

Verordening 2019/6 diergeneesmiddelen

Focus op antimicrobiële resistentie

AFMPS/FAGG

BRUXELLES/BRUSSEL

19.11.2019

International agenda

2015: WHO (OIE-FAO):

Global Action Plan on AMR
Coordination (Multi-sectoral)
national Action Plan (NAP)



2016: EU Council Conclusions:

NAP (by mid 2017) following a
'One Health' Network / Approach
(June 2016 - doc. 10278/16).

2017: EU COMM:

New EU One Health Action Plan against AMR
(June 2017)

*Guidelines for the prudent use of antimicrobials
in veterinary medicine (2015/C 299/04)*



Lutte AMR – Motif

New Vet REG (2019/6)

(Recitals (46))

ANTIBIOTIC RESISTANCE



Antibiotic resistance happens when bacteria change and become resistant to the antibiotics used to treat the infections they cause.

The over-use and misuse of antibiotics in livestock, aquaculture and crops is one key factor contributing to antibiotic resistance and its spread into the environment, food chain and humans. This is compromising our ability to treat infectious diseases and undermining many advances in medicine.

We must handle antibiotics with care so they remain effective for as long as possible.

WHAT THE AGRICULTURE SECTOR CAN DO



- 1 Ensure that antibiotics given to animals – including food-producing and companion animals – are **only** used to control or treat infectious diseases and under veterinary supervision
- 2 Vaccinate animals to reduce the need for antibiotics and develop **alternatives** to the use of antibiotics in plants
- 3 Promote and apply **good practices** at all steps of production and processing of foods from animal and plant sources
- 4 Adopt **sustainable systems** with improved hygiene, biosecurity and stress-free handling of animals
- 5 Implement **international standards** for the responsible use of antibiotics and guidelines, set out by OIE, FAO and WHO

www.who.int/drugresistance
www.oie.int/antimicrobial-resistance
www.fao.org/antimicrobial-resistance

#AntibioticResistance



Food and Agriculture
Organization of the
United Nations



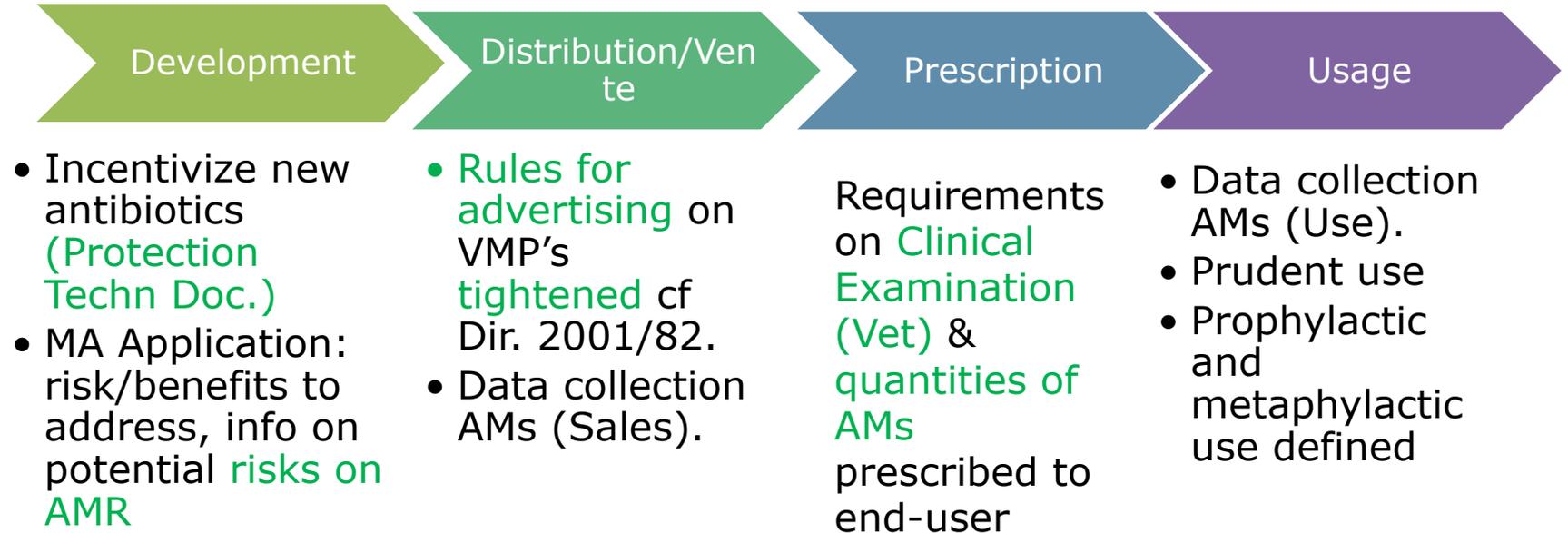
WORLD ORGANISATION
FOR ANIMAL HEALTH



World Health
Organization



Objectif AMR repris partout dans le règlement



Provisions NVR on AMR

- **Antimicrobials (AMs) vs Antibiotics (ABs): broader scope** (Art. 4)

- **AMs can be reserved for use in humans**

[Second Legislation, DA & IA]

(Art. 37, 4 & 5 ; Art. 107, 5 ~ use 'under cascade')

- **Ban/Restriction on off label use AMs**

[\[Refl. Paper 8/11/2018 EMA/CVMP/AWP/237294/2017\]](#)

→ Respect of SPC (Art. 106, 1)

→ List of AMs that cannot be used outside the terms of the marketing authorisation

[Second legislation, IA]

(Art. 107.6 ~ Art 112-114 - cascade)



Provisions NVR on AMR

AMs: Not to be used routinely nor to compensate for poor hygiene, inadequate animal husbandry or lack of care or to compensate for poor management. *Not to be used for promoting growth or increase yield.*

Rules ~ **prophylactic/metaphylactic use**

(Art. 4 ; Art 105, 1 & 2 ; Art. 107, 3 & 4)

- **Profylaxis:** Art. 107 (Use of AMs): only in exceptional cases for the administration to an individual animal or a restricted number of animals when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe.
(ABs more restricted: limited to an individual animal)
- **Metafylaxis:** Art 107 (Use of AMs): only when the risk of spread of an infection of an infectious disease in the group of animals is high and where no other appropriate alternatives are available.
Art. 105 (Vet Presc.): after diagnosis of the infectious disease by a vet.



Règlement VMPs – Prescription

Prescription of AMs (Art. 105)

Une ordonnance vétérinaire n'est délivrée qu'au terme d'un **examen clinique** ou de toute autre évaluation en bonne et due forme de l'état de santé de l'animal ou du groupe d'animaux par un vétérinaire.

- La quantité prescrite du médicament est limitée à la **quantité requise pour le traitement** ou la thérapie en question.
- toutes les mises en garde nécessaires **pour assurer la bonne utilisation**, y compris, le cas échéant, pour assurer un usage prudent des antimicrobiens (Art.105, (k))

(Une ordonnance pour des médicaments antimicrobiens est valable pendant cinq jours à compter de la date de délivrance.)



AMR : provisions NVR

- **MSs may further limit use of particular AMs** *(Art. 107 ; 7-9)*
 - BE : R.D. of 21/07/2016 : Mandatory sampling & AST before a critical important antibiotic can be used (FQ - 3&4 gen. CSP)
- **Measures to ensure effective & safe use in case of oral administration of VMPs** (other than premix & MF)
[Second legislation, DA] *(Art 106, 6)*
- **Reciprocity principle** *(Art. 118, 1 & 2)*
 - no import of animals/products treated with AMs used as growth promoters or substances cf Art 37, 5 (reserved for humans)



Titulaires d'AMM

Taxes AB

Taxes d'AB ~
quantité d'AB
par emballage

Grossistes –
Répart. & Fabriq.
Aliments Méd.

Suivi de vente
AB - BelvetSac

Ventes D'AB
(# emballages)

Détenteurs d'animaux

Sanitel-Med

Ventes =
utilisation d'AB
(# emballages)

Surveillance AMU in animals to combat AMResistance

Complex ecological link AMU & AMR (Interconnectivity A & H):

→ **Targets put on the main selective driver: AMU**

~ **Transfer of R :**

- *Direct : zoonotic disease agents*
- *Indirect : transmission of R determinants between ecosystems*

~ **Shared Use of AB's (also CIA's)**



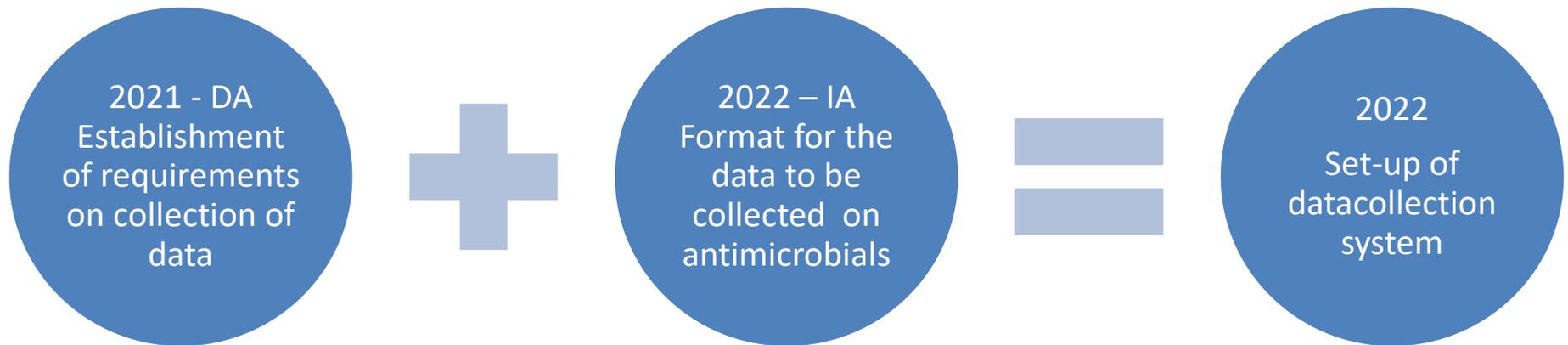
→ JIACRA reports (JIACRA III : Dec 2020)

REG 2019/5 - Recital (7)



New Objectives Data Collection

Art. 57 : « Member States shall collect relevant and comparable data on the volume of sales and the use of antimicrobial medicinal products used in animals, to enable in particular the **direct or indirect evaluation** of the use in food producing animals at farm level. »



EMA cooperates with MS to analyse data and publish an annual report on AMU (ESVAC).



Advice EMA Data collection: substances

Mandatory:

SALES DATA (BE → BelVet-Sac ~ ESVAC)

- **(Topical) Antibiotics & Antimycobact. (intram.)**

USE DATA (BE → Sanitel-Med ~ ESVAC)

- **(Topical) Antibiotics**

Voluntary (Sales, Use) :

- Antiprotozoals, Antifungals, Antimycotics, Antimycobacterials (intram.), Antivirals



Advice EMA Data collection: species

Stepwise approach: MS send collated data on the **volume of sales** and **volumes of use per animal species** and **per type of antimicrobial MP**.

2023 –
categories of
[2013/652/EU](#)

San-Med : + all bovines
+ turkeys

2026 – all food
producing
species

+ FPA (other poultry,
small Ru , fish, rabbits)
+ horses (FP & NFP)
+ other FPA (specified by MS)

2029 – all
other breded
or kept animals

+ pets (cats/dogs
– fur anim.)



Wenst u de presentaties nogmaals na te lezen ?

Souhaitez-vous consulter encore les présentations?

- www.fagg.be/nl/presentaties
www.afmps.be/fr/presentations

