

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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**Agenda Item 6**

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## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

**Twelfth Session Session**

**Washington, D.C., 28 - 31 March 2000**

#### **REPORT ON OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH)**

(Prepared by the OIE Collaborating Centre for Veterinary Medicinal Products)

#### **1. EUROPEAN SCIENTIFIC CONFERENCE "USE OF ANTIBIOTICS IN ANIMALS AND PUBLIC HEALTH PROTECTION"**

A European scientific conference entitled "The use of antibiotics in animals - Ensuring the protection of public health" was organised by the OIE collaborating centre for veterinary medicinal products, at the headquarters of the Office International des Epizooties (OIE) in Paris on 24-26 March 1999. The conference, which was attended by 280 participants from 29 countries, focused on means of implementing strategies to control antibiotic resistance arising from the use of antibiotics in animals. The summary and recommendations were adopted by the participants in plenary during the final session. The text was based on the presentations of papers and results of the three working groups established before the conference which dealt with the three following topics: analysis of the risks for public health, prudent use of antibiotics in animals and resistance monitoring.

Risk analysis is an important tool for estimating the potential risks for public health related to the use of antibiotics in animals based on scientific data and for taking the appropriate decisions in a transparent fashion. The conference recommended that studies should be carried out to provide the scientific data necessary to characterise and quantify these risks. The conference also recognised the need for establishing the risk management procedure and applying transparency rules for its implementation. The content of the precautionary principle as well as the conditions of its implementation, including the involvement of all interested parties, should be specified.

The conference furthermore agreed to support a set of principles for prudent use of antibiotics in animals which is mainly determined by the marketing authorisation conditions. It recommended a structured education programme about the therapeutic value of antibiotics in human and veterinary medicine and the responsible and prudent use of antibiotics.

Moreover, the conference proposed the establishment of a European antibiotic resistance monitoring system bacteria of animal origin. The purpose of the monitoring system is to detect the emergence of antibiotic resistance in those bacteria, which could present a potential public health risk.

A conference should be organised in a year's time to follow up the issues and evaluate progress of the recommendations.

## **2. PARTICIPATION IN MEETINGS ON ANTIMICROBIAL RESISTANCE**

### **2.1. Joint WHO/MZCP/WHO-CC workshop on the surveillance and monitoring of antimicrobial resistant foodborne bacteria**

The collaborating centre represented the OIE at this workshop on the surveillance of antimicrobial resistant foodborne bacteria which was held on 29-30 October in Heraklion (Crete). This meeting, which was organised by WHO, was intended for the representatives of ministers in charge of health and agriculture and microbiology laboratories from 10 Mediterranean countries.

The activities of the OIE collaborating centre regarding antimicrobial resistance and the importance granted by the OIE member countries to the risk analysis approach in this context raised much interest from most participating countries.

The workshop recognised the complexity of the topic which cannot be studied through a simplifying approach. It also underlined the importance of a quality assurance programme for laboratories working in this field and the need for standardising the methodologies used in order to obtain reliable and comparable data.

Even if very few countries currently have an official system for the surveillance of antimicrobial resistance, there are nevertheless a few limited activities in certain microbiology laboratories. As discussions showed that *salmonella thyphimurium* infections were the major public health problem in most countries participating in this meeting, participants agree to become involved in the surveillance of the resistance of salmonella to antibiotics in their countries.

To this end, a training workshop on laboratory techniques will soon be organised. Moreover, it appeared useful to contemplate organising the microbiology laboratories involved in this work into a network in the near future.

The Greek representatives, who were interested in the risk analysis approach, expressed their desire to organise a seminar on the application of this concept to antimicrobial resistance in collaboration with the OIE collaborating centre.

### **2.2. FDA workshop on the microbiological safety of antibacterial animal drug residues in food**

J. Boisseau participated in the workshop organised by the FDA on 20 and 21 September which intended to compare the *in vitro* and *in vivo* methodologies used to assess the microbiological risk for human intestinal flora related to antibiotic residues susceptible to contaminate food of animal origin.

### **2.3. Tripartite OIE/FAO/WHO meeting**

At the request of the OIE, a tripartite meeting of the OIE, FAO and WHO was held on 28<sup>th</sup> September at the offices of WHO in Geneva. In order to properly manage the complementarity of the actions undertaken by these three organisations, the OIE wished to exchange information with its international sister organisations FAO and WHO on the five following topics:

- Actions at present undertaken by the OIE, FAO and WHO
- Future projects for the coming years
- Degree of implication and respective responsibility of each organisation in the above mentioned actions and projects
- Points on which a co-operation between FAO, OIE and WHO should be organised through action plans
- Legal status of the documents produced by OIE, FAO and WHO

## **3. CONFERENCES ON VETERINARY MEDICINAL PRODUCTS**

### **3.1. 9<sup>th</sup> International Technical Consultation on Veterinary Medicinal Products (ITCVMP)**

The 9<sup>th</sup> ITCVMP was jointly organised by the Vietnamese Ministry of Agriculture and Rural Development and the OIE collaborating centre for veterinary medicinal products in Hanoi, Vietnam on

6-9 April 1999. The topics addressed during this conference, in which more than 100 individuals participated, were the national veterinary pharmaceutical legislation of Asian countries, the international harmonisation related to veterinary medicinal products in the frame of Codex Alimentarius, FAO/ WHO (JECFA) and OIE (VICH), the impact of the use of antimicrobial agents in animal husbandry on public health and aquaculture. In addition to its responsibilities pertaining to the scientific programme of this conference, the OIE Collaborating Centre presented speeches on the following topics: VICH, MRL and minor species, risk analysis and antimicrobial resistance, OIE report on antimicrobial resistance, prudent use of antibiotics in animal husbandry. A series of recommendations was adopted by the conference.

### **3.2. 4<sup>th</sup> seminar on veterinary medicinal products in Africa**

The OIE collaborating centre for veterinary medicinal products organised, on behalf of the OIE, the 4<sup>th</sup> seminar on veterinary medicinal products intended for French-speaking African countries. This seminar, which was opened by M. Mballo, the minister in charge of animal husbandry in Senegal, was held from 6 to 10 December 1999 at the Inter-State School of Veterinary Sciences and Medicine in Dakar (Senegal). It involved 40 individuals, heads of animal husbandry or veterinary services and veterinary pharmacy offices, originating from 14 countries participating in different inter-state African organisations, i.e. UEMOA (West African Economic and Monetary Union), CEMAC (Central African Economic and Monetary Community) and ECOWAS (Economic Community of West African States).

The programme of this seminar included 6 sessions on the main topics considered as a priority within this African sub-region,

- veterinary pharmaceutical regulations and their possible harmonisation
- manufacturing, importation and distribution of veterinary medicinal products
- the good use of veterinary medicinal products and public health protection (residues and antimicrobial resistance)

The participants in this seminar:

- enthusiastically agreed that the 10<sup>th</sup> international technical consultation on veterinary medicinal products takes place in Bamako, Mali in one year. This international forum, which is closely followed by the authorities involved and the veterinary pharmaceutical industry, makes it possible to review current topics regarding veterinary medicinal products every two years.
- Wished that the OIE pursues its training programme which is most beneficial.

## **4. INTERNATIONAL HARMONISATION - VICH**

### **4.1. 5<sup>th</sup> and 6<sup>th</sup> VICH steering committees**

J. Boisseau, head of the OIE collaborating centre for veterinary medicinal products, chaired the 5<sup>th</sup> meeting of the steering committee of the VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) in Rockville, Maryland (USA) on 18-20 May 1999 as well as the 6<sup>th</sup> meeting of the steering committee on 15, 16 and 19 November in Brussels.

The steering committee:

- adopted 10 final VICH guidelines (implementation in November 2000) and five draft guidelines for consultation
- reviewed a strategic plan for VICH and agreed to establish a working plan for future years.
- amended the organisational charter of VICH, particularly regarding the status of observers, the specific role of the OIE and the mechanism of the rotating chairmanship.
- endorsed the creation of two additional working groups on the following topics: Antimicrobial resistance and Target Animal Safety. The mandate of the antimicrobial resistance working Group is to elaborate requirements on pre-approval studies needed to predict the potential of antimicrobials to develop resistance.

The 7<sup>th</sup> meeting of the steering committee was scheduled for 14-16 June 2000 in Tokyo, Japan.

## **4.2. VICH1 public conference**

Over 280 delegates, representing European countries, Japan and the United States as well as Saudi Arabia, South Africa and Mexico met in Brussels on 17-18 November at the first VICH Conference. VICH is an international co-operation programme set up between Japan, EU and the USA to develop international guidelines for the registration of veterinary medicinal products. Australia and New Zealand also participate as observers.

The conference was opened by Dr Jean Blancou, Director General of OIE. He commended VICH members on the results obtained in areas such as: stability and impurities tests, environmental impact assessment, quality approach in respect to clinical trials and efficacy of anthelmintics.

These results are consigned in a set of 12 guidelines developed during the first three years of the VICH process.

The VICH conference provided an opportunity for non-VICH participants to make comments on specific guidelines and the VICH process in general.

The last session chaired by J. Boisseau and which was devoted to the activities of the working groups and the reports of the different workshops held during the conference, was particularly interesting for the participants who could consider the work achieved as well as the results obtained in international harmonisation. Many comments focused on how non-VICH participants could comment on guidelines under development, recognising their potential international impact, and they encouraged even greater transparency in the VICH process.

In closing the conference, N. Hirayama, from Japanese MAFF, recognised "the achievements of VICH in bringing together industry and regulatory agencies from countries with different cultures, languages and customs". M. McGowan from the US Animal Health Institute acknowledged "the major benefits that will accrue to industry from common data requirements in the VICH regions, as well as facilitating the availability of new innovative veterinary products."

In his closing speech, J. Blancou, Director General of the OIE, expressed the OIE's gratitude to J. Boisseau for its contribution to the creation of VICH as well as his success as chairman of the steering committee over the first three years of the implementation of VICH.

## **5. TRAINING**

Yuriy Kosenko, from the Laboratory of Expertise and Approbation of the State scientific-research control Institute of Veterinary Preparations and Food Additives in Ukraine, Maria Szabo, from the Hungarian State Control Institute for Veterinary Biologicals, Drugs, Feeds and Registration, and Najat El Alami, Khadija Id Sidi Yahia and Mourad Drhimer from the Moroccan National Laboratory for the Control of Veterinary Drugs performed training periods at the ANMV in Fougères in 1999.

## **6. INFORMATION**

### **Web site**

The OIE collaborating centre published a web site dedicated to its activities ([www.anmv.afssa.fr/oiecc](http://www.anmv.afssa.fr/oiecc)). The site contains the annual report of the collaborating centre and reports of conferences and announces forthcoming events. It also contains draft texts, such as the code of prudent use of antimicrobial agents, on which comments can be made.