New veterinary medicinal legislation from the view of central-european region - possibility or necessity of deeper co-operation?

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New veterinary legislation

- **Regulation (EU) 2019/6** of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC
- **Regulation (EU) 2019/4** of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC
- **Regulation (EU) 2019/5** of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency....
- New Regulation will include also DA and IA:
- Delegated acts – 8
- Implementing acts – 17
- Guidelines

IA a DA and mandates

1st package :

Following six acts to be prepared as a first priority:

- IA establishing a list of variations not requiring assessment,
- IA on good pharmacovigilance practice,
- IA on the pharmacovigilance system master file (PMSF),
- DA revising the Annex II to Regulation,
- DA on the collection of data on antimicrobial medicinal products used in animals,
- DA on criteria for the designation of antimicrobials reserved for human medicine,
- EK asked the Agency/EMA/for scientific advice – experts from MSs – voting to IA and DA at Standing Committee.

IA a DA and mandates

- 2nd package :
  - GDP, GMP for active substances,
  - Common logo for internet sales,
  - Import from 3rd countries,
  - Report from EC on environmental risk assessment (monographs system).

Key determinants of the future status in the area of VMPs 1/2

- Higher pressure to centralization of VMPs autorisation – incl. generics – CP,
- Authorisation conditions, technical requirements of VMPS authorisation,
- Future requirements in the area of impact evaluation to the environment and application of rules in the agricultural practice,
- New rules of distribution VMPs – internet sale, retail trade, parallel distribution – according new Regulation – new rules applicable to all MSs,

Key determinants of the future status in the area of VMPs 2/2

- New rules for prescription of VMPs and their use in the cross border treatments,
- New conditions in the area of protection of intellectual properties,
- New therapies and contributions of their use,
- New rules concerning antimicrobials,
- New IT databases,
- Antimicrobial resistance and many other conditions,
- Pharmacovigilance.

Contributions of new legislation

- New rules however realize also new possibilities, i.e.:

- In the area of VMPs authorisation for minor species and minor indications,
- Autorization of VMPs for exceptional circumstances whether clinical evaluations,
- Change of withrawal periods in using of VMPs under „cascade“ – higher safety of foodstuffs,
- New EU product database,
- Legalization of autogenous vaccines – cross border manufacturing and trade,
- Improvement of antimicrobials use – setting of new conditions, etc. ,
- Scientific advice – strenghtned role of NCAs in development new medicines,
- Clinical trials.

Influence of new legislation to central-european region

- Apart from the new rules for VMPs many other factors will intervene to this area:
- Development of new technologies, digitalization and artificial intelligence and their introducing to agriculture, questions „-omics“, including genetics and animals breeding,
- Availability of medicines (physical and price) – solving of market failure,
- Availlability of VMPs for minor species and minor indications,
- Longer protection of technical authorisation documentation,
- Change of legislative conditions decrease autorisation possibilities and also lower enforcement on the market of small and medium enterprices,
- As a consequence economic conditions for small and medium enterprices including substantial transformation of pharmaceutical industry and changes in properties, which are in progress in the last years,
- Questions of food safety, welfare and environment…

Co-operation of the central-european countries 1/2

Maximum usage of areas, which new rules provide us mutual regional co-operation:

- Creation of multinational teams, evaluation of VMPs,
- Focusing on education of assesors,
- Simplification od international authorization procedures in the region,
- Identification of areas uncovered by authorised VMPs (minor use),
- Setting of conditions and simplification of authorisation for these areas,
- Simplification of clinical evaluations performance for newly developed medicines,
- Availability of VMPs – solving of gaps,
- Antimicrobial resistance, resistance against antiparasitic substances,

Co-operation of the central-european countries 2/2

- Co-operation in the field of GMP – join inspections,
- Co-operation in the field of GDP – legal distribution chains,
- Mutual support in preparation of new legislation in favour of our region – forum of EC and Council,
- Mutual support in preparation of IA and DA in consideration of needs of small MSs and small pharmaceutical industry,
- In that manner support of competitiveness of small pharm. industries within EU (e.g. co-operation in the field of scientific advice),
- Support of activities in the area od science and development of pharmaceuticals or activities as Big data, Smart farming, Artificial intelligence, and interaction in these areas,
- Development of IT systems in the field of VMPs;
- Co-operation in the development of national legislation.

Conclusions

- Experiences of V4 from 1991 showed, that our co-operation is efficient in many areas:
- In the area of new vet. legislation we held together and were able to achieve also those provisions, which consider requirements of our pharma industry,
- We seek to use our long-term experiences so as next 20 years the VMPs veterinary legislation and medicated FS could be feasible in practice,
- Some of these provisions due to lack of time and differences in national legislations and long-term used practices failed,
- Common tactics in the important questions within EU,
- Central-european countries are willing to cooperate and we have also possibilities to realize it,
- Veterinary medicinal products together with human medicines, considering their importance is one of the areas, where co-operation is working and is essential,
- We have also successful co-operation with our austrian colleagues.

Thanks for attention!