

## **Global Principles and Perspectives on the Responsible Use of Medicines in Animals: [GPPRUMA]**

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The introduction of modern veterinary medicines since the 1950s has enhanced the health and welfare of animals. However, the responsible use of veterinary medicines is essential to maximise their benefit, minimise adverse effects and for some veterinary medicines to preserve their effectiveness. Responsible use of veterinary medicines is often associated with antibiotics but the general principles of responsible use can be extended to include all veterinary medicines. This document presents a set of general principles regarding the Responsible Use of Medicines in Animals that can be applied on a global basis.

Responsible Use of Medicines in Animals includes the following core elements:

- Taking appropriate measures to prevent disease in the first place e.g. sanitary conditions, husbandry,
- Using veterinary medicines which are appropriately licensed for use in animals, manufactured to the correct quality, marketed responsibly, and transported and stored correctly.
- Where a condition requires diagnosis this is done by a qualified professional, such as a veterinary surgeon.
- The most appropriate veterinary medicine is used taking account of the benefit-risk assessment.
- Correct instructions are given to the animal keeper when the veterinary medicine is supplied.
- The veterinary medicine is administered correctly according to the instructions.
- Records are kept of the use of the veterinary medicine in food-producing animals.
- Untoward effects or adverse reactions are appropriately recorded and reported.

Due to the differences in availability of specific medicines and veterinary services, it is recognised that more specific principles will be needed at the regional or country level.

As members of the animal health industry, HealthforAnimals member companies discover, develop and distribute quality products which are safe and effective. HealthforAnimals members are committed to supporting the responsible use of animal medicines through the initiation and participation in multi-stakeholder initiatives and by providing appropriate education materials on their use to both veterinary professionals and animal keepers (where allowed).

# **GPPRUMA - Global Principles and Perspectives on the Responsible Use of Medicines in Animals**

## **ADDENDUM to GPPRUMA One Page Document**

### **Additional Information:**

It is clear that there are a number of different responsibilities relating to different actors in GPPRUMA including national governments, veterinary professionals and animal keepers. These are explored further below:

It is important that the animal owner, in collaboration with all professionals, ensure appropriate housing, feeding and takes all measures to prevent or minimise disease. This is the fundamental point to any responsible use of Medicines.

#### **- An appropriately licensed veterinary medicine**

It is essential that veterinary medicines used for the treatment of animals are of appropriate safety, quality and efficacy. To assure this, governments must act at regional and/or local levels to ensure that effective regulatory bodies are in place for the licensing of veterinary medicines and the enforcement of the regulatory rules. Decisions in such regulatory systems must be science-based.

As part of the licensing process regulatory bodies define who may prescribe and/or supply the veterinary medicines. Factors taken into account include: the condition involved, whether the animal will enter the food chain, the potential risks, the extent of advice required and the infrastructure and distribution systems in place in the country. In the case of antibiotics, they should be prescribed by veterinary professionals. Other medicines, e.g. for a condition that does not require diagnosis by a qualified veterinary professional, can be made available over the counter to allow wider access of the medicine, e.g. flea treatment in pets.

Governments must act to ensure that animal and public health is protected by putting in place measures to prevent counterfeit medicines from reaching the market. In addition, and to avoid confusion and opportunities for the introduction of counterfeit medicines, unregulated importation of veterinary medicines licensed in other countries should be discouraged and systems put in place to permit this on an exceptional basis where needed.

#### **- Manufactured correctly and marketed responsibly**

Veterinary medicines manufacturers have the responsibility to manufacture veterinary medicines which meet or exceed required quality standards so that veterinarians and animal keepers receive veterinary medicines with a consistent safety and efficacy profile. Marketing and advertising are important in raising awareness of existing and new veterinary medicines for the benefit of animal patients but such marketing and promotional activities should be responsibly performed. Information on medicines should be accurate, not misleading and in accordance with local legislation or other guidelines. In some countries or regions HealthforAnimals members have cooperated to develop self-regulated guidelines which exceed the requirements of local legislation.

#### **- Stored and transported correctly**

Governments should aim to put in place appropriate guidance and control to ensure that when veterinary medicines reach the animal patient they are fit for use. The supply chain should be regulated and controlled to prevent distribution through inappropriate routes or the introduction of unlicensed or counterfeit veterinary medicines. The supply chain should be capable of maintaining specific temperature and storage conditions, as necessary.

**– An appropriately qualified or trained veterinary professional**

To support the use of products which are defined as requiring professional involvement in prescribing and/or supplying as part of the licensing process, governments must have in place regulations which define the standards which these professionals should meet. For example, the standards required to become a veterinary surgeon have to be set out as well as corresponding registration (and disciplinary) processes. For other types of veterinary professionals the requirements may be lower but still have to be in accordance to the type of veterinary medicines they deal with.

Continuous education of veterinary professionals should be ensured.

**– Undertake a direct or indirect diagnostic procedure on an animal or group of animals**

For conditions which require a diagnosis, ideally, and usually in the case of individual animals, a specific clinical examination (including relevant tests) will be made, leading to a specific diagnosis. However, allowed by country regulations and where the veterinary professional has ensured that appropriate skill sets and training are in place, indirect diagnostic procedures (ideally following a simple flow chart or standard operating procedures) may be followed: however the veterinary professional will always remain responsible for any such indirect diagnostic procedures. Another outcome which is aligned with a diagnostic-like process, is identifying the need for vaccination or preventative use of a veterinary medicine: here the veterinary professional is identifying or anticipating future disease challenges and taking action to prevent or mitigate them.

**– Perform an appropriate benefit-risk assessment**

Having made a diagnosis, the veterinary professional may choose to use a veterinary medicine for the treatment of animals (rather than surgery for example). From the list of licensed veterinary medicines available, the veterinary professional should choose an appropriate medicine considering the anticipated benefits (the efficacy or effectiveness of the medicine) and risks (the risk to the animal or the risk to the user). There are also more indirect risks that should be taken into account including risk to the environment and any potential public health risks regarding residues or development of resistance.

For many conditions in ‘major’ animal species (cattle, pigs, chickens, dogs) and for most/all conditions in ‘minor’ animal species (i.e. all others), a veterinary medicine licensed for the species/disease combination may not be available. In this situation the veterinary professional has to use their judgement as to which is the most appropriate alternative (extra-label or off-label medicine use): it is in the interests of animals, animal keepers and veterinary professionals that governments carefully consider what regulations or other advice should be provided to support necessary extra-label or off-label drug use.

Having weighed up the different alternatives the veterinary professional will make a final decision or have a range of recommendations to discuss with the animal keeper.

**– Prescribe and/or sell**

Following a discussion with the animal keeper, the veterinary professional will make a final decision and either directly, or indirectly, prescribe the veterinary medicine. Following a written prescription, the veterinary medicine will be then purchased (strictly in line with the prescription) from an appropriate outlet which is likely to be a veterinarian, pharmacist or other licensed outlet, according to local conditions, or sold by the prescriber in the countries where the veterinary professional is also authorised to deliver medicines.

**– Provide correct instructions**

It is essential that correct instructions are supplied with the veterinary medicine. Typically this would specify the animal to which they will be applied, the route of administration, the dose,

the frequency of administration and any special conditions which need to be followed such as a withholding period in a food-producing animal.

**– The veterinary medicine should be administered correctly**

Whether the veterinary medicine is administered by the veterinary professional or by the animal keeper it is essential that it is stored correctly prior to administration and then administered correctly: this means that the correct veterinary medicine is administered by the correct route and at the right dose and frequency as specified on the packaging leaflet of the product and the prescription.

**– Appropriate records are kept**

For food animals, it is obviously essential that the date of administration of a veterinary medicine and the appropriate withholding period are recorded to prevent potentially harmful residues entering the food chain. In addition, it is desirable that for all animals the identity of the animal or group of animals and the medicine are linked so that if there are found to be any safety or efficacy issues with the batch of the veterinary medicine, appropriate tracing, communication, observation and mitigation can be undertaken.

**– Any untoward effects or adverse events are recorded and reported**

Because the licensing process for a veterinary medicine is likely to involve relatively small, uniform groups of animals, a post-authorisation pharmacovigilance scheme should be implemented by governments as part of the extended licensing process.

**Additional Points:**

**Quality assurance and other surveillance schemes**

Governments should put in place appropriate quality assurance schemes such as statutory residues surveillance to assure the safety of food materials harvested from food producing animals. In addition, surveillance schemes for antiparasitic or antibiotic resistance may be appropriate to monitor any potential impact on both animal and human health and to influence future policy decisions on a national, supranational or global basis.

**HealthforAnimals member activities**

As members of the animal health industry, HealthforAnimals member companies discover, develop and distribute quality products. HealthforAnimals members are committed to supporting the responsible use of the animal medicines through the initiation and participation in multi-stakeholder initiatives and by providing appropriate education materials on their use to both veterinary professionals and animal keepers (where allowed). HealthforAnimals members have also contributed to the knowledge base supporting Responsible Use by themselves initiating and conducting surveillance schemes (e.g. antibiotic or antiparasitic resistance) where such activities have not yet been put in place. Additionally, HealthforAnimals members support antibiotic data collection programs on sales, dispensing or use based on generally accepted principles of intellectual property, privacy protection and competitive data protection