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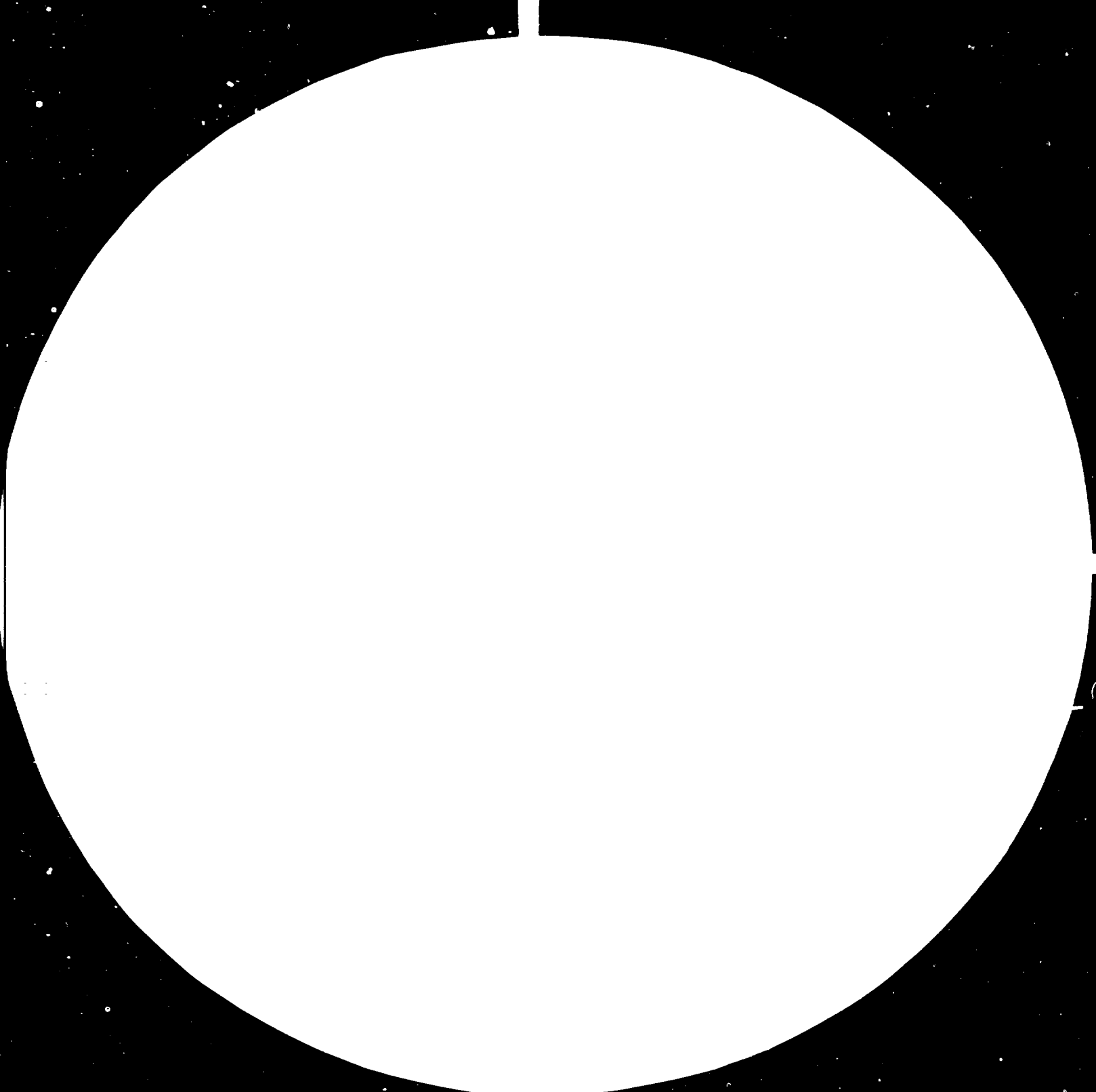
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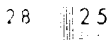
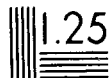
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UNITED NATIONS INDUSTRIAL
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Ad Hoc Expert Group Meeting on the Production
of Veterinary Drugs in Developing Countries

Vienna, 25 - 28 March 1980

R E P O R T**

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INTRODUCTION

The Lima Declaration and Plan of Action for Economic Co-operation and Development calls for the share of developing countries in total world industrial production to increase to at least 25 per cent by the year 2000. The world production of pharmaceuticals in 1976 amounted to US\$ 42.3 billion out of which about 10 per cent was the share of developing countries. This reveals the wide gap which exists between the current level of production in developing countries and the target embodied in the Lima Declaration.

Most of the developing countries have a large population of livestock. However, the animals very often suffer from malnutrition and contagious diseases, resulting in high mortality rate and posing a risk to human health. Since UNIDO is actively involved in programmes for the production of drugs for human use, it is appropriate that programmes for the production of drugs for veterinary use be developed based on the needs of the developing countries. Furthermore, the production of veterinary drugs is similar to that of drugs for human use and the same facilities can be used with minor adjustments. At present the requirements of veterinary drugs in developing countries are met mostly through imports. In view of this, an exchange of information on the disease pattern amongst livestock in developing countries and requirements of drugs for veterinary use assumes considerable importance.

More specifically, UNIDO is endeavouring to assist developing countries in this special industry by providing information through consultations and technical co-operation amongst developing countries. One possible area is the subject of the meeting.

The purpose of the meeting was to identify the needs for veterinary drugs and to develop programmes for production in developing countries in the existing facilities for the production of formulations for human use as well as establish new facilities for production.

Organisation of the Meeting

The meeting which took place in Vienna from 25 to 28 March, 1980 was opened by Ms. A. Tcheknavorian-Asenbauer, Chief, Pharmaceutical Industries Unit, UNIDO. She emphasised the importance of animal health particularly in the developing countries and the urgent need for an adequate supply of animal health products in these countries. Most of these countries still depend to a large extent on imports to meet their requirements of these products. Since the production of veterinary drugs is similar to that of drugs for human use, the existing facilities for the production of pharmaceuticals could be utilised for the production of veterinary drugs. She was confident that the Ad Hoc Expert Group Meeting being attended by well known experts from both the developed and developing countries would give direction and lay down guidelines for developing and implementing programmes for the production of drugs for veterinary use.

Ms. Tcheknavorian suggested that, after the presentation of the papers by the participants, detailed discussions be carried out in order to formulate a plan of action for the production of veterinary drugs.

Adoption of the Agenda

The agenda was adopted and it was agreed that the length of the presentation of papers and the duration of the ensuing discussions be kept flexible according to the interest shown.

Precis of the Meeting

13 experts presented papers on disease patterns in animals in developing countries, requirements of drugs for veterinary use, important drugs and biologicals needed, facilities needed for the production of drugs and the economics of production. After presentation of the papers, detailed discussions ensued. The meeting also constituted subgroups to finalise recommendations on different aspects which were subsequently ratified by the meeting. The draft report was adopted by the meeting. Summaries of the papers are given below.

The Production of Drugs for Veterinary Use and the Role of
UNIDO by A.Tcheknavorian-Asenbauer

Ms.Tcheknavorian described briefly the organizational structure of UNIDO, its aims and objectives with particular reference to the activity of the Pharmaceutical Industries Unit. The significance of the Lima Declaration calling for making every effort to increase the share of world industrial production in developing countries to 25 per cent by the year 2000 was explained. Recognising the importance of implementing the health programme required to achieve the target of "Health for all by the year 2000", WHO and UNIDO entered into an agreement in 1979 to co-ordinate the efforts of the two organizations.

The role of the system of consultations organised by UNIDO to establish dialogue between developed and developing countries was also explained.

She highlighted the policies and programmes developed by UNIDO with the assistance of the developing countries and experts to facilitate the growth and development of the pharmaceutical industry in such areas as production policies, TCDC, programmes for the transfer of technology, utilisation of medicinal plants etc. There has been considerable increase in the interest taken by developing countries as reflected in the increase of projects within the UNIDO Pharmaceutical Industries Unit. She also emphasised that the orientation of the type of projects has changed from simple technical assistance to the establishment of pilot plants or industrial scale operations such as the formulation and packaging units and multipurpose plants.

Ms.Tcheknavorian emphasised the importance of animal health and the urgent need for an adequate supply of drugs for veterinary use in developing countries. The existing production capacities for pharmaceuticals for human use in many developing countries are underutilised and these could be used for producing veterinary drugs.

She also emphasised the importance of producing some of the essential drugs in developing countries in order to develop the technological and industrial infrastructure and also to increase the technological capabilities of the developing countries. The drugs produced should obviously be according to the prevalent disease pattern. It is necessary to formulate programmes for production and training of personnel.

Paper presented by Prof. Fung Ki Fai, China

Animal Disease Pattern in China

Swine - pasteurellosis, mycoplasmal pneumonia
erysipelas, infectious atrophic rhinitis
blood diarrhoea, Toxoplasmosis, selenium deficiency

Fowl - marek diseases, infectious Laryngotracheitis,
Bursal diseases

Sheep
and - Lungworms, liver-flukes, nasal fly
Goats

Cattle - liver-flukes, grubs, trypanosomiasis, piroplasmosis,
mastitis, uteritis

Camels - Trypanosomiasis, lungworms

Horses - Gasterophilosis.

Drugs needed:

biological products:

vaccines for: rabies, mink enteritis, mink, canine distemper,
felinepanleukopenia, pseudo-rabies (for pigs)

antigens for: African swine fever, infectious bursal disease,
chicken embryo lethal organ virus, egg dropping
syndromes

Strains needed for research:

Streptomyces ranamyceticus
" spectabilis
" basiliense
" fradiae
E.coli K-99 strain

Drugs China can offer abroad:

antibiotics, sulfa drugs, anti-parasitic drugs,
vaccines, sera and diagnostics and other drugs of
108 kinds are recommended.

Strains provided for technical communication:

36 strains are provided

Paper presented by Prof.F.Awad, Egypt

Biologicals and veterinary drugs in the Middle East

It should be emphasised that in combatting diseases in these areas, there are only two methods:

- a) vaccination
- b) medication.

In the region, vaccines and sera are mainly produced in Egypt, Sudan and Iraq. Other countries depend mainly on the importing of these products. Recently, "Mereaux" opened up a laboratory in Iraq for foot and mouth and another in Saudi Arabia.

As far as medicine is concerned, it is mainly through imports, apart from a very small amount of medicine produced in Egypt.

As far as the disease pattern is concerned, the main one is epizootics and is mainly controlled by vaccination.

The field surveys of diseases in most of the countries are not complete and no veterinary drug industry should be established without this survey. Training of personnel and veterinary engineers are badly needed in this area.

Paper presented by Mr.M.S.Awad, UNIDO consultant, Guinea

The animal population of Guinea and the Government strategy in the field of animal health products especially for the local production of veterinary vaccines, as well as for diagnostic services for veterinary diseases were described.

The general pattern of animal diseases in Guinea according to their prevalence among the main animal groups is given, as well as the main diseases for which preventive and curative pharmaceuticals have to be provided and eventually produced.

The experiment of the development of local production of veterinary vaccines in Guinea is given: starting from the small nucleus in 1965, to 0.8 million doses in 1970, to the modernised production unit of 2.3 million doses annually that developed in 1975/1978, to the new target for annual production of 10 million doses in the current extension for 1978/1981. As an illustration, lists of equipment, materials, personnel and costs are given for both production levels.

Discussions with veterinary and pharmaceutical authorities initiated by this seminar, showed great interest in UNIDO's assistance in this field of production of veterinary pharmaceuticals, especially as there is a current UNIDO pharmaceutical project, and because of the great requirements for the progressive and long-term projects planned by the World Bank for the development of Animal Wealth on a country-wide scale.

Examples of the main categories of veterinary pharmaceuticals (antibiotics, trypanocides, parasiticides, other drugs, insecticides and feed supplements) are given, as well as some ideas for the initiation of first steps towards their local production.

Paper presented by Dr.M.Urban, Hungary

The paper consists of three parts:

I. Animal disease pattern in the developing countries - diseases are classified by the different breeds of animals. In case of each disease names of the countries where the disease in question occurs are listed.

II. List of animal health products:

A. drugs are grouped according to their pharmacological effect. The list is quite comprehensive in order to enable different countries to choose from it according to their own interest.

B. Important biologicals/vaccines, sera, diagnostics are listed according to the animal disease pattern.

III. Information on Hungary as far as production of animal health products is concerned:

1. registration (criteria) of veterinary products in Hungary.
2. some idea, how and in which territory Hungary has given assistance to developing countries, as well as what kind of preparations with finished products, technology, equipment, instruments Hungary could give the developing countries.

Paper presented by Dr.S.C.Srivastava, India

The paper is presented in 5 parts:

1. introduction;
2. disease pattern in animals and poultry;
3. requirement of drugs and biologicals;
4. facilities needed for the production of important drugs;
5. economics of production.

The introduction highlights the enormous cattle wealth available in India and the measures being taken for its improvement to obtain better yields. It also describes the number of veterinary teaching institutions.

The second part of the report deals with the various diseases prevalent in the country with incidence of livestock and poultry diseases in a tabulated form along with control measures being adopted in India.

In the third part, total market potential for veterinary drugs and pharmaceuticals in India has been described and important drugs which are not available in the country's market are mentioned for which either technology has to be imported for production or sources have to be found for importing the raw material for repacking etc. Most of the drugs mentioned are meant for use against parasitic diseases.

Lastly, there is mention of veterinary biological production centres in India distributed throughout the country which meet the country's demand for important vaccines. None of these centres is producing sera. There is a need for establishing facilities for the production of vaccines like the one for Marek's disease, foot and mouth disease and Gumboro diseases which have recently been introduced in the country and incidence is likely to rise.

Paper presented by Ms.Clavinda Bright-Parker, Liberia

The disease pattern in animals obtained in Liberia, the need for veterinary drugs including the list of important drugs and vaccines needed were described. At present there are no facilities for the production of drugs either for human or veterinary use. Liberia places great emphasis on economic relationship with other African countries. The importance of regional co-operation in this sector was highlighted. The Organization of African Unity and the Directors of Veterinary Services in Africa recommended that the production and supply of veterinary medicines and biologicals be centralised regionally.

Paper presented by Dr.M.Diakit , Mali

Status of animal health in Mali

Mali is situated in the tropical zone and is affected by many infectious and parasitic diseases, among which are the following:

- rinderpest
- bovine contagious pleuropneumonia
- anthrax
- clostridial diseases
- pasteurellosis
- brucellosis
- streptothrichosis
- trypanosomiasis
- piroplasmosis
- rickettsiosis
- helminthiasis
- coccidiosis
- ticks

Methods of prevention used:

1. preventive vaccination against the main infectious illnesses;
2. use of veterinary pharmaceutical products for medical treatment. main products used are antibiotics, sulfa drugs, anthelmintics, trypanocides, coccidiostatics, external antiparasitics, vitamins, minerals etc.

Paper presented by Dr. Arturo Medina, Mexico

I. Animal diseases in Mexico

- Cattle: Babesiosis, mastitis, paralytic bovine rabies, black leg, anthrax, internal and external parasites, anaplasmosis, leptospirosis, tuberculosis, brucellosis, vibriosis, rhinotracheitis in calf.
- Swine: hog cholera, internal parasites, pseudo rabies, atrophic rhinitis, TGE, erysipelas, dysentery, salmonellosis, leptospirosis.
- Poultry: marek's disease, salmonellosis, newcastle diseases, coccidiosis, internal parasites, infectious bronchitis, fowl pox, fowl cholera, laringe trachiatis, contagious respiratory disease, coryza.
- Horses: Internal parasites, influenza.
- Sheep/
Goats: brucellosis, mastitis, internal parasites, mange.

II. Registered Products

Animal feed	1840
Vitamins	250
Plaguicides	230
Chemicals	2000
Biologicals	580
Chemical Labs	236
Biological labs	77

III. Animal population in Mexico ('000)

Cattle	25,000
Swine	15,000
Horses	3,000
Sheep/Goats	7,000
Poultry	125,000

Paper presented by Mr.D.C.Sequeira, Nicaragua

The importance of cattle rearing in the economy of Nicaragua was stressed. It plays an important role in the diet of the Nicaraguan people (both milk and meat) and is also one of Nicaragua's main exports.

The new revolutionary government has set a goal to increase cattle population by 25-30% in the next 5 years (actual cattle population is between 2.5-3 million heads). Preventive medication will have to play a decisive role in achieving this goal.

Main diseases

Cattle: infectious: mastitis, paralytic bovine rabies, black leg, anthrax, peroplasmosis, brucellosis
pneumoenteritis in calves.

parasites: internal - gastrointestinal
external - ticks, screw worm.

swine: salmonellosis, dysentery, internal and external parasites.

poultry: Marek's disease, newcastle disease, cholera. Internal and external parasites. Infectious bronchitis

equine: encephelitis, tetanus, internal and external parasites.

Paper presented by Dr.C.Vior, Romania

Use of Drugs and Biological Products within Disease Prevention
and Control Programmes in Domestic Animals

1. Animal husbandry in the developing countries: livestock, production, level of animal products, availability.
2. Incidence of the main animal diseases in the developing countries: viral diseases, bacterial and mycoplasma diseases, tumoral diseases with viral ethiology, parasitic diseases, human contaminating microbial diseases, metabolic disorders. The most important methods intended to prevent and control the diseases (first of all using biologicals) are discussed.
3. Drugs and biological products required for prevention and control of diseases in domestic animals. Biological products: vaccines, sera, diagnostics. Drugs: antibiotics, synthesis chemotherapeutics, vitamins, biostimulators etc.
4. Technological elements in the veterinary drug and biological products industries. The report summarizes the main aspects concerning the technologies used in the production of the most important groups of products.
5. Role of drugs and biological products within disease prevention and control programmes in domestic animals. The importance of staff training is also mentioned. The use of drugs and biologicals should rely on the survey system implemented in all the countries.
6. Suggestions concerning the implementation of drugs and biologicals production in developing countries are made.

Paper presented by Mr. Torsten Moren, Sweden

In a developing country, there are many pressing needs. Good nutrition of the people is a basic one. The health of animals should be the responsibility not only of the owners but also of the governments. Many developing countries have realised the necessity of an established local production of animal health products and to that extent be independent. Here, as in many other fields, the local knowledge is of major importance. An imported product, if it is a finished drug, a raw material, a bacterial or viral strain may be good in the country of origin but of little use in the receiving country. It should be understood that veterinary science to a great extent is a local science. The aim at quality should mean a demand for efficacy.

The training of personnel should be both theoretical and practical, at all levels.

Paper presented by Mr. B. D. Hoskin, United Kingdom

The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) appreciates the opportunity of contributing to the review of the requirements for and the local formulation and packaging of important animal health products. IFPMA holds strongly to the view that the co-operation and support of the international pharmaceutical industry are needed if any worthwhile results are to be achieved in this sector. It should be placed on record that a considerable contribution has already been made by the international pharmaceutical manufacturing industry to the industrialisation of developing countries in extending new technology, managerial skills, training in operating and technical skills, and in the provision of medicines for use in humans and animals have produced incalculable benefits for the health and economy of local populations.

In order to produce significant advances in animal production the developing countries must have available an adequate number of the best animal health products in each therapeutic category; it is not in their interest to concentrate on least cost less effective products simply on grounds of availability.

The international pharmaceutical industry has the technology, willingness and resolve to co-operate with the developing countries to solve their problems. The expertise and experience of the pharmaceutical industry is a valuable source which must be used to maximise the progress of the developing countries.

Drugs and vaccines are an essential part of what is required for the animal production industry of the developing countries to make significant advances. Equally, greater emphasis must be given to improved animal nutrition and animal husbandry if the benefit of locally formulated animal health products is to be optimised.

Paper presented by Dr. Eiler D. Frederiksen, USA

The following are the salient points:

1. Major diseases in animals in developing countries.
2. Basic requirements for effective veterinary drugs.
3. Sources of reference for the biological, pharmaceutical and chemical agents.
4. Principal features of production facilities for drugs for veterinary use.
5. Criteria for economics of production.

Summary of paper submitted by Dr. W. R. Pritchard, USA

The patterns of livestock disease in the least developed countries is as follows: Economically disruptive highly contagious diseases such as rinderpest, contagious bovine pleuropneumonia and African horse sickness are capable of destroying large numbers of livestock and seriously disrupting agricultural production. Effective means to control most of the most-serious diseases in this group are available. There are many additional infectious diseases that reduce the productivity of the livestock industries in the least developed countries but unlike the former group are not such serious threats as to impair the development of these industries. Although much research on control remains, much of the technology necessary to control them is available. Specific biological products available in the least developed countries are essential to the success of efforts to limit the effects of these infections.

The hematoparasitic diseases (trypanosomiasis, theileriosis and babesiosis) are special problems. They exist throughout the tropics and practicable technology to control them is not yet available or yet in sight for most of them. African trypanosomiasis prevents the use of large areas in Africa for livestock production. Internal and external parasites cause heavy losses throughout all the tropical regions of the world and deserve the most careful consideration. Effective anthelmintics and coccidiostatic agents as well as effective means of reducing losses from external parasites are essential for effective disease control programmes in the least developed countries.

Endemic disease problems currently are of lesser importance in the least developed countries than the epidemic infectious diseases and the parasites. They shall assume greater importance as economic development occurs. It is important that veterinarians in the least developed countries have available the required biological and pharmaceutical products necessary to minimize losses from the endemic diseases.

Summary of Discussions

Animal wealth plays an important part in the economy of the developing countries and it is well recognised that the animal production potential of these regions has to be realised to increase the level of human nutrition and so improve the economies. The need for animal protein is rapidly growing as these nations experience rapid growth in their population due to improved human health conditions. The Ad Hoc Expert Group Meeting convened by UNIDO in Vienna in March 1980 wishes to emphasise that pursuit of traditional clinical approaches to individual animals will not assist the realisation of the dormant potential but that a new approach of preventive medicine be adopted aimed at improving animal productivity. This approach must be undertaken on a national or regional/subregional basis. However, the Meeting wishes to emphasise that before any new measures are taken it is essential that all available information on livestock population, husbandry practices, veterinary services, drug availability should be carefully collected according to the proposed questionnaire (see Appendix 1). The purpose of the Meeting was to consider the production (formulation and packaging) of veterinary drugs in the developing countries by

1. disease pattern in animals for veterinary use;
2. requirements of drugs for veterinary use;
3. list of important animal health products needed -
 - a) pharmaceuticals
 - b) biologicals
 - c) diagnostics
4. facilities needed for the production of important animal health products
 - a) in existing formulation and packaging units for production of drugs for human use
 - b) new facilities required for formulation and packaging
5. economics of production.

The control of animal diseases in the developing countries presents special difficulties because, in addition to the presence of many diseases found in temperate climates, there occur also others peculiar to subtropical and tropical regions.

Current standards of animal husbandry, communal grazing, illicit stock movement, importation of breeding stock, the lack of understanding of the principles of animal health by the stockowners and inadequate numbers trained and experienced personnel and facilities are all factors which make it difficult to attain reasonably high standards of animal health.

The control of highly infectious diseases is made more difficult by the frequent migratory movement of animals over long distances, while the periodic occurrence of drought leads to close contact between flocks and herds on village communal grazing lands and at waterpoints in the arid and semi-arid rangelands. The presence of wildlife as reservoirs of infection is also an important factor in the transmission of diseases. Therefore, the regional/organisational approach in disease control is essential.

Disease Patterns of Animals in Developing Countries

Diseases and parasites of livestock constitute one of the most important constraints to efficient livestock production in both developed and developing countries of the world. In developed countries such as the USA, European countries, Australia, New Zealand, Japan and the USSR, the majority of the most contagious epidemic diseases have been or are being controlled and losses are caused mainly by the so-called endemic diseases, many of which cause no recognisable clinical signs of disease but seriously reduce the productivity of livestock production units. In developing countries epidemic infectious diseases, some of which are capable of killing large numbers of animals, and parasites are responsible for the highest proportion of disease loss. Endemic diseases also cause losses in developing countries and will become more important when the livestock industries are better developed.

The working group reviewed the disease patterns and the lists of diseases with general priorities are attached as Appendix II.

Groups of Important Animal Health Products

The meeting reviewed the lists of animal health products presented by different experts to the meeting. Based on this, an illustrative list of animal health products was drawn up (Appendix III). However, it should be borne in mind that this list must be reviewed by each government according to the disease pattern, environment and local needs. Based on the illustrative list, the Meeting identified a group of drugs for production in developing countries (Appendix IV a, b). However, before planning any production of any of these drugs, a feasibility study should be carried out.

Requirements of Drugs for Veterinary Use

Veterinary drugs must be effective, safe and affordable. Basic requirement for effective veterinary drugs is packaging in dosage forms and sizes that readily adapt to local use. Proper storage and transport is essential. Efficiency of a drug is well known from research data available from reliable industry or government sources as it applies to therapy, or prevention of a given disease. It is important that the safety margin is such that the animals are not damaged by secondary effects.

Safety must also apply to any drug residue that may remain in edible tissue. People who consume food from treated animals may not be injured by such residue.

The drugs must be safe to the person administering the drugs or packaged in such a way that it can be safely handled.

Veterinary drug cost must be within the economic reach of the local farmer. Its cost for preventative or therapeutic use must have a profitable benefit on the animal and for the farmer.

Oral dosage forms are best adapted for areas where individual animals or small herds are kept. Most forms are capable of oral administration, either by liquid drench or introducing a dry powder or bolus. Dry powder may be mixed in feed. Soluble dosages may be administered in the drinking water. Dosage can be controlled by simple measure or count.

Injectable dosage may be preferable where better technical knowledge is available to the farmers. In the case of several biologicals it is only available in dosage form. In such cases veterinarians or animal technicians must either administer the product or train the farmers to do so.

Practical economics of purchase price and avoiding contamination or spoilage or remaining materials must determine package size. Holdings of individual animals or small herds require unit packaging. Multi-dose packaging is only practical where a large number will receive treatment at one time. However, packaging of pharmaceuticals for veterinary use should be designed to protect the product from the environment of those countries.

The drugs must be warehoused and transported in such a way that they are not damaged by temperature or other extreme climatic conditions. Many drugs require constant refrigeration.

Facilities Needed for Production

- a) In existing formulation and packaging units for production of drugs for human use

Pharmaceuticals can be compounded and conditioned in the same facility for both veterinary and human use. Problems occur primarily because package unit sizes for food producing animals are larger and many drugs are conditioned in multidose packs for herds treatments. If the plants are producing small batch sizes and utilizing semi-automatic or hand operated equipment, the same facilities adapt well to both product lines. Possibly this is the case in many developing areas. However, if modern automatic equipment has been installed then, because of the varied package sizes required for animal use, specialised facilities need be built either separately or as an addition to the existing facilities.

It is important that whenever possible the plants are designed so that specialised packaging does not interfere with the common utilisation of the plant infrastructure, control laboratories, common purchases of raw materials, warehousing and management personnel.

Biologicals, due to package size and possible cross contamination, would best be served by specialised veterinary units. Usually the production volume will justify special production facilities. Control laboratories and infrastructure can be common with human facilities.

Insecticides and fungicides must be compounded and packaged in specialised facilities. These products have little in common with human medicine.

b) New facilities for formulation and packaging

Construction of new facilities specifically designed for production of veterinary drugs is ideal where a developing country, or an area comprising several countries, can justify the need. Modern standards have been developed by various organisations such as WHO, IOD, FDA which can be adopted in developing countries, without sacrificing the capability of proper production, but reference to these standards is necessary before local production is taken up.

Pharmaceutical compounding facilities must be designed for production of liquids (sterile and non-sterile), ointments, tablets and boluses and powders. Each section must be self-contained to the degree necessary for quality control. Contamination with other chemicals cannot be tolerated. In the case of antibiotics, separate equipment and rooms may be required to produce pure products and to avoid the danger of adulterating other pharmaceuticals. Equipment can be hand operated or automated. It can be designed for multiple use. Sterilizing equipment if centrally located can service several areas of production.

Biological production requires the most exact plant design in order to control sterility and quality of vaccine and sera. Several working areas are required to be isolated from each other. Air locks must be available for passage of material and personnel into and out of these areas. The walls and floors must be designed for easy cleaning and sterilization. Air flow must protect the working areas and the environment surrounding the plant location. One must also keep in mind that modest sized equipment can produce millions of doses of vaccine. In fact, quite unsophisticated equipment can be utilised in most cases if need be.

Nutritional supplements such as vitamins, minerals, antibiotics and other chemicals are normally compounded in simple bulk mixing equipment. The greatest problem is dust control. Most are packaged in 1 to 25 Kg. containers.

Growth promoters are often handled in the same manner as nutritional supplements. Some are compounded into pellets for subcutaneous implanting. These can be produced in the areas reserved for tablet production.

A quality control laboratory is required to monitor raw materials, some products during manufacturing and all finished goods. The personnel must accept the responsibility for certifying the quality of the finished products. To accomplish this, they need adequate laboratory facilities.

Conditioning - filling, labelling* and packaging - is the area where greatest utility can be generated in having a plant specially designed for veterinary production. Semi-automated or hand-operated equipment can be quite competitive because the great variety of package size and short production runs, inherent in veterinary product lines, do not lend themselves to automated equipment.

Warehousing must be designed to adequately protect the products from the environment. Raw materials require facilities wherein proper control can be effected. Finished goods normally require simple storage areas. Certain products must be kept under refrigeration.

Infrastructure supplying adequate dependable power, water and waste disposal is essential to good operations. Power interruption can ruin products in production, especially biologicals. Clean water supply is fundamental for compounding and plant maintenance. Several chemicals and biological agents are hazardous to people and animals if allowed to contaminate the environment. Therefore, complete controlled waste disposal systems must be employed.

One cannot overstress the need for properly trained personnel at all levels to operate the production facilities. Constructing adequate facilities is a waste of time and money if knowledgeable operations people are not available.

In order to facilitate the development of veterinary pharmaceutical industry, the Meeting suggests the following possibilities:

- a) joint venture arrangements between developed and developing countries;
- b) TCDC;
- c) royalty based including long range arrangements;
- d) direct assistance from UN systems.

ECONOMICS OF PRODUCTION

The economics of production of drugs for veterinary use are dependent on various factors such as technology and production volume, cost of materials, labour etc. The economics of food production are dependent on proper utilisation of the products. Effective marketing and distribution make both economics possible at a high level. The economic effect of local research should also be considered.

One realises the desire and need for animal health product production in developing countries. The industrial development is needed to improve the general economy and technical capabilities. These products are needed to improve the health and economics of animal food producing industries and the milk, eggs and meat which have high nutritional value, should carry no infectious, parasitic, nor chemical agent hazardous to human health.

* description should be understood by user.

Recognizing the merits of the above, one cannot ignore the practical aspects of adequate technical expertise. Failing to have a well-trained, well-disciplined cadre to operate a production facility will lead to poor quality products, in effect, raising the cost due to product failure. This sets off a chain reaction which dooms the viable economics of production.

Certain minimum production volumes are required to justify the cost of establishing and operating veterinary drug production plants. Normally, high production volume with automated equipment produces the least cost product, but the developing countries do not need to begin with such plants. Plants designed and equipped to meet local needs can be profitable by utilising hand labour and taking advantage of their nearness to the market.

In addition to the need for industrial development, there are political reasons for local production in developing countries. But the countries may also look to regional co-operation wherever possible to benefit from higher production volume. One cannot ignore the economic advantage of achieving high volume production. Besides social benefits, creating infrastructure, saving of foreign exchange including freight charges and self reliance are reasons which justify local production.

The production entity with local knowledge of the social and business manners of the livestock industry must be capable of developing a sophisticated marketing system that reaches and reaches the farmer - whether or not local veterinarians are available. They must accept this challenge because if viable effective drugs, vaccine and sera are not properly and in a timely manner applied, infectious diseases cannot be effectively controlled.

Farmers will soon see the economic advantages of good preventive medicine. The key is teaching the farmer the advantages. The mass use and sales of animal health products will follow. This must be recognised as a long term on-going effort.

The economics of production depends on technology, production volume, product consumption and research to meet local needs. Local veterinary drug industry in the developing countries must cope with all these factors to be economically successful. Before development of an integrated veterinary pharmaceutical industry, it is necessary to carry out a detailed study on the availability of raw materials, intermediates, technology and techno-economic study.

GENERAL RECOMMENDATIONS

A. Recommendations to the governments

1. Taking into consideration the economics of the livestock industry, the governments of developing countries should pay increasing attention to animal health.
2. The governments should conduct on a continuous basis field surveys of their livestock population and animal disease problems in order to assess their local needs for animal health products.
3. The development of animal health products' industry must make a major contribution towards the improvement of animal health.
4. The Meeting recommends to the governments of developing countries to lay more emphasis on the use of animal health products for the prevention rather than the treatment of diseases.
5. The Meeting highlights the important role played by nutrition and husbandry in animal production and recommends to the governments to take more adequate measures in these areas alongside the development of animal health products' industry.
6. The governments should make use of the existing cattlemen's organisations for the implementation of the above recommendations. Where no such organisation exists, the establishment of the same is suggested.

B. Recommendations to the International Organisations including UNIDO

1. UNIDO is requested to assist developing countries in carrying out surveys of surplus facilities available in units engaged in the production of drugs for human use which could be utilised for the production of animal health products.
2. As training of personnel is one of the important elements for the successful development of animal health products' industry, UNIDO is requested to organise appropriate training programmes at all levels in production and quality control at national, sub-regional and regional levels.
3. The Meeting strongly recommends to UNIDO to take appropriate action for
a) the development and expansion of formulation and packaging industry
and b) the preparation of detailed feasibility studies for the backward integration into local production of active ingredients.

4. Since the quality control of animal health products is as important as that for drugs for human use, appropriate measures for quality control should be taken. WHO/UNIDO are requested to assist in this regard.

5. FAO/WHO/IOE (International Office of Epizootics) are invited to assist the governments in conducting surveys on animal diseases and their control.

6. UNIDO is immediately requested to include in their existing pharmaceutical projects (formulation and packaging) the production of animal health products identified in this report as illustrated. This should also be extended to the feasibility studies and utilization of local raw materials for basic manufacture of active ingredients.

C. Regional Recommendations

1. The developing countries are invited to consider the importance of regional co-operation for effective control of animal diseases and production of biologicals as illustrated in the report in order to achieve economic production. For implementation of this recommendation WHO/UNIDO are requested to assist.

2. The establishment of regional research and development centres is recommended for:

- a) formulation and packaging;
- b) use of local excipients;
- c) biologicals.
- d) valorization of raw materials for the production of active ingredients.

UNIDO is requested to extend necessary assistance for the same.

QUESTIONNAIRE

Livestock Industry in Developing Countries

The purpose of this questionnaire is to gather basic information concerning a local market. It is not intended that any one respondent can answer all the questions nor that all questions are relevant to a given State. Therefore, please supply the information you may have available for any question listed.

I. Introduction

1.1. How important is the livestock industry in your State's economy?

2. Economic structure of agriculture.

- 2.1 How well is agriculture developed?
- 2.2 List the agricultural regions
- 2.3 What regions are to be developed in the next 10 years?
- 2.4 What is the potential for livestock production?

3. Agricultural structure.

- 3.1 How many farms are there in your state?
- 3.2 How many hectares are there in the average farm?
- 3.3 What is the range in farm size?
- 3.4 Are the farms state or privately owned?
- 3.5 Are farmer co-operatives active in the livestock industry?
- 3.6 Does the Ministry of Agriculture operate livestock farms?

4. Livestock production.

4.1 List the animal populations for 1979 and your estimate for 1985:

	1979	1985
Sheep		
Goats		
Native cattle		
European dairy cattle		
European beef cattle		
Buffalo		
Donkeys, horses and mules		
Camels		
Poultry broilers		
Poultry layers		
Fish farms		

- 4.1.1. If dogs or other small animals are vaccinated for rabies, estimate their populations.
- 4.2 How many animals are there in the small, large and average herds, flocks or units?

Small Large Average

Sheep
Goats
Native cattle
European dairy cattle
European beef cattle
Buffalo
Donkeys, horses and mules
Camels
Poultry broilers
Poultry layers
Fish farms

- 4.3 Are the cattle used for food production or farm work?
- 4.4 Are the cattle confined or on range?
- 4.5. What is being done to improve the livestock?
- 4.6 Does your government subsidize livestock farming directly or indirectly?
- 4.7 List the agricultural and veterinary schools or universities

5. Livestock nutrition.

- 5.1 Are the pastures or range lands improved (fertilised, irrigated etc.)?
 - 5.1.1 How many months do the pastures provide adequate food?
 - 5.1.2 Is the nutritional level adequate for the entire year's feeding cycle?
 - 5.1.3 What crops are raised for livestock feed?
 - 5.1.4 Is the crop land fertilised?
- 5.2 How is feed stored for the non-pasture season?
- 5.3 What feeds are imported?
- 5.4 What feed supplements are used such as protein, minerals, salt, vitamins, antibiotics, etc. for dairy, beef and poultry?
- 5.5 What growth promotants are used?
- 5.6 Give the rations fed to dairy cattle and poultry

6. Animal disease

- 6.1 List the major disease problems in each class of livestock (non-infectious, infectious, parasitic, nutritional, toxicity)

Sheep
Goats
Native cattle
Dairy cattle
Buffalo
Donkeys, horses and mules
Camels
Poultry
Fish
Dogs

- 6.2 What disease control programmes does your government enforce?
 - 6.3 What disease control practices are exercised by the farmers, such as worming sheep or vaccinating poultry and livestock?
 - 6.4 Are dogs vaccinated for rabies?
7. Veterinary service.
- 7.1 Do veterinarians conduct private practice on the farms?
 - 7.2 Do veterinarians work for state extension services?
 - 7.3 Do veterinarians work for the co-operatives?
 - 7.4 How many veterinarians practice?
 - 7.5 What is the total number of veterinarians?
 - 7.6 Will veterinarians become available during the next 10 years?
 - 7.7 How do the farmers learn about animal health and nutrition products?
 - 7.7.1 Does the industry effectively educate (propaganda) the farmer on the benefits and use of the products?
 - 7.7.2 Does the state operate an extension service that effectively brings information to the farmers about the use and benefits of the products?
 - 7.8 Are the farmers able to originate therapy or conduct follow up treatment of sick animals?
 - 7.9 Are the farmers willing to use animal health products for small operations?
8. Veterinary and animal nutrition research
- 8.1 Does your state conduct research in animal disease? If so, briefly list the areas of research.
 - 8.2 Describe what animal nutritional research is conducted.
 - 8.3 Is artificial insemination practiced in your cattle operations?
9. Veterinary products
- 9.1 For the following four questions, classify the products as: biologicals, pharmaceuticals, anthelmintics, coccidiostats, insecticides, feed additives and growth promotants. Attach any available statistics.
 - 9.1.1 List the manufacturers or suppliers and the products each sell on the market (catalogues or price lists may be returned in answer to this question)
 - 9.1.2 For imported products, list the name of the manufacturer and country of origin
 - 9.1.3 Estimate the market share held by each manufacturer or supplier
 - 9.1.4 Give the total sales for each class of products
10. Marketing and Distribution
- 10.1 Are the products sold to the farmer by the government, co-operatives or local merchants?
 - 10.2 How many wholesale and retail outlets are there?
 - 10.3 How are the products stored at the wholesale and retail outlets?
 - 10.4 How are the products transported from the manufacturer, wholesaler and retailer to the farmer?

11. Legislation

- 11.1 Supply a summary (or the documents) of regulations requiring product registration
- 11.2 Does the government control the import (or export) and distribution of raw materials or finished products?
- 11.3 Does your government control the manufacture of the products (Government monopoly)?
- 11.4 Does your state control prices?
- 11.5 Does your state control wages?
- 11.6 Does your state restrict the use of growth promotants?

12. Future development in the livestock industry

- 12.1 What important changes do you see for livestock populations?
- 12.2 Will livestock operations become larger or smaller?
- 12.3 Will the farmers increasingly utilise animal health, nutrition and growth promotants?

13. General information

- 13.1 Can temperature sensitive products such as vaccines and antibiotics reach the farmer by proper handling during distribution; if not, will adequate facilities be available in the future?
- 13.2 List your recommendations for products which could benefit your livestock which are not now available.

Animal diseases in developing countries

I. AFRICA

A. Cattle

Anaplasmosis
Anthrax
Babesiosis
Bovine Contagious Pleuropneumonia
Brucellosis
Calf enteritis
Calf pneumonia
Clostridial diseases
Coccidiosis
Cysticercus bovis
Echinococcosis
Fascioliasis
Foot and Mouth Disease
Mange and Scab
Mastitis
Parasitic gastroenteritis
Pasteurellosis
Rickettsiosis
Rinderpest
Ring worm
Streptothrichosis
Theileriasis
Ticks
Trypanosomiasis
Tuberculosis

B. Sheep

Bluetongue
Clostridial diseases
Coccidiosis
Contagious agalactia
Contagious Pustular Dermatitis
Fascioliasis
Foot rot
Mange
Mastitis
Parasitic gastroenteritis
Pasteurellosis
Pseudotuberculosis
Rickettsiosis
Sheep Pox
Trypanosomiasis

C. Swine

Anthrax
Brucellosis
Dysentery
Helminthiasis
Salmonellosis
Trypanosomiasis

D. Poultry

Chronic Respiratory Disease
Coccidiosis
Gumboro disease
Marek's disease
Newcastle Disease
Salmonellosis
Avian Laryngo-Trachiatis
External Parasites
Fowl Cholera
Fowl Pox
Helminthiasis
Mycosis

E. Horse

African Horse sickness
Trypanosomiasis

F. Camel

Anthrax
Echinococcosis
Helminthiasis
Mange
Pasteurellosis
Trypanosomiasis

II. ASIA

A. Cattle

Amphistomiasis
Anaplasmosis
Babesiosis
Brucellosis
Calf enteritis
Calf pneumonia
Clostridial diseases
Fascioliasis
Foot and Mouth Disease
Mange
Mastitis
Pasteurellosis
Rabies
Theileriasis
Trypanosomiasis
Tuberculosis
Vibriosis

B. Sheep/Goat

Bedsoniosis
Clostridial diseases
Contagious caprine pneumonia
Fascioliasis
Foot and Mouth Disease
Foot rot
Listeriosis
Mange
Toxoplasmosis

C. Swine

Swine erysipelas
Swine fever
Swine influenza

D. Poultry

Chronic respiratory disease
Coccidiosis
Fowl cholera
Fowl pox
Gumbouro
Infectious bronchitis
Infectious hepatitis
Infectious trachiatis
Marek's disease
Newcastle disease
Salmonellosis
Round Worm
Ticks

E. Horse

African horse sickness
Helminthiasis
Trypanosomiasis

F. Camel

Anthrax
Echinococcosis
Helminthiasis
Mange
Pasteurellosis
Trypanosomiasis

III. LATIN AMERICA*

A. Cattle

Anaplasmosis
Anthrax
Babesiosis
Brucellosis
Clostridial diseases
Foot rot
Helminthiasis
Infectious bovine rhinotracheitis
Leptospirosis
Mange
Mastitis
Paralytic bovine
Pneumo-enteritis
Rabies
Screw worm
Ticks
Tuberculosis
Vibriosis

E. Horses

Helminthiasis
Tetanus
Venezuelan encephalitis

B. Sheep/Goats

Brucellosis
Helminthiasis
Mange
Mastitis

C. Swine

Atrophic rhinitis
Dysentery
Erysipelas
Helminthiasis
Leptospirosis
Pseudo rabies
Salmonellosis
Swine fever
Transmissible gastroenteritis

D. Poultry

Coccidiosis
Contagious respiratory diseases
Fowl cholera
Fowl pox
Helminthiasis
Infectious bronchitis
Infectious coryza
Infectious hepatitis
Laryngo tracheitis infections
Marek's disease
Newcastle disease
Salmonellosis

* does not cover South America

Group of Important Animal Health Products

1. Anaesthetics

general - halothane thioental sodium

local - chloraethyl
lidocaine
procaine
tetracaine

2. Analgesics, antipyretics, spasmolitics

atropine
noramidopyrin

3. Antiallergics

thenalidin
tripellenamin

4. Antiinfective drugs

4.1 Antibiotics

β - lactamantibiotics - ampicillin-group
benzathine benzylpenicillin
bynzylpenicillin
benzylpenicillin procaine
carbenicillin
cephalosporine
cloxacillin
oxacillin
penicillin

Aminoglycoside group - gentamycin
kanamycin
neomycin
pen-strep
spectinomycin
streptomycin

Polypeptid group - polymyxin B
polymyxin E
polymyxin M

Classic wide-spectrum
antibiotics - chloramphenicol
tetracycline
chlor-
oxy-
doxy-cycline
thiamphenicol

Macrolidantibiotics - erythromycin
fumagillin
lincomycin
oleandomycin
spiramycin
tylosin

4.2 Chemotherapeutics

sulphonamids - sulphamethoxazole+Trimethoprim
sulphamethoxydiazin
sulphamethoxyryridazin
sulphathiazol
triple sulpha (sulphadimidine, sulphamerazine,
sulphathiazole)

dimetridazol

4.3 Antiparasitic drugs

4.3.1 Coccidiostatics

amprolium
buquinolat
clopidol
diaveridin
halofuginon
lasalocid
monensin

4.3.2 Anthelmintics

bunamidin
diethylcarbamazine citrate
levamisole
mebendazole
niclopholane
niclosamide
oxyclozanide
peperazine adipate
praziquantel
tetramisole
thiodiphenylamin/phenothiazin

7. Gastrointestinal drugs

antidiarrhoea
carbo activatus
dimethylpolysiloxane
kaolin
magnesium sulphate
pectin
sodium sulphate
sulpha guanidine

8. Hormones

adrenal hormones and synthetic substitutes
adrenaline
choriongonadotropine
corticotrophine
dexamethazone
flumethazone
hydrocortisone
oestradiol
PMSG
prednisolone
progesterone
sexual hormones
triamcinolon

9. Muscle relaxants

suxamethonium
tubocurarine

10. Drugs with action on the uterus

10.1 Oxytocics

ergometrine
oxytocin

10.2 Uterine relaxants

Isoxsuprinlactate

11. Solutions correcting water, electrolyte and acid-base disturbances

glucose (5% and 50%)
oral rehydration salts (for glucose-salt solution for oral use)
potassium chloride injection (15%) and oral solution
sodium bicarbonate (7.5%)
sodium chloride injection (0.9%)
sodium lactate compound injection
water for injection

12. Vitamins and minerals

12.1 Minerals

Na, K, Se, Mg, Co, Mn, Zn, Ca, Fe, Cu

12.2 Vitamines

A, B complex, C, D, E, K

13. Feed additives

14. Growth promoters

List of Priority Animal Health Products to be Considered for Production

1. Anti-infective drugs

1.1 Antibiotics

ampicillin
chloramphenical (reservation)
penicillin
streptomycin
tetracyclin

1.2 Triple sulpha preparations

1.3.1 Coccidiostatics

amprolium
monesin
nitrofurazolidene

1.3.2 Anthelmintics

Antinematods

bendazol group
piperazineadipate

Antitrematode

niclopholane

Anticestods

oxychlonaizid

niclosamide

1.3.3 Antiblood Parasite

Babesia

anaplasmosis
trypanosomiasis
diaceturate
diethyl carbanazine citrate
imidocarb ,oxychlonaizid
quinapyramine

Theileria

Filaria

Diethylcarbamazine

Citrate

1.3.4 Ectoparasits

organophosphoric compound
benzyl benzoate

1.4 Fugicides

Nystatin

1.5 Antiseptic

Quaternary Ammonium salts

2. Gastro intestinal drugs

Antidiarrhoeal

non specific specific
kaoline sulphaguanadine

pectine

purgative

magnesium sulphate

sodium sulphate

Antifermentive - activated carbon

dimethyl polysiloxane

3. Hormones

Prednisolen

progesterone

oestradiol

prostaglandin

4. Drugs having action on uterus

oxytocin (posterior pituitary extract)

5. Solutions correcting water, electrolyte and acid-base disturbances

glucose (5% and 50%)

oral rehydration salts (from glucose-salt solution for oral use)

potassium chloride injection (15%) and oral solution

sodium bicarbonate (7.5%)

sodium lactate compound injection

sodium chloride injection (0.9%)

water for injection

6. Minerals

NA,K,Se,Mg,Co,Mn,Zn,Ca,Fe,Cu

7. Vitamins

A,B complex,C,D,E,K

8. Feed additives

according to need and in accordance with the feed additive compendium

The Priority Biologicals to be Considered for Production in the Developing Countries

1. Vaccines

1.1 Viral

Foot and mouth disease	(A)1/
Rinderpest	(A)
Bovine contagious pleuropneumonia	(A)
Rabies (including paralytic bovine)	(B)
Sheep pox	(B)
Blue tongue	(A)
Swine fever	(B)
Pseudorabies	(B)
Transmissible gastro-enteritis	(A)
Newcastle disease	(B)
Marek's disease	(A)
Avian infectious bronchitis	(A)
Gumboro disease	(A)
Avian laryngo tracheitis	(A)
Fowl pox	(B)

1.2 Bacterial

Anthrax	(B)
Clostridiosis	(B)
Pasteurellosis	(B)
Brucellosis	(B)
Erysipelas	(B)
Paratuberculosis	(A)
Fowl cholera	(B)

1.3 Blood parasites

anaplasmosis	(A)
babesiosis	(A)

2. Diagnostics

tuberculins (PPD)	(A)
brucella antigens	(A)
California mastitis test solution	(B)
rickettsia antigens	(A)
chlamydia antigens	(A)
FITC antirabies serum	(A)
anthrax serum (Ascoli)	(B)
clostridia sera	(B)
leptospira sera	(B)
salmonella sera	(A)
salmonella pullorum antigen	(B)
mycoplasma gallisepticum antigen	(A)
paratuberculosis antigens	(A)
equine infectious anaemia antigen	(A)
infectious bovine rhino, bovine viral diarrhoea-MD, P13 diagnostic sera	(A)
foot and mouth disease sera	(A)
blue tongue antigen	(A)
newcastle disease antigen (FAI)	(A)

1/ It is suggested to produce the biologicals marked by (A) in regional institutes and those marked by (B) in practically all the developing countries.

Special Technological Features Within the Production of Biologicals

For the production of the biologicals adequate buildings should be designed; the complexity of the devices should be in accordance with the nature of the products manufactured, with the safety conditions which have to be secured (depending on the virulence of the ethiologic agents, on the danger of human contamination) with the quantities to be produced etc.

The main technical features are:

- separate buildings intended for the preparation of the different viral products;
- auxiliary station for water sterilization;
- aeration (mostly evacuation) through absolute filters for very dangerous viruses such as FMD-virus;
- compulsory filters for the staff;
- special laboratory equipment for cultivation, vaccine processing and filling;
- cold rooms and incubators (including egg incubators);
- deep freezers and refrigerators;
- different types of microscopes;
- centrifuges and ultra-centrifuges;
- equipment for the preparation of bacterial-media;
- autoclaves;
- energy supply (including own electric generators);
- equipment for preparing distilled and deionized water;
- filter sterilization equipment;
- buildings for animals (biologicals' control and various experiments);
- equipment and animals for biologicals' quality control;
- reliable sources for chemicals;
- various glass or plastic containers.

N.B. An important point in the development of the biologicals and drugs production is the proper training of the staff involved in this work. Also important are transport and storage facilities from the production unit up to the animal in order to maintain efficacy.

Veterinary Institutes Involved in the Standardization of Biologicals

1. Central Veterinary Laboratory - Weybridge - England
2. Virus Research Laboratory - Pirbright - England
3. Pan American Foot and Mouth Disease Institute - Brazil
4. Danish Institute for Foot and Mouth Disease - Lindholm - Denmark
5. Central Veterinary Laboratory - Alfort - Paris
6. Serum Institute - Copenhagen - Denmark
7. Central Veterinary Institute - Ames-Iowa - USA
8. Institute for Foot and Mouth Disease - Plum Island - USA
9. Chinoin Richter, Hungary
10. Pasteur Institute, Bucharest, Romania
11. Sweden Pharmacia Drugs, National Veterinary Institute Stockholm
Vaccine and sera, Sweden
12. General Administration of Animal Husbandry, Ministry of Agriculture,
Peking
13. Laboratoire Vétérinaire, Dakar, Senegal
14. Laboratoire Vétérinaire, Bamako, Mali
15. Laboratoire Vétérinaire, Pharsha, Tchad
16. Indian Veterinary Research Institute, Izatnagar, Bareilly, India
17. Indian Drugs and Pharmaceuticals Limited, New Delhi, India

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