Conclusions and recommendations

XV Seminar on Harmonization for Registration and Control of Veterinary Medicines
Americas Committee on Veterinary Medicines (CAMEVET)
Guadalajara, Jalisco, Mexican United States
2009, August 10th -15th

1. Assumption of the Presidency of CAMEVET

Dr. Fernando Rivera Espinoza formally takes upon the role as the president of the Seminar at the beginning of the meeting.

According to the decision taken by the General Assembly, Dr. Néstor Guerrero Lozano is appointed as President of the Committee by the closure of the present Seminar, being his position in force until the closure of the next meeting to be carried out during year 2010.

The positions in the Executive Board are listed as follows

President:

Néstor Guerrero Lozano – Colombia

Official Representatives:

Fernando Rivera Espinoza (honorary member) – México
Marcos Vinicius de Santana Leandro - Brasil
Adela Encinosa Liñero - Cuba
Luis Zamora Chavarri – Costa Rica
Virginia Quiñones – Dominican Republic

Representatives for the Veterinary Industrial sector

Enrique Argento – CAPROVE (Argentina)
Carlos Rufrano – CLAMEVET (Argentina)
Margarita Pinto – INFARVET (México)
Milson da Silva Pereira – SINDAN (Brasil)

The positions of the Executive Board Members shall be in force until the closure of the 2010 Seminar.

Dr Fernando Rivera Espinoza holds office as honorary representative for the Official sector, in order to share his experience in the present Seminar and to participate in the organizational aspects of the next meeting.

2. Secretariat and Executive Board activities report

Registration of CAMEVET internet domain and electronic mail address
The Secretariat has made the arrangements for the registration of the internet domain **camevet.org** and the setup of the electronic mail address.

CAMEVET logo design
The logo developed for the Committee was presented which shall be applied on the visual identity of the documents and the activities carried out by the Committee.

Executive Board meetings
During the period prior to the celebration of the present Seminar, the Executive Board has accomplished thirteen meetings. The minutes of the meetings are included in the Seminar memories.

3. Institutional issues discussed during the Seminar

CAMEVET relevance on OIE topics
The activities developed by OIE over the field of veterinary medicines were outlined.
This addresses the need for the Committee to actively participate in the elaboration of proposals for the different issues actually discussed by OIE, being of crucial importance the preparation and the revision of international standards.
The Recommendations of the 19th Conference of the Regional Commission for the Americas, as well as the Resolutions N° 25 and 28 of the 77th Annual General Assembly of the OIE are attached as Annexes of the present conclusions.
It has to be remarked that the Veterinary Services are international Public Goods, for which their strengthening is considered an Essential issue, providing their unavoidable role in the surveillance and control of animal and zoonotic diseases.
It is important that the Veterinary Medicines Focal Points shall take an active part in making the proposals to OIE, through the Veterinary Services Delegates

Focal Points Training
The continuing training of the Focal Points is one of the priorities which have been established into the OIE mandate, and as such, it takes a special part into the Strategic Plan.
Regarding this, it must be outlined that next CAMEVET meeting shall include a specific training activity for all of the Veterinary Medicines Focal Points of the American continent.

VICH participation and other agreements in force
Within the framework of the agreements held by the OIE and VICH, the opportunity for the Committee to participate in the activities carried out by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products shall be evaluated.
The interaction of the CAMEVET with the continental regional and sub regional organizations is also recommended.

CAMEVET interaction with other Technical Committees and Regional Projects
It is recommendable to strengthen the interaction between the different Technical Committees which depend on the OIE Regional Representation for the Americas.

Furthermore, the CAMEVET´s active participation in the distribution of the Regional Experts List which is being carried out at the Regional Representation is required.

State of implementation of harmonized documents
The results of the revision on the state of application of the documents harmonized by the Committee were presented.
A remarkable fact is the the future application of the Central American Technical Regulation, which incorporates the work carried out by the Committee to the date.

Proposals made to the OIE related to harmonized documents
The follow up of the status of the harmonized document related to veterinary products labeling is requested to the Regional Representation, standing out that no Veterinary Services have sent this proposal formally to OIE up to the date, being this an essential issue to be arranged by all the countries.
Likewise, it is also proposed that the Secretariat shall conclude the revision of the document related to Good Usage Practices for veterinary products, to be submitted to OIE headquarters through the Regional Representation.

3. Technical topics developed during the Seminar.

Good Manufacture Practices for ectoparasiticides
The working paper prepared by the ad-hoc group, which is formed by representatives of ALANAC, CAPROVE, CLAMEVET, SINDAN, and the official representatives from Argentina and Brazil, was presented.
The document is given the status of Step III, being required the submission of the criteria and opinions by the Animal Health competent authorities and the industrial representatives from CAMEVET member countries after its distribution.
The issuing of the comments shall be made to the Secretariat, within 120 days after the distribution of the draft, being the ad-hoc group in charge of the consolidation of the observations received.

The proposal for the final document shall be submitted to the representatives by the Secretariat in the term of 60 days before the celebration of the next Seminar, for its final approval.

Proposal for registration of veterinary homeopathic products
A presentation relative to the criteria applied on the evaluation and registration of veterinary homeopathic products was made.
On these grounds, a working group formed by INFARVET, SINDAN and the official reppresentatives from Cuba, Mexico and Costa Rica is organized.
This working group shall prepare the first draft of the document, for which the status of Step I is provided, establishing a 120 days deadline for the preparation and distribution of the draft.

Criteria for the registration of dietary supplements
The working paper elaborated by the ad-hoc working group formed by the reppresentatives from CLAMEVET, CAPROVE and the official authorities from Argentina was presented.
It was agreed to assign the status of Step III to the document, being required the submission of the criteria and opinions by the Animal Health competent authorities and the industrial representatives from CAMEVET member countries after its distribution.

The issuing of the opinions shall be directed to the Secretariat, with a 90 days deadline after the circulation of the draft, being in charge the ad-hoc group of the consolidation of the observations received.
Representatives from ALANAC, SINDAN, INFARVET, INDUVET and the official delegations from Colombia and México join the working group.

Approach for the registration of phytotherapics used on veterinary medicine
A presentarion comprising the situation and the specific characteristics of phytotherapic veterinary products was carried out.
In virtue of the information presented, it was agreed that a draft working paper was needed, assigning to such the status of Step I.
ALANAC shall coordinate the ad-hoc working group, with the participation of SINDAN and the official representatives from Colombia, Costa Rica y Nicaragua.

Guideline for the registration of biotechnologically obtained veterinary products
The first draft of the guideline for the registration of biotechnologically produced subunit immunogens was presented.
The development of this document is considered of prioritary relevance, regarding the conclusions and recommendations of the 19th Conference of the OIE Regional Commission for the Americas.
The working group shall be coordinated by the official delegation from Cuba, with the collaboration of the official representatives from United States of America, Chile and Mexican United States.
The first draft of the document shall be available in 120 days for its distribution and the submission of observations shall be within the next 90 days after the circulation.

Stability of veterinary pharmacological products
The observations for the working paper were presented.
Due to the complexity related to the consolidation of the final draft, it is agreed to request to the official representatives from Uruguay for the technical support for such task, for which the official delegation from Argentina offered its participation.
A deadline of 90 days shall be set for the preparation of the consolidated draft; which shall include the observations presented and be in concordance with the adopted format for the Committee's documents.
After that term the Secretariat shall distribute such document, within a 120 days limit for the submission of comments.

Proposals for new documents to be developed

Glossary of terms and definitions
The continuity of the development of the document regarding the harmonized glossary of terms and definitions is considered as mandatory.
The official delegations from Argentina and Nicaragua, together with Caprove, CLAMEVET and INFARVET shall review the working paper, and the delegation of Brazil, together with SINDAN and ALANAC shall provide the Portuguese translation.
It is proposed that the draft of the document shall be available for its distribution 60 days before the next Seminar.

Unlawful practices in veterinary products trade
The representative of APROVET proposed the development of a concept paper related to unlawful practices in the commercialization of veterinary products, for which the status of Step I is appointed.

CAMEVET strategic plan
According to the proposal made during the Seminar, the Executive Board shall take on the development of the Committee's Strategic Plan.
Representatives from CAPROVE and CLAMEVET with the collaboration of the OIE Regional Representative for the Americas shall develop the first draft which shall be distributed within the Executive Board, and finally discussed in a formal meeting.

4. Expenses report, financial status and 2009/2010 budget

The balance sheet, the financial status and the budget were presented.
The detailed balance sheet is included in the Seminar's memories.

Available resources by August 6, 2009	6.751,00
Incomes	
• XV Seminar registration fees (U$s 200 / participant)	17.800,00
Available resources by the Seminar closure	24.551,00

Budget for the 2009/2010 financial year
Expenditures

• Personnel	4.800,00
• Office expenses	1.800,00
• CAMEVET Secretary travel expenses for XVI Seminar	3.000,00
Subtotal expenditures 2009-2010 budget	9.600,00
Estimated resources available by the beginning of the XVI Seminar	14.951,00

These figures are expressed in US Dollars

5. Other issues presented

Communications

Web page updating
The updating of the contents available at the Committee's web page is required.
It was observed that the harmonized documents were not available at the web page.

Appreciation for the Committee participants
Regarding the number of meetings made by the Committee, the sending of appreciation letters for those individuals who have participated in the formation and the advancement of CAMEVET is proposed.

Review of CAMEVET harmonized documents
It was considered that the Secretariat shall review and communicate the activities made by the Committee in order to bring them to attention to all of the interested parties.

The need to communicate the results obtained during the activities held by the Committee to the Veterinary Services and to outline the importance of the participation of the heads of the registration areas and Focal Points on Veterinary Medicines from member countries are considered necessary.

It is also recommended that the information produced during the present Seminar shall be distributed to the Chief Veterinary Officers so as an acknowledgement note for the participation of the heads of the registration areas and Focal Points on Veterinary Medicines, motivating and recommending the participation in the case of those countries which have not participated.

A special appreciation mention for the official Mexican authorities and the private sector supporting the event for the outstanding organization of the present Seminar is made.

Next Seminar organization
The proposal made by the official delegation from the Republic of Colombia was accepted, regarding the celebration of next Seminar in the Republic of Colombia.

The final date for the Seminar shall be confirmed in brief since there are many factors affecting the organization of such.

It was agreed to celebrate the 2011 Seminar in Central America.

Annexes

Annex I – Veterinary Industry Position Paper

Annex II – Official sector Position Paper

Annex III – Reccommendations and Resolutions

- Recommendation No. 1 - Biotechnology and its application to veterinary science
  19th conference of the OIE Regional Commission for the Americas

- Recommendation No. 2 - Application of OIE International Standards by Member Countries
  19th conference of the OIE Regional Commission for the Americas

- Resolution No. 25 - Veterinary products
  OIE 77th General Session - Paris, 24-29 May 2009

- Resolution No. 28 - Adoption of eleven draft chapters for the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
  OIE 77th General Session - Paris, 24-29 May 2009

Annex IV - List of acronyms used in the document

Annex I

The most important problems of the CAMEVET veterinary medicine industry

After more than 15 years of yearly meetings, first as an OIE Harmonization Seminar for the Licensing and Control of Veterinary Medicines and later as CAMEVET, the industry considers necessary to outline, as a balance, some of the important facts for the development of its activity. Like in any balance, positive and negative aspects are found, which give configuration to new problems, some of which need urgent solution.

Amongst the positive aspects it must be recognized that great advances have been made in the update of the regulations in force of the countries in the region, a very fruitful task that must be highlighted, as this has allowed to slowly put some order into the markets. From the licensing of products stand point, although not absolutely coincidental, even having agreed and recognized model application forms, the requirements are very similar, what eases the process for obtaining the required product licenses for marketing. It must also be emphasized that a free discussion and participative space has been generated where all voices can be heard. This fact stimulates the trust amongst the different actors and has allowed a more agile reach to conclusions.

Anyhow, each advance has generated at the same time new problems which need tackling, to keep up with the advancements and deepening the change.

The adoption of the CAMEVET guidelines has improved a lot. Anyhow their applicability with no flexibility generates new problems that were not expected until now. An example of this is the labelling of veterinary products, the use of phrases in different countries which are equivalent in meaning but slightly different in the wording used, brings a good deal of problems for the production of specifics destined to various markets. A less rigorous attitude from the authorities would allow a quick solution to these inconveniences.

The update of regulations has made that most of the countries of the region start the path for adopting Good Manufacturing Practices. This is a very favourable fact that should be highlighted. But again it has had unthought-of consequences. Amongst others, the important rise of the costs in production and control must be mentioned, associated to a fall in the capacity for competent authority surveillance, have led to a considerable rise of the presence of non-licensed products and contraband trade. This seems to be due to the fact that some inapprehensive actors, who face an increase in the pressure of the requirements and the lack of proper government police enforcement, shift to informal trade economies and become strong disloyal competitors.

This fact gets worse as it also leads to the development of quality differences even within the formal market, with actors that dilate indispensable investments to fulfil the laws in force, what also determines differences when competing in the market. The lack of resources of the official organisms limits the control to only the formal and proactive sector, while others receive little or no control at all.

The activity of the sector is subjected to an excess of rules. As an industry, the companies are subjected to control from various organisms. Each organism has its own regulations and often these superimpose or even oppose. It is necessary and urgent to start a path to solve this problem. This excess of regulations also eases and encourages illegal product trade.

As an attempt to solve these inconveniences in some countries some projects are starting to be developed on mechanisms intended to endue greater traceability in the marketing of veterinary products. Unfortunately some of these projects have been elaborated behind the back of the sector industry and even of the licensing authority, whereby introducing unreal elements which are only new setbacks to be tackled.

Conclusions and recommendations

Therefore, the veterinary products industry gathered in CAMEVET, request that a strong claim be sought to the Animal Health World Organization (OIE, Oficina International de Epizootias) for interceding in the sense of reaching an increase of the resources destined to the activities of manufacturing control and marketing of veterinary products. This request is based on the fact that the veterinary medicines are at the beginning of food safety and that it is unthought-of to produce safe and innocuous food without counting on good quality veterinary products. Besides the risk that this implies for our population, it will undoubtedly negatively influence international trade of products of animal origin.

In the same sense, it is necessary to request to the OIE its collaboration to increase the participation of the representatives of the official sectors in the next meetings.

Last, it is essential to look into the near future, for which it is necessary to develop a CAMEVET Strategic Plan for the next years to come and a mechanism that may allow to evaluate the activities, and update the plan according to the changes that may arise in the time to come. The industry proposes that the executive board elaborate a first draft of the plan to be considered in the next meeting.

Annex II

Americas Committee of Veterinary Medicines (CAMEVET)
Minute of the official sector meeting

Three different topics were discussed, which are related to the following issues:

1. **Promotion for the participation of the official sector in the Committee activities**
2. **Adoption of harmonized documents by Member Countries**
3. **Institutional participation of the Committee**

1. Measures needed to promote the participation of the official representatives in the Committee

Level of participation in the Seminars
As a diagnostic about the participation, the countries represented in the meeting are listed, remarking the fact that only representatives from 13 countries out of 28 Member Countries assisted to the Seminar, being less than 50% of the countries of the continent.

Another remarkable fact is that most of the countries which have not sent their representatives to the meeting have not designed their Veterinary Medicines Focal Pints to OIE.

Based on that, the measures in order to encourage the designation and participation of the Veterinary Medicines Focal Points must be taken, so as the sustainment and stability of the Focal Points in their positions, in concordance with the OIE priorities.

The need for the diffusion of the Committee´s activities is also considered, reaffirming the fact that the compromises taken by the countries of the region to the OIE.

It is also important for the Chief Veterinay Officers and the OIE Delegates to be permanently informed on the activities and the importance of the CAMEVET.
In many occasions, and due to the changes in structures and authorities, the new authorities are unaware of the actions taken by the Committee.

It is considered that the extension in the diffusion of the CAMEVET activities should have the result on the ampliation in the number of countries participating.

Financing for the participation
Another point to be consigned relates to the availability of funds for the assistance of the official representatives from those countries which have actively participated in the Seminars.

It can be considered that the lack of financial support for the participation in the Seminars is a result of the scarce interest of the Veterinary Services on the activities related to Veterinary products.

In the case of OIRSA member countries, the solicitude of the budget allocation needed for the participation of the representatives and Veterinary Medicines Focal Points is required.

Participation in the production and revision of working papers

The activities of the official sector representatives are essential for the Committee´s performance.
Due to the low response rates after the distribution of the working papers, it is considered that the heads of the registration areas and the Veterinary Medicines Focal Points shall participate actively in the revision and the submission of commentaries on the distributed documents, in order to reinforce the Committee and achieve the institutional support which is required.

The organization in electronic working groups is a remarkable fact, due to its effect on the speeding up of the preparation and revision of the documents. Besides the methodology provides an agile discussion tool, it does not supplant the participation of the official sector representatives.

2. Implementation of harmonized documents

It must be considered that the documents produced by the Committee are not mandatory for the member countries.

The exigency level set in the documents must point to a base standard, in order to balance the differences between countries.

In the case of those countries where standards are not set, the objective is their provision, and in those cases where standards are below the proposed ones, the tendence shall tend to contribute in its adequation.

This concept must be a guiding principle for the implementation of the harmonized documents, and CAMEVET must point towards the update and constant enhancement of those standards.

On the other hand, it is needed for those countries which apply the documents to make it effectively, and in case of the adoption of any measure modifying the regulations based on the documents, the communication of those measures.

3. Institutional Participation of the Committee

Within the frame of the need of the increase of the presence of the CAMEVET in the discussion forums related to veterinary products, obtaining the reincorporation of the Committee into the activities held by VICH is considered as necessary.

Annex III

19TH CONFERENCE OF THE OIE REGIONAL COMMISSION FOR THE AMERICAS
Havana, Cuba from 17 to 22 November 2008

Recommendation No. 1

Biotechnology and its application to veterinary science

CONSIDERING THAT

1. The Member Countries of the OIE Regional Commission for the Americas (hereinafter referred to as the Members) recognise the important role that modern biotechnology techniques play in veterinary science and for the benefit of the society,

2. There are differences between the Members of the region in the knowledge and use of these technologies,

3. Not all the Members have legislation regarding biosecurity related to the introduction and the safe use of the modern biotechnology tools and all should have a specific legislation with a systematic update in this field,

4. There are in the Region centres for the development of biotechnology applicable to veterinary sciences,

5. There is a need to continue developing new vaccines, products and diagnostic tools to help to identify, prevent, control and eradicate animal diseases, including zoonoses, that already affect or pose a threat to the Members,

6. The Government of Cuba has made application to the OIE for the recognition of a biotechnology Collaborating Centre which already had the support of the Regional Commission,

THE OIE REGIONAL COMMISSION FOR THE AMERICAS RECOMMENDS THAT

1. The OIE evaluate regulatory frameworks in its members on biotechnology and develop and propose a generic model that would help Members in their elaboration and implementation of biotechnology regulations.

2. The OIE Regional Representation draw up a list of experts and reference centres in the region in matters of biotechnology as they apply to veterinary science and also promote the candidature of these experts for their inclusion in the OIE Working Groups and ad hoc Groups.

3. Members, with the support of the Regional Representation, promote the exchange of experiences, joint research and cooperation in matters of biotechnology applications to veterinary science.

4. The OIE Regional Representation, through the Committee of the Americas for the Harmonization of the Registration and Control of Veterinary Medicines (CAMEVET), among

others, promote the proposal of standards and requirements for the registration and use of biotechnology based veterinary products with the aim of updating the related OIE standards. Also once adopted by the OIE International Committee, the countries incorporate and apply them in order to harmonise the systems between the different countries.

5. The OIE consider the development of communication approaches which address the potential benefits and the security given by the regulatory framework for the use of biotechnology in order to ensure that the public is informed about these technologies. In particular, training for veterinary personnel and all parties involved should be promoted.

6. The Members of the Region reaffirm the support and endorsement of the application made by the Government of Cuba for the recognition of a Collaborating Centre for Biotechnology in Animal Production.

(Adopted by the OIE Regional Commission for the Americas on 21 November 2008 and endorsed by the International Committee of the OIE on 28 May 2009)

19TH CONFERENCE OF THE OIE REGIONAL COMMISSION FOR THE AMERICAS

Havana, Cuba from 17 to 22 November 2008

Recommendation No. 2

Application of OIE International Standards by Member Countries

CONSIDERING THAT

1. The OIE is the international organisation that sets technical reference standards and guidelines and adopts resolutions under its own activities and under a mandate given within the Agreement on the application of Sanitary and Phytosanitary Measures of the World Trade Organisation (WTO) to enable the safe international trade of animals and animal products and to prevent the transmission of animal diseases, including zoonoses,

2. The OIE standards are scientifically based, avoiding that the trade of animals and animal products is not slowed down for arbitrary reasons,

3. The OIE has transparent and democratic mechanisms that permit the active and permanent participation of all its Members for the update and development of new standards,

4. Importing countries should undertake to adopt zoosanitary requirements in accordance with an appropriate level of protection, based on OIE standards and guidelines. Exporting countries, for their part, should draw up measures, based also on the OIE standards and guidelines, that should guarantee to the importing countries the compliance with these requirements,

5. Countries do not always comply with international standards when they establish zoosanitary requirements for the international trade of animals and animal products, resulting in scientifically unjustified barriers to trade between countries,

6. The majority of Members have a low participation in the process of commenting and contributing to the elaboration of the OIE standards,

7. The best international experts of the Region are part of the OIE Specialist Commissions and they are proposed by the Members of the Region,

8. The interpretation of the established standards is sometimes not consistent between the Members, depending on their interests,

9. Food safety is part of the process for complying with the standards and part of the sanitary bilateral negotiation which may be the cause of trade problems linked to animal health,

10. The countries, especially the less developed, have difficulties to achieve a zoosanitary negotiation relative to the animal health and food safety of the animal origin food products,

11. Decision making regarding zoosanitary negotiation implies a complex relationship between the Veterinary Services and other public and private sectors,

12. The OIE possesses a scientifically based mediation mechanism available to its Members in order to resolve trade issues related to animal health,

THE REGIONAL COMMISSION FOR THE AMERICAS RECOMMENDS THAT

1. The knowledge and understanding of the scientific principles of the OIE standards and the specific content of the OIE Codes and Manuals among Member Countries be promoted.

2. The OIE continue to support its Members in the strengthening of their technical capacities and in the management and good governance of the Veterinary Services in order to comply with the OIE international standards and to give sufficient guarantees to the importing countries while allowing them to have the necessary tools for a fair bilateral zoosanitary negotiation and the resolution of conflicts.

3. The countries continue to work on the mechanisms to incorporate food safety aspects that are linked to OIE standards. In the same way, the OIE continue and pursue its work of coordination with the Codex and the incorporation, in the Code, of items related to the safety of food of animal origin related to international trade.

4. The OIE continue to support the governments, through the OIE Regional Representation for the Americas and the Sub-Regional Representation for Central America, to organise seminars and to improve the awareness of the public and private sectors to the importance of the OIE international standards and the conditions for their application.

5. When Members identify a difference in interpretation or potential impediments to the practical implementation of a standard, the matter should be referred to the Regional Representative and to the respective Specialist Commission for clarification or the possible consideration of a revision of such standard in accordance with the best available science.

6. Coordinated by the OIE Regional Representation, the active and permanent participation of all the OIE members in the process of the development of international standards as well as a close interaction with the elected members in the OIE Specialist Commissions, especially those of the Region, be promoted.

7. Members fully incorporate and apply the OIE standards and resolutions. Special attention should be given to the OIE official sanitary status recognition.

8. All the regional organisations should have common strategies for the control of transboundary diseases and their implications to trade. In parallel, it is recommended to develop regional protocols for establishing health and trade contingency plans to face health events.

9. The countries ask for the OIE intervention through the technical mediation mechanism for solving disputes when trade restrictions occur related to animal health and food safety of food of animal origin.

10. The OIE continue and intensify its work of support to the Members for the strengthening of the Veterinary Services, through the PVS tool and other activities, including the leadership of the Veterinary Services on the aspects of the public-public and public-private coordination for the compliance with the OIE standards.

11. The OIE/FAO GF-TADs Agreement will be used to continue supporting the implementation of OIE standards by Member Countries.

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(Adopted by the OIE Regional Commission for the Americas on 21 November 2008 and endorsed by the International Committee of the OIE on 28 May 2009)

RESOLUTION No. 25
Veterinary products

CONSIDERING

1. That during the 62nd General Session of the OIE in May 1994, the International Committee adopted Resolution No. X, endorsing the need for initiatives and programmes, supported by the OIE and the Delegates of the OIE Members, to foster the harmonisation of registration requirements for veterinary drugs,

2. The role and the work of the OIE in promoting the responsible and prudent use of antimicrobials in terrestrial and aquatic animals so as to preserve their therapeutic efficacy and prolong their use in both animals and humans, and in promoting the monitoring of antimicrobial resistance (Resolution No. XXV of the 69th General Session 2001, Resolution No. XXX of the 71st General Session 2003, Resolution No. XXXIII of the 74th General Session 2006, and Resolution No. XXVIII of the 75th General Session 2007),

3. That during the 74th General Session of the OIE in May 2006, the International Committee adopted Resolution No. XXXII on the recognition and implementation of OIE standards for the validation and registration of diagnostic assays by OIE Members,

4. The recommendations adopted during the OIE conference on veterinary medicinal products in Africa, "Towards harmonisation and improvement of registration, distribution and quality control", which took place in March 2008 in Dakar, Senegal,

5. The active support of the VICH initiative (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) by the OIE,

6. The setting up by the OIE of two new ad hoc Groups on biotechnology: one devoted to vaccines and the other to molecular diagnostic tests,

7. The existence of OIE, standards, guidelines and recommendations related to veterinary products and quality standards for veterinary laboratories and vaccine production,

THE COMMITTEE

RECOMMENDS THAT OIE MEMBERS

1. Promote and enhance in their respective countries good veterinary governance, which includes the compliance of Veterinary Services with OIE international standards, as an instrumental and essential prerequisite to the establishment and effective implementation of adequate and appropriate legislation covering all aspects of products for veterinary use, including registration, quality control, distribution and final use.

2. Develop and improve international and regional cooperation in the establishment and enforcement of legislation to harmonise the regulatory framework between Members so as to assist countries in need to effectively institute and maintain such mechanisms.

3. Allocate appropriate human and financial resources to Veterinary Services and laboratories to correctly implement the OIE standards and guidelines related to veterinary products and their control.
4. Nominate a national focal point for OIE on matters related to veterinary products according to the suggested Terms of Reference and encourage his/her participation in training sessions and appropriate international gatherings and meetings.

5. Promote the responsible and prudent use of veterinary medicinal products, in particular of antimicrobials used in veterinary medicine, and the monitoring of the potential existence or development of antimicrobial resistance.
6. Actively encourage the recognition and application of the international recommendations, guidelines and tools developed by the OIE and adopted by the International Committee on veterinary products.

AND THAT THE OIE

1. Continue to develop and update standards, guidelines and recommendations on diagnostic tests, vaccines and veterinary drugs, including antimicrobials.
2. Continue to work on the use of biotechnologies to improve vaccines and diagnostic tests, as well as on the innocuity of recombinant vaccines with regard to food safety.
3. Continue to strengthen capacity building activities including training particularly directed at Delegates and focal points, to enable OIE Members to organise, manage and implement appropriate legislation for veterinary products including registration, quality control, distribution and final use of veterinary products preferably using a regional or sub-regional basis.
4. Provide and promote communication on OIE standards, guidelines, and recommendations related to veterinary products, particularly on veterinary drugs and vaccines.
5. Continue to actively participate in and support VICH activities and to share outcomes with OIE Members with a view to promoting VICH guidelines at global level.
6. Develop and improve collaboration with relevant international and regional organisations on issues related to veterinary products and, whenever appropriate, in support of the mandate of the OIE.
7. Include and strengthen all above-mentioned matters within the Fifth Strategic Plan of the OIE.

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(Adopted by the International Committee of the OIE on 28 May 2009)

RESOLUTION No. 28

Adoption of eleven draft chapters for the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CONSIDERING THAT

1. The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual), like the Terrestrial Animal Health Code, is an important contribution to the international harmonisation and promotion of trade in animals and animal products,
2. A revised edition of the printed version of the Terrestrial Manual is published approximately every four years. It is the intention of the OIE and of the Biological Standards Commission that, following approval of changes by the International Committee, the Web version of the Terrestrial Manual will be updated on an annual basis,
3. Member Countries and Territories have been asked for the contributions of their specialists for the proposed eleven revised chapters of the Terrestrial Manual before they are finalised by the Biological Standards Commission,
4. All chapters for the revised edition have been sent to Member Countries and Territories, and the Biological Standards Commission will address any pending comments,

THE COMMITTEE
RESOLVES

To adopt the eleven updated chapters of the Terrestrial Manual.

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(Adopted by the International Committee of the OIE on 28 May 2009)

Annex IV – List of acronyms used in the document

ALANAC	Asociación de Laboratorios Farmacéuticos Nacionales (Brasil)
APROVET	Asociación Nacional de Laboratorios de Productos Veterinarios (Colombia)
CAMEVET	Comité de las Américas de Medicamentos Veterinarios
CAPROVE	Cámara Argentina de Productos Veterinarios (Argentina)
CLAMEVET	Cámara de Laboratorios Argentinos Medicinales Veterinarios (Argentina)
GF-TADS	Global Framework for the Progressive Control of Transboundary Animal Diseases - Programa Global para el Control Progresivo de las Enfermedades Transfronterizas de los Animales
INDUVET	Industria Veterinaria – Cámara Regional de la Industria de Transformación del Estado de Jalisco (México)
INFARVET	Industria Farmacéutica Veterinaria - Cámara Nacional de la Industria Farmacéutica (México)
OIE	Organización Mundial de Sanidad Animal
OIRSA	Organismo Internacional Regional de Sanidad Agropecuaria
SINDAN	Sindicato Nacional da Industria de Produtos para Saúde Animal (Brasil)
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products