Human and veterinary pharmaceuticals regulation

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

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# Effect of a single market availability of veterinary medicines

Perspective of IFAH-Europe, representing the animal health industry

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# Directive 2004/28/EC

- "The main purpose of any regulation on the manufacture and distribution of veterinary medicinal products should be to ***safeguard animal health and welfare as well as public health***. The legislation on marketing authorizations for VMP's, and the criteria governing the granting of authorizations, are such as to ***strengthen the protection of public health***.

That aim should, however, be achieved ***by means that do not hinder the development of the pharmaceutical industry or trade*** in VMP's within the community".

# Regulators & Industry

- All need to achieve high standards for the quality, safety and efficacy of VMP's
- If VMP's are not of high standard compared with competition
  -  no advantage
  -  only damage
- Any one poor product will reflect badly on total product range (brand image)

VMP = veterinary medicinal product

# Lessons learned from previous EU enlargements

- Any review (= upgrading) of national registrations to EU level preferably to be performed before entrance date, or
  - at least started before EU entrance
  - with a clear deadline

# Lessons learned from previous EU enlargements

- New MS should realize that registrations in EU are based on (mutual) trust and experience
- For “old” nationally registered products harmonized SPC’s do not exist but these MA’s do comply with the requirements of Directive 2001/82/EC

SPC = summary of product characteristics
MA = marketing authorisation

# Lessons learned from previous EU enlargements

- Industry can not update all dossiers every time a new MS joins EU, therefore reference to other MAs must be possible

- Most new Member States have done so successfully
  - Also old MS have done it

# 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

- Compliance can be proven/demonstrated in various ways, preferably in a practical way!

- N.B. Pharmacovigilance ('in-use') data: safety record

# Lessons learned from previous EU enlargements

- Literal interpretation of Dir. 2001/82/EC creates medicines availability problems, e.g.
  - Request for country specific packaging materials
  - Lack of bi-lingual application forms
  - European MAH should be acceptable
  - API-GMP certification by QP suffices
  - Re-analysis of API/FP products should not be required within EU
  - Inclusion of EAN code in Serbian MA – huge impact on packaging

- Good examples: Finland, Slovenia, Slovakia and Baltic States

# Looking ahead

- Allow new MS to participate from sideline in MRP / DCP **prior** to EU entrance
- Of course
  1. not officially, as new MS is not EU member yet
  2. national requirements will be fulfilled (but there should not be any additional “national” requirements)

# Observe MRP / DCP on 'sideline'

- **Advantage for authorities**:
  - practice MRP/DCP procedure (training of staff)
  - after EU entrance no need for review.

- **Advantage industry:**
  - train their local registration people
  - register new product simultaneously in EU and new MS.

# National renewals

- Pharmacovigilance reports have replaced renewal procedures within the EU since November 2010 (Directive 2004/28/EC) *(N.B. Poland 2013)*
- Therefore we assume and recommend that any new MS will automatically implement this rule
  - Example : Bulgaria

# Looking ahead

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