

PRE-ACCESSION CHALLENGES - **HALMED PERSPECTIVE**

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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

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

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

New Croatian legislation and transitional measures

The screenshot displays the HALMED website homepage. The header features the HALMED logo, agency name, and a 'WELCOME TO THE WEBSITE' message. A navigation bar lists categories: MEDICINAL PRODUCTS, MEDICAL DEVICES, HOMEOPATHIC PRODUCTS, LICENCES - MANUFACTURING AND SALE, PHARMACOVIGILANCE, and PHARMACOPOEIA. The main content area is divided into several sections:

- OPENING HOURS OF THE REGISTRY OFFICE:** Additional Information on Submission of Documentation. KSAVERSKA CESTA 4, ZAGREB. Customer service: 8.00 a.m. to 3.30 p.m. Sample submission: 8.00 a.m. to 2.00 p.m.
- For patients:** INFORMATION ON MEDICINES and ON-LINE REPORTING OF ADRs.
- UPGRADING OF DOCUMENTATION FOR MEDICINAL PRODUCTS:** MORE >>>
- NEWS:**
 - Newly approved medicinal products 24.04.2013.** Here you can find a list of newly approved medicinal products between 1st March 2013 and 31st March 2013. [more]
 - Newly approved medicinal products 12.04.2013.** Here you can find a list of newly approved medicinal products between 1st February 2013 and 28th February 2013.
- CROATIAN ACCESSION TO THE EU:** Guidelines for Marketing Authorisation Holders. MORE >>>
- WORKSHOPS / EVENTS:** Dubrovnik, 6-7 May 2013. The international conference "EU28: science, medicines, health - a regulatory system fit for the future".

A red circle highlights the 'CROATIAN ACCESSION TO THE EU' section, which is related to the new Croatian legislation and transitional measures mentioned in the slide title.

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



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



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



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



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



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 submission of simplified RUP → nCADREAC procedure to be followed

New Croatian legislation and transitional measures

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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

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

New Croatian legislation and transitional measures

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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

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

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

New Croatian legislation and transitional measures

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New Croatian legislation and transitional measures

Most significant proposed transitional and final measures

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

New Croatian legislation and transitional measures

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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

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

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 Accession Treaty
- Deadline for submission of documentation 28 February 2013

UPGRADING OF DOCUMENTATION
FOR MEDICINAL PRODUCTS



MORE >>

New Croatian legislation and transitional measures

Most significant proposed transitional and final measures

Upgrading of documentation

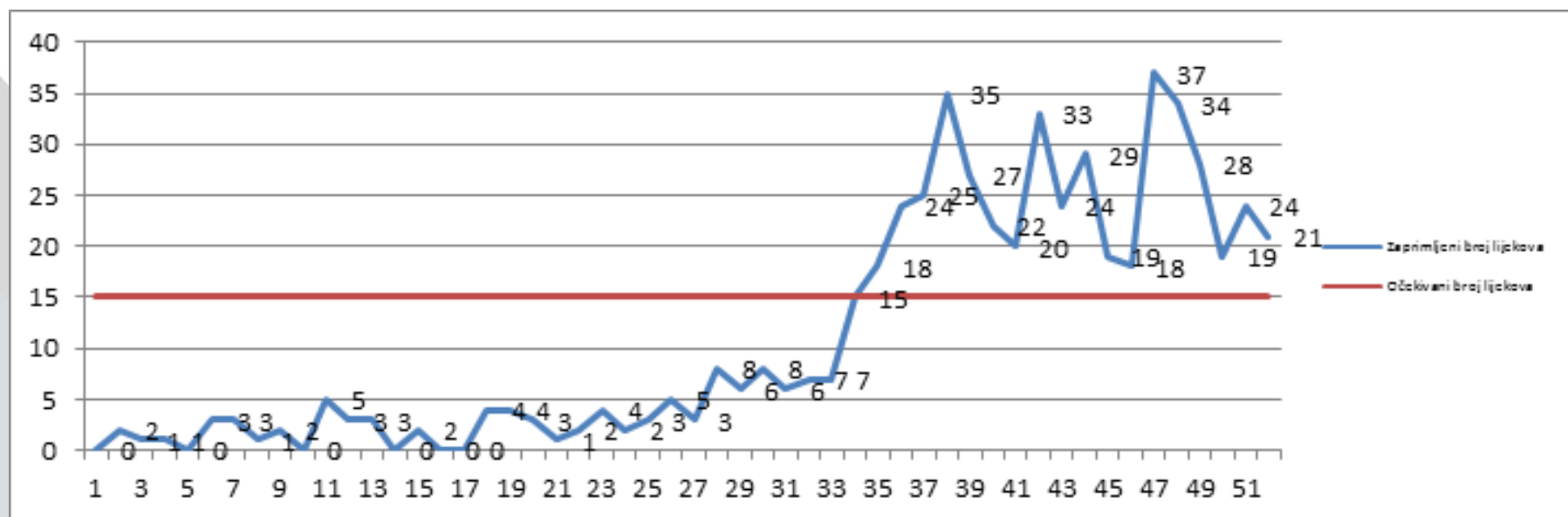
- All Marketing Authorisations listed in Accession Treaty Annex for which the application for upgrading has not been submitted or for which the documentation has not been upgraded shall be revoked

UPGRADING OF DOCUMENTATION
FOR MEDICINAL PRODUCTS



MORE >>

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



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

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

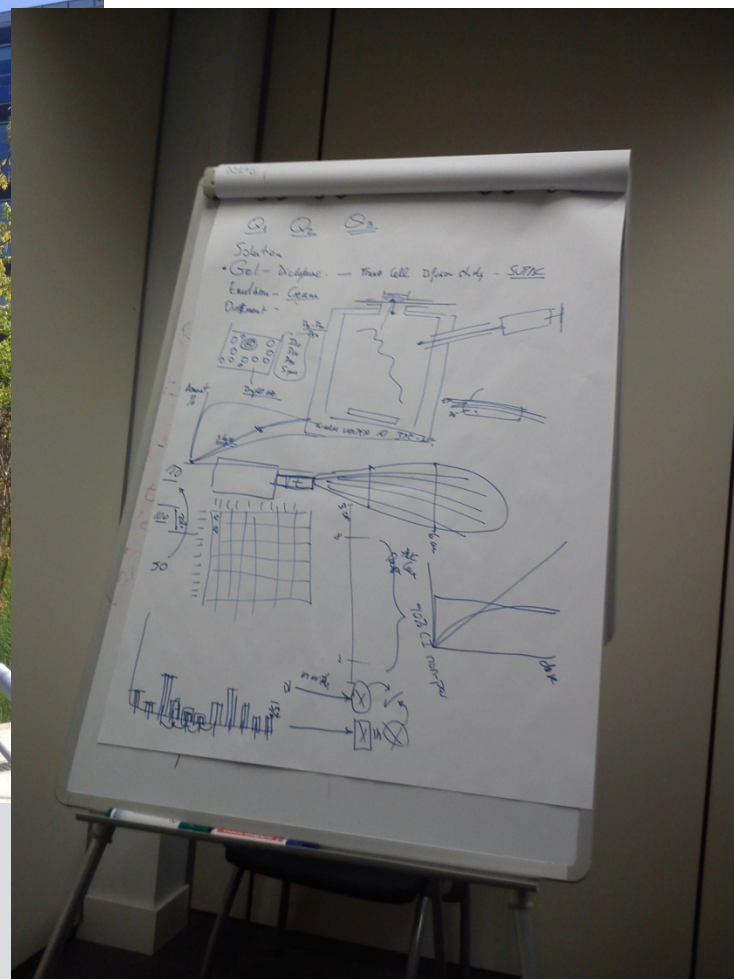
2012

- CHMP observer

2013

- Study visits to Spanish Agency of Medicines and Medical Devices

Preparation for participation in CP, MRP & DCP procedures



The flowchart illustrates the regulatory process for medicinal products, starting with **Documentation validation** (red box) and **la and other administrative variations** (blue box). These lead to **Coordination of the Committee for Human medicinal products** (blue box) and **Committee for Human medicinal products** (pink box). The process then moves to **Issuining of the documentation (MA etc)** (blue box), which is influenced by **Coordination of National procedures** (green box), **Coordination for MRP/DCP procedures** (green box), and **Coordination for CP/PALC procedures** (green box). The final step is **Issuining of the documentation (MA etc)** (blue box), which leads to **Classification of medicines regarding their supply** (blue box). The process also involves **Quality assessment** (orange box), **Clinical/non-clinical documentation assessment** (orange box), **Assessment of safety documentation (phV – RMP etc)** (orange box), and **Committee for the safety of medicinal products** (purple box). The process concludes with **External experts** (green oval) and **Committee for the safety of medicinal products** (purple box).

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graph TD
    DV[Documentation validation] --> LA[la and other administrative variations]
    LA --> CHMP[Coordination of the Committee for Human medicinal products]
    CHMP <--> CHMP_C[Committee for Human medicinal products]
    CHMP --> CNP[Coordination of National procedures]
    CHMP --> CMRP[Coordination for MRP/DCP procedures]
    CHMP --> CCP[Coordination for CP/PALC procedures]
    CHMP --> ID[Issuining of the documentation MA etc]
    CHMP --> QA[Quality assessment]
    CHMP --> CNA[Clinical/non-clinical documentation assessment]
    CHMP --> ASA[Assessment of safety documentation phV - RMP etc]
    CHMP --> CSM[Committee for the safety of medicinal products]
    CHMP --> EE((External experts))
    CHMP --> CM[Classification of medicines regarding their supply]
    CNP --> ID
    CMRP --> ID
    CCP --> ID
    QA --> ID
    CNA --> ID
    ASA --> ID
    CM --> ID
    ID --> CM_S[Committee for the safety of medicinal products]
    CM_S --> EE
    EE --> QA
    EE --> CNA
    EE --> ASA
    EE --> CM_S
    
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