Inter-American registered veterinary products compendium *


Summary: The authors describe the efforts of the Inter-American Institute for Cooperation in Agriculture (IICA) to set up an information system for registered veterinary products. The goals of this system include: identification of national laws and regulations, use of efficient methods for maintaining a data base on veterinary drugs, and publication of data from member countries in the form of compendia. Various extensions of this programme are also planned, e.g. development of a model drug registration system and listing of other veterinary products such as biologicals.

KEYWORDS: Americas - Data bases - International cooperation - Legislation - Registration procedures - Veterinary products.

Information sharing in most disciplines of the veterinary medical sciences and between most countries of the world is extensive. In the areas of drug regulation, drug approval, feed additive registration, and drug and chemical residues of animal origin that represent a risk to the public health, the world literature is less extensive. The reasons are multiple and include political as well as commercial proprietary considerations. The primary reason, though, seems to be the lack of an organised system to collect and manage the data. The United States Food and Drug Administration (FDA) became particularly concerned about the situation in 1979 when through the judicial process, the government elected to ban the use of diethylstilbestrol (DES). The FDA was asked by a number of governmental agencies, by the Congress and by consumer groups to provide the rationales invoked in other countries for the decision either to ban or maintain DES. The FDA attempted to obtain this information and generally found it unavailable except by word of mouth.

The logistics of obtaining, compiling and managing a comprehensive international data base on drug information has been thought to be difficult. Each country of the world has its own system of registering drugs and animal feed additives. As Blajan and Meissonnier have pointed out (1), while it is justifiable that the approval
procedures for veterinary drugs be the responsibility of individual countries, it seems desirable that all countries should have access to a certain amount of information regarding registered products in other countries.

Conditions of use, dosages and species in which use of a compound is approved vary among countries. Critical parameters such as withdrawal times, detection methodology and allowable drug combinations also vary widely. My colleague and co-author of this paper, L.V. Meléndez, presented a paper in 1983 defining the importance of having such information available for the enhancement of international trade and human as well as animal health (3).

During 1984 several member countries of the Inter-American Institute for Cooperation in Agriculture (IICA) expressed the need to start obtaining information in these areas. The need was formally attested to by a resolution passed at the Second Meeting of the Inter-American Commission on Animal Health held in May 1985 in Brasilia (2). All member countries of IICA signed the resolution. The US Food and Drug Administration and the US Department of Agriculture agreed to assist with the funding of the project.

The objective of the project is to develop and implement a system to collect, analyse and manage data concerning registered veterinary products from member countries of IICA. The specific aims are to:

1. identify appropriate officials and agencies in each country and obtain the laws and regulations used to register veterinary products;
2. develop a system for receiving and sending back information to each country;
3. define the data elements and the standardised nomenclature for the information management system;
4. evaluate commercially available information management systems and develop one which is appropriate for use on the project;
5. publish compendia utilising the data collected;
6. develop mechanisms to update the data base and means to make the project self-supporting;
7. develop means to provide immediate access to the data base and logic systems electronically, for member countries and organisations in need of the data.

To date, the first four specific aims have been accomplished, and a compendium summarising the laws and regulations and the responsible agency in each country has been published.

The system for obtaining data and communication with the responsible officials in each country has been developed using the official structure of IICA. The Animal Health officers of the member countries together with the respective officers of IICA are the key personnel that provide the liaison and obtain the essential data for the project. This approach proved quite effective in attaining the first objective as evidenced by the cooperation of 26 of the 28 IICA countries.

The first data collected were the laws, regulations, official structures and agencies responsible for registration of veterinary products. These data have now been catalogued, analysed, summarised and published in both English and Spanish editions.
Data elements and standardised nomenclature for the information base have been defined. Where possible, medical nomenclature being used is a subset of Standardized Nomenclature of Medicine (SNOMED) called Standardized Nomenclature of Veterinary Medicine (SNOVET). SNOVET has recently been adopted by the American Veterinary Medical Association for veterinary medicine in general. In our data base, all generic and ingredient names, where applicable, use standard international nonproprietary names (INN) published by the World Health Organisation, the United States Adapted Names (USAN) and the USP Dictionary of Drug Names. Proprietary names, as published by the organisation marketing or providing the product, are used. The data elements for the information system are:

a) Country registering the drug  
b) Official number of the drug  
c) Status regarding use (Rx or OTC)  
d) Date of first official approval  
e) Route(s) of administration approved  
f) Trade name  
g) Ingredients  
h) Company providing  
i) Species for which the drug is approved for use  
j) Form of the drug  
k) Concentration of the active ingredients  
l) Withdrawal time prior to slaughter of food animals  
m) Milk withholding time  
n) Tissue residues allowed.

During the past year we evaluated several commercial data base management systems. These included Datatrieve and SPIRES on main-frame computers, Power-Base, Reflex, SAvvy, Knowledgeman, Framework, and dBASEIII on 80286 microprocessor machines. We chose dBASEIII and have since updated to dBASEIII PLUS.

To date, we have received registered product data from over fifteen of the IICA countries. Information on a total of over 10,000 products has been received and entered into the data bases (Table I).

During the past year we also have designed report generating systems to make publication of the compendia and other reports as convenient as possible. Information directly from the data base is formatted by a computer and printed on our laser printers.

During this year and next year the last three specific aims will be accomplished and compendia of the registered products published. We are hopeful that the countries that have not as yet reported will be able to submit their data so that there will be no omissions in this important compendium series. We recognise that lack of sufficient human resources to carry out reporting is a serious problem in many of the countries
### TABLE I

**Registered product data received by IICA**

<table>
<thead>
<tr>
<th>Country</th>
<th>Products reported</th>
<th>Country</th>
<th>Products reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>—</td>
<td>Guatemala</td>
<td>—</td>
</tr>
<tr>
<td>Barbados</td>
<td>—</td>
<td>Guyana</td>
<td>—</td>
</tr>
<tr>
<td>Bolivia</td>
<td>83</td>
<td>Haiti</td>
<td>18</td>
</tr>
<tr>
<td>Brazil</td>
<td>1,196</td>
<td>Honduras</td>
<td>971</td>
</tr>
<tr>
<td>Canada</td>
<td>848</td>
<td>Jamaica</td>
<td>36</td>
</tr>
<tr>
<td>Chile</td>
<td>339</td>
<td>Mexico</td>
<td>70</td>
</tr>
<tr>
<td>Colombia</td>
<td>1,066</td>
<td>Panama</td>
<td>708</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>—</td>
<td>Paraguay</td>
<td>49</td>
</tr>
<tr>
<td>Dominica</td>
<td>105</td>
<td>Peru</td>
<td>50</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>20</td>
<td>Saint Lucia</td>
<td>—</td>
</tr>
<tr>
<td>Ecuador</td>
<td>1,210</td>
<td>Suriname</td>
<td>—</td>
</tr>
<tr>
<td>El Salvador</td>
<td>—</td>
<td>Uruguay</td>
<td>964</td>
</tr>
<tr>
<td>Grenada</td>
<td>38</td>
<td>United States</td>
<td>1,327</td>
</tr>
</tbody>
</table>

but we also believe that completion of this phase of the project will contribute to developing the necessary expertise for expanding and harmonising the registration procedures in those countries.

Because there are considerably more drugs already reported than we had estimated, it will probably take most of the current year to enter, review and verify the accuracy of the data. During this year we have also begun development of the mechanisms to update the data base and keep it current. We are also exploring means of making the updating and publication of future editions of the compendium self-supporting. Lastly, we are developing means to provide immediate electronic access to the data base for member countries and organisations.

We also have begun plans to utilise the information gathered to date to develop a model registration system for consideration by the countries. We hope that development of such a model system can take place through continued cooperative efforts by the countries so that we can receive continual input and comments during the development phases. This system, which we envisage as taking the best components from all of the existing systems and then automating them for use on computers, would thus be available to participating countries for adaptation to their own unique situation. In addition, we are seeking financial support to add registered veterinary biologicals to the drug data base. The system for managing this extension is in place and we believe it will be advantageous to the countries to have all data on drugs, feed additives and biologicals on one information system.

In summary, the work has progressed according to schedule. A system has been established for obtaining the data, and more than 15 of the 28 countries have replied. We hope the remaining ones will have their data to us in time for publication. An information system has been developed for managing the data and preparing it for publication. We look forward to the publishing of the compendium and to work on the next stage of the project which will be to develop a model registration system for adaptation and use by those countries desiring to harmonise efforts in this area.
We also look forward to expanding the data base to include biologicals and possibly even to working with other countries in the world that may want to join in these efforts.

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COMPENDIUM INTER-AMÉRICAIN DES PRODUITS VÉTÉRINAIRES ENREGISTRÉS.

Résumé : Les auteurs décrivent les efforts accomplis par l’Institut Inter-américain de Coopération en Agriculture (IICA) en vue de mettre en place un système d’information sur l’enregistrement des produits vétérinaires. Ce système a pour objectifs : l’identification des législations et réglementations nationales, l’utilisation de méthodes efficaces pour le maintien d’une base de données sur les médicaments vétérinaires et la publication des données fournies par les Pays Membres sous la forme de compendiums. Il est prévu d’étendre ce programme à des domaines tels que la mise au point d’un système harmonisé d’enregistrement des médicaments et d’une liste d’autres produits à usage vétérinaire, notamment des produits biologiques.

MOTS-CLÉS : Amériques - Bases de données - Coopération internationale - Législation - Procédures d’enregistrement - Produits vétérinaires.

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COMPENDIO INTERAMERICANO DE PRODUCTOS VETERINARIOS REGISTRADOS.

Resumen: Los autores describen los esfuerzos efectuados por el Instituto Interamericano de Cooperación para la Agricultura (IICA) con miras a implantar un sistema de información sobre el registro de productos veterinarios. Los objetivos de este sistema son: identificación de las legislaciones y reglamentaciones nacionales, utilización de métodos eficaces para el mantenimiento de una base de datos sobre los medicamentos veterinarios y la publicación de los datos proporcionados por los Países Miembros en forma de compendios. Se ha previsto ampliar este programa a otros campos, como la creación de un sistema modelo de registro de medicamentos y de una lista de otros productos de uso veterinario, especialmente los productos biológicos.

PALABRAS CLAVE: Américas - Bases de datos - Cooperación internacional - Legislación - Métodos de registro - Productos veterinarios.

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REFERENCES