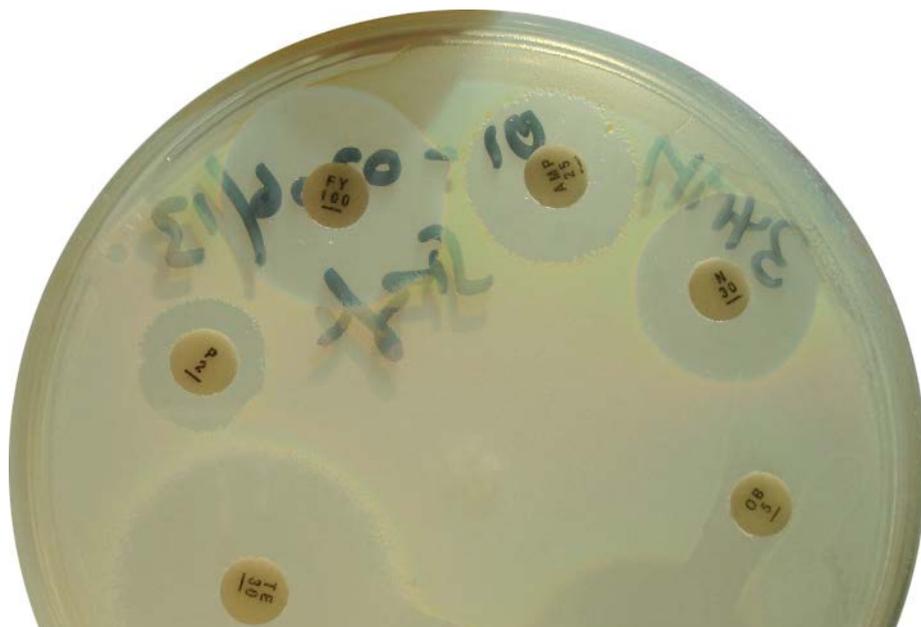




Antimicrobial Resistance

Standards, Recommendations and Work
of the World Organisation for Animal Health (OIE)

July 2015



Risks associated with the use of antimicrobials in animals worldwide



Dr Vallat,
Director General
of the World Organisation
for Animal Health
(OIE)

The World Organisation for Animal Health (OIE) has evaluated the quality of national animal health systems, including Veterinary Services, in more than 130 countries.

More than 110 of the countries evaluated – mainly developing and emerging countries – do not yet have relevant legislation concerning appropriate conditions for the importation, manufacture, distribution and use of veterinary products, including antimicrobials. In some cases, legislation is totally non-existent. Where it does exist it is very often not properly applied because of lack of public funds for the implementation of controls.

In such countries, antimicrobials are usually freely available to anyone, directly or indirectly, without restriction. Worse still, they circulate as normal goods and are often adulterated (dosage less than that mentioned on the packaging, different molecule or complete placebo). **Thousands of tonnes of adulterated antimicrobials destined for use in animals are circulating worldwide** (and the same is true of antimicrobials for human use).

Unfortunately, the use of antimicrobials in animals by untrained personnel is not confined to developing and emerging countries. In a significant number of member countries of the Organisation for Economic Co-operation and Development (OECD), it is easy to acquire antimicrobials, particularly via the internet, and many farmers do so. Some of these countries still allow the use of some antimicrobials on fruit trees to control certain bacterial diseases, as well as the incorporation of some antimicrobials into animal feed as growth promoters or for other non-therapeutic purposes. Political action, for example by the G8 countries or the World Trade Organization, could hope to persuade countries in this category to change these practices, estimated by many credible scientists as risky.

In the area of preventing antimicrobial resistance in animals (and its potential benefits for public health), although some countries and regions are already very cautious, the adoption of effective provisions by the rest of the world is likely to be long, difficult and controversial, not to say illusory.

Unfortunately, globalisation of the food trade, coupled with traditional and medical tourism, enable (and will continue to enable) existing or future resistant bacteria to colonise the entire planet with ease, regardless of any preventive measures implemented locally.

How can we face this important challenge?

– **The OIE trains national Focal Points appointed by its Member Countries and forms networks** to enable them to develop and modernise legislation on the production, importation, distribution and use of veterinary products, as well as to carry out such tasks as monitoring the consumption of antimicrobials, because very little is yet known about actual volumes used in the 180 Member Countries involved in the OIE veterinary legislation support programme.

– **OIE Member Countries adopt international standards on the prudent use of antimicrobial agents and on the harmonisation of the risk assessments that they undertake to implement.** International cooperation in the form of development aid is crucial to helping developing countries, and even emerging countries, to apply these standards, especially since, in the short term, animal production is expected to grow by more than 50% owing to increasing use of intensive production systems in these countries.

– **The OIE also recommends policies to introduce minimum geographical coverage by veterinarians so as to ensure animal health surveillance,** using this network to guarantee the early detection of potential epizootics (including zoonoses such as animal influenza) and a rapid response to contain outbreaks at source. Such a network can also improve the general health of animals by allowing the judicious and proper limited use of antimicrobials. The network's existence and sustainability is partly dependent on revenues from services provided by veterinarians, many to mainly poor customers in the isolated or deprived areas where they work, which are home to the numerous animals to be monitored. These revenues come mainly from the delivery of products, including antimicrobials, which veterinarians administer directly to the animals. This can raise a potential conflict of interest that needs to be addressed. It is why our organisation provides:

- **Standards and programmes to improve the quality of veterinary education worldwide,** including in the fields of microbiology, pharmacology and ethics.
- **A standard on the design and functioning of national and regional Veterinary Statutory Bodies** empowered by the law and by State delegation of the necessary powers to oversee qualifications, ethical standards and professional excellence, as well as to expel anyone whose conduct is improper.

While some countries have decoupled prescription from delivery for certain veterinary drugs, including antimicrobials, this may pose logistical problems of responsiveness to diseases, particularly at the farm level, and may facilitate illegal practices (direct and uncontrolled self-supply and intervention of unscrupulous and ignorant individuals, mainly via the internet). The risks associated with these practices may have consequences that are much more serious than any irregularities in drug prescription or delivery by veterinarians, which are much easier to control and prevent. Several countries that have implemented decoupling have seen an increase in the general consumption of antimicrobials (according to those in a position to assess such consumption). It is worth noting that the human consumption of antimicrobials continues to grow despite the fact that decoupling of drug prescription and delivery is widespread in human medicine.

‘Several countries that have implemented decoupling prescription and delivery of antimicrobials have seen an increase in the general consumption of antimicrobials’

It appears that measures to limit the emergence of resistance in animals, including managing and limiting globally what are deemed to be the riskiest practices, (including their use in plant production), should be made a global priority, including in developed countries.

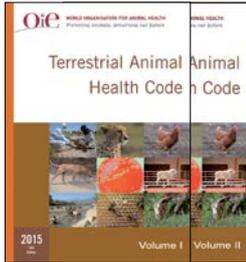


Bernard Vallat
Director General
of the World Organisation for Animal Health (OIE)

OIE ACTIVITIES

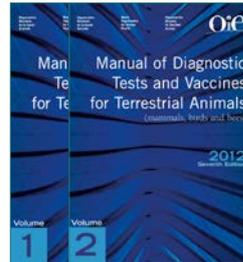
Summary of OIE outcomes on Antimicrobial in animals (since 2010)

OIE intergovernmental standards for Terrestrial Animals



OIE Terrestrial Animal Health Code
(Updated Chapters)

- **Chapter 6.6.** Introduction to the recommendations for controlling antimicrobial resistance (adopted by the World Assembly of Delegates during the General Session in May 2012)
- **Chapter 6.7.** Harmonisation of national antimicrobial resistance surveillance and monitoring programmes (adopted by the World Assembly of Delegates during the General Session in May 2012, updated in May 2015)
- **Chapter 6.8.** Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals (adopted by the World Assembly of Delegates during the General Session In May 2012)
- **Chapter 6.9.** Responsible and prudent use of antimicrobial agents in veterinary medicine (adopted by the World Assembly of Delegates during the General Session In May 2012)
- **Chapter 6.10.** Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals (adopted by the World Assembly of Delegates during the General Session in May 2012 , updated in May 2015)



OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
(Updated Guidelines)

- **Guidelines 4.1.** Laboratory methodologies for bacterial antimicrobial susceptibility testing

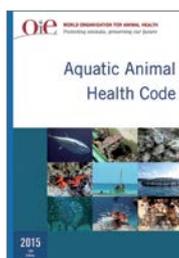
The expert groups involved in the preparation of all OIE standards include, among other high level international experts, WHO¹ and FAO² representatives.



Updated version of the OIE **List of antimicrobial agents of veterinary importance** (adopted by the World Assembly of Delegates during the General Session in May 2012, latest update: May 2015)

resistance and Use of antimicrobial agents

OIE intergovernmental standards for Aquatic Animals



OIE Aquatic Animal Health Code (New Chapters)

- **Chapter 6.1.** Introduction to the recommendations for controlling antimicrobial resistance (adopted by the World Assembly of Delegates during the General Session in May 2011)
- **Chapter 6.2.** Principles for responsible and prudent use of antimicrobial agents in aquatic animals (adopted by the World Assembly of Delegates during the General Session in May 2011)
- **Chapter 6.3.** Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals (adopted by the World Assembly of Delegates during the General Session in May 2012)
- **Chapter 6.4.** Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals (adopted by the World Assembly of Delegates during the General Session in May 2012)
- **Chapter 6.5.** Risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in aquatic (adopted by the World Assembly of Delegates during the General Session in May 2015)

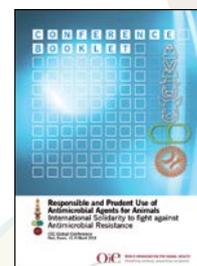
OIE Global Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals, International Solidarity to fight against Antimicrobial Resistance

Paris, France, 13-15 March 2013

More than 300 participants from over 100 countries (OIE Delegates, OIE national Focal Points for Veterinary Products, WHO¹, FAO², experts, professionals, policymakers, industry representatives, non-governmental organisations and potential donors).

Outcomes:

- Recommendations (page 9)
- Conference booklet
- Based on the recommendation n°7 to the OIE 'to collect harmonised quantitative data on the use of antimicrobial agents in animals with a view to establish a global database' and on the results of a questionnaire sent to all Member Countries, the OIE established a new *ad hoc* Group to set up a global database on the use of antimicrobial agents in animals (first meeting January 2014, second July 2014, third December 2014)



1- World Health Organization.

2- Food and Agriculture Organization of the United Nations.

OIE ACTIVITIES

Capacity building

Regional Seminars for OIE National Focal Points for Veterinary Products (180 Member Countries)

Three cycles organised: Quality of antimicrobial agents, prudent use and Antimicrobial resistance (AMR) were included in all the 3 cycles

Cycle 1:

- Europe (Serbia), July 2010
- Americas (Colombia), September 2010
- Africa (South Africa), November 2010
- Asia (Cambodia), June 2011

In addition Quality of Veterinary Medicinal Products, Good Governance of antimicrobials and VICH were part of the programme.

Cycle 2:

(FAO and WHO representatives were invited to make a presentation)

- Africa (Senegal), September 2011
- Middle East and Africa (Morocco), December 2011
- Africa (Kenya), Mars 2012
- Asia (Thailand), July 2012
- Americas (Brazil), October 2012
- Europe (Austria), November 2012

The tracking and identification of counterfeit products, and the importance of prudent and responsible use of veterinary drugs and working groups on the collection of data on antimicrobial agents were part of the programme.

Cycle 3:

(FAO and WHO representatives present the Tripartite approach in a specific session dedicated to AMR)

- Africa (Algeria), October 2013
- Africa (Mozambique), December 2013
- Americas (Canada), August 2014
- Europe (Macedonia), November 2014
- Asia (Japan), December 2014

Feedback of Member Countries on achievements related to antimicrobial use and AMR were main topics.



Intersectoral & international collaboration

Curbing the emergence of antimicrobial resistance requires global, multi-sector harmonisation of the strategies and measures designed to improve the coordination of and environmental policies human health, animal health and environmental policies. Humans and animals share the same bacteria since 60% of pathogens dangerous to man are of animal origin. This constitutes the basis of the ‘One Health’ concept.

In this context, the OIE collaborates with numerous international organisations, such as WHO, FAO, the Codex Alimentarius Commission (CAC), which are key partners for sharing information and formulating recommendations.

Tripartite Alliance FAO/OIE/WHO



A Tripartite Fact sheet on the topic has been recently developed
www.oie.int/TripAMR2014/EN

They have set themselves the following goals:

- ensure that antimicrobial agents maintain their efficacy
- promote prudent and responsible use of these agents
- facilitate access to quality drugs.

Since 2010, the OIE, alongside the WHO and FAO, has been engaged in a Tripartite Alliance that stipulates the respective responsibilities of the three organisations in the fight against diseases with a high health and economic impact, particularly zoonotic diseases. Combating antimicrobial resistance is one of the organisations' three priorities.

The tripartite actions consist in coordinating strategies to combat antimicrobial resistance in the short, medium and long terms at global level, and in supporting their implementation at the national and regional levels.

Global action plan on antimicrobial resistance

The OIE recently made a strong contribution to the WHO's global action plan on antimicrobial resistance, adopted in 2015, which seeks to ensure, for as long as possible, the treatment of infectious diseases with effective, quality antimicrobial agents. The OIE's 180 Member Countries have pledged their support for the plan through a Resolution adopted unanimously in May 2015.

The plan, while proposing key actions to be implemented in the next five to ten years, emphasises the importance of the OIE's intergovernmental standards and supports the implementation by the OIE of a global database on the use of antimicrobial agents in animals.

Monitoring the use of antimicrobial agents

Today, in many countries, including developed countries, antimicrobial agents are widely available, directly or indirectly, practically without restriction. Of 130 countries recently evaluated by the OIE, more than 110 do not yet have relevant legislation on the appropriate conditions for the import, manufacture, distribution and use of veterinary products, including antimicrobial agents. Consequently, these products circulate

uncontrolled like ordinary goods and are often falsified.

To date, there is no harmonised system of surveillance on the worldwide use and circulation of antimicrobial agents. That information is necessary, however, to monitor and control the origin of medicines, obtain reliable data on imports, trace their circulation, and evaluate the quality of the products in circulation. It is in this context that the OIE was mandated by its Member Countries to gather that missing information and create a global database for monitoring the use of antimicrobial agents, linked to the OIE's World Animal Health Information System (WAHIS).

That mandate is also supported by FAO and the WHO within the framework of the WHO's global action plan on antimicrobial resistance. The database will form a solid basis for the work of FAO, WHO and OIE to combat antimicrobial resistance.

RESOLUTIONS

26th Resolution of the 83rd World Assembly of the OIE Delegates

‘Combating antimicrobial resistance and promoting the prudent use of antimicrobial agents in animals’

Paris, France - 24-29 May 2015

CONSIDERING

1. That antimicrobial agents are essential tools for protecting animal health and welfare and also contribute to meeting the increasing global demand for safe meat, milk, fish and eggs, and other products of animal origin,
2. That antimicrobial resistance (AMR) is a significant global animal and human health threat that is influenced by the use of antimicrobial agents in some conditions,
3. That during the 77th General Session 2009, the World Assembly of Delegates (the Assembly) adopted Resolution No. 25 on Veterinary Products, which considered previous Resolutions on harmonisation of registration requirements for veterinary drugs, their responsible and prudent use and monitoring of resistance,
4. The recommendations of the OIE Global Conference on the responsible and prudent use of antimicrobial agents in animals, held in March 2013 in Paris, France, including recommendation No.7 to collect harmonised quantitative data on the use of antimicrobial agents in animals with the view to establishing a global database,
5. The recent update and development of OIE standards and guidelines related to antimicrobial resistance, which include references to the relevant standards developed by Codex Alimentarius,
6. The tripartite agreement between FAO, OIE and WHO to address as a priority antimicrobial resistance and the important contribution of the OIE to the development and achievement of the WHO global action plan on antimicrobial resistance,
7. The network of OIE National Focal Points for Veterinary Products and its role in supporting the global implementation of the OIE standards regarding veterinary products,
8. The importance of the PVS pathway in supporting compliance of national veterinary services with OIE standards including legislation, as a prerequisite to ensuring good governance covering production, registration, distribution and use of antimicrobial agents at the national level,
9. The importance of appropriate Veterinary Education and Veterinary Statutory Bodies in the promotion of veterinary oversight to ensure responsible use of antimicrobial agents in animals,

THE ASSEMBLY RECOMMENDS THAT

1. The OIE continue to develop and update standards and guidelines related to antimicrobial resistance and the prudent use of antimicrobial agents including updating regularly the OIE List of Antimicrobial Agents of Veterinary Importance.
2. The OIE, with support from relevant organisations and donors, work with Member Countries to support them to implement OIE standards and guidelines using the PVS pathway and other relevant OIE capacity building mechanisms, including twinning and regional seminars.
3. The OIE develop a procedure and standards for data quality for collecting data annually from OIE Member Countries on the use of antimicrobial agents in food-producing animals with the aim of creating an OIE global database to be managed in parallel with the World Animal Health Information System (WAHIS).

RESOLUTIONS

4. OIE Member Countries set up an official harmonised national system, based on OIE standards, for the surveillance of antimicrobial resistance and the collection of data on the use of antimicrobial agents in food-producing animals, and actively participate in the development of the OIE global database.
5. The participation of OIE Member Countries in the VICH Outreach Forum be facilitated with the aim of adopting and utilising harmonised international guidelines related to the technical requirements for registration of veterinary medicinal products.
6. OIE Member Countries improve veterinary legislation and education, where necessary, in order to facilitate implementation of OIE and Codex Alimentarius standards and guidelines related to antimicrobial resistance and veterinary oversight of the use of antimicrobial agents.
7. The OIE and OIE Member Countries encourage Veterinary Statutory Bodies and the veterinary profession as a whole to develop, implement and ensure compliance with ethics and codes of good veterinary practices, with particular reference to the prescription and delivery of antimicrobial agents by well-trained veterinarians or veterinary para professionals under their direct oversight.
8. OIE Member Countries follow the guidance of the WHO Global Action Plan on Antimicrobial Resistance, developed with the support of the OIE in the spirit of the “One Health” approach, in particular by developing national action plans, with the support of FAO and WHO where feasible and warranted, in respect of the use of antimicrobial agents in animals and ensuring their close collaboration with public health officials.
9. The OIE continue to seek donor support for the organisation of dedicated regional training seminars for OIE National Focal Points for Veterinary Products with the participation of FAO and WHO within the tripartite collaboration and invite other relevant partners to build capacity at the national and regional levels to enable the implementation of OIE and Codex Alimentarius intergovernmental standards to combat antimicrobial resistance and support the recommendations of the WHO Global Action Plan on Antimicrobial Resistance.
10. The OIE strengthen its collaboration with international organisations, such as the World Customs Organisation and Interpol, and stakeholders to combat counterfeit products with the aim of ensuring access to antimicrobial agents of proven quality.
11. Research be promoted to improve tools for rapid diagnostics for use in animals and to explore alternatives to antimicrobial use in animals, including the development of vaccines and other tools for priority diseases.

(Adopted by the World Assembly of Delegates of the OIE on 26 May 2015 in view of an entry into force on 30 May 2015)

RECOMMENDATIONS

OIE Global Conference on the responsible and prudent use of antimicrobial agents for animals

'International solidarity to fight against antimicrobial resistance'

Paris, France, 13-15 March 2013

CONSIDERING

1. That antimicrobial agents are essential tools for protecting animal health and welfare;
2. That antimicrobial agents also contribute to satisfying the increasing world demand for safe food of animal origin, such as milk, meat, fish and eggs;
3. That antimicrobial resistance is a global human and animal health concern that is influenced by both human and non-human usages of antimicrobial agents;
4. The importance of good governance practices, including national legislation and regulatory frameworks for import, marketing authorisation, production, distribution (including transport and storage) and use of quality veterinary medicinal products worldwide;
5. The importance of strong Veterinary Services to promote the responsible and prudent use of antimicrobial agents in animals;
6. The implementation of the OIE¹ PVS Pathway worldwide;
7. The need to increase the capacity of all countries to conduct surveillance of antimicrobial resistance and monitoring of quantities of antimicrobial agents used in food-producing animals;
8. The necessity of international solidarity to help all Member Countries to effectively develop and implement measures for responsible and prudent use of antimicrobial agents in animals;
9. The international standards and guidelines developed by the OIE and other international organisations such as *Codex Alimentarius* to promote the responsible and prudent use of antimicrobial agents in terrestrial and aquatic animals;
10. The OIE List of Antimicrobial Agents of Veterinary Importance and the WHO² List of Critically Important Antimicrobials for Human Medicine;
11. The network of OIE national Focal Points for Veterinary Products;
12. The cooperation with Veterinary Statutory Bodies, the veterinary profession, and interested parties to ensure responsible and prudent use of antimicrobial agents in terrestrial and aquatic animals based on OIE standards;
13. The tripartite mechanisms between FAO³, the OIE and WHO for promoting the 'One Health' concept;
14. The active support of VICH⁴ by the OIE

The participants of the OIE global conference on the responsible and prudent use of antimicrobial agents for animals

RECOMMEND TO THE OIE

1. To strengthen international cooperation through the tripartite (FAO–OIE–WHO) approach to promote the responsible and prudent use of antimicrobial agents in humans and animals and to minimise the development and spread of antimicrobial resistance.

² World Health Organization

³ Food and Agriculture Organization of the United Nations

⁴ International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

¹ World Organisation for Animal Health

RECOMMENDATIONS

2. To continue to develop and update OIE standards, the OIE List of Antimicrobial Agents of Veterinary Importance and policies on the responsible and prudent use of antimicrobial agents with the support of OIE Reference Centres and all relevant OIE experts.
3. To assist Member Countries in strengthening their Veterinary Services and other Competent Authorities to promote good governance practices, including national legislation and regulatory frameworks for import, marketing authorisation, production, distribution (including transport and storage) and use of high-quality veterinary medicinal products worldwide, using, if needed, the OIE PVS Pathway.
4. To encourage Member Countries and OIE Delegates to utilise their OIE national Focal Points on Veterinary Products to identify needs for national capacity building.
5. To continue organising regional training seminars for OIE National Focal Points for Veterinary Products and invite FAO, WHO and stakeholders to participate.
6. To assist Member Countries to conduct surveillance on antimicrobial resistance for animal and human pathogens.
7. To collect harmonised quantitative data on the use of antimicrobial agents in animals with the view to establish a global database.
8. To strengthen cooperation with Veterinary Statutory Bodies and the veterinary profession in Member Countries to implement responsible and prudent use of antimicrobial agents in animals.
9. To explore and promote opportunities for more communication, collaboration and partnerships with relevant public and private interested parties from the human and animal sectors at international, regional and national levels.
10. To encourage intersectoral collaboration and research to better understand and minimise the mechanisms of development of antimicrobial resistance and to develop new molecules.
11. To promote international solidarity and advocate all potential donors to support developing countries to implement OIE standards on the responsible and prudent use of antimicrobial agents.
12. To facilitate the participation of OIE Member Countries in the VICH Outreach Forum with the aim of adopting and utilising harmonised international guidelines related to the technical requirements for registration of veterinary medicinal products, to ensure the quality of these products.

RECOMMEND TO OIE MEMBER COUNTRIES

1. To ensure that the national Veterinary Services fulfil their responsibilities and, where needed, seek assistance through the OIE PVS Pathway to comply with the OIE standards.
2. To implement OIE and Codex Alimentarius international standards and guidelines related to the responsible and prudent use of antimicrobial agents and to follow the recommendations of the OIE List of Antimicrobial Agents of Veterinary Importance, including recommendations on fluoroquinolones and on the third- and fourth-generation of cephalosporins that are considered to be critically important for both human and animal health.
3. To develop and set up an official harmonised national system for collecting data on the monitoring of antimicrobial resistance in relevant animal pathogens and quantities of antimicrobial agents used in food-producing animals at the national level based on the OIE standards.
4. To contribute to the OIE initiative to collect data on the antimicrobial agents used in food-producing animals (including through medicated feed) with the ultimate aim to create a global database hosted by the OIE.
5. To develop or update appropriate legislation and regulation on import, marketing authorisation, production, distribution (including transport and storage) and use of high-quality veterinary medicinal products in interaction with other relevant Competent Authorities and private interested parties, and to ensure their efficient implementation.

6. To encourage the Veterinary Statutory Bodies and the veterinary profession as a whole to develop, implement and ensure compliance with ethics and codes of good veterinary practice, with particular reference to the prescription and delivery of antimicrobial agents by well-trained veterinarians and veterinary para-professionals under their authority.
7. To advocate the inclusion in the curriculum for pre-graduate veterinary education (Day 1 competencies) of knowledge on antimicrobial resistance and of codes of good veterinary practices for the responsible and prudent use of antimicrobial agents in animals.
8. That the Veterinary Statutory Bodies have the capacity and authority to develop and institute continuing professional development and continuing education programmes directed, in particular, at the responsible and prudent use of antimicrobial agents in animals (including companion animals and wildlife) and at related new technologies that will become available, including diagnostic tests.
9. To nominate, support and maintain national OIE Focal Points for Veterinary Products in their tasks and to ensure close contact with relevant WHO, FAO and *Codex Alimentarius* contact points.
10. To support developing and in-transition Member Countries to strengthen their Veterinary Services, to implement good governance and legislation related to antimicrobial agents in compliance with OIE and *Codex Alimentarius* standards, and to help them to fight against the use of unlicensed/ counterfeit products.
11. To contribute to and participate in global or regional cooperation aiming at developing measures for responsible and prudent use of antimicrobial agents in animals.
12. To promote good agriculture and aquaculture practices, including the use of vaccines where applicable, and interact with all relevant interested parties while ensuring compliance with OIE and *Codex Alimentarius* standards to minimise the development and spread of antimicrobial resistance.
13. To support relevant research to improve the understanding of the efficacy of current antimicrobial agents with the aim of prolonging their usage while minimising the development of resistance, to develop new molecules and to find alternatives that could be used in animal production for antimicrobial agent substitutions.
14. To facilitate the market authorisation of new molecules and innovative technologies for antimicrobial agent substitutions, and to promote their use.
15. To develop risk assessment and to carefully evaluate practices of use of antimicrobial agents that are not intended to combat animal diseases.
16. To use VICH guidelines to ensure the quality of veterinary medicinal products registered at national level, and to follow closely the VICH Outreach Forum initiative.



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