EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Croatia – Decision Making phasing-in

EU 28: science, medicines, health – a regulatory system fit for the future
6 – 7 May 2013, Dubrovnik, Croatia

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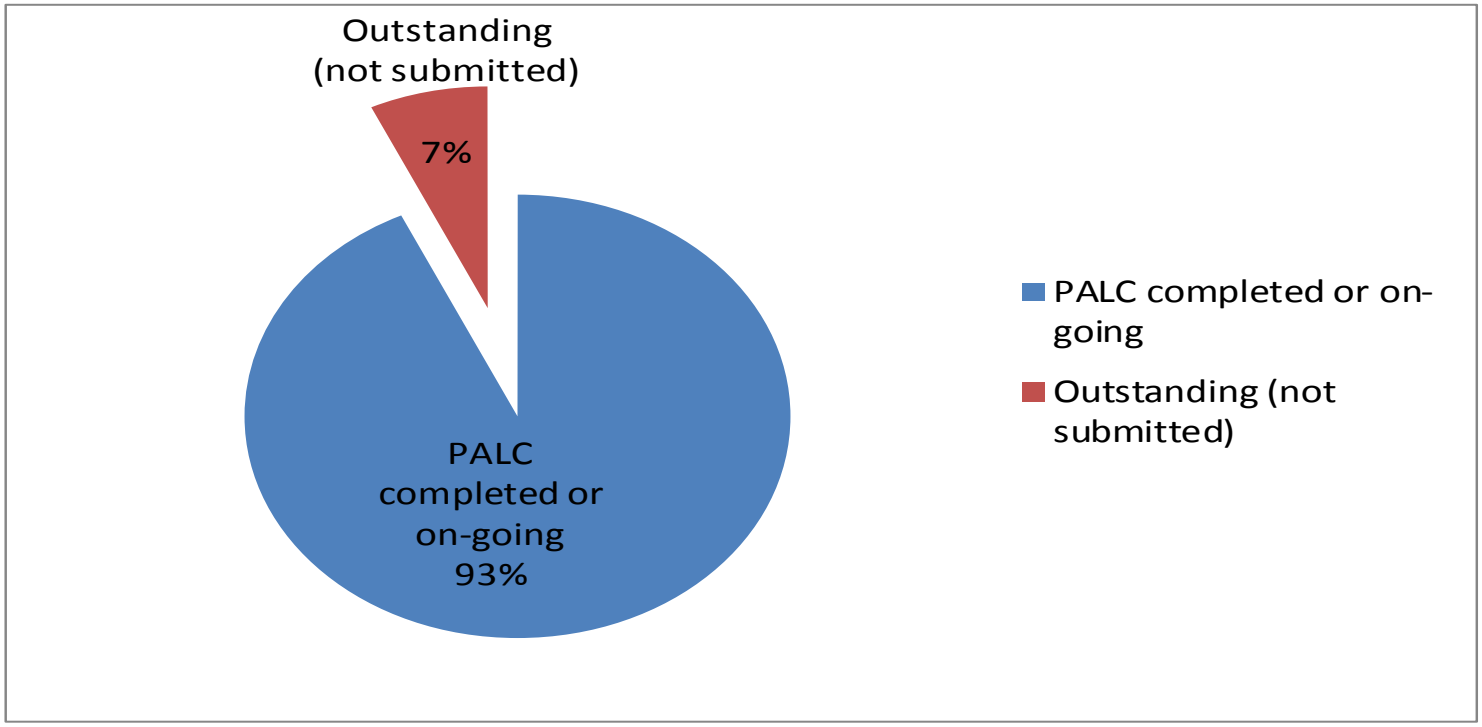
Patient Health Protection

List of HUMAN products last updated with March CHMP

Number of products	**481**	PALC completed or on-going	571	93.00%
Duplicates	**86**	Outstanding (not submitted)	43	7.00%
Generics	**133**	Currently under Croatian reviev	156	25.41%
Total:	**700**			
Total due for PALC	**614**			



Overview of PI requirements for the phasing-in

Submission of complete set of Annexes in all EU languages (including HR)	New Application (and referrals)	Line Extension	PSUR	Renewal	Type II Variation	Type IA/IB Variation	Transfer	Art. 61(3) Notification
At the time of MAA submission					(30-day TT) 2 months prior to accession date	1 month prior to accession date	2 months prior to accession date	2 months prior to accession date (only if no other reg acitvity)
After CHMP Opinion	3 months prior to accession date	3 months prior to accession date	3 months prior to accession date (when CHMP adopts an opinion on the variation of the MA)	3 months prior to accession date	(60/90-day TT) 2 months prior to accession date			

Overview of PI requirements for the phasing-in

- ✓ Update list of LRs with HR details in all PL language versions.
- ✓ Art 61(3) exceptionally allowed for CAPs with no regulatory activity → declaration needed
- ✓ Art 61(3) compulsory if no regulatory activity within 2 years after accession.
- ✓ Delays envisaged for MAs that have not undergone PALC III.

Blue box Guideline on the packaging information of medicinal products for human use authorised by the Community

The **price** of the medicinal product is **not required** on the label

The **reimbursement** conditions are **not required** on the label

The following are the specific requirements for the expression of the **legal status** in the boxed area:

- "Lijek se izdaje na recept." = Medicinal product subject to medical prescription.
- "Lijek se izdaje bez recepta." = Medicinal product not subject to medical prescription.

Identification and authenticity: The EAN code is acceptable, but not required

Expected Contribution to the Network

Members of the committees and experts responsible for evaluating medicinal products shall rely on the scientific evaluation and resources available to national marketing authorisation bodies. Each competent national authority shall monitor the scientific level and independence of the evaluation carried out and facilitate the activities of nominated committee members and experts. Member States shall refrain from giving committee members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency.