IGDRP International Generic Drug Regulators Programme

Information and work sharing models

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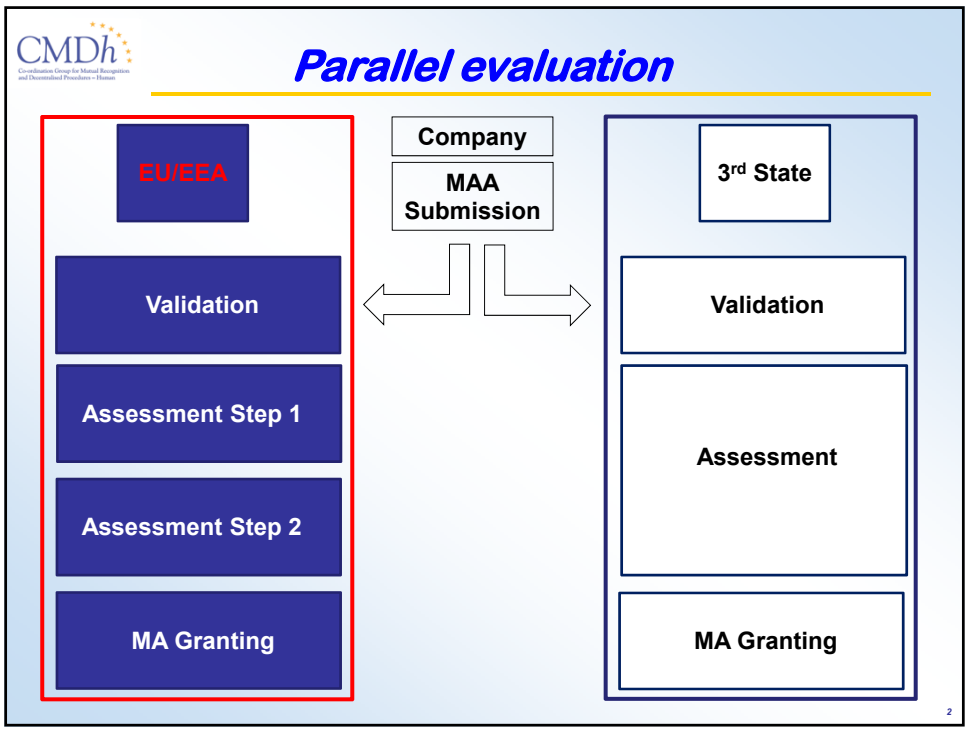
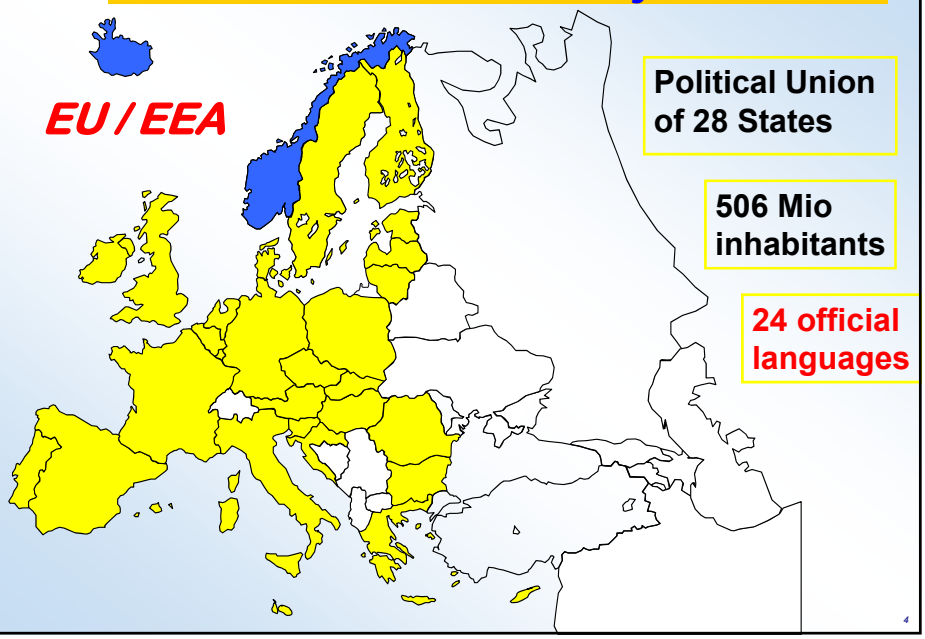
Dr. Peter Bachmann
Chair CMDh
co/European and International Affairs
Federal Institute for Drugs and
Medical Devices (BfArM), Germany



How to save resources ?

3

"United in Diversity"



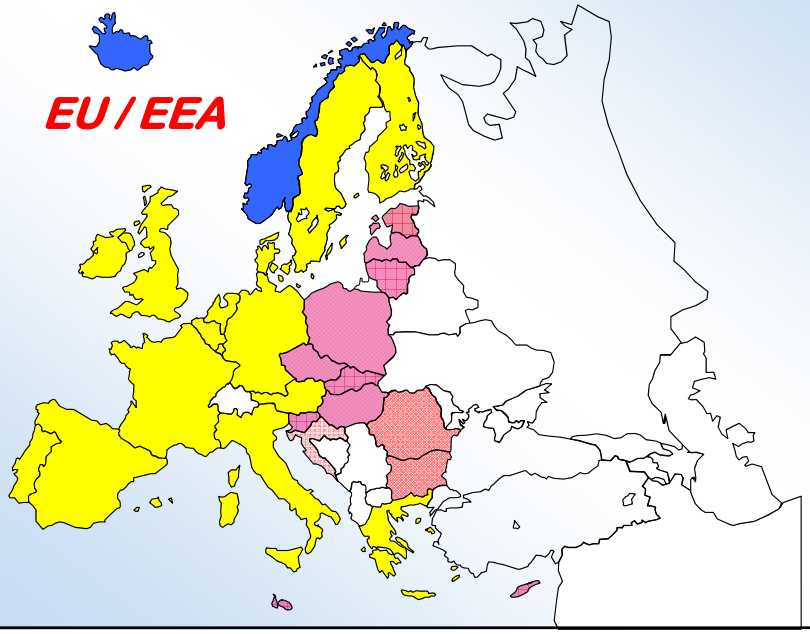
Political Union of 28 States

506 Mio inhabitants

24 official languages

4

"Enlargement of the EU"



5

The CADREAC Procedure

= **C**ollaboration **A**greement between **D**rug **R**egulatory Authorities in **E**uropean Union **A**ssociated **C**ountries

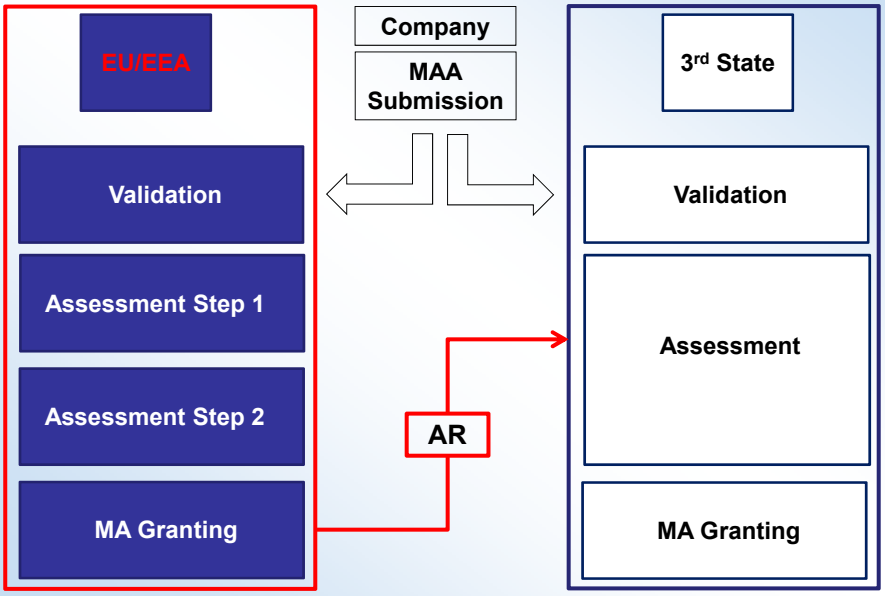
The Task:
At the time of accession, all medicinal products on the market must be fully in compliance with the EU pharmaceutical legislation (acquis communautaire)

How has it worked?

- Applicant /MAH send a dossier already approved in an EU MS to a CADREAC MS
- CADREAC MS requested from an EU MS the Assessment Report (AR) for this dossier
- Granting of the MA in the CADREAC MS

6

Current situation: subsequential



7

Can we do even better ?

European Procedures as a model for information sharing?

8

The EU is working as a Network

- of European Experts
  - for the Authorisation of Medicinal Products
  - for Pharmacovigilance (PSUR, RMP, …)
  - for GXP and other quality related inspections and surveillance tasks (eg. OMCL, …)

9

The EU is based on Worksharing – (1)

... long (and still growing) European experience
... can be devided in two types

- worksharing between experts from MS
  - ✓ Central Marketing Authorisation
  - ✓ Certificate of Suitability (CEP)
  - ✓ Plasma Master File Procedure
- worksharing between MS
  - ✓ voluntary framework (PSUR worksharing), ASMF worksharing
  - ✓ legislative framework MRP/DCP, GXP (GMP, GCP, …)

10

The EU is based on Worksharing – (2)

.... but
all is enshrined within one legal framework !!!

➡ **no questions concerning the exchange of confidential data between EU- and EEA-MS**

.... and the EU is based on open systems
- to allow the accession of new MS
- to be flexible with the number of participants in a procedure - e.g. the DCP can be run with 2, but also with 10 or with 31 MS

11

General Remark

European authorisation procedures for MA
- consists usually of 2 phases with a clock-stop to enable the applicant to answer questions
- are characterised by the principle of worksharing and trust in the evaluation of the evaluating MS (RMS). The other MS (CMS) in the procedure can send comments – therefore each phase is subdivided in two phases

12

Terminology and Principles – (1)

- **Applicant**
  - choose RMS and CMS's
  - submit the application to all MS concerned
- **RMS** (= Reference Member State)
  - administrator of the procedure (validation, start, clock-stop, restart, closing and finalisation)
  - evaluation of the dossier and preparation of the Assessment Report (AR) and Product Information (PI = SmPC, PL, labelling)

13

Terminology and Principles – (2)

- **CMS** (= Concerned (participate) MS)
  - to agree with the RMS AR and proposed PI and to grant a MA
  - or to send questions for clarification
  - or in case of fundamental disagreement go for a referral to the CMDh (or CMDv)

14

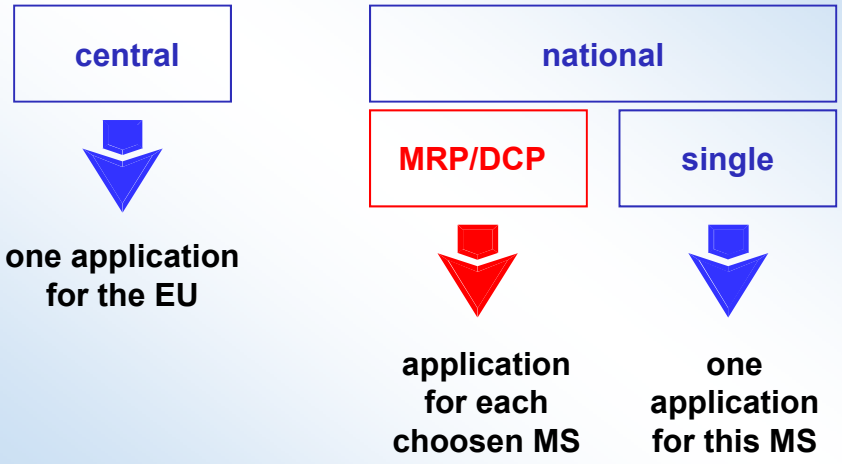
Types of MA in the EU

central	national
MA valid for the entire EU	MA valid for a single EEA-MS

- same dossier requirements
- same legal and scientific requirements for Quality, Safety and Efficacy

15

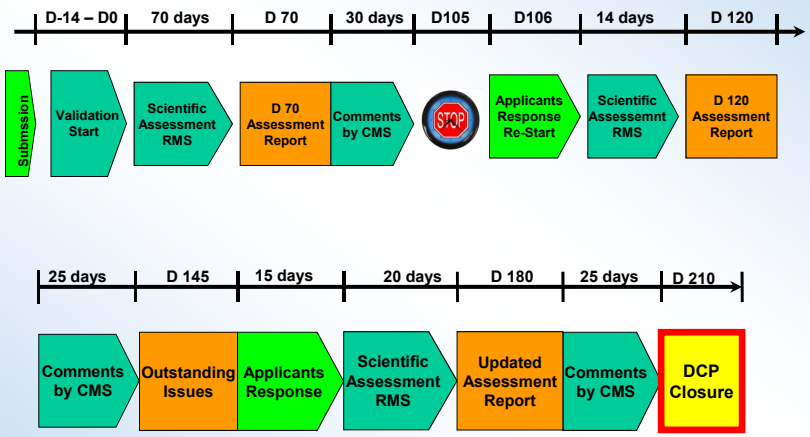
Procedures for a MA-Application



… but for all procedures: only one assessment

16

The Decentralised Procedure (DCP) as a model?



17

IGDRP
International Generic Drug Regulators Programme

IGDRP Information Sharing Pilot

18

IGDRP Information Sharing – (1)

- **Objective:** Explore and pilot information and work-sharing models for premarket review of generic drugs
- **Prerequiste for information and worksharing:**
  - Requires **"near identical " submissions**
    - same product (active, formulation, manufacturer, dose form, strength)
    - very similar clinical context (indications, target patient population, dose and administration)
  - **Timely sharing** of reports to enable prompt review is critical

19

IGDRP Information Sharing – (2)

The agreed policy model is based on some pillars

- no confidentiality problems, therefore the process has to be initiated and run on request of the applicant
- (is restricted to the DCP only)
- the integrity of the DCP (e.g. structure, timelines, …) is not for discussion
- to provide information must have a minimal influence on RMS-resources

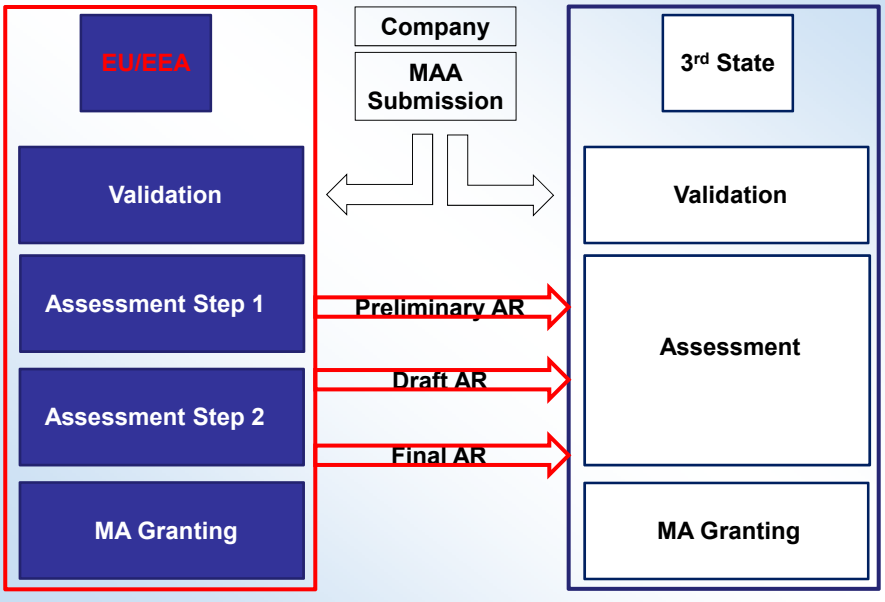
20

IGDRP Information Sharing – (3)

- HMA agreement (28-29 November 2013, Ljubljana)
  - to sent on request of the MAH finalised assessment reports to the 'IGDRP-States'
  - to sent on request of the Applicant during an ongoing DCP information on the evaluation in real time under the conditions
    - no impact on DCP incl. timelines in the EU
    - unidirectional information from EU to 'IGDRP'
    - minimal administrative burden for the RMS

21

… an 'Information Sharing'-Model



22

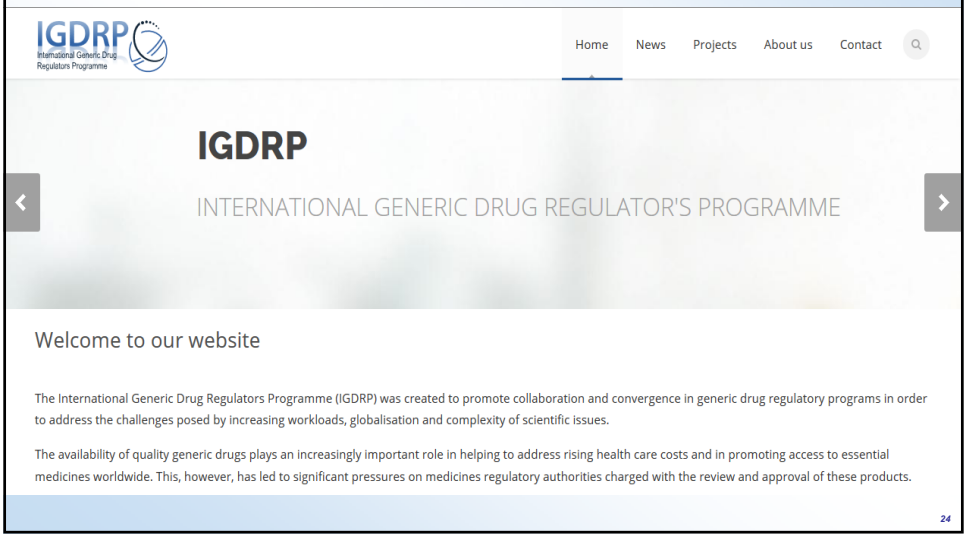
IGDRP Information Sharing – (4)

- agreement of the IGDRP-Steering Committee (May 2014, Yilan, Chinese Taipei) to start an information-sharing pilot based on the European DCP
- invitation send to industry/trade associations for expression of interest (EoI)
- participating agencies:
  - Health Canada
  - TGA
  - Swissmedic
  - TFDA
- where to find information ?

23

IGDRP Information Sharing – (5)

www.igdrp.com



24

IGDRP Information Sharing – (6)

EU Centralised Procedure – Pilot

- IGDRP Singapore Meeting (November 2014):
  offer from EMA to join the pilot with generic applications in the centralised procedure
- Goal: EoI until 31. 03. 2015 for 10 procedures
  press release on 21. 04. 2015:
  ”The deadline for submitting expressions of interest to participate in the information-sharing initiative for generics has been extended to give more time to companies to submit their applications.”
  EoI received so far: 4 – but no started procedure !

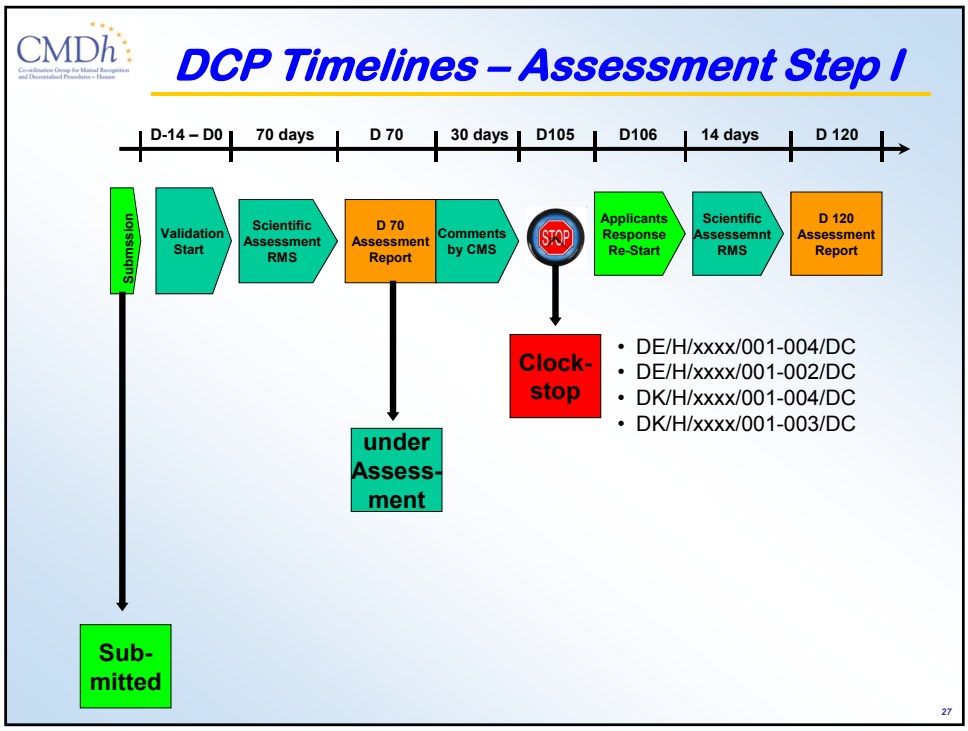
25

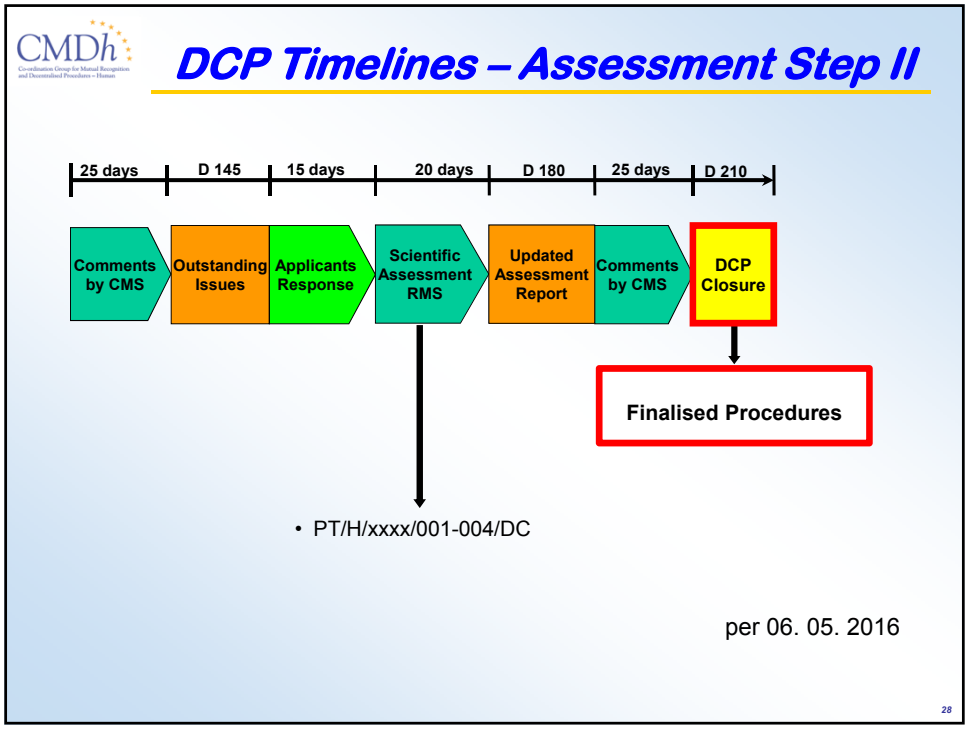
IGDRP Information Sharing – (7)

EU DCP – Pilot

- feedback
  - 26 expression of intentions received
    - 1 duplicate for DCP and CP
  - from 12 companies
  - for 27 DCP
  - for 7 different RMS
  - highest interest for
    TGA – HC – Swissmedic – TFDA

26


DCP Timelines – Assessment Step I
D-14 – D0
70 days
D 70
30 days
D105
D106
14 days
D 120
Submsson
Validation Start
Scientific Assessment RMS
D 70 Assessment Report
Comments by CMS
STOP
Applicants Response Re-Start
Scientific Assessemnt RMS
D 120 Assessment Report
Clock-stop
under Assess-ment
Sub-mitted
• DE/H/xxxx/001-004/DC
• DE/H/xxxx/001-002/DC
• DK/H/xxxx/001-004/DC
• DK/H/xxxx/001-003/DC
27


DCP Timelines – Assessment Step II
25 days
D 145
15 days
20 days
D 180
25 days
D 210
Comments by CMS
Outstanding Issues
Applicants Response
Scientific Assessment RMS
Updated Assessment Report
Comments by CMS
DCP Closure
Finalised Procedures
• PT/H/xxxx/001-004/DC
per 06. 05. 2016
28

Finalised Information Sharings

Applicant A	TGA	HC	Swissmedic
DE/H/xxxx/001-008/DC	x		
DE/H/xxxx/001-003/DC	x		
DE/H/xxxx-xxxx/001-003/DC			x
DE/H/xxxx/001-003/DC	x		x
DE/H/xxxx/001-003/DC			x
AT/H/xxxx/001-002/DC		x	x
NL/H/xxxx/001/DC	x		
PT/H/xxxx/001-004/DC		x	

Applicant B	TGA	HC	Swissmedic
NL/H/xxxx/001/DC	x	x	

29

Information sharing is still ongoing …

… but lessons learned so far:

- Assessment Report
  - is regarded as very useful and helps during the assessment process of the receiving Agency
  - comparable good quality, despite different RMS
  - common conclusion on the assessment between the sending and the receiving Agency
- Questions during the Assessment
  - numbers of questions are in general comparable
  - no fundamental differences, but focus of the questions may differ
- Building confidence between participating Agencies

30

Information sharing is still ongoing …

… identified areas for improvement:

- need of more coordination between participating Agencies
- perhaps more guidance to the applicants

and

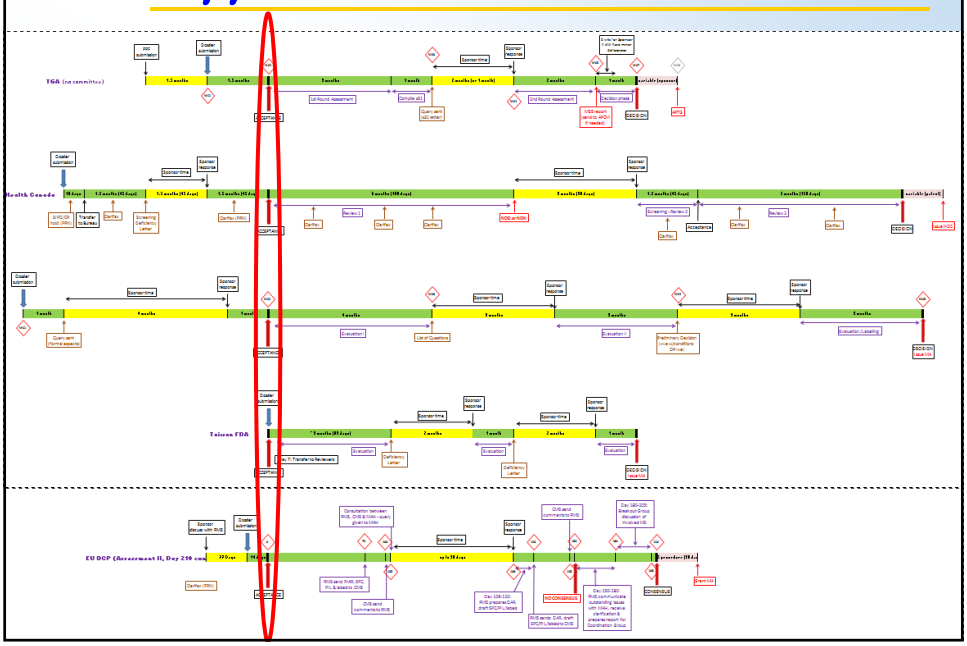
TIMELINES

(internal and external)

- when to submit an application
- start of the procedure
- re-start of the procedure

31

Application for a MA: Timelines



Information sharing is still ongoing …

- Feedback so far
  - from industry
  - from participating agencies

    Positive, but improvement will be helpful
- the information sharing has no negative effect on the speed of the authorisation process !
- but
  - legal requirements of the participating agencies for the submission of an application have to be fulfilled (eg data exclusivity, reference product, local sponsor, …)

33

Questions ?

YES !

- Where are the applications ?
- Why not more?
- Why you are so shy ?

34