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TECHNICAL ITEM I

Report on the current scenario of critical veterinary products

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The current scenario of critical veterinary products

Summary:

Veterinary products are important in preventing and controlling animal diseases, in addition to their use in animal welfare. Furthermore, they are indispensable for the development of actions that fall in line with “One Health” principles.

Some regulatory bodies and private associations have qualified as essential or critical, veterinary products whose shortages wreak havoc on animal health, public health and even production chains.

The various criteria used by governmental authorities to qualify certain veterinary products as essential, cover aspects such as: the protection of national security, their use in official health programmes, the demand for primary care or the lack of therapeutic alternatives.

Several factors underlie the root causes of critical veterinary product shortages, and in most cases, they are economically driven. Governmental organisations have examined these causes in depth to identify the most effective prevention and mitigation actions.

Several countries have formulated and implemented proposals that involve the creation of working groups to assess shortage events; the extension or creation of communication systems between the public sector, industries, veterinary professionals and the population; drawing up lists of essential medicines; writing guides for the regulated sector, private organisations and veterinary professionals; recognising and rewarding industries that have implemented efficient quality management systems and creating and revising the relevant standards.

Yet, solutions to the shortage of critical veterinary products are simple, and the design and implementation of action programmes must involve the public sector, the private sector, the professionals and society.

Introduction:

Veterinary products are important in preventing and controlling animal diseases, in addition to their use in animal welfare (14).

When “One Health” aspects are taken into account, the importance of veterinary products broadens, as they are fundamental in mitigating zoonotic diseases, antimicrobial resistance and food insecurity (17).

In this respect, it is understood that veterinary product shortages may give rise to situations that have negative repercussions on animal health, public health and even food production chains.

Furthermore, product shortages may stimulate the counterfeit products and substandard quality market.

A series of variables may result in the lack of availability of specific products being even more harmful than the shortage of others. We can cite examples of essential products for maintaining national security, strategic products for the development of official health programmes, and palliative care products.

Many countries that are aware of the need to prevent and mitigate the shortage of these products are rolling out specifically devised programmes and action plans. Some of these countries call these products “critical or essential veterinary products”. We will use the term “critical veterinary products“ for the purposes of this report.

The primary aims of this report are to present:

- The classification criteria for critical veterinary products;
- The main causes and impacts relating to shortages of these products;
- Initiatives adopted by Veterinary Authorities to prevent and contain critical veterinary product shortages;
- Veterinary authority proposals for the design and implementation of a programme to prevent and mitigate critical veterinary product shortages.

Accordingly, the text is divided into the following chapters:

1. Definition and classification of critical veterinary products;
2. Impacts and causes of critical veterinary product stockouts;
3. Actions across the world to prevent and control critical veterinary product shortages;
4. References for listing critical products;
5. Proposed actions for preventing and mitigating critical veterinary product shortages;
6. Conclusion.

1. Definition and classification of critical veterinary products:

The World Health Organisation (WHO) defines essential medicines in the area of human health as those that satisfy the priority health care needs of a population (18).

They are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and safety and comparative cost-effectiveness (18).

Yet, there is no single definition for critical veterinary products (2;11;19;20).

The regulatory agencies and private associations of various countries make allowance for different variables when considering a veterinary product as critical.

The European Medicines Agency (EMA) has no harmonised approach for classifying critical products, as the importance of a specific product may vary between Member States on the basis of factors such as the availability of alternative products (including the capacity to meet demand), the seriousness of the disease or the requirements of a national diseases control programme (for example, vaccination campaigns) (2).

The EMA considers that two important aspects should be examined when considering a veterinary product to be critical: the therapeutic use and the existence of alternatives (2).

As for therapeutic use, a veterinary product may be classified as critical when its unavailability may cause negative impacts on disease control programmes or threaten the sustainability of regional or national livestock production (2).

As for the existence of alternatives, when a product is classified as critical by the therapeutic use criterion, this classification will not be retained when adequate available alternatives exist, namely: (2)

- The existence of other manufacturers with adequate technical and manufacturing capacity, as well as appropriate regulatory deadlines for its substitution.
- The existence of different dosages or formulations of the same product, with the exception of the need for adequate formulations for its use in special populations;
- The possibility of using an alternative dosage (lower dose or treatment discontinuation) or limiting its use to high-risk animals;
- The existence of generic products;
- The existence of other products of the same or other therapeutic classes.

In the United States of America (USA), the private sector asked the Food and Drug Administration (FDA) to draw up a list of critical drugs and examine the possibility of increasing the financial incentives or notification requirements for these products. The FDA decided to draw up a series of criteria to enable manufactures to easily ascertain whether a medicine is considered to be at risk of stockout. This approach was adopted as a static list of drugs with no scope for changing factors such as the approval of additional products, changes in manufacturing conditions and installations, changes to medical practices and other variables that may vary over time (11).

As for products whose shortage could affect national security, the FDA considered critical products to be those used in response to emergencies, chemical, biological and nuclear threats and emerging infectious diseases (11).

When considering product-related risk factors, the FDA proposed to use the criterion that supports the mandatory obligation to notify stockout events. In this case, critical products whose shortage must be notified would be those that keep alive patients suffering from serious diseases and those intended for the prevention or treatment of debilitating diseases or conditions, including products used in emergency medical care and during surgery (11).

In Brazil, the Ministry of Agriculture and Livestock (Ministerio de Agricultura e Pecuária), the body responsible for regulating veterinary products, conducted a Regulatory Impact Analysis (RIA). The RIA consists of a procedure prior to issuing normative acts that assesses their probable effects on the bodies to be regulated by its guidelines. Strategic products and inputs were identified during this process.

Thus, we can conclude that veterinary products classified as critical are those whose restriction or shortage makes control, eradication and prevention of diseases that affect animal health, in addition to animal health emergency responses, difficult or unviable.

Some non-governmental organisations have also defined criteria for classifying certain veterinary products as critical.

The World Veterinary Association (WVA) and the World Small Animal Veterinary Association (WSAVA) have defined as a criterion for classifying veterinary products as critical that the latter must meet the primary health care and welfare needs of food producing animals and dogs and cats, respectively (19;20).

For the inclusion of medicines in the list, they took into account the prevalence of the disease and its relevance for public health; the proofs of effectiveness and safety; comparative cost-benefits as well as the low probability that these medicines might be substituted. Hence, the shortage of these products would put public health or the health and welfare of the animals at risk. Moreover, they consider that these medicines should enable veterinarians to provide adequate preventive care and treatment for the most common and major diseases of the animals targeted by the medicines, while maintaining high levels of animal welfare (19;20).

2. Impact and causes of critical veterinary product stockouts:

According to the EMA guidelines, investigating the factors that cause medicine shortages is the vital first step towards identifying measures that could prevent these shortages. Moreover, the supply chain and different functions played by the various parties involved need to be better understood (3).

The EMA, along with the Heads of Medicines Agencies (HMA), created a task force to develop and coordinate the actions needed to prevent, identify, manage and communicate on the stockouts of medicines for human use and veterinary products. This task force has identified non-conformities with regard to compliance with Best Manufacturing Practices (BMP), Best Clinical Practices (BCP) Best Distribution Practices, quality defects, sales disruptions and increased demand as the main causes of stockouts of medicines for human use. The task force is currently assessing whether these same causes apply to veterinary products (10).

Brazil's Ministry of Agriculture and Livestock held discussions with government and private sector representatives to identify the basic causes of the lack of availability of critical veterinary products. They identified the main causes as:

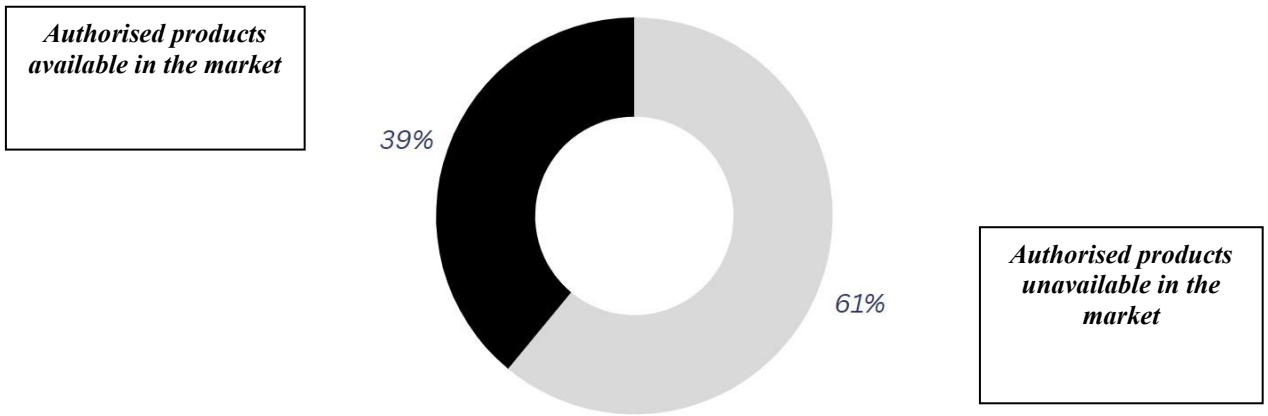
1. Batches rejected by official controls due to quality issues;
2. Delays in the official release of veterinary product batches by the official governmental control;
3. Insufficient production of veterinary products, raw materials and other veterinary inputs to satisfy actual demand;
4. Disincentives in the private sector to manufacture veterinary products, raw materials and other inputs.

The FDA, through a task force led by professionals who work in different units of the agency, tried to understand the root causes for shortages of drugs for human use, that may also apply to veterinary products. The task force conclusions pointed to economic factors as the main drivers of drug shortages (11).
After assessing the FDA's own data and bibliography and listening to various production chain players, the task force identified the three main root causes (11):

1. Lack of incentives to manufacture less profitable drugs. If a manufacturer suspects that a product will not be profitable or that its profitability will be uncertain, it may decide not to launch the product, even if the product in question already has a product or marketing registration approved by the Regulatory Body (figure 1).

   If the company is already marketing the product and its profitability is eroded, its management could halt production or make minimal investments in manufacturing, which could lead to supply disruptions. These disruptions may result in shortages. The cycle of minimal investments in manufacturing, manufacturing stoppages and shortages will continue without sustained profitability (11).

Figure 1 – All requests for generic drugs for humans approved by the FDA in 2019



Source: (11)

Image caption: In June 2019, for all generic drugs approved for humans by the FDA, 39% were available for sale, and 61% were unavailable for sale.

2. Lack of recognition and reward for manufacturers who have a mature quality management system. As a result, manufacturers tend to keep costs down, minimising investments in manufacturing quality, which gradually leads to quality issues, causing disruptions and shortages.
3. Logistical and regulatory challenges hamper the market's recovery after a disruption. Today, the drug supply chain is more complex and fragmented, as companies have located their production overseas and increased the use of contract manufacturers (figures 2 & 3). When companies want to increase output, in response to product shortages for example, they can modify their manufacturing installations or buy a new plant. In both cases, they must obtain new licences from various governmental bodies (11).

Figure 2 – Location of the manufacturers of the main pharmaceutical active ingredients for the US market. 2018

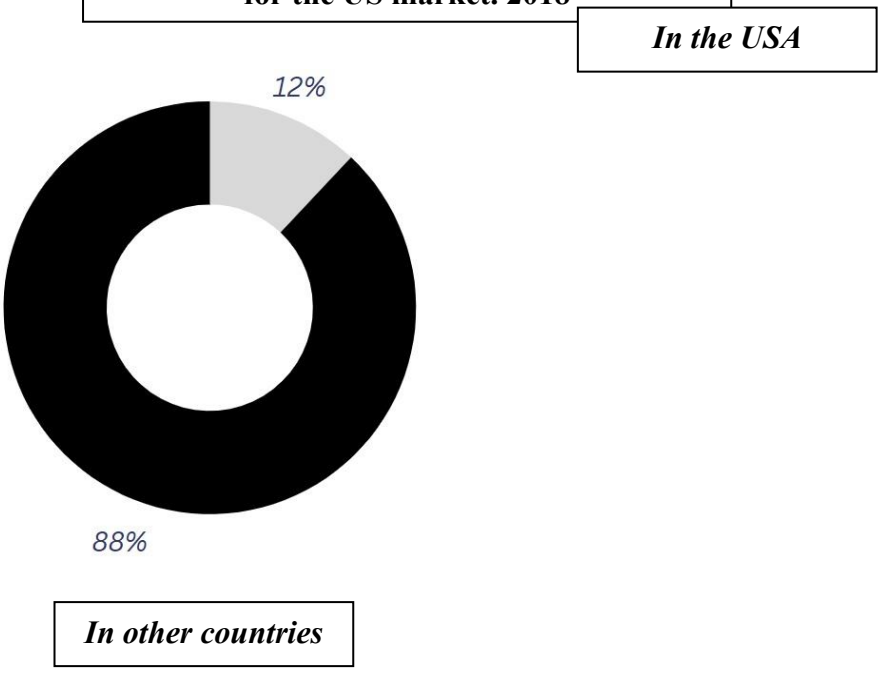
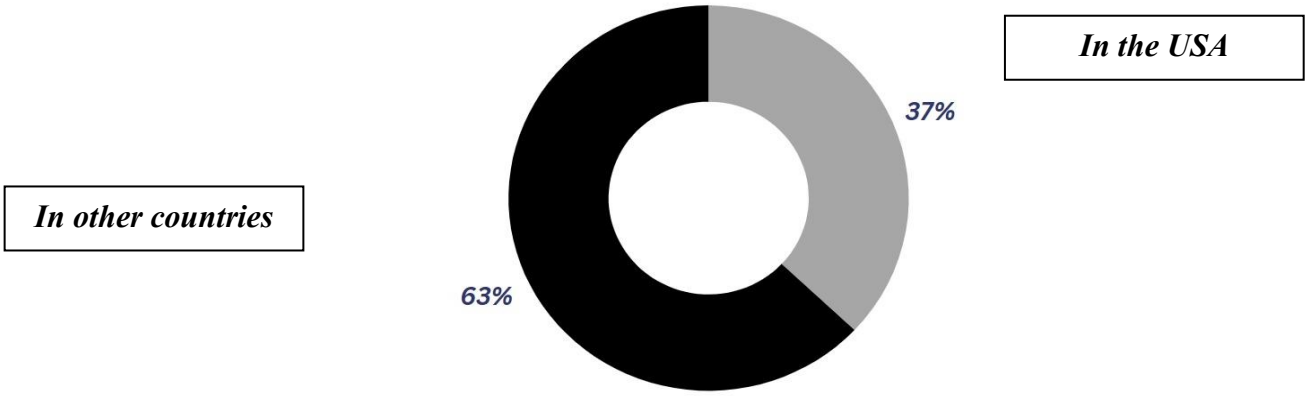


Figure 3 – Location of the manufacturers of finished pharmaceutical forms for the US market. 2018



Source figures 2 & 3: (11)

Figures 2 & 3: In 2018, the majority of manufacturers of the main pharmaceutical active ingredients and finished pharmaceutical forms for the US market were based outside of the country.

3. Actions across the world to prevent and control critical veterinary product shortages:

3.1 United States of America:

In June 2018, The United States Congress asked the FDA for help to assess the national drug shortage crisis. In response, the Agency created a working group with members from its various units to examine the problem, draft a report on the causes of these product shortages and make recommendations to find long-lasting solutions (11).

The factors behind the stockouts were assessed from 2013 to 2017, and their root causes were identified, as explained in chapter 2 of this report (11).

It is vital to focus on the root causes, although the task force concluded that a complex set of factors contributes to the emergence and stabilisation of critical veterinary product stockouts. They presented three recommendations: (11)

1. Understand the impact of shortages and the practices that contribute to their occurrence. The task force understood that too few public and private efforts are made to compile, analyse and understand the information to characterise shortages, quantify their effects and observe the practices that contribute to their emergence.
2. Create a classification system to motivate manufacturers to invest in more mature quality management systems. By doing so, the companies would broaden their approach beyond BMP to institutionalise processes and continuous efforts to improve their systems. This characterises the achievement of quality management system maturity. The classification system will also serve to inform purchasers and consumers about the company's commitment along with the maturity of the quality management systems.
3. Promote sustainable contracting practices. When contracting to veterinary product manufacturers, contractors must guarantee that the establishments receive sufficient remuneration to make a return on the investments made to launch or maintain a product in the market. Additionally, contractors must recognise and reward manufacturers that have mature quality management systems. This could be achieved by paying higher prices for those products that are manufactured in top-

tier installations, by demanding qualification of the mature quality management system as a condition for contracting or guaranteeing a purchase volume of products manufactured in centres that have been awarded a specific mature quality management system qualification.

The FDA itself also considered that, in addition to the above recommendations, there should be proposals for planned governmental regulations and initiatives focussed on preventing interruptions to product supplies and mitigating the effects when shortages occur: (11)

1. Legislation that demands that information about manufacturing disruptions be notified and that sanctions be applied to manufacturers who flout this guideline;
2. Guides for assessing companies on how to notify the FDA of disruptions and other specific information to help prevent or mitigate stockouts;
3. Legislation that insists on a risk management plan from critical product licence holders, so that periodic assessments can be conducted to identify vulnerabilities in the supply chain and mitigate their relevant risks;
4. Risk management guide to direct industries on the production, application and maintenance of a risk management plan, with the aim of preventing and mitigating product shortages;
5. Legislation that enables the Agency to demand the presentation of studies to extend the useful life of products. These studies must be scientifically based;
6. Guidelines describing methods to improve understanding of product and process development to establish efficient quality systems. The incentives for adopting these guidelines include the prospect of lighter statutory supervision of some post-approval manufacturing changes. If manufacturers apply these guidelines, the regulatory environment would be less demanding and ease process and equipment modernisation efforts.

3.2 European Union:

The EMA, together with the HMAs, set up a working group to address the issues of the availability of medicines authorised for human and veterinary use (HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use – AAM-TF) (9).

The AAM-TF priorities are to: (9)

1. Develop strategies to improve the prevention and management of medicine stockouts caused by supply chain disruptions (for example, by drawing up guidelines so that companies notify product shortfalls);
2. Encourage the application of best practices to prevent stockouts;
3. Increase information exchanges and best practices between the regulatory authorities to coordinate more efficient actions in the European Union;
4. Promote joint work with the private sector and increase communication about shortage problems to the population.

The AAM-TF comprises a steering committee and two focus groups: the first focusses on the availability of medicines and supply chain disruptions, and the second on communications (9).

The working group has conducted a study on the shortage of medicines for human use and, by 2025, will assess whether the root causes, as well as the prevention and mitigation measures, could be the same for cases of veterinary product shortages (10).

Among the actions applied or ongoing by the EMA to prevent or control the shortage of medicines for human use in addition to setting up the working group, we can cite: (10)

1. The publication of information on the shortage of medicines for human use. In the case of veterinary products, the Agency provides every European Union country with national registers of shortages of these products with links to its website; (8)

2. Coordination of the European Union's responses to the medicine supply issues caused by public health crises or emergencies. The EMA also plays an important role in monitoring the shortage of medicines that cannot be resolved by measures adopted at national level and that can lead to a crisis situation; (1)
3. Provide guides to product licence holders, manufacturers, wholesalers and distributors to prevent stockouts and reduce the impact of those that occur; (5)
4. Make available, prior to 2025, a preliminary version of an information-gathering platform on the supply and demand of medicines to prevent, detect and manage stockouts of medicines for human use in the European Union (EU) and the European Economic Area (EEA); (4)
5. Production of guidelines on the measures that patients and health professionals can adopt to help prevent and manage shortages of medicines for human use in the EU; (6)
6. Provide guides to help the competent national authorities of the EU to communicate efficiently with the public on issues relating to the availability of medicines for human and veterinary use. Resources are also provided to help them manage stockouts caused by manufacturing or quality problems (7).

3.3 Brazil:

As previously mentioned, the Ministry of Agriculture and Livestock embarked on its drive to prevent and manage critical product shortages, by holding discussions with the veterinary products industry and by conducting a Regulatory Impact Analysis - RIA.

It identified the roots and underlying causes of product shortages.

It concluded by identifying the need to draw up a Strategic Plan for Inputs for Animal Health, whose general aim is to guarantee the availability of strategic inputs, conduct official animal health programmes and respond to animal health emergencies.

The Plan's specific goals would be to:

1. Provide a solution to supervise strategic input manufacturing and distribution;
2. Have action plans ready in the event of risk detection or facing strategic input stockouts;
3. Propose a policy to promote or adjust the statutory requirements for the manufacture/import/marketing of strategic inputs;
4. Have ready mechanisms to maintain "strategic" stocks and make emergency purchases of strategic inputs.

Building solutions to achieve the proposed targets for each strategic input listed may possibly require data such as:

1. Specification, commercial name and cost of the inputs;
2. Study of the existing regulatory mechanisms to guarantee input quality and determine which steps fall under the responsibility of the Ministry (register, laboratory analysis);
3. Research into demand to deal with health programmes regularly;
4. Forecast demand for the initial response to an animal health emergency (considering different scenarios/diseases/species);
5. National and international manufacturers and distributors;
6. Potential new manufacturers or distributors;
7. Definition of the minimum mandatory stocks (to cater for health programmes and the initial response to an animal health emergency);
8. Designate the strategic stocks storage and logistical distribution sites;
9. Available stocks and stock supervision method;
10. Manufacturing capacity and time frames for meeting exceptional demands;

11. Action plan to deal with stockout risk detection;
12. Action plan to deal with an input stockout;
13. Regular purchase mechanisms for inputs (maintaining strategic stocks);
14. Action plan for emergency input purchasing;
15. Operational capacity of the laboratories and their accredited network.

4. References for drawing up lists of critical products:

Governmental and non-governmental organisations have drawn up lists of critical medicines for countries to use as the basis for drawing up their own lists.

Allowance must be built in for the epidemiological specifics of each country including those of regions within a single country.

The list of critical medicines for dogs and cats and the list of critical medicines for food producing animals are organised as a core list and a complementary list (19;20).

The core list includes primary care medicines, i.e., the most effective, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public/animal health relevance and potential for safe and cost-effective treatment (19;20).

The complementary list presents critical medicines for priority diseases, that require specialised diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training. Medicines may also be listed as complementary on the basis of consistent higher costs or less attractive cost-effectiveness in a variety of settings and wide availability in the profession (19;20).

The Brazilian regulatory authority has drawn up a list of critical products for the Strategic Plan of Inputs for Animal Health. The proposal to regulate this Plan, which has yet to be published, anticipates the publication and update of the list of products for veterinary use and inputs used in their manufacture or import that will be included in the Programme, on the Ministry of Agriculture and Livestock website. The list comprises vaccines, antigens, inputs and diagnostic kits.

Antimicrobial agents are essential medicines for human and animal health and welfare. Antimicrobial resistance is a worldwide public and animal health problem in which human and non-human use of antimicrobials play an equal part (13).

In this respect, the World Organisation of Animal Health (WOAH) has drawn up a list of critically important antimicrobial agents for veterinary medicine (13).

The list includes antimicrobials authorised for use in food producing animals. It omits antimicrobial classes or subclasses used exclusively in human medicine and antimicrobials used exclusively as growth promotors, as it concentrates solely on important antimicrobials used in veterinary medicine (13).

The list was revised in 2024, to make allowance for the new categorisation criteria of the World Health Organisation's (WHO) list of Medically Important Antimicrobials for human medicine (MIA). In this respect, phosphonic acid derivatives (such as phosphomicin) have been reclassified as highest priority critically important antimicrobials (HPCIA) (13).

Health authorities should refer to this list of critically important antimicrobial agents in veterinary medicine compiled by the WOAH, when drawing up their national critical product lists, given the importance of antimicrobials for animal and public health.

Moreover, the WOAH has drawn up lists of infectious diseases that affect food producing animals. The use of new or improved vaccines can significantly reduce the need to resort to antimicrobials, which mitigates antimicrobial resistance. Veterinary authorities should also take these lists into consideration when drawing up their national critical products lists (12;13).

Incidentally, veterinary authorities should encourage the availability of authorised products on the market and in collaboration with the veterinary pharmaceutical industry follow-up any potential drug shortages, according

to the Terrestrial Animal Health Code, Chapter 6.10 on the “Responsible and prudent use of antimicrobial agents in veterinary medicine” (16).

Furthermore, the pharmaceutical industry should endeavour to ensure that authorised products are available and cooperate with the Competent Authority to forecast and avoid any drug shortages (16).

5. Proposed actions for preventing and mitigating critical veterinary product shortages:

If decisive results are to be achieved, critical veterinary product shortage prevention and mitigation measures must be structured in an action programme.

Governmental authorities and everyone in the veterinary product supply chain, the health professionals and society must take part in the development and application of the programme.

Now, consideration could be given to setting up public-private partnerships (PPPs), involving a joint approach where the public and private sectors agree on responsibilities and share resources and risks to achieve common aims that will generate sustainable benefits. Incidentally, the WOAH, along with the Centre for International Cooperation in Agricultural Research for Development (CIRAD), supported by the Melinda and Bill Gates Foundation, have produced a manual on the topic of PPPs (15).

It is suggested, as in the case of Brazil, that broad discussions should be held between the regulatory authorities and all the institutions that may be involved or affected by the decisions adopted, prior to developing and publishing normative acts.

The creation of a working group is crucial for the mapping and assessment of all aspects relating to critical product shortages, including shortage characterisation, the definition of root causes and their impacts. Once completed, they will be in a position to propose effective measures to prevent and mitigate the unavailability of these products.

It is important to establish communication mechanisms with information exchanges between the regulatory authorities and private sector companies such as manufacturers, importers, distributors and marketers, so that a critical veterinary product stockout risk assessment system can be introduced. Information, such as output, warehoused and marketed quantities must be compiled, stored and assessed.

The communication mechanisms should include the possibility of publicly notifying events of shortages so that measures can be taken before the problem is exacerbated. Also, information exchanges between different countries may stimulate cooperation between them, as shortage problems may affect several nations whose authorities could join forces to mitigate them. We should emphasise, that in the interests of transparency, society should also be informed about shortage events.

The stockout prevention and mitigation programme should also include contention measures. In this case, a resilient outlook could be used, as part of a risk-benefit approach, directed towards the adoption of measures such as authorisations for the emergency use of non-licenced products, the use of products whose manufacture may have been suspended because of BMP failures or variances detected by pharmacovigilance, and the lengthening of product shelf lives.

The fight against the main root causes of shortages cannot be neglected. Investments in ever-improving quality systems, to avoid the risk of product supply disruptions will be abetted by promoting incentives through formal recognition of companies that operate highly efficient quality systems.

Although drawing up a list of critical products is no mean task, as it has to include variables that change over time, the authorities must define clear and objective criteria for classifying a product as a critical veterinary product. In the event that they do draw up a list of such products, they should update it regularly.

Lastly, the programme adopted and all the actions that arise from its application must enjoy legal backing. Furthermore, updated to the legislation must be encouraged to synchronise the legal guidelines with scientific developments. Research into future scenarios with prior knowledge of innovations by the regulatory bodies may avoid regulatory barriers.

6. Conclusion:

Critical veterinary product shortages may have adverse repercussions for animal and public health, as well as for rolling out actions relating to the promotion of “One Health”.

There is no single definition or harmonised classification of veterinary products that are considered critical. Different regulatory authorities adopt diverse criteria that may stem from the protection of national security, their use in official health programmes, the need for primary care or the absence of therapeutic alternatives, to name a few.

Governmental authorities have striven to characterise critical veterinary product shortage events, their root causes and impacts, and to define effective prevention and mitigation measures.

These measures have already been implemented in some countries and entail the creation of working groups to assess stockout events; the extension or creation of communication systems between the public sector, the industries, veterinary professionals and the population; drawing up lists of critical medicines; writing guides for the regulated sector, private organisations and veterinary professionals; recognising and rewarding industries that have efficient quality systems and creating and revising the relevant standards.

The definition of solutions to mitigate and prevent critical veterinary product shortages must be backed by legally instituted programmes, whose design and implementation must be based on the participation of the governmental authorities, private bodies and society.

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