

Regulation 2019/6 on Veterinary Medicinal Products

General framework

FAMHP

BRUSSELS

Date 19.11.2019

Observations

Proposed solutions

A multi-species and stagnant market

- Expand the market beyond 4 species

Pluri-national market costs to bring product to market

- Simplify procedures for MA in multiple-national market

Complex requirements to keep on market

- Simplify post-authorisation requirements

Lack of clarity in legislation

- Clarity on internet retailing, new diseases,

Use of antimicrobials

- Strengthening use of antimicrobials

2019/6 - Objectives

Increase the availability of veterinary medicinal products

Reduce administrative burden

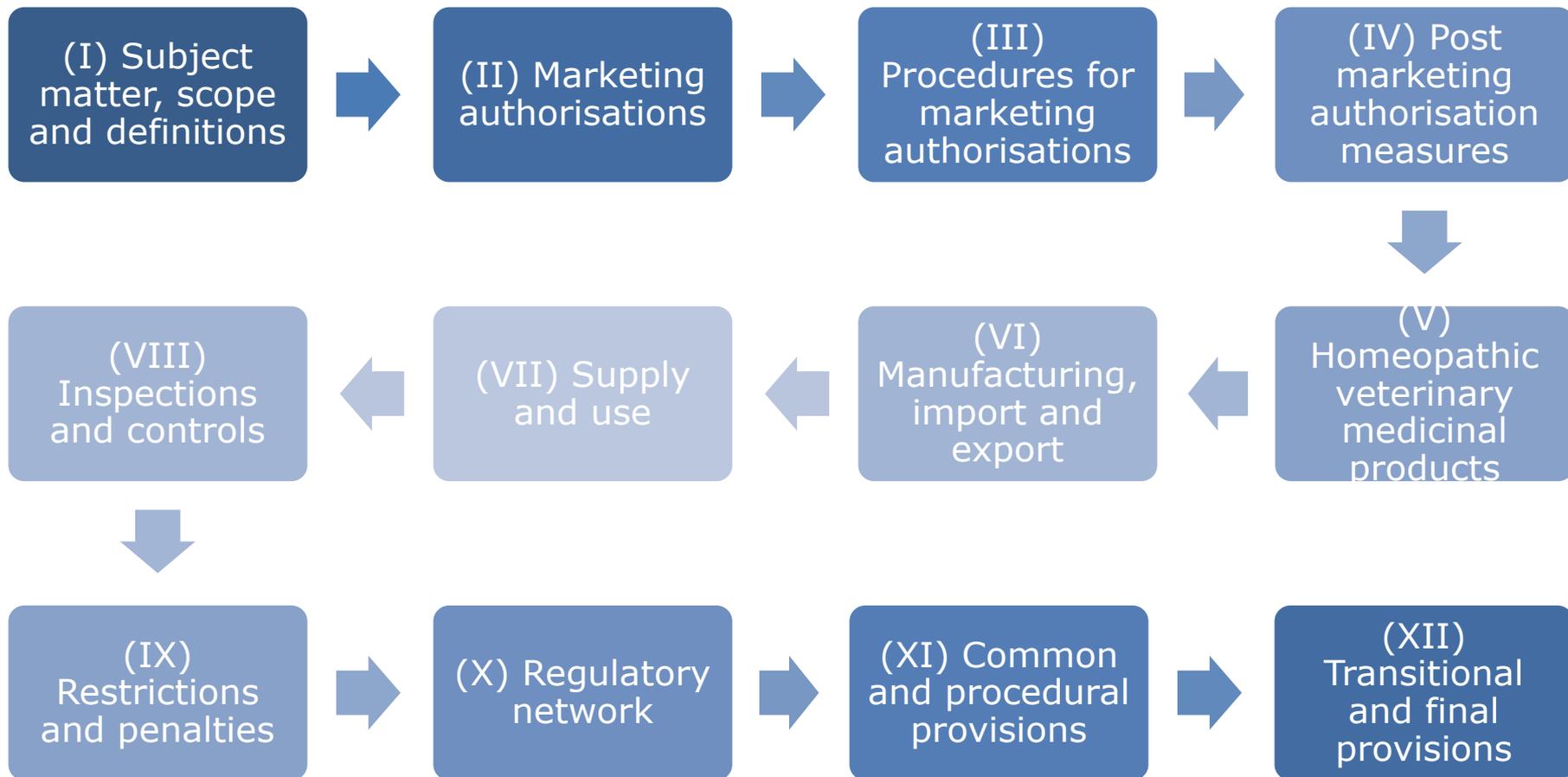
Stimulate competitiveness and innovation

Improve internal market functioning

Address public health risk of antimicrobial resistance



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Legislative framework



**Regulation
726/2004
CP – EMA
H&V**

**Variation
Regulation
1234/2008
H&V**

**VMP
Directive
2001/82**

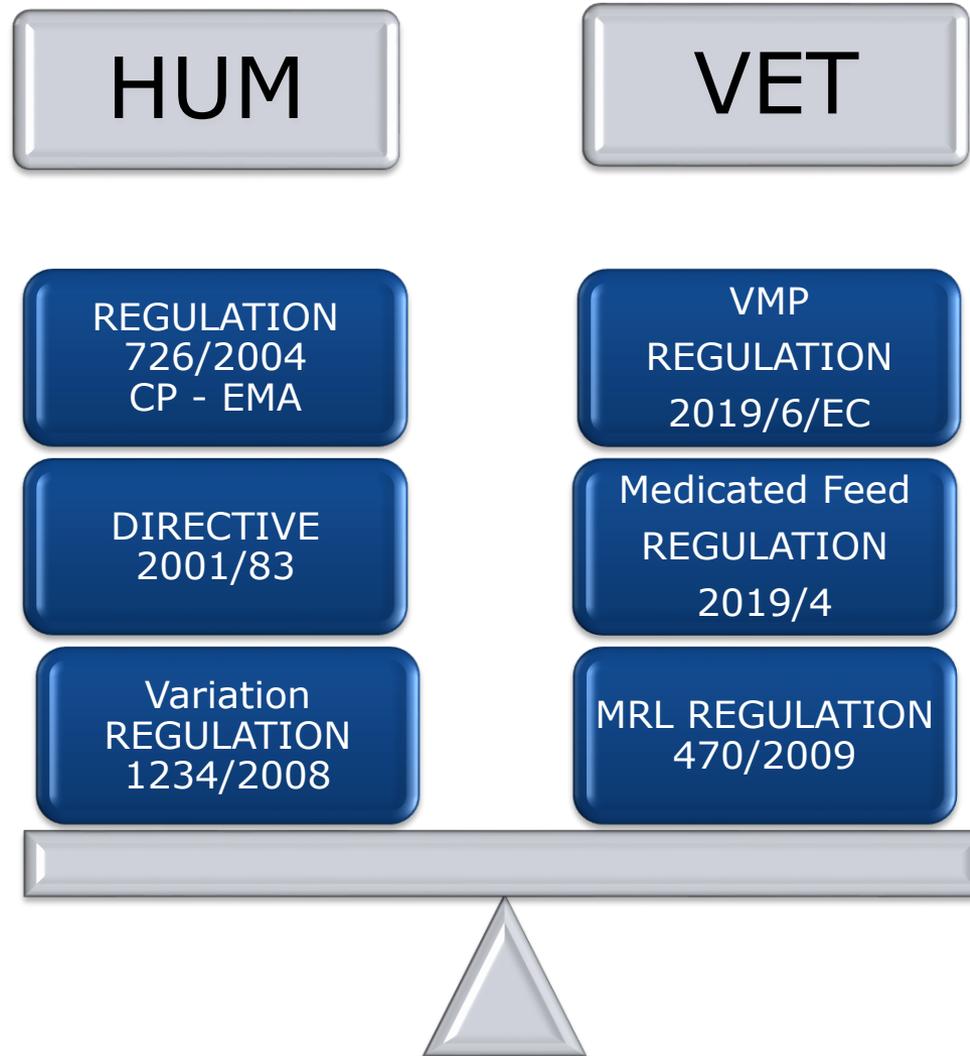
'human'
directive
(2001/83)

**MRL
Regulation
470/2009**

**Medicated
Feed
Directive
90/167**



Futur legislative framework



BE - legal framework



2019

25.03.1964 – Law regarding medicines

14.12.2006 – Royal decree on medicines for human and veterinary use

New (!) Law regarding medicines **for veterinary use**

NEW (!) Executive acts

2022



Legislative framework > 28 January 2022



Regulation
2019/6 and
annexes



Implementing
and delegating
acts



Separate Belgian
Law on veterinary
medicinal
products



New acts of
execution



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