

Symposium on the new European legislation on veterinary medicines

Application procedures and dossier
requirements
under the New Veterinary Regulation

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Topics to be discussed

- Marketing authorisation procedures and dossier requirements under the New Veterinary Regulation (NVR);

What is changed compared to current legislation
- Impact of these changes for industry

Marketing authorisation procedures

Centralised procedures (CP)

Decentralised procedures (DCP)

Mutual Recognition procedures (MRP)

Subsequent Recognition procedures (SRP) (formerly repeat use procedures) – official status now

National procedures (NP)

Marketing authorisation procedures - Scopes

Changed for CP only

Mandatory

- Biotech products (i.a. recombinant DNA technology)
- VMPs primarily for use as performance enhancers
- VMPs with an active substance not yet authorised as a VMP in the EU (at the date of submission of the application)
- biological VMPs which contain or consist of engineered allogeneic tissues or cells
- novel therapy VMPs

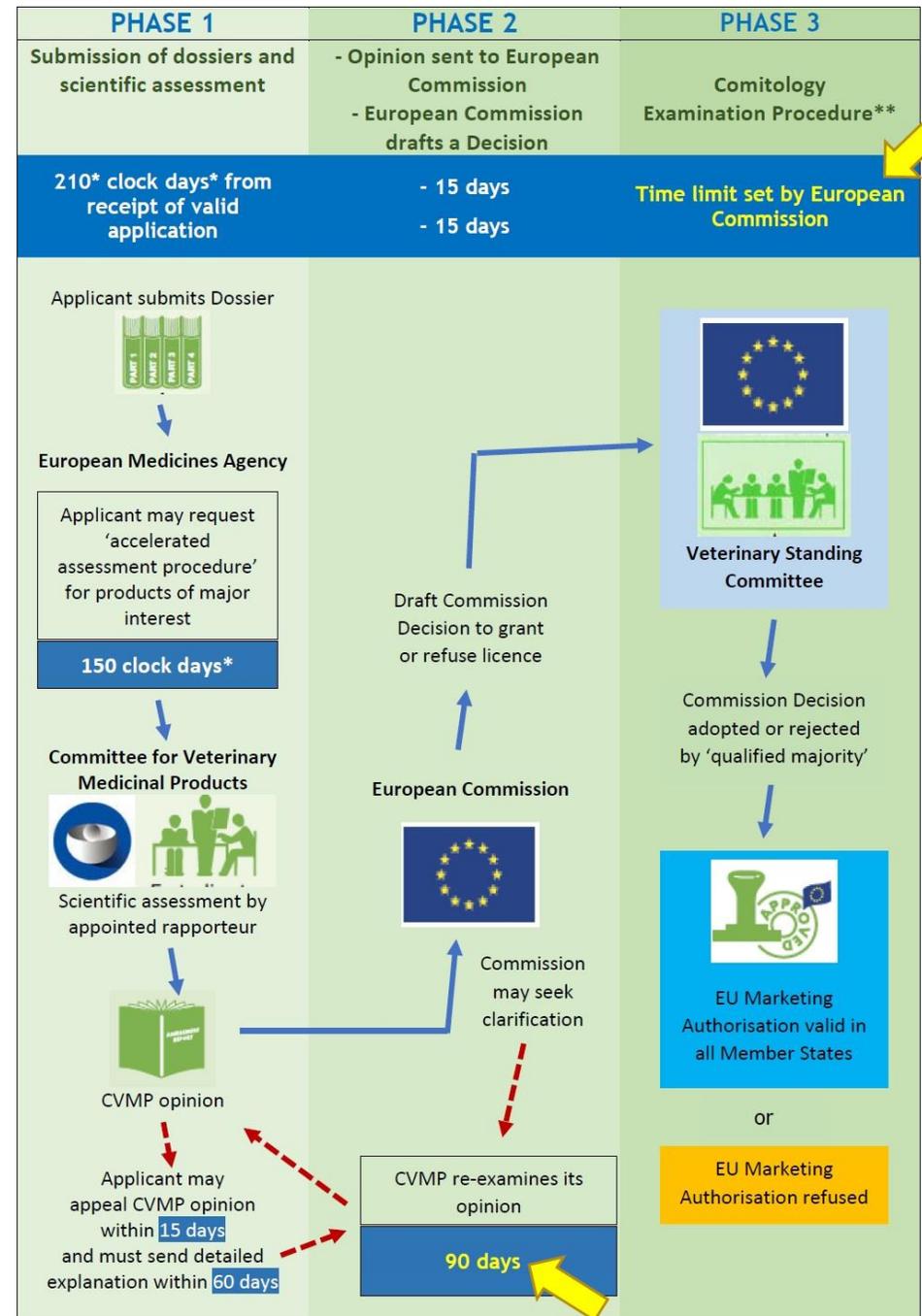
Optional

- ALL OTHER VMPS IF NO OTHER MARKETING AUTHORISATION HAS BEEN

Centralised procedure

Changes (highlighted in yellow)

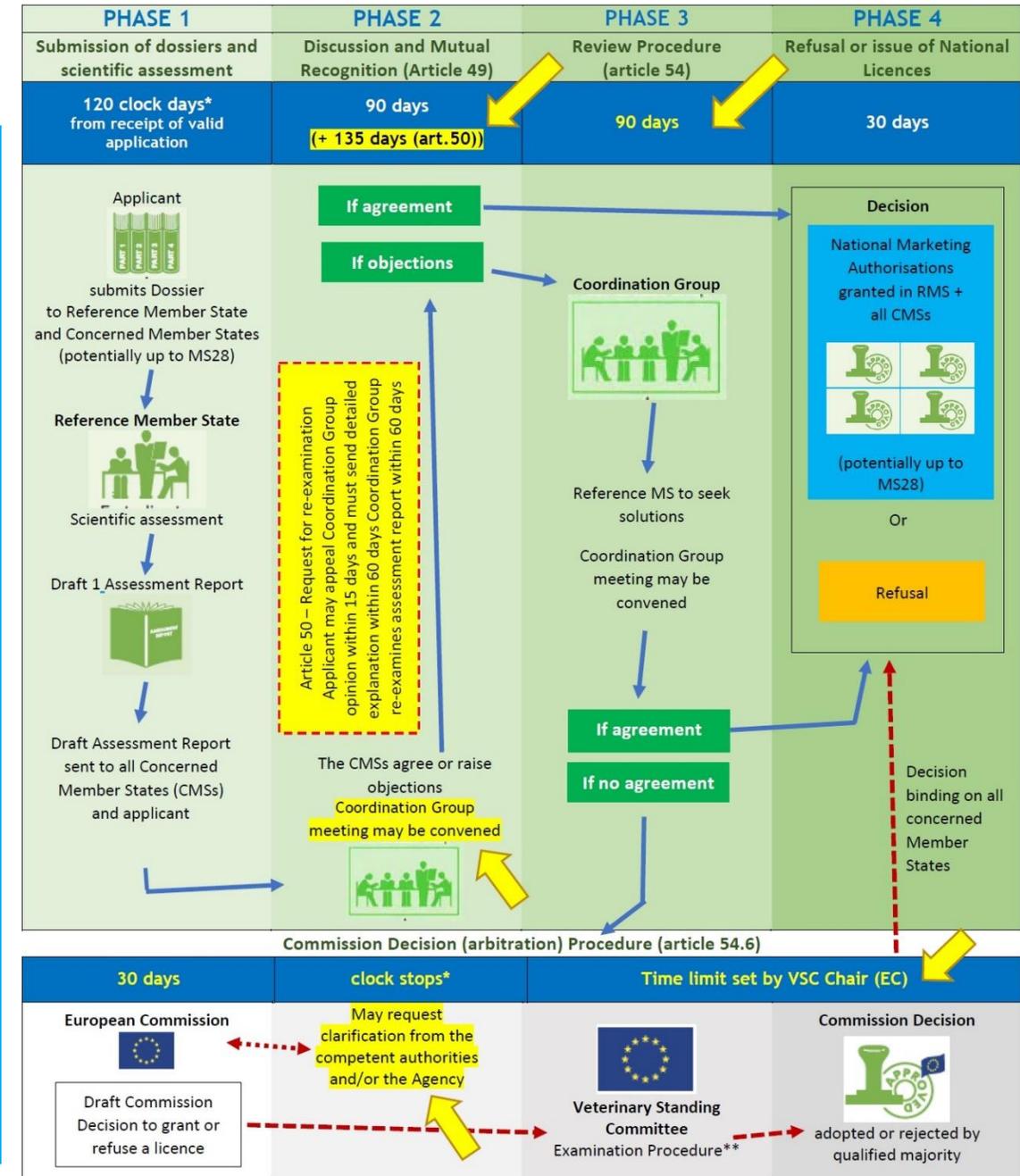
- Time for CVMP to re-examine its opinion increased from 60 to 90 days
- There is **no set time limit** for phase 3 (comitology);
- Currently the Veterinary Standing Committee has 22 days to comment, and the EC must issue the final Decision within 15 days after the end of the comitology procedure.



Decentralised

Changes (highlighted in yellow):

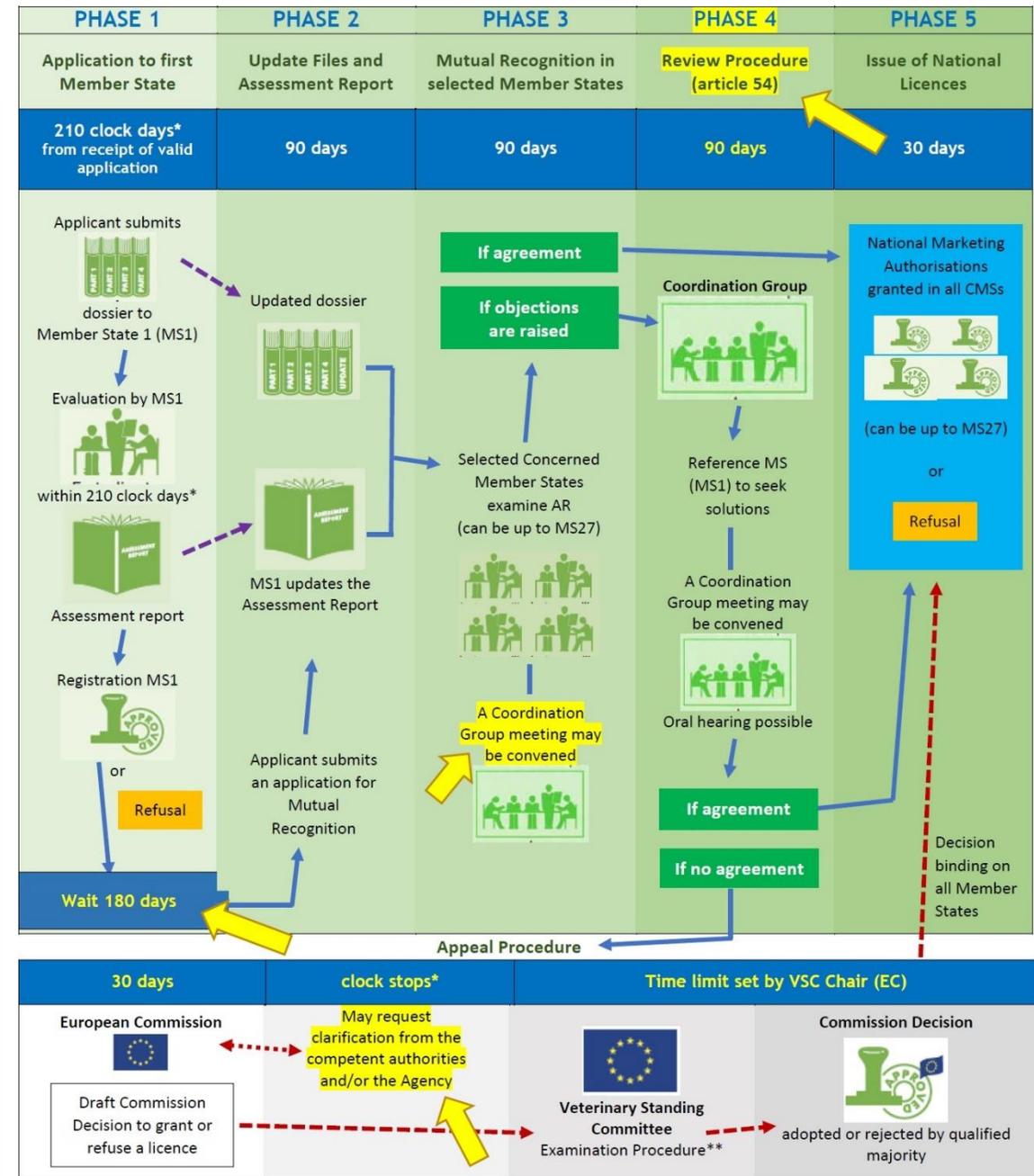
- A Coordination Group meeting may be convened during the 90-day MR period (already in practice)
- <Request for re-examination of Assessment Report by applicant: + 135 days>
- Review procedure increased from 60 to 90 days
- The CVMP referral is replaced with a CG 'Review Procedure' and if necessary a referral to the EC, which "may request clarification from the CAs and/or the Agency"



Mutual recognition

Changes (highlighted in yellow):

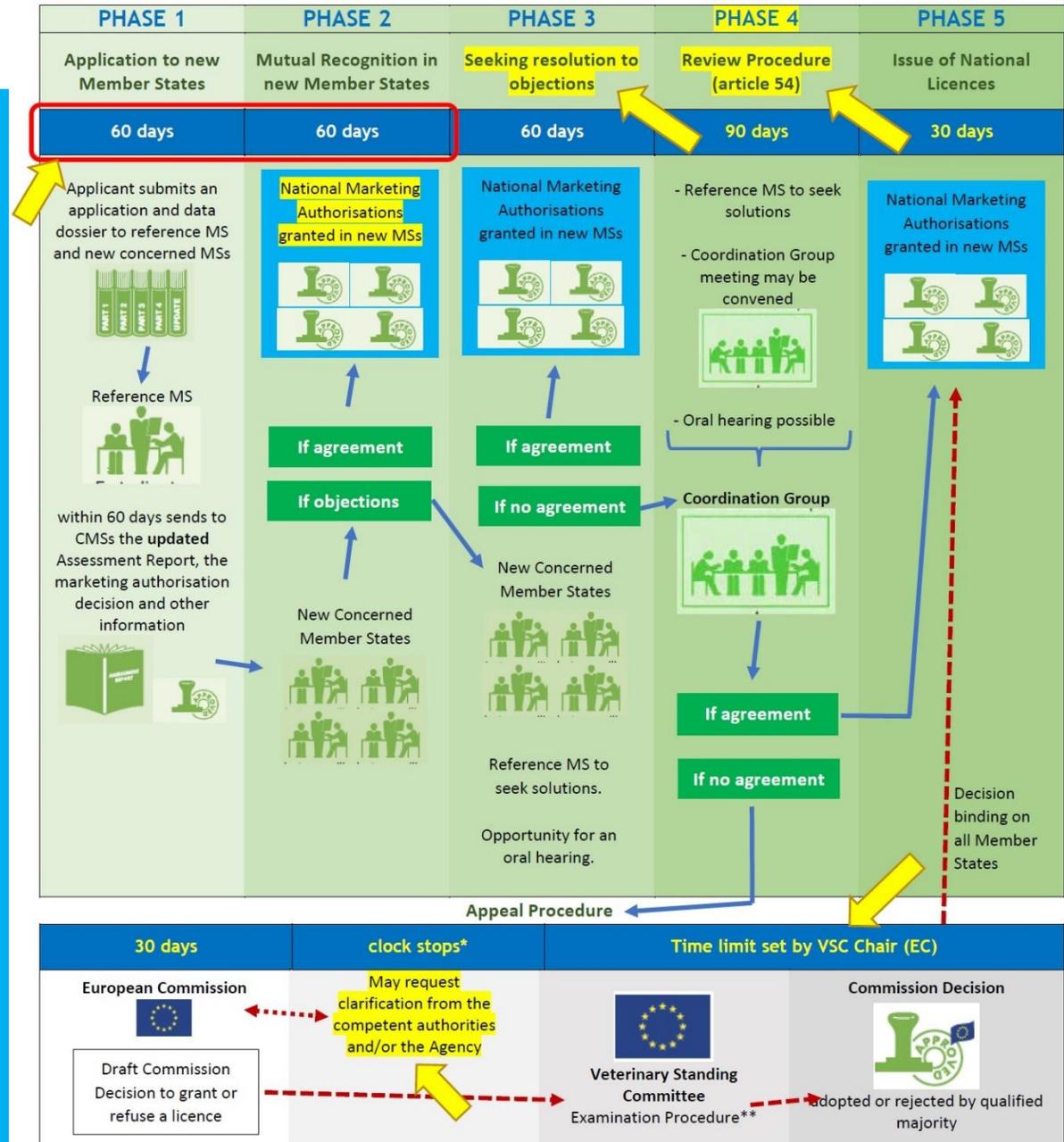
- 6 months must elapse between national MA in RMS and MRP
- A Coordination Group (CG) meeting may be convened during the 90-day MR period (already in practice)
- The CVMP referral is replaced with a CG 'Review Procedure' and if necessary a referral to the EC, which "may request clarification from the CAs and/or the Agency"
- The EC Decision Making Procedure timelines have been changed, and will



Subsequent recognition

Changes (highlighted in yellow):

- After completion of DCP or MRP.
- The fastest timeline is reduced to 120 days;
- BUT this can be extended by 60 days (= 180 days) and by a further 90 days (art. 54) +30 days if there is no agreement (= 300 days).
- In addition, there could be an Appeal Procedure, which could be longer and less predictable than the current CVMP arbitration procedure.



Specific authorisations

Limited market

What?

- Application where deviation from dossier requirements regarding **safety and efficacy** are allowed

Conditions?

- Benefit availability > risk
- Applicant must demonstrate the limited market

Characteristics

- Clearly stated on SPC 'limited market'
- 5 years validity with possibility for renewal
- When all data are provided, option for a std MAA

Procedure: NP, MRP, DCP or CP

All provisions of the Regulation are applicable (Ph. Vig, GMP, advertising,...)

Specific authorisations

Exceptional circumstances

What?

- Application where deviation from dossier requirements regarding **quality, efficacy and safety** are allowed

Obligations MAH

- Obligation for restrictions or limitations regarding safety of the VMP
- Obligation to inform on any adverse events
- Obligation to conduct the required post-authorisation studies

Characteristics

- Clearly stated on SPC 'exceptional circumstances'
- **1 year** validity with possibility for renewal
- When all data are provided, option for a std MAA

Procedure: NP, MRP, DCP or CP

All provisions of the Regulation are applicable (Ph. Vig, GMP, advertising,...)

Marketing authorisation procedures – other changes

- Electronic submission mandatory for all procedures: common format defined by EMA
- Complete translations not provided within 6 months after closure of the procedure = application considered as have been withdrawn
- No renewals – except for Limited Markets and Exceptional circumstances

Dossier requirements

- Administrative data: Annex I (application form incl. reference no. of pharmacovigilance system master file, proposed SPC + PI, expert reports)
- Summary of the pharmacovigilance system master file
- Technical documentation demonstrating the quality, safety and efficacy of the veterinary medicine: revised Annex II (delegated act)
- Biologicals other than immunologicals
- Novel therapies

EMA/CVMP Scientific recommendations on the revision of Annex II to Regulation (EU) 2019/6 on veterinary medicinal products

Dossier requirements Antimicrobials

In addition:

- Documentation on the direct or indirect risks to public or animal health or to the environment of use of the antimicrobial VMP in animals
- Information about risk mitigation measures to limit antimicrobial resistance development related to the use of the VMP

Dossier requirements Generics

Ecotox data required or not?

Competent authority or the agency **may require** the applicant to provide safety data concerning the potential **risks posed by the generic VMP to the environment** where the marketing authorisation of the **reference VMP was granted before 1 October 2005**

Criteria?

Decisions granting marketing authorisations

Positive benefit-risk balance of the VMP

Antimicrobial VMPs:

Competent authority or the agency may require the MAH to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive given the potential development of AMR

Decisions refusing marketing authorisations

MORE reasons to refuse:

- Risk to public health from AMR or APR outweighs benefits
- Antimicrobials reserved for treatment of certain infections in human (criteria to be defined in DA, designation (of groups) of antimicrobials in IA)
- Active substance meets the criteria for being PBT (persistent, bioaccumulative and toxic) or very persistent and very bioaccumulative and the VMP is for food producing animals, unless it is demonstrated that the AS is essential to prevent or control a

Impact of these changes for industry

Not only the regulation itself but also secondary legislation will determine the impact for industry

9 delegated acts

19 implementing acts (+ 6 IA procedural decision making)

Implementation is staggered, majority has deadlines

Impact of THESE changes for industry

Timelines MA procedures are longer (in general)
and less predictable

Less administrative burden

- No renewals
- No sunset clause
- E submission mandatory

Impact of these changes for industry

Centralised procedure: open for all types of VMPS if no other marketing authorisation has been granted within the union

Switch from DCP to CP to be expected.

Pros of using CP usually outweigh the pros of using DCP

- 1-1-1 principle = 1 application (EMA), 1 assessment, 1 MA (valid all over EU)
- Purely scientific assessment (no national hobbyhorses)
- Majority vote
- Less administrative burden (easier lifecycle management (initial

Impact of these changes for industry

Additional requirements for antimicrobials

Will influence the pipeline (product development)

- CIA for human health; MA refused
- If AMR outweighs the benefit; MA refused
- Post authorisation studies “may” be required; why & when?
- Specific restrictions on SPC
- [Strict rules for **the use** of antimicrobials, including additional restrictions at national level]

Impact of these changes for industry

Environmental safety

PBT and vPvB substances in VMPs for food producing animals
MA refused unless it is demonstrated that the active substance
is
essential to prevent or control a serious risk to animal health

Hazard assessment of a substance instead of
benefit/risk assessment of a product

Uncertainties; difficult to estimate the regulatory risk!

Thank you for your
attention

Questions ?

