Human and veterinary pharmaceuticals regulation

Towards EU accession: Serbia's regulatory challenges, expectations and opportunities

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Republika Srbija
Ministarstvo zdravlja
Ministarstvo poljoprivrede, šumarstva i vodoprivrede,
Uprava za veterinu

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Ministry of Health
Ministry of Agriculture, Forestry and Water Management,
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Agencija za lekove i medicinska sredstva Srbije
Medicines and Medical Devices Agency of Serbia

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Acquis communautaire

# Perspectives of industry

Perspective of IFAH-Europe, representing the animal health industry

Presented by: Rick Clayton, Technical Director, IFAH-Europe
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# Acquis communautaire - perspective of IFAH-Europe

**Serbian authorities should be congratulated for implementing EU laws/guidelines**

# Acquis communautaire - perspective of IFAH-Europe

## Acquis communautaire for veterinary medicinal products (VMPs)

- The code relating to veterinary VMPs (Directive 2001/82/EC as amended) by Directive 2004/28/EC and by Directive 2009/9/EC (the 'Annex')
- EMA and centralised procedure (Regulation 726/2004)
- Variations (Regulation 1234/2008 and Directive 2009/53/EC)
- Maximum residue limits (Regulation 470/2009)
- Pharmacovigilance

# Acquis communautaire - perspective of IFAH-Europe

## Acquis communautaire for veterinary medicinal products (VMPs)

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- Maximum residue limits (Regulation 470/2009)
- Variations (Regulation 1234/2008 and Directive 2009/53/EC)
- Guidelines, 'The Rules…', GMP, GCP, GLP
- Systems and procedures (tracking systems, databases, Eudravigilance)
- EU regulatory precedents, regulatory memory, scientific advice, centrally authorised products, MRP/DCP products?, etc
- Policies – transparency; consultation; regular dialogue with stakeholders

# Acquis communautaire - perspective of IFAH-Europe

What is the experience from other accessions?

Our experience
Enthusiasm

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## Wikipedia:

"**Gold-plating** is a term relating to EU law…

Gold-plating refers to the practice of national bodies exceeding the terms of European Community directives when implementing them into national law. Business lobbyists argue that governments and their agencies often add additional measures on top of European Directives which place EU business at a competitive disadvantage.

EU governments committed themselves to a deregulation agenda at the Lisbon Summit in 2000, and as a consequence the European Commission has supported more maximum harmonisation measures in recent years, which effectively prohibit gold-plating."

# Acquis communautaire - perspective of IFAH-Europe

## How is the acquis evolving?

- EC Better Regulation initiative / Lisbon agenda
- Drive to reduce administrative burden and simplify legislation and procedures
  - E.g. New variations regulation, PSUR Synchronisation
    - Simplify, grouping, work-sharing, avoid duplication of effort, increase efficiency, reduce admin burden
- Electronic submissions; single portal for submissions
  - Requires a single EU dossier
    - In English
    - No additional national requirements (e.g. notarised certificates)

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## Acquis objectives

There is a fine balance to be achieved between

The primary objective to protect public health

by means that do not hinder industry

This is best achieved by pre-accession participation (CVMP, CMDv) and open dialogue with stakeholders

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## Profile of the animal health sector

- Market value – 3-5% of the human pharma sector
- Small fragmented market (numerous species)
- Equivalent regulatory requirements to human pharma
- Proportionately double level of administrative burden
- 90% SMEs
- Long-term investments – need predictable, science-based regulatory environment

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## Current acquis

- Complex system, but mature and workable
- Too many procedures: CP, MRP, DCP, national
- Duplication of effort vs insufficient resources
- Open to interpretation:  hinders efficiency
- No true single market for VMPs yet

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## Current acquis – data matrix codes

We have standardised on datamatrix as an electronic identification technology

The veterinary sector does not want or need individual product serialisation numbers

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## Future acquis

- Veterinary code is under review (2010 – 2014)
- Drivers:
  - Simplification
    - 1 dossier, 1 scientific assessment, 1 decision
  - Reduce admin burden
  - Stimulate innovation
  - predictable, science-based regulatory environment

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## Conclusion

- Serbia is congratulated for implementing EU law & GLs

- Avoid over-zealous interpretation

- Gain experience via pre-accession participation

- EU acquis is not just the legal text of Directives and Regulations – it is also the spirit of a confident system with trusted partners

- Remove all additional national requirements (especially notarised certificates and statements); no serialisation

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## Conclusion

- The future is s1mpl1f1cat1on