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Monitoring antimicrobial usage in food animals for the protection of human health

Report of a WHO consultation
Oslo, Norway 10-13 September 2001

World Health Organization

Department of Communicable Disease,
Surveillance and Response

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1. Preface

The World Health Organization convened a consultation on the monitoring of antimicrobial usage in food animals for the protection of human health, in Oslo, Norway from 10 to 13 September 2001. More than sixty participants from twenty-four countries participated in the consultation to discuss monitoring of antimicrobial usage in food animals. The consultation was opened by Dr G. Bakken, General Director of the Ministry of Agriculture, Norway, Dr B. Naess, Director of the National Veterinary Institute, and Dr P. Braam, Department of Communicable Disease Surveillance and Response, on behalf of the World Health Organization. Dr A. E. van den Bogaard and Dr H. Kruse were elected as chair and co-chair respectively and Dr P. Collignon was nominated rapporteur.

The situation of antimicrobial usage in food animals in both developed and developing countries was highlighted through plenary presentations. In addition to presentations from selected countries, several international organizations also contributed. During the course of the consultation, working groups were created to enable informal discussion on selected aspects of monitoring antimicrobial use. The consultation resulted in a set of recommendations on the monitoring of antimicrobial usage in food animals for the protection of human health.

This report also provides a summary of the presentations that were made at the consultation. They provide a useful overview of the situation regarding monitoring of antimicrobial usage in various parts of the world.

2. Background

The consultation on the monitoring of antimicrobial usage in food animals for the protection of human health, Oslo, Norway (10 to 13 September 2001), built on earlier WHO consultations and recommendations.

In 1997 WHO convened an expert meeting on “The Medical Impact of the Use of Antimicrobials in Food Animals” in Berlin (13-17 October, 1997). The objectives were to achieve, if possible, an international consensus on priority medical problems arising from the use of antimicrobials in livestock production. It also made recommendations¹ to WHO on the next steps toward the development of guidelines for control and containment of the emergence of medically-relevant antimicrobial resistance in food animals.

The meeting acknowledged that antimicrobial use can select resistant forms of bacteria in the ecosystem and resistant bacteria and resistance genes can be exchanged between human, animal and other ecosystems. The following adverse consequences of selecting resistant bacteria in animals were identified:

1. Transfer of resistant pathogens to humans via direct contact with animals or through the consumption of contaminated food or water.
2. Transfer of resistance genes to human bacteria.
3. Increased incidence of human infections caused by resistant pathogens.
4. Potential therapeutic failures.

The meeting underlined the importance of monitoring antimicrobial resistance from farm-to-table, and the importance of prudent use of antimicrobials as a risk management tool at primary production level for the containment of antimicrobial resistance.

It was recommended that:

- the use of any antimicrobial growth promoters should be terminated if they are used as human therapeutics, or known to select for cross-resistance to antimicrobials used in human medicine;
- no antimicrobial should be administered to a food animal unless it has been evaluated and authorised by competent national authorities;
- a systematic approach aiming at replacing growth-promoting antimicrobials with safer non-antimicrobial alternatives should be established;
- national authorities should maintain records of export/import figures of bulk chemicals with potential antimicrobial use, as such information is vital for quantitative assessments of the medical risks related to the use of antimicrobials in livestock production;
- national authorities should continue to monitor and review levels of antimicrobial agent residues in food from animal sources and ensure compliance with national standards;
- WHO/FAO should convene an expert consultation to develop a code of practice for prudent use of antimicrobials in food animal production.

¹ Report of a WHO meeting: The Medical Impact of the Use of Antimicrobials in Food Animals, Berlin, Germany, 13-17 October 1997, WHO/EMC/ZOO/97.4

In summary, the meeting in 1997 concluded that the use of antimicrobials in food animals is a public health issue on which prudent use guidelines should be implemented, and that monitoring of both antimicrobial resistance as well as antimicrobial usage is warranted.

Subsequently in June 2000, WHO convened a meeting in Geneva, and a consensus agreement was reached on the principles involved with the use of antibiotics in animals intended for food. These principles were subsequently published as “WHO global principles for the containment of antimicrobial resistance in animals intended for food”.² These principles were intended to help reduce the misuse and the overuse of antimicrobials in animals intended for food. Forty principles were agreed upon.

These covered such areas as:

- the responsibilities of regulatory and other relevant authorities;
- quality and manufacturing;
- distribution/sales and marketing;
- antimicrobial growth promoters;
- surveillance of antimicrobial resistance and antimicrobial usage;
- prudent use of antimicrobials;
- prophylactic use of antimicrobials;
- education and training;
- research.

The overall purpose of these principles was to minimize the potential negative public health impact of the use of antimicrobial agents in food producing animals while recognizing the ongoing need for antimicrobial treatment of diseased animals.

Two specific sections of these agreed principles specifically addressed the issue of monitoring the usage of antibiotics.

1. The surveillance of antimicrobial resistance and antimicrobial usage:
“Data generated from the surveillance of antimicrobial resistance and antimicrobial usage should play a key role in the development of national policies for the containment of antimicrobial resistance. These data are all essential in the pre- and post- licensing process and in the development and treatment guidelines for veterinary use.”
2. The surveillance of antimicrobial usage:
“Relevant authorities should establish systems to determine the amounts of antimicrobials given to food animals.”
“Information on the amounts of antimicrobials given to food animals should be made publicly available at regular intervals, be compared to data from surveillance programmes on antimicrobial resistance, and be structured to permit further epidemiological analysis.”

² Report of a WHO consultation: WHO Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food, 5-9 June 2000, WHO/CDS/CSR/APH/200.4

In the WHO Global Principles document it was stressed that “the real challenge will be to translate the Global Principles into national rules and regulations, codes of practices and standard operating procedures. This will only occur if we succeed in engaging in an open, transparent and collaborative effort at national as well as international level, bringing together all stakeholders in the complex process of reducing health risks from the misuse and overuse of antimicrobials in animals intended for food.” The consultation on the monitoring of antimicrobial usage in food animals for the protection of human health, Oslo, Norway, 10-13 September 2001 and this report, are a critical part of that process.

3. Introduction

The WHO consultation on the monitoring of antimicrobial usage in food animals for the protection of human health was expected to:

- Set up an inventory of existing national and international strategies or systems that are currently used for the national and international monitoring of antimicrobial usage in food animals.
- Suggest methods/models that could be introduced for the monitoring of antimicrobial usage in food animals both on a national and international level.
- Develop recommendations to support governments, national authorities, the pharmaceutical industry, international organizations and other stakeholders in their endeavours to establish national monitoring systems for usage of all antimicrobials in food animals.

It is recognized that the emergence of antimicrobial resistance is a multi-factorial problem and thus requires a multifaceted solution. This involves all stakeholders concerned with the use of antimicrobials in both food animals and humans. WHO has therefore sought the active participation of many national and international organizations, associations and federations associated with human and public health.

Data generated from the monitoring of antimicrobial usage and the surveillance of antimicrobial resistance play a key role in the:

- development of national and international (for example WHO, the Food and Agricultural Organization of the United Nations - FAO, Codex Alimentarius and the *Organization International des Epizooties* - OIE) policies for the containment of antimicrobial resistance;
- comparison of the use of antimicrobials at different levels (local, regional, national, international);
- informing and in the education of stakeholders;
- correlation with data from antimicrobial resistance monitoring in humans, animals, and food;
- application of risk analysis processes pertaining to the issue of antimicrobial resistance;
- evaluation of the impact of the implementation of the prudent use of antimicrobials and of other interventions.

Data on usage in pets and other non-food production animals should be differentiated. This usage does not represent a food safety issue and is outside the scope of this consultation.

4. Recommendations

1. Countries should establish a national monitoring programme of the usage of antimicrobial agents in food animals.

In each country, a competent regulatory authority should collect data on the total usage of antimicrobials in food animals. The methods of how to collect or obtain this usage will depend upon the national situation because different countries might have different distribution and registration processes.

This can be done by collecting data from one or more of the following sources:

- Importers and exporters as well as production data from manufacturers.
- Data on intended and actual usage from manufacturers, distributors including feed mills, pharmacies and veterinary prescription records.
- Veterinarians, farmers, animal producers.

It is important that each country develop system requirements that are clear and transparent, as this will facilitate data comparison within and among countries as well as interpretation of trends. For this purpose data on animal population and production should be provided, for example numbers of animals slaughtered per year or animal census data.

2. Countries should have a regulatory approval and control system for antimicrobial agents and products containing antimicrobial agents.

Such a system could include, but not be limited to, listing of available antimicrobial agents in the country, a registration mechanism, or an approval mechanism. Countries should devote the necessary resources for enforcement of the relevant laws and regulations as well as post-marketing surveillance systems.

Research relating to monitoring and analysis of data on usage of antimicrobial agents should be supported as well as education of stakeholders as a means to achieve compliance.

3. Countries should collect data on the total amounts of each antimicrobial agent and report these data in kilograms of active ingredient on an annual basis.

The following details should preferably be collected and reported in priority order:

- Usage in the various animals species and may include animal production classes.
- Routes of administration such as oral, including in-feed or in-water, parenteral (injection), intramammary, intrauterine, and topical.
- Therapeutic, prophylactic, and growth promotion use.

In addition, the following could also be of added value:

- Further subdivision into regional or local usage.
- If it is difficult to collect detailed data for an entire country, the data could be collected in a representative area by a statistically robust sampling scheme.

Data should be made widely available in a timely fashion, preferably both in a printed form as well as in an electronic form. Data may be posted on an appropriate website. A description of the monitoring system and the methods used to collect and collate the data should also be published. Each country is urged to solicit input from all stakeholders to determine the most effective, transparent, and interpretable method of publishing the data.

It is also recommended that WHO in collaboration with FAO and OIE establish a website where national data and the analyses are published. This should be linked to data available on antimicrobial use in humans.

Within each country, confidentiality agreements and laws should be reviewed and obstacles to reporting usage data resolved. However, where it is necessary to protect confidentiality in certain countries, data may be aggregated into compound classes prior to publication by the national government.

4. WHO in collaboration with other relevant international organizations should recommend a system to identify and classify antimicrobial agents and quantify their use in order to make data comparable.

Standardized national and international terminology and methodology of reporting is essential so that it is clear which antimicrobials are used. A system is required to identify and classify antimicrobials similar to the Anatomical Therapeutic Chemical (ATC), which is used for human antimicrobials. One such system being developed is ATC-vet. The system chosen should be adapted to the needs of the monitoring programmes and be compatible with other relevant international systems.

Further research and development is needed into methods to analyse these data and to facilitate the comparison between different animal species and with human use. One such concept may be an analogue of Defined Daily Dose (DDD). The DDD-system is a way in human medicine to express drug usage and compare antimicrobial agents of varying potency. It is recommended that a working party be established to address this issue.

5. Countries should link antimicrobial usage data with antimicrobial resistance data.

The monitoring of antimicrobial resistance in both food animals and humans within countries has previously been recommended in “The WHO Global Principles for the Containment of Antimicrobial Resistance in animals Intended for Food”.

Resistance and drug usage monitoring systems are databases with very valuable information that should be made available for analyses and need to be compatible. It is recommended to link these data at least within the same species, but the ultimate goal is to analyse the potential risk to humans. The analyses should be conducted using sound scientific principles, but descriptive data alone can be very useful. Further research will need to be undertaken and supported to accomplish these goals.

5. Summary of presentations

Through the many excellent presentations during the consultation, participants gained knowledge about the monitoring of antimicrobial usage in food producing animals in many countries throughout the world. Scientists, industry, international, governmental and nongovernmental organizations were represented among the speakers. It became obvious that the level of control with antimicrobial usage is highly variable between different countries and that the feasibility of implementing monitoring schemes for antimicrobial usage differs greatly between countries. The following section contains examples of monitoring schemes in a few selected countries, in an attempt to outline some of the differences that exist.

In Denmark, antimicrobial usage in food animals has been monitored and published in the annual DANMAP report since 1995. The system provides an estimate of the national usage of veterinary antimicrobials at the wholesalers level. Most veterinary antimicrobial formulations in Denmark are available on prescription only. In order to be able to determine further details about the usage, such as target species and main indication for use, usage data will be collected at endpoint through cooperation with veterinary practitioners. This comprehensive system is expensive, but has placed Denmark at the pinnacle of antimicrobial usage monitoring in food animals. Other individual countries in Europe have also developed monitoring programmes for usage of antimicrobial drugs in food animals. And in the European Union further action at Community level has been proposed as part of a strategy against antimicrobial resistance. Several antimicrobial growth promoters have also been withdrawn from the market due to the public health impact of emerging antimicrobial resistance. In Australia all antibiotics are imported. The government requires details from importers on the intended end-use of all these imported antibiotics. Hence there is data available on the quantities of different antibiotics used in animals and in people within that country.

Several speakers from the United States (US) were represented. They all agreed that the knowledge about the amount of antimicrobials used in agriculture in the US today is limited. The Union of Concerned Scientists has published a report that estimates the non-therapeutic usage of antimicrobials in the US exceeds the human use by far. However, this report was based on publicly available information like herd sizes, indications for antimicrobial use and dosages, not on actual sales figures. There are several obstacles to obtaining correct estimates of the antimicrobial usage in US agriculture. Many drugs that are used in food-producing animals require no prescription and are sold straight from manufacturers to distributors, without going through a pharmacy. Also, when the sponsors of approved animal drugs in the United States submit their annual reports on the sales of each drug they are not required to specify whether the substance is meant for domestic use or export or what the actual conditions for use are. The US Food and Drug Administration is proposing changes in this recording system, to enable a more accurate estimate of the antimicrobial usage in food animals.

In Brazil, the large poultry industry commonly uses a wide selection of antimicrobials as growth promoters and as anticoccidial drugs. Surveys have shown an increase in the level of resistance among pathogenic bacteria like *Salmonella sp.* in Brazil, and both industry and scientific institutions are working to develop alternatives to antimicrobials in poultry production.

Speakers from developing countries frequently reported a lack of control with antimicrobial use in animals intended for food. In India there is no legislation regarding antimicrobial usage or residues in food. A recent survey of Indian water buffalo milk revealed

high levels of oxytetracycline residues, indicating that antimicrobial use is widespread and under little control. A similar situation was reported from Indonesia, as well as in other countries in the same area. Thailand has a large production of swine and poultry, where many antimicrobials are applied for growth promotion purposes. The Thai aquaculture industry, with production of shrimp in particular, routinely uses large quantities of antimicrobials.

In African countries such as the United Republic of Tanzania and Uganda, veterinary antimicrobials are easily accessible and under low levels of control from government authorities. The fact that expired antimicrobial drugs have been given new labels and subsequently exported to developing countries is another issue of concern. An extensive study performed in Kenya between 1995 and 1999 estimated the use of antimicrobial agents to food animals using data from both local manufacturers and official import records. This work stands to prove that reasonably accurate estimates of antimicrobial usage can be obtained without high costs, as long as there is a transparent regulation of the pharmaceutical trade present. Overall, a strong need for control measures and prudent use guidelines was emphasized by several speakers from developing countries.

Because the countries represented at the consultation have such different levels of control with the antimicrobial usage for animals intended for food, some system of standardization is needed to enable comparisons of usage between countries and regions. Both units of measurement and the categories of antimicrobials need to be defined and standardized.

Annex 1: Glossary

Antimicrobial agent

Any substance of natural, synthetic or semi-synthetic origin which at low concentrations kills or inhibits the growth of microorganisms but causes little or no host damage.

Antimicrobial class

Antimicrobials with a related molecular structure, often with a similar mode of action. Variations in the properties of antimicrobials within a class often arise as a result of the presence of different side chains of the molecule, which confer different patterns of pharmacokinetic and pharmacodynamic behaviour on the molecule.

Antimicrobial growth promoter

Antimicrobial agents used for the purpose of increasing daily weight gain or feed efficiency (feed-weight gain ratio) of food-producing animals.

Antimicrobial resistance

The ability of a microorganism to continue to multiply or persist in the presence of therapeutic levels of an antimicrobial agent.

Antimicrobial resistance genes

Genes in microorganisms which confer resistance to antimicrobials. These are often located on mobile genetic elements thereby enabling transmission from resistant to susceptible strains.

Containment of antimicrobial resistance

Infectious disease control measures that minimize the emergence and spread of antimicrobial - resistant microorganisms.

Disease control

Activities aimed at preventing or curing disease in animals intended for food.

Empirical therapy

Therapy that is initiated based on observation of clinical symptoms and patient history only, without previous confirmation of diagnosis by laboratory or other methods.

Food-producing animal

Animals raised for the purpose of providing food for humans. Most commonly this refers to poultry, swine, cattle and sheep, but does not exclude other domestically managed animals.

Good management/farming practices

Routine practices that minimize risk from harmful antimicrobial resistant bacteria or resistance genes through good farm management and hygiene practices (e.g. optimal housing conditions and feeding strategies) and other non-antimicrobial disease preventive strategies, whilst maximizing the productivity of food animal production.

Pharmacokinetics

The ways in which antimicrobials (principally drugs/medicines) are absorbed by, move within, and are finally eliminated from animals, humans, etc.

Pharmacodynamics

The behaviour (e.g. quick, slow, short term, long term, etc.) of an antimicrobial at its receptor site (i.e. where it initiates its effect).

Prescribing practices

The behaviour of licensed medical or veterinary practitioners regarding their prescription of medicines, including such aspects as high or low propensity to prescribe such medicines, and procedural aspects such as readiness to delegate to non-medically-qualified staff decisions on repeat prescriptions and other routine demands.

Prescription-only medicines

Medicines that are only legally available to the "end user" if he/she obtains a prescription from a licensed professional (e.g. veterinarian, medical doctor, dentist).

Prophylactic use

The administration of an antimicrobial to healthy animals prior to an expected exposure to an infectious agent or, following such an exposure prior to onset of laboratory-confirmed clinical disease. Generally such usage is in a herd or flock situation and not an individual animal.

Prudent use of antimicrobials

Usage of antimicrobials, which maximizes therapeutic effect and minimizes the development of antimicrobial resistance.

Registration (Licensing, Authorization, Approval)

The process of approving a drug for marketing in a country/region. Includes assessment using particularly the criteria of safety, quality and efficacy. As a consequence of inadequate local capacity many developing countries rely on "third party certification", i.e. granting market authorization to products approved in certain developed countries.

Regulatory authority

A government agency responsible for codifying and enforcing rules and regulations as mandated by law.

Relevant authority

An authority with jurisdiction over relevant areas of concern in relation to use of antimicrobials in animals, including registration, licensing, sale, distribution, marketing and dispensing of antimicrobial agents.

Risk

A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

Risk-based evaluation

Evaluation of scientific and other relevant information with the aim of obtaining a qualitative and/or quantitative estimation of the probability of occurrence and severity of known or potential adverse public health effects.

Stakeholder

A person or group of persons, or an industry, association, organization, etc. with an economic or professional interest/responsibility in an area or (involuntarily) affected by the developments in the same area. In the field of antimicrobial usage in food animals the farmers, veterinarians, animal feed manufacturers, food processors and distributors, retailers, relevant government organizations, pharmaceutical companies, consumers, public health officials, academic and other related groups are recognized as stakeholders.

Therapeutic use

Application of antimicrobials in curative doses in an adequate period of time to combat an established infection.

Zoonotic bacteria

Bacteria that are present in animal reservoirs, that can be transferred to, and cause infections in humans

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Annex 3: Agenda

Time	Monday 10 September 2001	Speaker
9.00 – 9.30 9.30 – 10.00	<ul style="list-style-type: none"> • Registration • Welcome, practical information • Opening address 	<ul style="list-style-type: none"> • Dr H. Kruse • 1) General Director, Dr G. Bakken Norwegian Ministry of Agriculture • 2) Director Dr B. Næss National Veterinary Institute
10.00 – 10.15	Introduction, agenda, scope of consultation, presentation of participants, election of chairman	<ul style="list-style-type: none"> • Dr P. Braam
10.15 – 10.30	<ul style="list-style-type: none"> • Background: Berlin Meeting/Global Principles 	<ul style="list-style-type: none"> • Dr H. Kruse/ Dr P. Collignon
10.30 – 11.00	<ul style="list-style-type: none"> • Use of data for public health interventions 	<ul style="list-style-type: none"> • Dr A. Anderson
11.30 – 13.00	<p><u>(Session One – continued)</u></p> <ul style="list-style-type: none"> • “Monitoring antimicrobial use in food animals – Experiences and perspectives from various countries” <p>Emphasis on the presentations will vary; drug usage in total, usage of different categories of drugs, usage in various animal categories, specific consumption data, patterns of use, systems for monitoring, obstacles, political issues</p> <p><i>10 min. presentations+5 min. discussion</i></p>	<ul style="list-style-type: none"> • Australia (Dr T. Dyke) • France (Dr P. Sanders) • Kenya (Dr E. Mitema) • Canada (Dr R. Reid-Smith) • Uganda (Dr S. Majalija)
14.00 – 16.00	<p>(Session One – Continued)</p>	<ul style="list-style-type: none"> • Brazil (Dr E. da Silva) • South Africa (Dr G. Swan) • India (Dr R. Bhat) • United Republic of Tanzania (Dr L. Kinabo) • USA (AHI) (Dr R. Carnevale) • USA (Union of Concerned Scientists) (Dr M. Mellon)

Time	Tuesday, 11 September 2001	Speaker
9.00 – 11.00	<u>(Session One – Continued)</u> <i>10 min. presentations+5 min. discussion</i>	<ul style="list-style-type: none"> • Norway (Dr K. Grave) • Sweden (Dr C. Greko) • USA (FDA) (Dr L. Tollefson) • Denmark (Dr F. Bager) <i>(20 min + 5 min for questions)</i>
11.30 – 13.00	<u>Session Two</u> "Perspectives from international regulatory agencies, international organizations, consumers, industry and other stakeholders" <i>10 min.+5 min. discussion</i>	<ul style="list-style-type: none"> • FAO • OIE (Dr J. Boisseau) • European Commission (Dr P. Makela) • EMEA (Dr P. Jones) • IFAH (Dr T. Mudd)
14.00 – 16.00	<u>(Continued – Session Two)</u>	<ul style="list-style-type: none"> • FEDESA (Dr J. Vanhemelrijk) • Consumers' International (Dr E. Silbergeld) • FEFANA (Dr R. Bywater) • Sadia S. A, Brazil (Dr I. Delazari) • Bayer (Dr A. de Jong) • APUA, USA (Dr S. DeVincent) • World Veterinary Association (Dr H. Schneider)
16.30 – 18.00	<ul style="list-style-type: none"> • General discussion and introduction to working groups 	

Time	Wednesday, 12 September 2001	Speaker
9.00 – 10.30	<ul style="list-style-type: none"> • <u>Working groups</u> Split into four working groups 	
11.00 – 13.00	<ul style="list-style-type: none"> • Working groups 	
14.00 – 16.00	<ul style="list-style-type: none"> • Plenary presentations from working groups – discussions 	
16.30 – 18.30	<ul style="list-style-type: none"> • Continuation discussion, finishing drafts from working groups 	

Time	Thursday, 13 September 2001	Speaker
8.30 – 10.00	<ul style="list-style-type: none">• Plenary discussion draft report	
10.30 – 12.00	Continued discussion draft report	
13.00 – 15.00	<ul style="list-style-type: none">• Summing up/recommendations• Closure, adjourn	