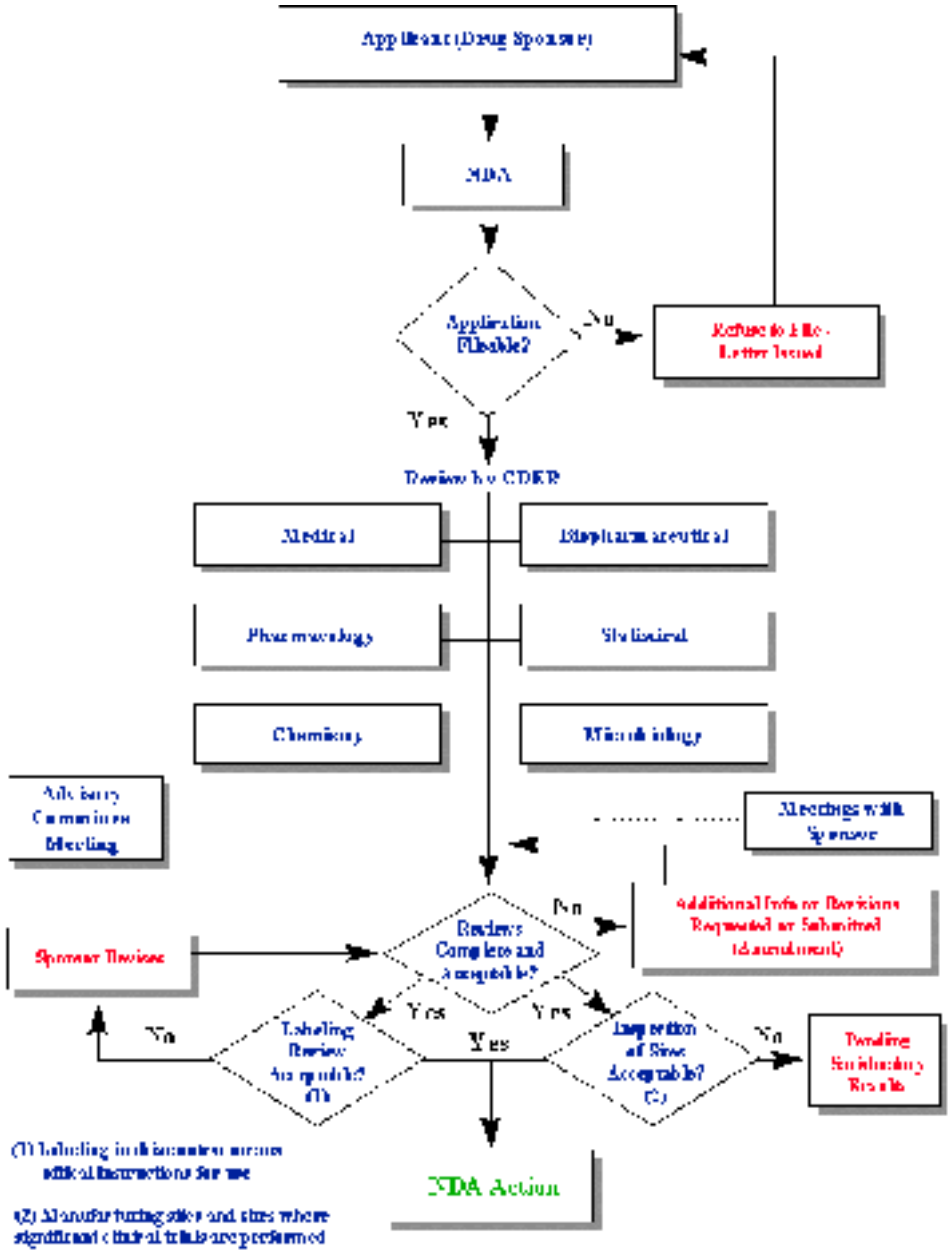
NDA Review Process



http://www.fda.gov/cder/handbook/

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Marketing Authorisation Procedure EU/EMEA

- Centralised Procedure
- Mutual Recognition Procedure

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Centralised Procedure (EMEA)

Medicinal Products developed by means of:
- rDNA technology
- Expression of genes coding for proteins
- Hybridoma and monoclonal antibody methods

As of 20 November 2005:

New Active Substances for Specified Therapeutic Areas:
- AIDS
- Cancer
- Neurodegenerative disorders
- Diabetes

- Orphan medicinal products

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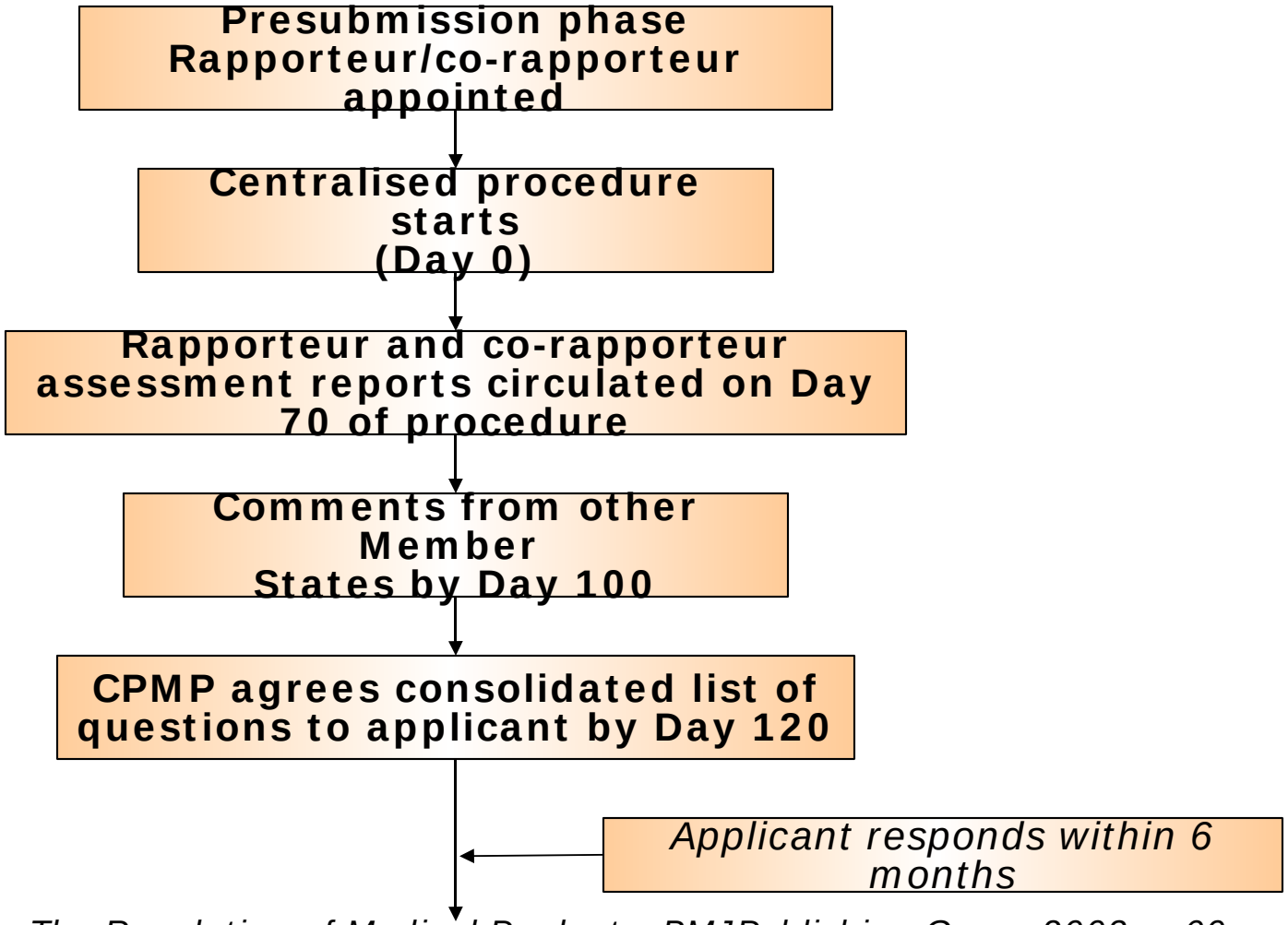
Centralised procedure (EMEA)



JP Griffin, JO'Grady, The Regulation of Medical Products, BMJPublishing Group 2003, p.60.

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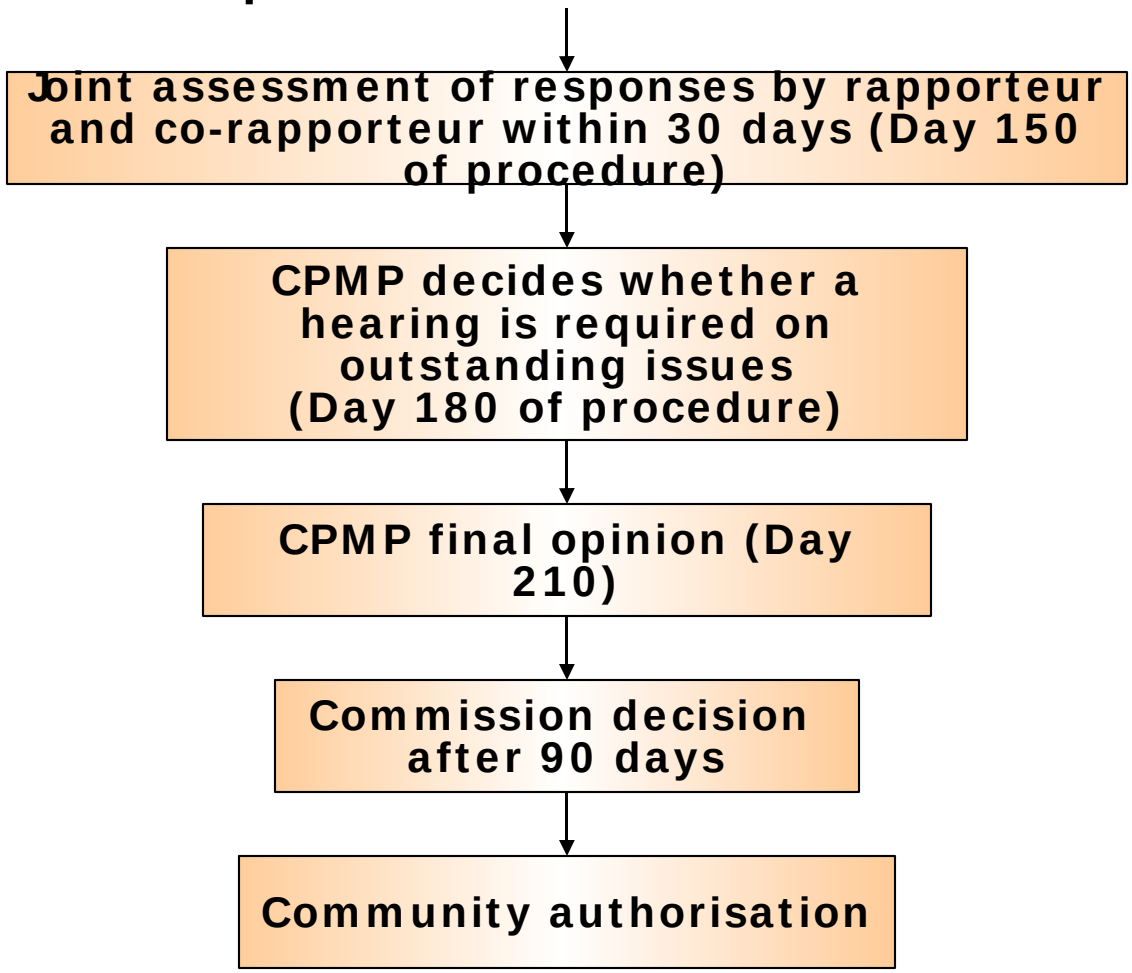
Centralised procedure



JP Griffin, JO'Grady, The Regulation of Medical Products, BMJPublishing Group 2003, p.60.

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Marketing Authorisation Procedure

Swiss Agency for Therapeutic Products

Since January 2002

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Responsibilities of Swissmedic

- Swissmedic is responsible for the evaluation of the benefit/risk relationship
  - NOT Price (l'OFAS)
  - NOT Reimbursement (l'OFAS)
- No treaties with other Agencies (FDA, EMEA) about mutual recognition of the evaluation and MA:
  Swissmedic has to evaluate the dossier on its own

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Responsibilities of Swissmedic (2)

The law on Therapeutic Products Art. 13 on medicinal products and procedures authorized in foreign countries states:

"If a medicinal product or procedure is already authorized in a country having equivalent medicinal product control, the results of tests (of the other Agency) carried out for this purpose shall be taken into account."

Many countries take into consideration Swissmedic decisions

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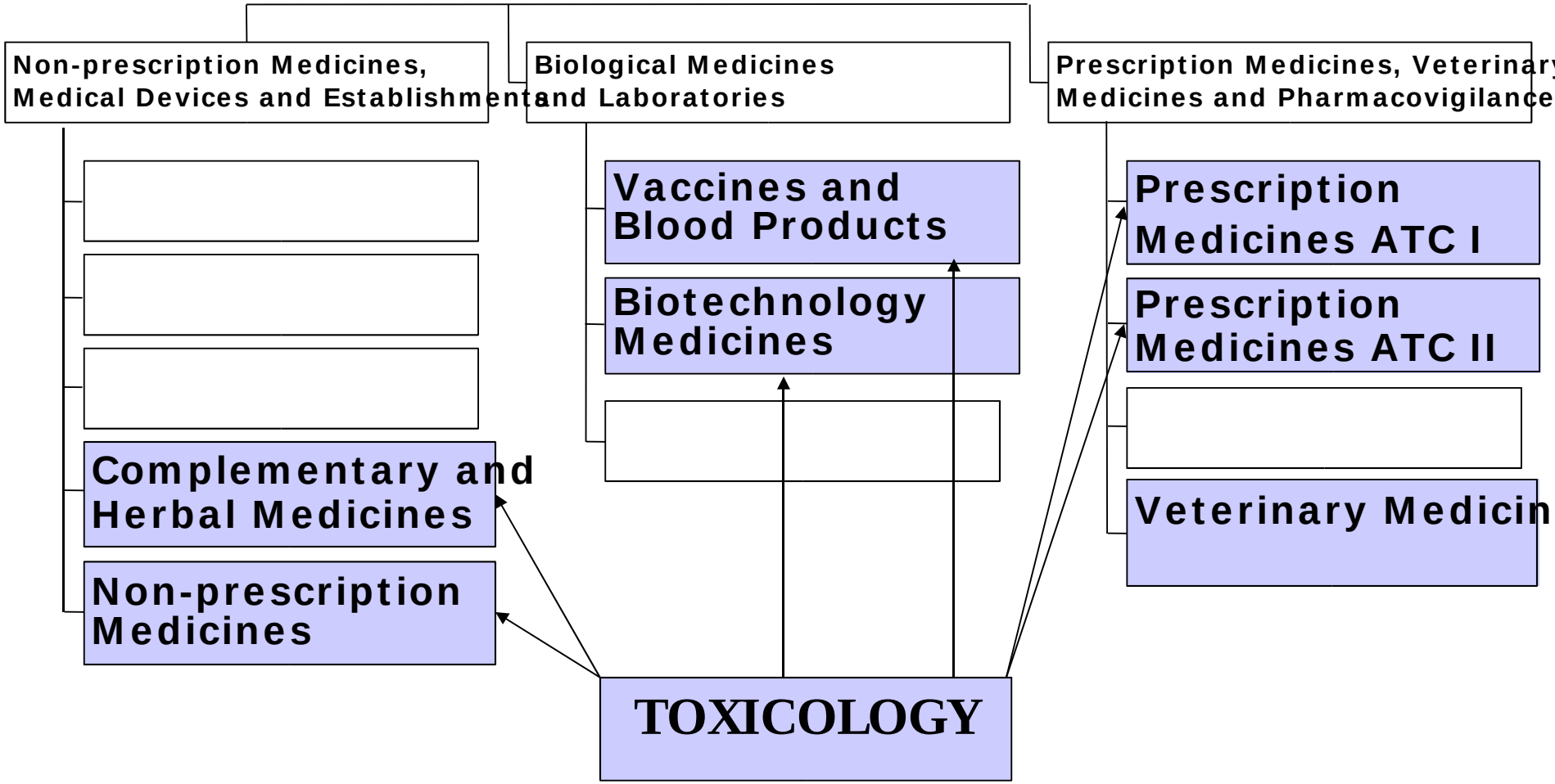
Divisions with MA process



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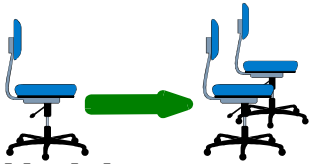
Review Process

Building of case team

Regulatory
Quality
Preclinical
Clinical



Individual review

Peer review

Division meeting

Medicines Expert Committee meeting

(Division meeting)

Final opinion and Decision letter

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Review Timelines

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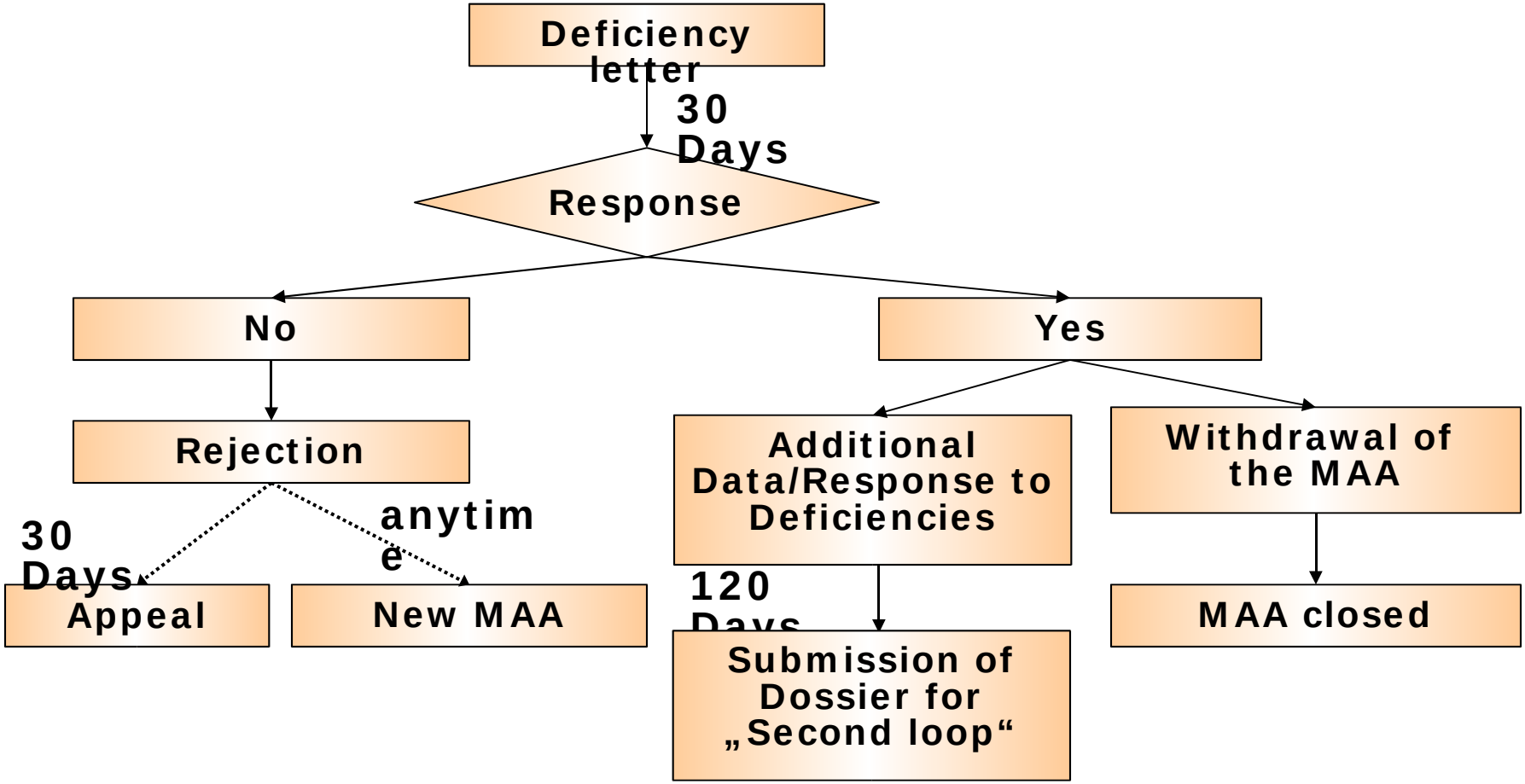
Negative opinion



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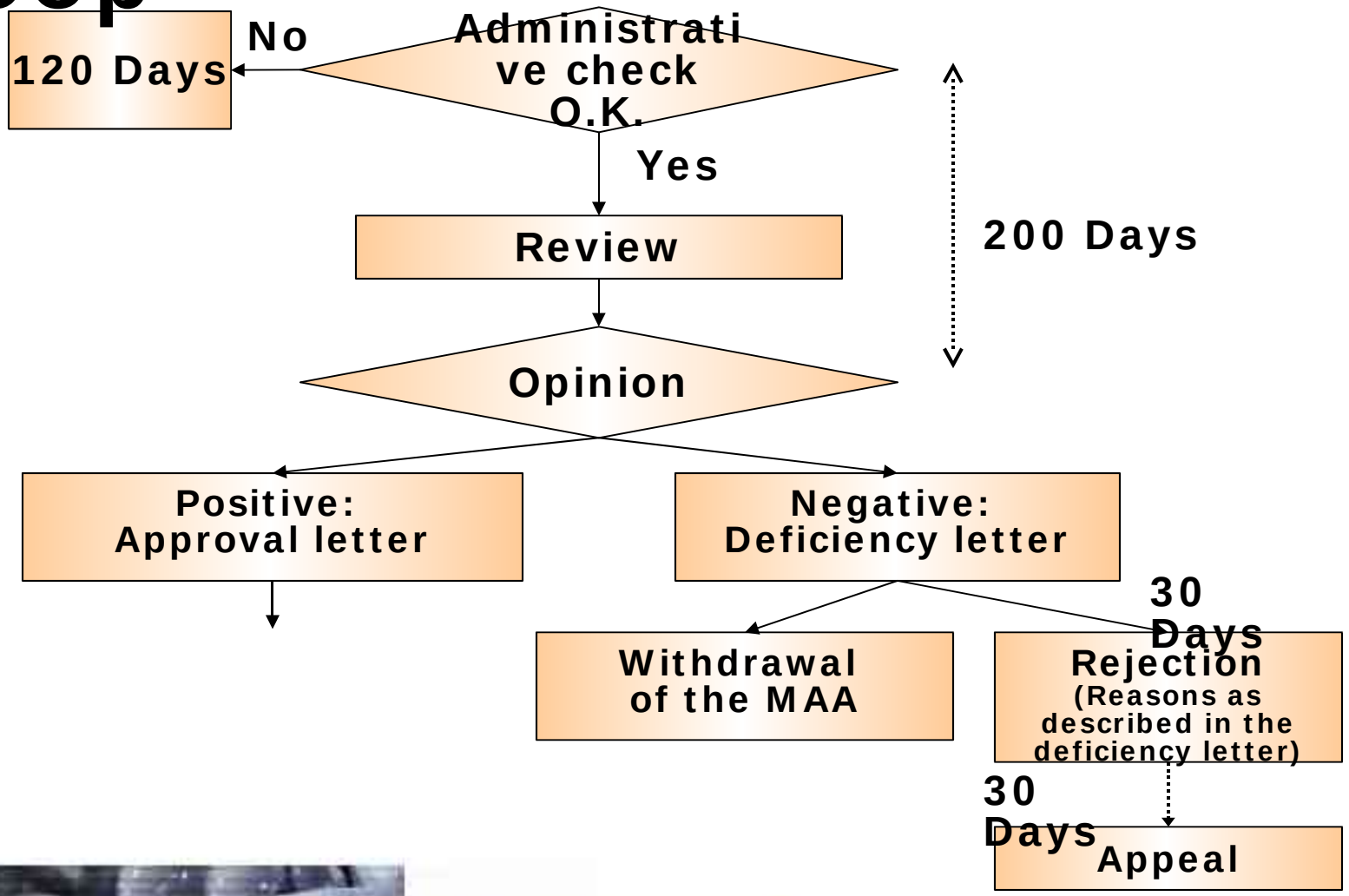
„Second loop“



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Switzerland

2 weeks — Administrative check

2 weeks — Building of case team

Individual and Peer Review

9 weeks — Division meeting

9 weeks — Medicines Expert Committee meeting

5 weeks — Approval/ deficiency letter (~ 200 days)

Centralised procedure (EME

Presubmission phase
Rapporteur/co-rapporteur appointed

Centralised procedure starts
(Day 0)

Rapporteur and co-rapporteur assessment reports circulated on Day 70 of procedure

Comments from other Member States by Day 100

CPMP agrees consolidated list of questions to applicant by Day 120

Applicant responds within 6 months

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Switzerland

Positive: Approval letter

90 Days (Applicant)

Resolution of minor deficiencies (e.g. Quality), SmPC modifications, Conditions

90 Days (Swissmedic)

Marketing Authorisation

Appeal

No Appeal

Centralised procedure(EMEA

Joint assessment of responses by rapporteur and co-rapporteur within 30 days (Day 150 of procedure)

CPMP decides whether a hearing is required on outstanding issues (Day 180 of procedure)

CPMP final opinion (Day 210)

Commission decision after 90 days

Community authorisation

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Average Annual Applications

EMEA	**25**
Swissmedic	**24**
FDA	**26**

Per year for New Active Substances
Time Period: 1997 – 2001

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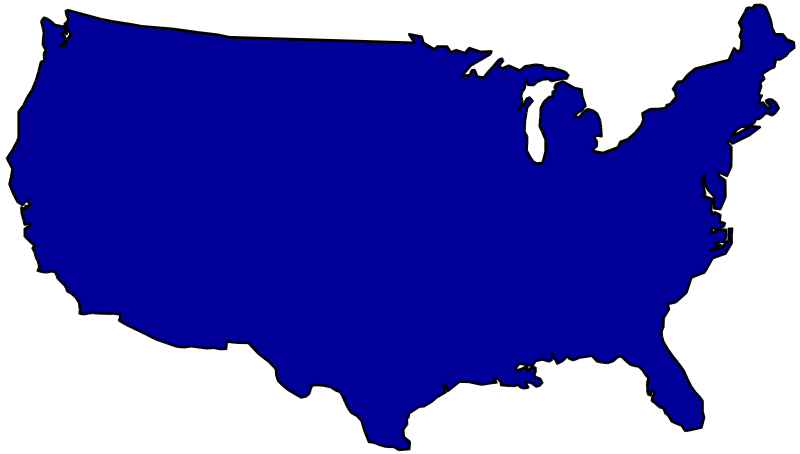
Differences between Swissmedic FDA

USA



CH

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Differences Between Swissmedic EMEA/FDA

- Decision based on the submitted dossier.
  No „consolidated list of questions“ before primary opinion. No „rolling review“
- Only minor deficiencies can be dealt with during the review process

→ Short review times for applications of high quality

→ Inconvenience for incomplete or premature dossiers