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Agency for Medicinal Products
and Medical Devices of Croatia

PRE-ACCESSION CHALLENGES
-
HALMED PERSPECTIVE

Maja Lovrek
Head of Medicines Authorisation Division

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- preparation of new Croatian legislation and transitional measures
- upgrading of documentation
- pre-accession linguistic check for Centrally Authorised products (PALC)
- review of authorised medicinal products
- preparation for participation in CP, MRP and DCP procedures
- backlog of pending applications
- organisational changes in HALMED

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New Croatian legislation and transitional measures

Medicinal Products Act

- Proposal of text published for public consultation in January 2013
- Public hearing on proposal of text held in February 2013
- Comments from European Commission awaited

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New Croatian legislation and transitional measures

Most significant changes

- Introduction of Centralised Procedure
- Introduction of MRP&DCP procedures
- Data exclusivity (8+2+1 vs. 6 years)
- Batch release and batch testing to be performed in EU
- Braille & RUT mandatory
- Renewal to be submitted at least 9 months before MA ceases to be valid
- Variation classification, timelines and workflow

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New Croatian legislation and transitional measures

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- Centrally authorised products (CAPs)
- Medicinal products authorised through the Mutual Recognition procedure (MRP), Decentralised procedure (DCP) and National procedure (NP)
- MRP and DCP procedures and EU enlargement – new version of CMDh Q&As
- "Blue box requirements" – for national, MRP and DCP procedures

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New Croatian legislation and transitional measures

Most significant proposed transitional and final measures

Data and market exclusivity for Centrally Authorised Medicinal Products

- Marketing authorisations issued according to previous Croatian legislation for which data exclusivity of reference medicinal product authorised in the EU via CP procedure has not elapsed shall be revoked

- If only market exclusivity applies, no batch shall be released to market after Croatia's accession to the European Union

European Commission

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Review of authorised medicinal products

Breach of CP reference Medicinal Products' Data/Market exclusivity

- Q&A document published on HALMED's website in May 2012
- Breach of Data exclusivity identified for only 2 active substances

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MAs for these Medicinal Products will have be revoked as of 01 July 2013

European Commission

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New Croatian legislation and transitional measures

Most significant proposed transitional and final measures

Batches of nationally approved CP products

- Batch of Medicinal Product authorised through CP and manufactured in accordance with Croatian national Marketing Authorisation issued before Croatia's accession to the European Union may enter Croatia and may be on the Croatian market 12 months after accession

European Commission

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New Croatian legislation and transitional measures

Most significant proposed transitional and final measures

Simplified Repeat Use Procedure (RUP) based on nCADREAC procedure

- Simplified RUP based on nCADREAC procedure may be initiated 12 months after Croatia's accession to the European Union at latest
- Until submmission of simplified RUP → nCADREAC procedure to be followed

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- Batch release of Medicinal Products after Croatia's accession to the European Union
- Import of Medicinal Products from third countries after Croatia's accession to the European Union

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Review of authorised medicinal products

Batch release sites located in third countries

- Awareness text published on HALMED's website in January 2013
- 4100 valid Marketing Authorisations in Croatia (excluding CP)
  - 300 – at least one batch release site approved for Croatia is outside EU
    - 170 – no variation submitted

Individual letters to be sent to MAHs

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- Guidelines for Marketing Authorisation Holders on introduction of Braille on the labelling
- Guidelines for Marketing Authorisation Holders on Readability User Testing

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New Croatian legislation and transitional measures

Most significant proposed transitional and final measures

Braille requirement on packaging

- Medicinal Products authorised before Croatia's accession to EU → Braille required on packaging from 1 January 2015

- MPs listed on transitional list of Annex Treaty → Braille proposal to be included in the application for upgrading

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New Croatian legislation and transitional measures

Most significant proposed transitional and final measures

Readability user testing (RUT) requirement

- Medicinal Products authorised before Croatia's accession to EU → RUT to be submitted to HALMED by 01 January 2016

- MPs listed on transitional list of Annex Treaty → RUT to be included in the application for upgrading

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Renewals

- Marketing authorisations which cease to be valid in period 01 January 2014 - 31 March 2014 → renewals to be submitted at least 6 months before MA ceases to be valid

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New Croatian legislation and transitional measures

Most significant proposed transitional and final measures

Variation Regulation

- Regulation 1234/2008 applicable to nationally authorised MPs from 01 July 2013

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New Croatian legislation and transitional measures

Most significant changes

- Applicant/MAH may be established in the Community
- Concept of „Same Applicant/Marketing authorisation holder”:
  - belonging to the same mother company or group of companies
  - not belonging to the same mother company or group of companies, but have concluded agreements or which exercise concerted practices concerning the placing on the market of the relevant medicinal product in different Member States

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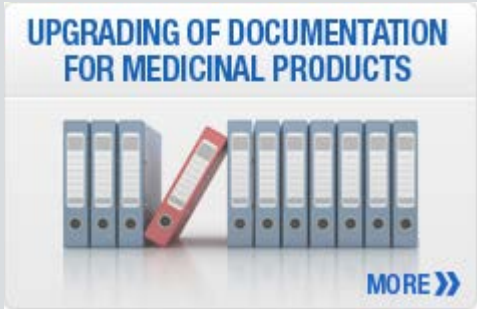
Upgrading of documentation

- In September 2012 a web-application set up by HALMED → review of MAs status
- In November 2012 detailed procedural guidance issued by HALMED
- Preaccession priority → upgrading of documentation for Medicinal Products not covered by Acession Treaty
- Deadline for submission of documentation 28 February 2013



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New Croatian legislation and transitional measures

Most significant proposed transitional and final measures

Upgrading of documentation

- All Marketing Authorisations listed in Accession Treaty Annex for which the application for upgrading has not been submitted or for which the documentation has not been upgraded shall be revoked

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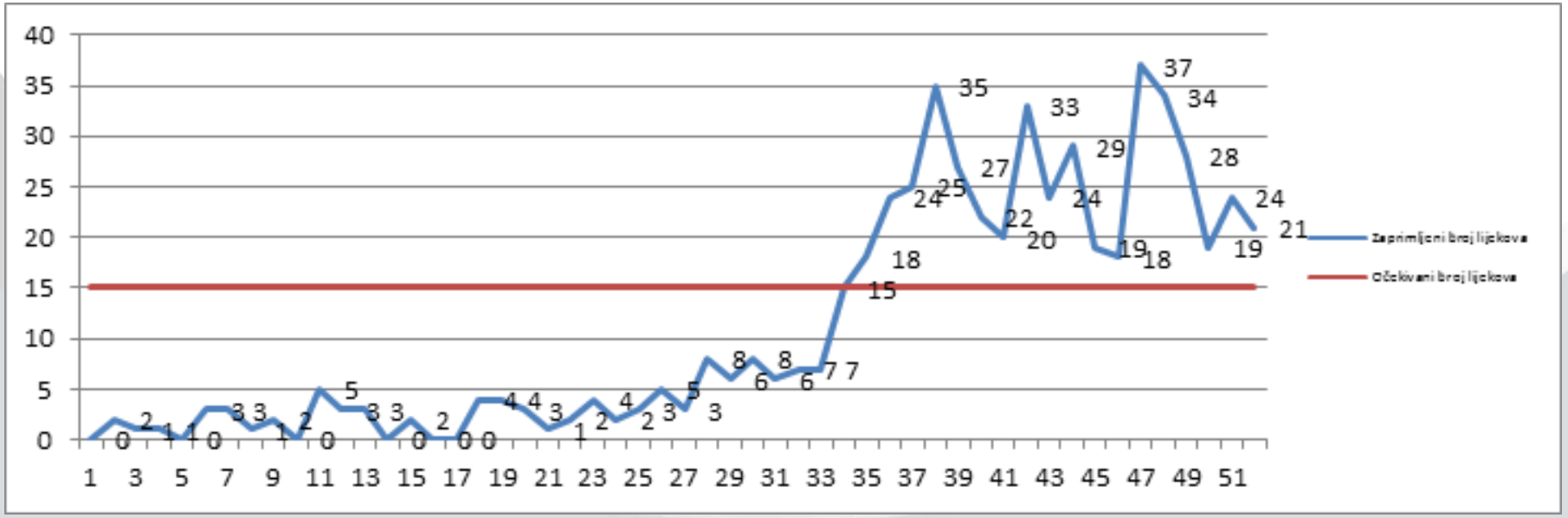
Pre-accession linguistic check for Centrally Authorised products (PALC)



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Pre-accession linguistic check for Centrally Authorised products (PALC)

- 41 products have not yet submitted for PALC III
- EMA is contacting MAHs to allow one additional slot for products to be submitted for PALC III
- Deadline - 6th May

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Preparation for participation in CP, MRP & DCP procedures

- **2006**
  - nCADREAC agreement signed
- **2010**
  - Twinning light with Spanish Agency of Medicines and Medical Devices
- **2011**
  - CMDh observer
- **2012**
  - CHMP observer
- **2013**
  - Study visits to Spanish Agency of Medicines and Medical Devices

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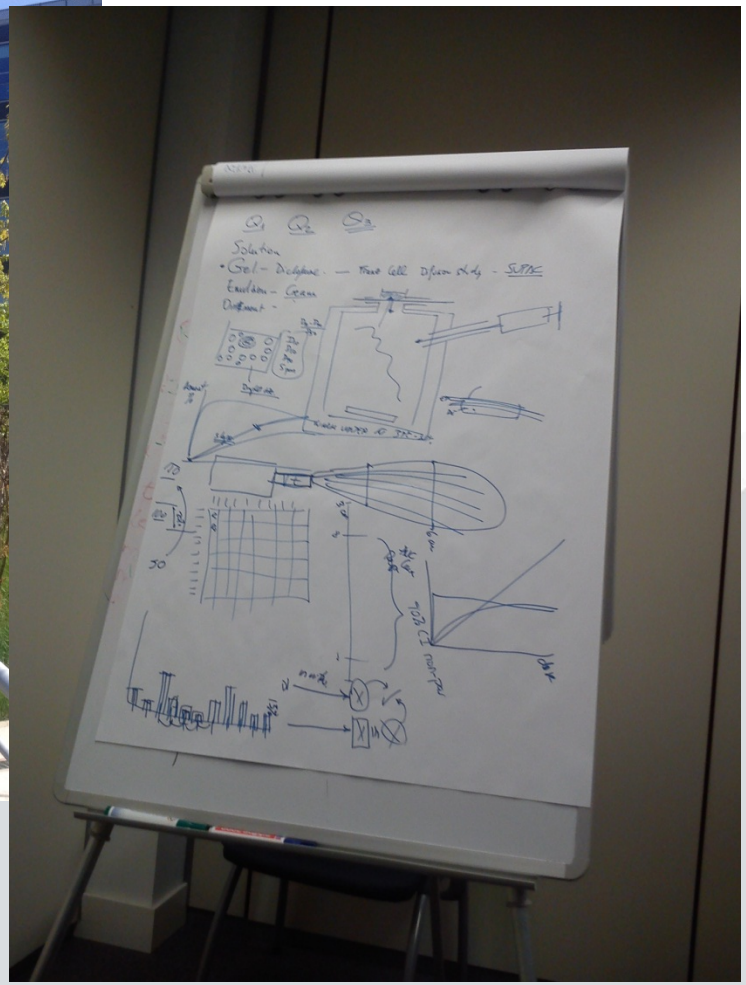

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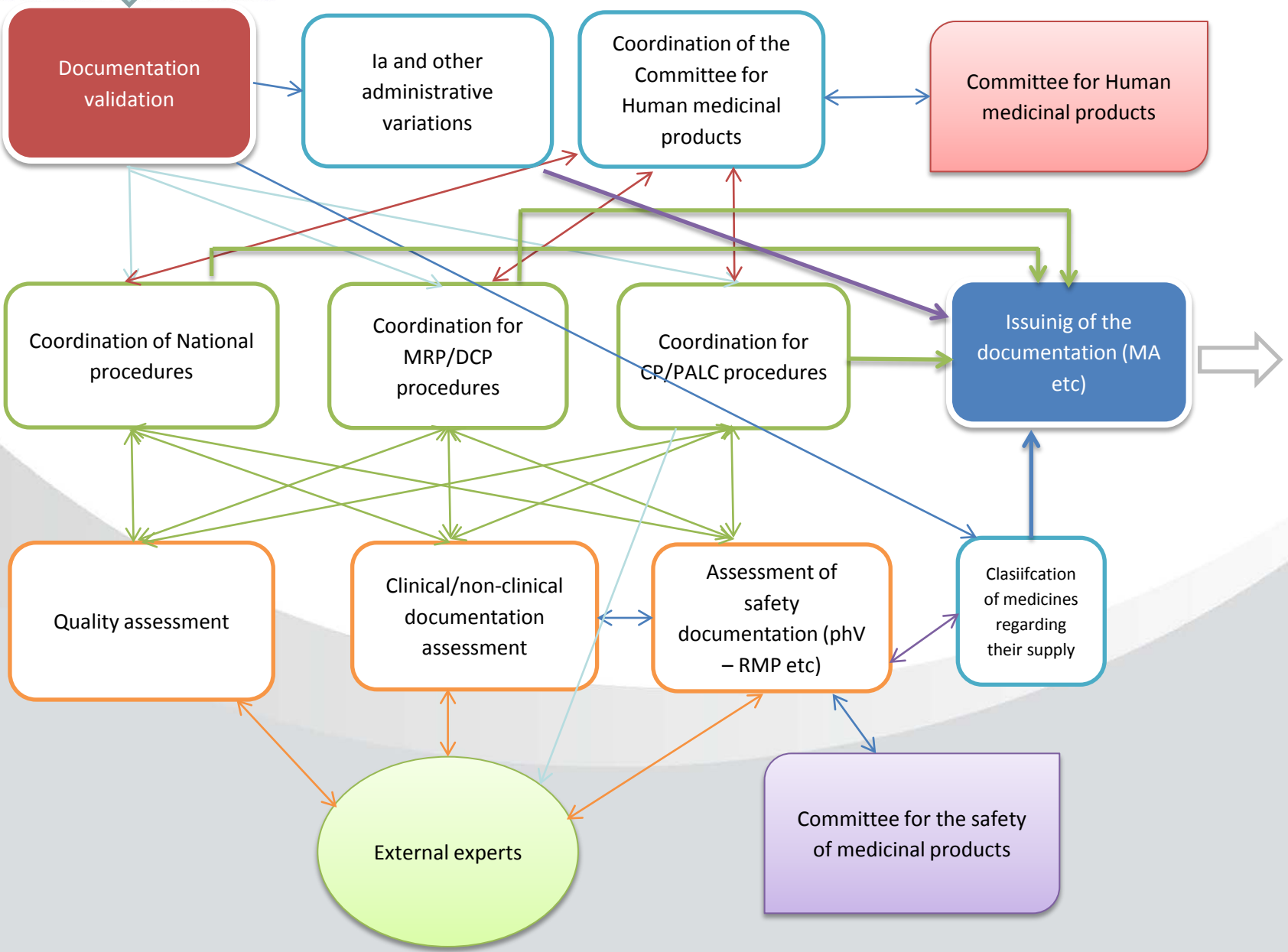
Organisational changes in HALMED



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