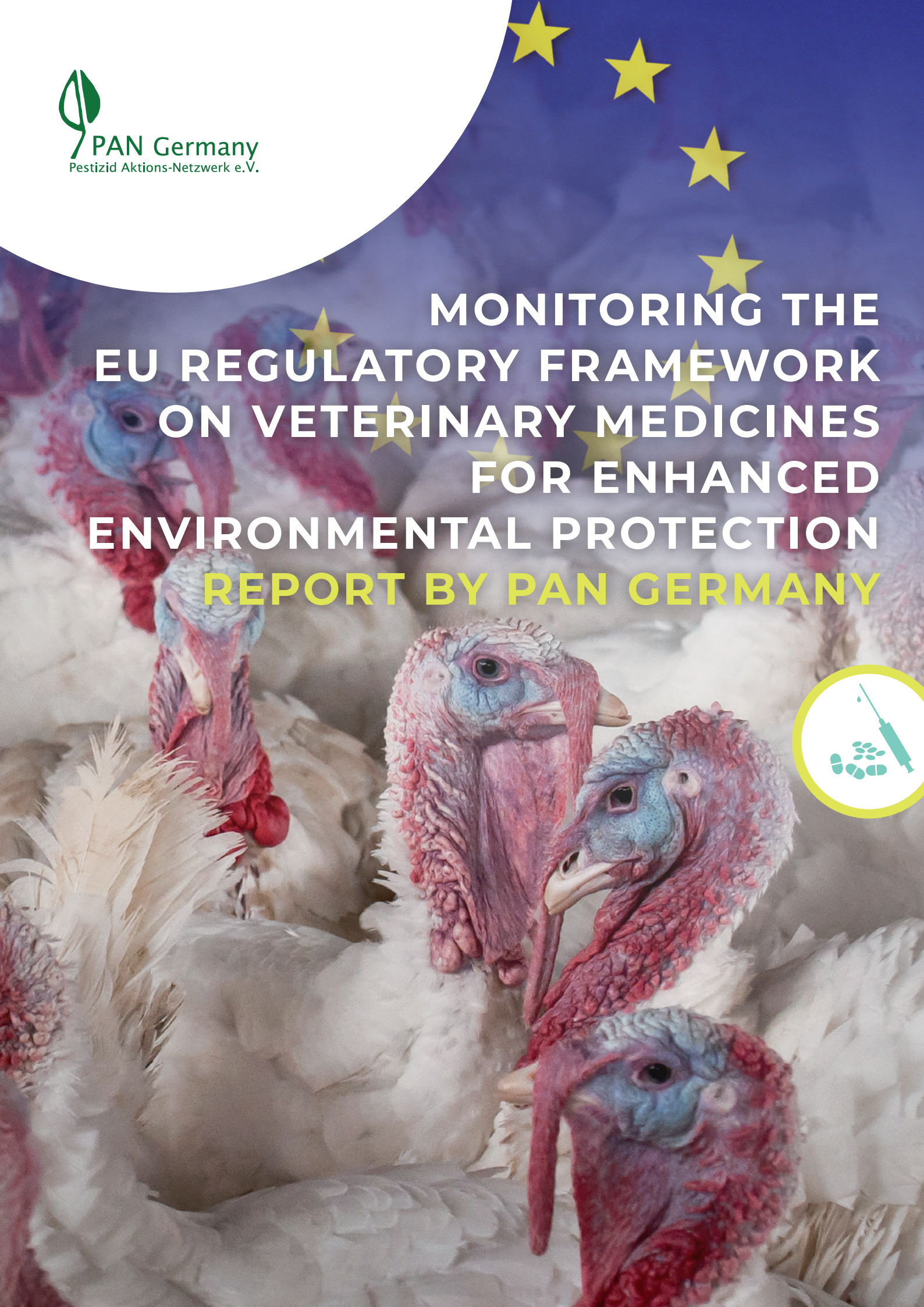
PAN Germany
Pestizid Aktions-Netzwerk e.V.

MONITORING THE EU REGULATORY FRAMEWORK ON VETERINARY MEDICINES FOR ENHANCED ENVIRONMENTAL PROTECTION

REPORT BY PAN GERMANY



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VETERINARY PHARMA-CEUTICALS – AN ENVIRON-MENTAL ISSUE

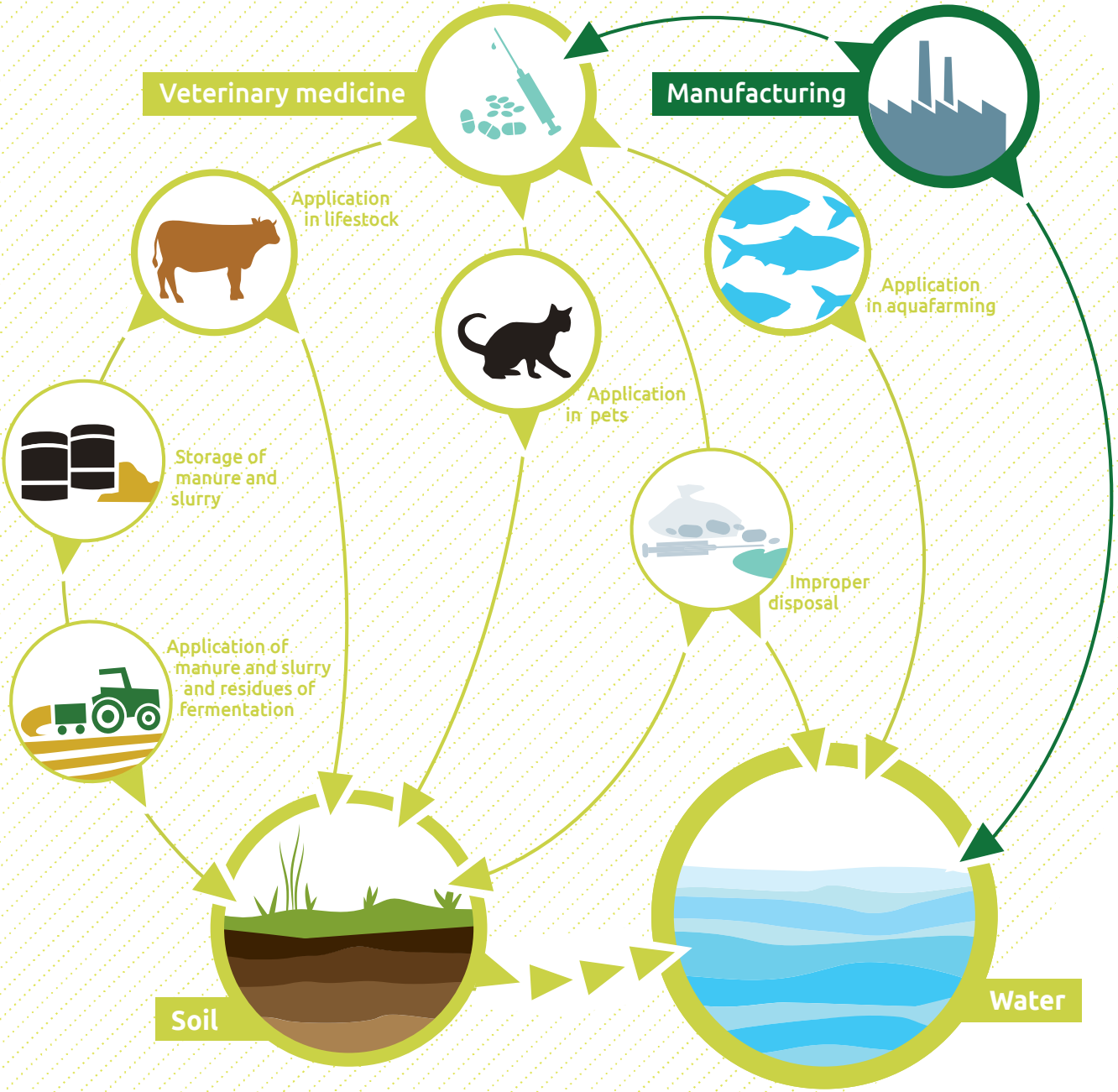
Despite the fact that pharmaceuticals are one of the great inventions of our time, without which our life today would be unthinkable, the growing contamination of surface water, soil and food with residues from pharmaceuticals has increasingly attracted the attention of policymakers and the general public.[1, 2, 3] Pharmaceuticals can enter terrestrial and aquatic environments during their life cycle – starting with production, via use through waste disposal. In the environment, pharmaceuticals can accumulate or relocate and they can have negative impacts on non-target organisms and ecosystem functions.[4]

Thus, it has become apparent that measures are needed to enhance protection of the environment and human health from adverse effects of hazardous pharmaceutical residues on various levels – husbandry standards, pharmaceutical approval, regulations for use, as well as technical processes such as wastewater treatment.[5]

Veterinary medicinal products (VMP) are intended for use in treating, mitigating or preventing illnesses or to influence specific body functions in animals. They include antiparasitics that target parasites such as protozoa, worms and insects, antibiotics that combat pathogenic bacteria, substances for treating infections, and immunological pharmaceuticals. VMP are used by veterinarians, pet owners, professional livestock holders such as breeders and feedlot operators as well as aquafarming operators. Especially in the use of VMP in farm animals, considerable amounts of active substances and their degradation products are released into the environment via animal excrements on pastures, the spreading of slurry or manure on agricultural fields, the rinse off of so-called pour-on products on grazing animals, as well as waste water and waste disposal of the livestock keeping facilities. Open aquafarming plants pose a particular risk, because VMP enter surface water directly.

The purpose of this report is to monitor the efficiency of the implementation of the EU regulatory framework on veterinary medicines in terms of a better environmental protection. The analysis includes an overview on the current status of the legal framework on VMP (Regulation (EU) 2019/6) and medicated feed (Regulation (EU) 2019/4) in the EU after its revision, on improvements and deficits with respect to enhance environmental protection, as well as on opportunities and threats that can be derived. The key deficits identified and recommendations formulated by PAN Germany during the revision process for consistent improvement of environmental protection serve as basis for this evaluation.

ENTRY PATHWAYS AND DISTRIBUTION



PAN GERMANY DEMANDS TO ENHANCE ENVIRONMENTAL PROTECTION

For several years, PAN Germany has been concerned with the environmental impacts of VMP and pointed out key deficits in the former regulative framework of veterinary medicines: lack of data on the volume of VMP sold and used, lack of systematic environmental monitoring for VMP, the fact that there are VMP on the market that have never been tested for their environmental impacts, as well as the dependency on the use of pharmaceuticals in animal production due to disease-promoting animal husbandry conditions.

PAN Germany constantly advocated for more environmental protection in the authorisation procedure, for more transparency and better availability of use data, for monitoring the environmental occurrence of pharmaceuticals, for responsible reduction of the use of VMP – especially antimicrobials, for more animal welfare in animal production, and for more coherence with other areas of substance law, such as pesticide and biocide law.[6, 7, 8, 9, 10, 11] In this context, PAN Germany has critically accompanied the lengthy negotiation process of a new legal framework on veterinary medicines and repeatedly demanded improvements to ensure that the environment and human health will be effectively protected from adverse effects of VMP.

In order to improve environmental protection PAN Germany has recommended to include the following aspects in the EU regulatory framework on veterinary medicines:

- **Introduce mandatory data collection** and annual publications on the amounts of all VMP marketed and on the amounts of all VMP used for more transparency;
- **Retain the time-limited first market authorisation** and introduce a regular renewal of all authorised VMP including an environmental review scheme;
- **Exclude products from authorisation containing active substances, which are highly hazardous** to the environment such as substances that are at the same time persistent, bio-accumulative and toxic substances (PBT), very persistent and very bio-accumulative substances (vPvB), or endocrine disrupting substances (EDs);
- **Improve the knowledge on the fate** of veterinary pharmaceuticals in the environment by introducing an environmental monitoring;
- **Introduce an active substance-based monograph system** in the risk assessment;
- **Improve availability of data by ensuring public access** to the product database for all authorised VMP including information from the environmental risk assessment;
- **Include the comparative assessment and substitution principle in the authorisation procedure** in order to promote alternatives with less environmental impact;
- **Introduce a comprehensive reduction strategy for the use of antimicrobials in animal production** to combat antimicrobial resistance (AMR) and promote a health-oriented system through better animal husbandry in animal production;
- **Introduce a general exclusion from authorisation for antimicrobials,** which are used as reserve antibiotics in human medicine.

THE NEW EU REGULATORY FRAMEWORK ON VETERINARY MEDICINES

With the ambitious objectives to adapt to scientific progress and current market conditions, while ensuring protection of the environment, public health and animal welfare, the EU regulatory framework on VMP as well as on medicated feed has been revised. After four years of negotiations, representatives of the EU Parliament, the EU Commission and the EU Member States agreed on a new regulatory framework in the so-called trialogue. This was followed by a positive vote in the EU Parliament on 25 October 2018.[12]

Regulation (EU) 2019/6 on VMP and Regulation (EU) 2019/4 on medicated feed introduce new rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of VMP and medicated feed across the EU Member States. As part of the implementation, the EU Commission is required to adopt several delegated and implementing acts. Although both regulations have been in force since 28 January 2022 and are binding for the EU Member States since then, the implementation process has not yet been completed. Until now the EU Commission adopted four delegated regulations and ten implementing regulations in the context of Regulation (EU) 2019/6, while the processing of at least three delegated acts and nine implementing acts of Regulation (EU) 2019/6 and at least one delegated act of Regulation (EU) 2019/4 is still pending.[13]

IMPROVEMENTS

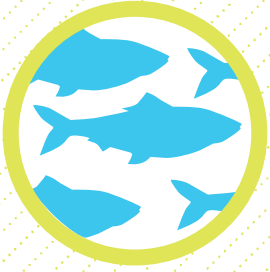
Assessing Regulation (EU) 2019/6[14] on VMP against former deficits and PAN Germany's recommendations for an enhanced environmental protection, PAN Germany considers the following new legal rules as an improvement:

- EU Member States are obliged to collect relevant and comparable data on the volume of sales and the use of veterinary antimicrobials used for all food-producing animal species within five years.
- Marketing authorisation holders are obliged to update relevant environmental safety documentation for veterinary medicines identified as potentially harmful to the environment, and which were authorised without environmental risk assessment.
- The marketing of a VMP can be prohibited, if the benefit-risk balance is negative due to a risk for public health, animal health or the environment.
- EU Member States are obligated to ensure appropriate systems for waste collection and disposal of VMP.
- The quantity of the pharmaceutical prescribed must be limited to the amount required for the treatment concerned.
- Environmental risk assessment as part for the authorisation procedure are mandatory for new VMP to improve environmental protection of VMP.
- Especially hazardous substances like PBT and vPvB substances are to be excluded from approval.
- A first step to enhance public access to information in the product database is made.

Assessing Regulation (EU) 2019/4[15] on medicated feed against former deficits and PAN Germany's recommendations for an enhanced environmental protection, PAN Germany considers the following new legal rules as an improvement:

- Using medicated feed requires a clinical examination of the animal(s) by a veterinarian (derogations possible) and a veterinary prescription.
- The duration of a treatment must comply with the summary of product characteristics (SmPC) of the pharmaceutical(s) in the feed.
- If not specified otherwise, the duration of treatment through medicated feed cannot exceed one month for all pharmaceuticals or two weeks when containing antibiotic active substances.
- Veterinarians are no longer allowed to prescribe medicated feed with more than one VMP containing antimicrobials.

In addition, the EU regulatory framework on veterinary medicines includes rules to achieve the jointly agreed objectives of the EU One Health Action Plan against Antimicrobial Resistance, adopted in June 2017 by the EU Commission , which pursues the 'One Health' approach by recognising the interdependence between human health, animal health and the environment.



DEFICITS

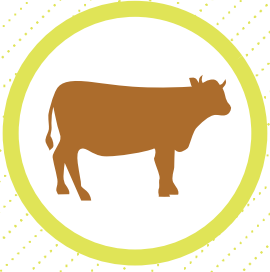
The new rules on antimicrobials and especially on antibiotics shall serve the purpose to no longer allow their use to compensate for poor hygiene, inadequate animal husbandry or poor farm management (Regulation (EU) 2019/6; Article 107 (1)). From PAN Germany's perspective, these new rules generally can be considered positive because they contribute to a sensitive reduction of antimicrobial uses and contribute to a general reduction of dependency on veterinary pharmaceuticals in animal production which could consequently lead to a relief of the environment in terms of pharmaceutical pollution:

- EU Member States are obliged to ban the preventive use of antibiotics in groups of animals, to ban the preventive use of antimicrobials via medicated feed, and to restrict the metaphylactic use of antimicrobials (control treatment).
- EU Member States have to reinforce the ban on the use of antimicrobials for promoting growth and increasing yield (using antibiotics as growth promoters in feed is prohibited in the EU since 2006).
- Antimicrobials can be banned from use, if they are of high concern for treatment in human medicine.
- Non-EU countries will have to respect the ban on antimicrobials for promoting growth and increasing yield, and the use restrictions on antimicrobials designated as reserved for human medicine for their exports of animal products into the EU.
- EU Member States are obliged to introduce science-based maximum limits for cross contamination of feed with antimicrobials.

Unlimited marketing authorisation hinders environmental review of pharmaceuticals

According to Regulation (EU) 2019/6 *'a marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time'* (Article 5 (2)), while according to the previous regulation the first marketing authorisation was granted for 5 years and the authorisation only became indefinite after the application for extension has been approved. In consequence, this precludes the possibility that new scientific evidence on potential hazards from the use of a VMP will be considered in a regulated setting. Unlimited marketing authorisation is in contrast to other EU legislation such as the regulations on pesticides and biocides.

Moreover, numerous VMP in use were authorised before environmental impact assessment became a mandatory component of the authorisation process. The new legislation stipulates that so-called 'old' pharmaceuticals are to be tested for their environmental impact in suspected cases, but there is no obligation to do so, and so far no comprehensive framework has been established (Article 58 (9); Article 60 (2 a)). In order to enhance environmental protection in accordance with the 'precautionary principle', PAN Germany sees the urgent need for the introduction of a mandatory review programme to evaluate the environmental effects of VMP that have been approved without being tested for their environmental impacts as well as a regular environmental review of authorised VMP based on the current state of scientific knowledge and including supplementary results from independent research on the environmental impacts of VMP.



Specific provisions for substances of high concern are not comprehensive

Substances regarded as especially hazardous to the environment are those that are at the same time persistent, bio-accumulative and toxic (PBT), very persistent and very bio-accumulative (vPvB) or hormonally active substances – so called endocrine disrupters (EDs). It has been recognised that an effective protection of human health and the environment from such substances can only be secured by excluding their approval and use. It is therefore positive that the identification of a substance as PBT or vPvB has been recognised as exclusion criteria for approval according to the new rules of the EU regulatory framework. However, the derogation 'the active substance is essential to prevent or control a serious risk to animal health' (Article 37 (2 j)) could lead to a VMP being approved anyway, despite knowledge of an environmental hazard. Without further provisions on such a decision-making process it is difficult to assess whether this measure can contribute to an improvement in environmental protection anyhow.

Furthermore, by neglecting the criterion of EDs regarding an approval exclusion, the legal framework neglects coherence with other EU legislation on chemicals (e.g. pesticides and biocides) regarding substances of high environmental concern. Since a process to define and implement criteria for EDs in VMP is missing so far, PAN Germany sees the need to establish these in order to exclude or severely restrict the authorisation of VMP containing EDs.

Lack of data and transparency regarding pharmaceutical residues in the environment

Although an environmental risk assessment is mandatory for the authorisation process (Regulation (EU) 2019/6, Recital (31)), it is only when a VMP is in use, and in consequence, released into the environment, that knowledge about possible adverse environmental effects (such as interactions with other substances) and processes (e.g. accumulation) becomes more comprehensive. Observing pharmaceuticals through environmental monitoring and linking monitoring results to the authorisation process are therefore of great importance for detecting and preventing environmental pollution. Recital (32) gives the possibility that due to the concern of a serious risk to the environment from an active substance, this substance can be investigated under EU environmental legislation. This comprises the inclusion of the substance in the monitoring list for surface waters for the collection of monitoring data or the inclusion in the list of priority substances for the establishment of environmental quality standards and reduction measures.

However, the EU legal framework on veterinary medicine does not refer to environmental monitoring schemes. PAN Germany would also be in favour of using such information on the occurrence of VMP in the environmental in the pharmacovigilance system.

Substance-based monograph system for VMP is still missing

Data collected for approval purposes including data on the physio-chemical properties of active substances and on their environmental key effects are initially private property of the manufacturer. This system leads to duplicated testing and in some cases to different results. Regulation (EU) 2019/6 Recital (35) recognises these deficits and considers an active substance-based review (monograph) as a potential alternative. In addition, the regulation obliged the EU Commission, the EU Parliament and the EU Council to submit a report on the feasibility on a monograph system and other possible alternatives for the environmental risk assessment of VMP by 28 January 2022.

In October 2021, a feaseability study commissioned by the EU Commission concluded that a monograph system for veterinary medicines would be justified, proportionate and probably financially viable in the long term. Among others, it would support the EU's strategic approach to medicines in the environment and the European Green Deal's 'one active substance – one assessment' approach.

Consequently, PAN Germany urges the EU Commission to do their duty and draft a legislative proposal on a substance-based monograph system of VMP, that would secure harmonisation of environmental risk assessment, reduce the amount of test animals favoring for more animal protection, and lead to enhanced harmonisation of EU legislations (e.g. on pesticides and biocides).

Lack of effective feed-back system from the 'environment' to the 'law'

Even though Recital (55) of Regulation (EU) 2019/6 acknowledges *'pharmacovigilance rules are necessary for the protection of public and animal health and of the environment'*, the pharmacovigilance system for identifying and evaluating undesirable effects of VMP focuses on the wellbeing of treated animals and does not cover effects on wildlife, aquatic or terrestrial organisms. Although, possibilities for securing an eco-pharmacovigilance system have been discussed during the revision process, the new regulation does not provide measures in this direction. Furthermore, the former obligation for applicants to workout regular PSURs (periodic safety update reports) is missing in the new legal framework. PAN Germany sees this as a weakening of the pharmacovigilance system.

It is important to secure an effective post-authorisation and post-marketing control. Regulation (EU) 2019/6 states that EU Member States or the EU Commission can request a re-evaluation of authorised VMP on the ground that they may pose a risk to animal or public health or the environment (Article 60 (2 a)). As long as environmental pollution by veterinary pharmaceuticals is not evaluated through adequate environmental monitoring, relevant information causing a decision to re-evaluate a VMP could be missed.

No introduction of the substitution principle and a comparative assessment

Despite the need for availability and effectiveness of VMP for treatment of serious illnesses in animals to maintain animal health and animal protection, products that are hazardous to the environment should be substituted by products less hazardous. The implementation of the substitution principle depends on the availability of alternative methods or substances. In order to favour the inclusion of less harmful substances in VMP, it is appropriate to identify such substances and to facilitate their placing on the market. This requires the introduction of a comparative assessment in the process of granting authorisation for VMP. PAN Germany sees this as best option to secure optimal animal treatment while ensuring the

best environmental protection. The fact that the EU regulatory framework of veterinary medicines has failed to make improvements here and does not take into account the substitution principle in the authorisation process is to be considered negatively.

Improvements of data collection and transparency are incomplete

Transparency is the basis for an effective monitoring to assess the environmental impacts of veterinary medicines and for an effective risk management. So far, access to data on the use of VMP and on their toxicological risk potential was limited. In order to enhance transparency Article 56 (3) of Regulation (EU) 2019/6 specifies the access to information in the product database for the general public regarding the list of the VMP, the summary of product characteristics, package leaflets and, after the deletion of any commercially confidential information by the competent authority, assessment reports.

Moreover, EU Member States are obliged to collect relevant and comparable data on the volume of sales and the use of veterinary antimicrobials used for all food-producing animal species within five years (Article 57). By restricting this obligation to antimicrobials only, the opportunity is missed to introduce an all-encompassing data collection on VMP. In addition, the EU Commission missed to launch a delegated regulation on 'Requirements for the collection of data on antimicrobial medicinal products used in animals' required by Article 57 (3) so far, so that no assessment of this measure is possible at this time.

Lack of ambition regarding restrictions of antimicrobials used in animal production

The reduction of antibiotic use has been identified as key to combat the growing threat of AMR. Since it is common knowledge, that the amount of antimicrobials used in animal production is too high, the EU Farm to Fork Strategy, adopted on 20 May 2020, includes a reduction target of the overall EU sales of antimicrobials for farmed animals and in aquafarming of 50 % by 2030, through the new Regulations on VMP and Medicated Feed.[18]

The general way of 'implementing' demands and agreed objectives of a political strategy, is by including those into binding legislations. In this case however, both regulations were already adopted in 2019, before the EU Green Deal and the EU Farm to Fork Strategy. Despite that, the EU legal framework of veterinary medicines introduces several new rules regarding the use of antibiotics in particular in food-producing animals. However, it does not set a specific reduction goal for antimicrobials used and it lacks to introduce the principle of minimum necessary as well as a definition of best practices in due consideration of animal welfare and adequate animal husbandry practice. Therefore, it must be assumed that additional political efforts are necessary to achieve the 50 % reduction target of the EU Farm to Fork Strategy. According to a study by the EU Commission on measures and instruments promoting animal welfare and reduction of antimicrobials use, EU Member States need to implement ambitious strategies to address antimicrobial use by farmers. National plans should rely on instruments and measures to foster specific practices on-farm such as health prophylaxis, alternative treatment and biosecurity.[19] In Germany this has been implemented with

the entry into force of the new Veterinary Medicinal Products Act in January 2023 and a fixed reduction target for antibiotic consumption of 50 % by 2030.[20]

With growing antimicrobial resistance securing human health is more and more depending on the effectiveness of so-called reserve antibiotics. The World Health Organization (WHO) recommends that such antibiotics designated as *'highest priority critically important antimicrobials'* (HP CIA) should not be used in food-producing animals in order to slow down the transfer of resistance to humans and to preserve the effectiveness of these particularly important substances.[21] Under Article 37 (5) of Regulation (EU) 2019/6 it is regulated that antimicrobials can be banned from use in veterinary medicine, if they are of high concern for treatment of certain infections in humans. However, by way of derogation veterinarians may, under defined conditions, exceptionally treat animals with a pharmaceutical for human use (Article 112, Article 113, Article 114). In order to prevent an accelerated resistance against reserve antibiotics and to maintain their effectiveness as long as possible, a treatment of food-producing animals with antibiotics of this group should strictly be excluded from any derogations in the opinion of PAN Germany.

Unfortunately, the criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans and consequently the list of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, laid down by Commission Delegated Regulation (EU) 2021/1760 and Commission Implementing Regulation (EU) 2022/1255, are not in line with the recommendations of the WHO.[22, 23] So far, the list only contains antimicrobials that are not used in veterinary medicine in the EU. Thus, this implementation has no effect and cannot contribute to a use reduction of reserve antibiotics in animal production.

PAN Germany therefore considers this restriction made in the EU regulations as not ambitious enough – especially considering that targeted national measures in several EU Member States, such as Denmark and the Netherlands, have long contributed to the result that reserve antibiotics such as colistin is hardly or no longer used at all in animal production.[24] Examples such as these demonstrate indisputably the feasibility of drastically reducing or even phasing out the use of reserve antibiotics to treat food-producing animals.

Breeding for high performance, accelerated stress levels and the lack of physical movement caused by high stocking densities, as well as the lack of climate stimuli and the unnatural proximity to excrements favour high infection rates in animal husbandry. Single-animal treatments are not cost-effective, which has led to the fact that not only sick but also healthy animals are treated with pharmaceuticals during group treatments. With the aim to reduce the use of antimicrobials the EU legal framework on veterinary medicines contains several specific rules to restrict group treatment. Yet, the effectiveness of these rules depends on the interpretation of the ban of 'routine use' as well as on provisions that hinders the misuse of 'methaphylactic use' for control treatment (Article 107).

OPPORTUNITIES AND THREATS REGARDING ENVIRONMENTAL PROTECTION OF VETERINARY MEDICINES

In order to maintain animal health and animal protection the availability and effectiveness of VMP for treatment of serious illnesses in animals is essential. However, disease-promoting animal husbandry conditions have created a dependency on the use of veterinary medicines in animal production, that leads to an unreasonable exposure of the environment to pharmaceuticals and unintended risks for ecosystems and human health.

The past revision of the EU regulatory framework on veterinary medicines therefore offered an adequate opportunity to overcome those challenges and to secure protection of human health and environment from adverse effects of VMP. Key deficits identified by PAN Germany such as lack of data on VMP sold and used, the fact that there are VMP on the market that have never been tested for their environmental impacts, as well as the dependency on the use of veterinary medicines in animal production due to disease-promoting animal husbandry conditions, have been addressed by Regulation (EU) 2019/6 on VMP and Regulation (EU) 2019/4 on medicated feed. Since the use of medicated feed has a significant impact on rearing and keeping of food-producing animals, new rules regarding medicated feed are generally intended to favour a responsible reduction of the use of antimicrobials in animal production.

All things considered, from PAN Germany's point of view the legal framework remains far behind its possibilities and the urgent need for a systemic change in animal production towards a health-oriented system. **The framework falls far short of the possibilities that should have been exploited, to reduce the dependency on VMP, to generate knowledge about the use, fate and environmental impact of veterinary medicines, as well as fighting AMR.** The authorisation process is failing regarding an adequate environmental review of pharmaceuticals due to unlimited authorisations of VMP, as well as the missing of the substitution principle and the criterion of EDs for approval exclusion.

Moreover, the EU regulatory framework on veterinary medicines lacks ambition regarding the implementation of restrictions on antimicrobials used in animal production. **It also does not include environmental monitoring schemes, which leads to the fact that relevant information causing a re-evaluation of VMP could be missed.** Additionally, so far it misses the introduction of a substance-based monograph system for VMP. By restricting use related data collection to antimicrobials only, the framework misses the opportunity to introduce an all-encompassing data collection on VMP used.

PAN Germany points out that the analysis on which this report is based on does not claim to be complete. This is partly due to the fact, that no statement can be made about the implementation of aspects, for which the implementation process has not yet been completed.

In order to enhance the protection of the environment and human health from adverse effects of VMP in the future, all stakeholders – pharmaceutical producers, livestock and aqua-farming operators, veterinarians, consumers, marketers, and political decision makers – are called upon to contribute to reduce pharmaceutical contamination of the environment. This includes appropriate measures such as waste-less production plants, pharmaceuticals with reduced environmental impacts, stringent environmental impacts assessment of all veterinary pharmaceuticals and systematic environmental monitoring, as well as a health-oriented animal production system favouring husbandry practices that preserve animal health with a minimal use of pharmaceuticals.

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