

Perspective and Challenges for Industry (including authorisation procedures)

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Content

- History and current situation EU (enlargements)
- EU licensing procedures
- Regulators & Industry: share common goals
- Lessons learned from previous EU enlargements
- Looking ahead



Year	History of European Union membership			No.
1957	Belgium Italy	France Luxembourg	West Germany Netherlands	6
1973	Denmark	Ireland	United Kingdom	9
1981	Greece			10
1986	Portugal	Spain		12
1995	Austria	Finland	Sweden	15
2004	Cyprus Hungary Malta Slovenia	Czech Republic Latvia Poland	Estonia Lithuania Slovakia	25
2007	Bulgaria	Romania		27



Candidate (& Potential) Countries

- Albania
- Bosnia & Herzegovina
- Croatia
- Kosovo
- Macedonia
- Montenegro
- Serbia
- Turkey



New member States

Any new MS must align its legislation with EU Acquis Communautaire (approx. 60.000 pages) and ensure implementation and enforcement.

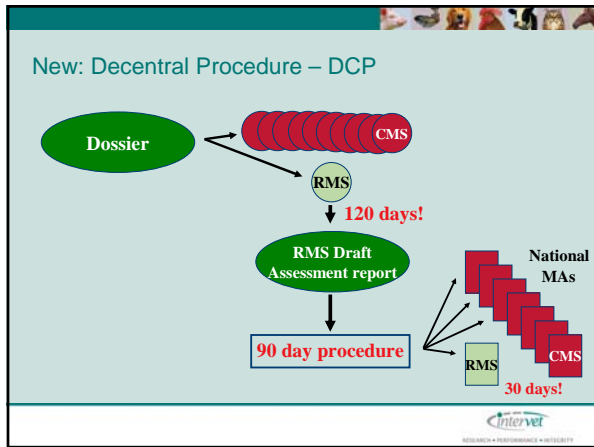
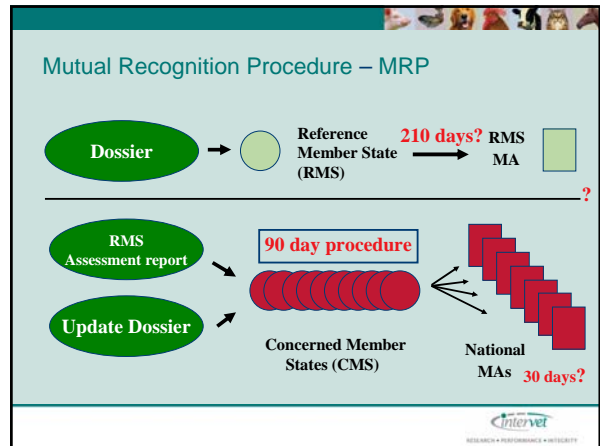
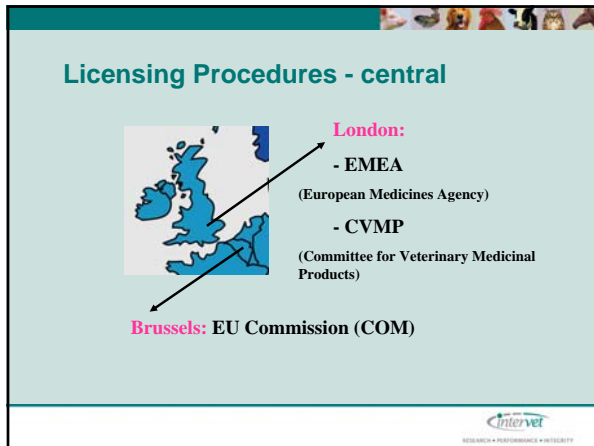
This means a lot of EU laws, regulations, directives and guidelines.



EU Registration Procedures

- National procedures
- MRP (Mutual Recognition Procedure)
- DCP (Decentral Procedure)
- Central Procedure





Regulators & Industry

Want to achieve high standards for the quality, safety and efficacy of VMP's (Directive 2001/82/EC)

- EU dossier
- GMP certification
- if VMP is manufactured outside EU then all QC tests have to be (re-)done in an EU member state

Intervet
RESEARCH • PERFORMANCE • INTEGRITY

Lessons learned from previous EU enlargements

- Review (= upgrading of national registrations to EU level) preferably be performed before entrance date

or at least started before EU entrance with a clear deadline

Intervet
RESEARCH • PERFORMANCE • INTEGRITY

Lessons learned from previous EU enlargements

- New MS should realise that review of all nationally registered VMP's will involve a lot of time/work and the authorities' organisation should be able to deal with these reviews.

Intervet
RESEARCH • PERFORMANCE • INTEGRITY

Lessons learned from previous EU enlargements

- Industry can not update all dossiers every time a new MS joins EU, therefore reference to other MA's should be possible
- Most new Member States have successfully done so



Lessons learned from previous EU enlargements

- Authorities should be practical, do not lose sight of the aim i.e. only products that comply with Directive 2001/82/EC should be allowed to stay on the market
- This can be proven/demonstrated in various ways, preferably a practical way!



Lessons learned from previous EU enlargements

- New (small) MS should not insist on country specific packaging materials
- Literal interpretation of Dir. 2001/82/EC creates medicines availability problems
- Good examples: Finland, Slovenia, Slovakia and Baltic States



Looking ahead

- Allow new MS to participate from sideline in MRP / DCP **prior** to EU entrance
- Naturally,
 - 1) not officially, as new MS is not EU member yet
 - 2) national requirements should be fulfilled



Sideline MRP/DCP

- Advantage for authorities: they can already practice MRP/DCP procedure (training of staff) and after EU entrance no need for review.
- Advantage for industry: they can train their local registration people and register new products simultaneously in EU and new MS.



National renewals

After November 2010 (for Poland 2013) pharmacovigilance reports will replace the renewal procedures within the EU (Directive 2004/28/EC)

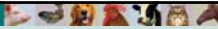
Therefore any new MS should automatically implement this rule.





Centrally registered products

- EMEA will organise a short procedure prior to the EU entrance date for translation of SPC + label+leaflet of each centrally registered product.
- All centrally registered products will automatically be registered in the new EU member state as per entrance date.



Looking ahead

- Authorities new MS please discuss EU entrance with other new MS and with industry (IFAH) for a smooth transition into EU.
- They have the experience, so valuable lessons can be learned and practical issues can be tackled before they become problems.



Thank you for your attention

