Health Canada Santé Canada

REPORT OF THE CONSULTATION WITH STAKEHOLDERS ON THE *DEVELOPMENT OF A RISK MANAGEMENT STRATEGY ON ANTIMICROBIAL RESISTANCE ASSOCIATED WITH ANIMAL USE OF ANTIMICROBIAL AGENTS*

GATINEAU, QUEBEC MAY 22-23, 2003 **VETERINARY DRUGS DIRECTORATE**

INTRODUCTION

On May 22-23, 2003, the Veterinary Drugs Directorate of Health Canada brought together stakeholders to share information and discuss the human health implications of antimicrobial resistance and risk management approaches of the use of antimicrobials in veterinary medicine and livestock production. The consultation focussed on Health Canada's proposed options in response to the recommendations of the Advisory Committee on Animal Uses of Antimicrobials and Impact on Resistance and Human Health (AMR Advisory Committee).

The consultation format included presentations to build a common understanding of the issues associated with the proposed options, question and answer sessions, table group discussions and plenary reports. The topics covered were Regulation and Distribution of Antimicrobial Drugs (Prescription Status Issues; Importation of Antimicrobials; Extra-Label Drug Use; Harmonization Issues); Management of Antimicrobial Resistance Risks (Risk Analysis of Veterinary Antimicrobials; Antimicrobial Growth Promotants); and Prudent Use of Antimicrobials, Research and Education.

This report provides an outline of the consultation and a summary of stakeholder discussions and views, as presented in plenary report and table discussion records.

PRESENTATIONS

Diane Kirkpatrick, Director General, Veterinary Drugs Directorate, Health Canada, provided an overview of how Health Canada has been addressing antimicrobial resistance, the objectives for the consultation, and the options as presented in the discussion paper. She told participants that the involvement of stakeholders is an important step in the process of developing policy and risk management strategies and implementing the recommendations of the AMR Advisory Committee. "By working together in partnership, we can control the spread of antimicrobial resistance."

Rebecca Irwin, Coordinator, Antimicrobial Resistance Surveillance Unit, Laboratory for Foodborne Zoonoses, Health Canada, spoke to participants about surveillance and monitoring of the use of antimicrobials.

The Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS) has been created to collect, analyse and disseminate information and data on the use of antimicrobials and their implications for human health, including emerging antimicrobial resistance evidence and trends. A goal of CIPARS is to "work towards the preservation of effective antimicrobials in humans and animals." She noted that stakeholders have a key role to play in monitoring and surveillance.

CONTENTS

Canada

Part 1
REGULATION AND DISTRIBUTION OF ANTIMICROBIAL DRUGS

Prescription Status Issues

Health Canada's Proposed Option: All veterinary antimicrobials for disease treatment and control should be available by prescription only.

Organizations Responsible for Implementation: Health Canada, provincial/territorial authorities in consultation with drug sponsors, producer groups, and veterinarians.

Timeline for Implementation: Fall 2004

Summary of Discussion

Although a number of concerns were raised regarding this option, there was a general agreement that further research and consultation is needed. However several participants indicated that the prescription-only approach would reduce the inappropriate use of antimicrobials, thereby helping to reduce the development of antimicrobial resistance and its potential consequences for human health.

Participants noted that a national policy is desirable because it would eliminate inconsistencies across jurisdictions and ensure common rules in all provinces. A national policy would also lead to an increase in trade partner and consumer confidence in Canadian food products.

A prescription-only option might encourage the use of alternatives to antimicrobials, such as improved herd management, sanitation, and housing practices, increased use of vaccinations, etc., and complement on farm food safety (OFFS) programs. Participants emphasized that OFFSwould need to be in place for this option to be effective.

This option would enhance record keeping – "We'll know where, when and how much has been used." This data will be useful in tracking changes and assessing program success.

To be effective, the regulation must be supported by producer education on the proper use of antimicrobials. Some participants preferred an "education not regulation" approach.

On the veterinary side, education in prescription writing to provide complete and clear instructions needs to be provided both in the veterinary colleges and to existing veterinaries.

Participants suggested that the use of tools, such as electronic prescription writing software, drug databases, etc., be encouraged.

Participants were concerned that a prescription-only regulation would add significant costs for producers, as prescription drugs will be more expensive than the same drug over the counter. There could also be increased veterinarian charges (for writing the prescription, visiting the farms, etc.). Suppliers (farm co-ops, over-the-counter distributors) would face decreased income through loss of sales.

Concern was expressed that the option would place increased pressure on veterinarians, who would have to be available "24/7." In some areas, there is a shortage of veterinarians, particularly for large animals and in the western provinces. The option will need to be reviewed in terms of the capacity of veterinarians to serve producers.

Participants noted the importance of timely treatment when disease strikes an animal, herd or flock, and cautioned that the prescription-only option could lead to delays in the provision of medication. This could result in unnecessary pain and suffering by the animal and/or health implications for the entire herd or flock. It was noted that restrictions on barn visits for biosecurity reasons further increase inaccessibility of veterinarians and could extend the length of time before starting treatment.

Participants cautioned that an overly restrictive system could lead to a "black market" and unrecorded use of antimicrobials, which would further exacerbate the antimicrobial resistance situation and erode confidence in Canadian farm animal products. Internet sales could also present similar problems. Enforcement issues will need to be considered.

The issue of conflict of interest is inherent in this option (i.e. the notion that the more a veterinary prescribes, the more money he/she makes). The effectiveness of the option depends on the commitment of veterinarians to prescribe in a judicious and prudent manner. Participants suggested that a mechanism to deal with conflict of interest be developed.

Participants felt that more consultation and discussion with provinces and stakeholders is needed, particularly around definitions, implementation and impacts. Specifically:

- The term "prescription" needs to be clearly defined. For example, is it for an individual animal, for an individual incident of disease? Could a veterinary prescribe a year's worth of a drug, which would then be used by the producer as required. It was suggested that a prescription could be issued on a herd basis, e.g., a feed lot for six months to be administered under a specific protocol.
- "Disease treatment and control" needs to be clarified. Does this option exclude antimicrobials used for growth promotion purposes?
- The range of antimicrobial drugs covered needs to be clarified. Would disinfectants, low impact drugs, etc., require a prescription?

In light of the need for further consultation, participants felt that implementation by Fall 2004 would not likely be possible.

Other comments and suggestions for improvement/consideration included:

- Review the model used by Quebec, which seems to be very effective. Investigate whether use of antimicrobials in Quebec has decreased since the introduction of the regulation (1995).
- Conduct regulatory risk/economic impact assessments with producers, consumers, and associations.
- Create a system whereby farmers can be "licensed" to purchase drugs through co-ops. To obtain such a license, a producer would have to go through education and training on the proper use of antimicrobials.
- Build flexibility into the policy to provide for exemption from prescription if it can be supported by science.
- Research and evaluation is needed prior to implementation of programs with outcomes being monitored.

Importation of Antimicrobials

Health Canada Proposed Option: Develop approaches and means to control the importation, sale and use of antimicrobials to close the "own use" loophole. Importation of active pharmaceutical ingredients (APIs) would be strictly under a Health Canada permit.

Organizations Responsible for Implementation: Health Canada, Canadian Food Inspection Agency (CFIA), Canada Customs and Revenue Agency (CCRA), and affected stakeholders.

Timeline for Implementation: Winter 2004/2005.

Summary of Discussion

The proposed option was seen by participants to be a positive move toward more effectively controlling the use of antimicrobials, although some participants commented that they require more information and understanding to have a full discussion on the option. It is important that this "back door" be closed. In addition, a permit process will provide a paper trail for improved record keeping, surveillance, quality assurance and research on use and impacts. Permits must apply to all quantities – participants noted that currently non-commercial quantities are not questioned.

The economic impact of this option on producers will need to be studied. Participants noted that the impact of *not* imposing importation controls should also be examined relative to trade, consumer confidence and research and development.

The permit process and requirements will need to be well defined and understandable, including the conditions that must be met to receive a permit, time required for issuance, and what is covered by the permit in terms of quantity and time period.

It was also suggested that importation of API's be limited to Establishment Licensed facilities, specially licensed compounding pharmacists and veterinarians. It was recommended that the own use policy only apply to individuals travelling with their animals and in ownership of the animal(s) at border control points.

Having the Health Canada permits issued to manufacturers holding an establishment license will eliminate the possibility of increased costs to our member's provided the establishment licensing costs remain stable, and no increased administrative burden is incurred.

Permits will need to be issued in a timely manner so as not to unduly impede treatment. Participants recommended that there be a "single window" system to ensure an uncomplicated application process.

Participants emphasized the importance of tying the permit process to enforcement. As one group noted, "regulations are only as good as the enforcement." There will need to be strong consequences, such as fines, revocation of license or jail terms. Suggested potential tools for enforcement include establishing licenses that manufacturers and warehouses hold, further licensing of veterinarians and pharmacists, residue analysis, border controls, feed manufacture inspection, on-farm audits and development of an expanded emergency drug release process. It was suggested that the regulations and tools used by the U.S. be reviewed.

Some participants felt that the use of APIs should be banned for food production animals, noting that some processors won't use animals that have had APIs or own-use drugs.

Other comments and suggestions included:

- The definition of API must be clarified – will non-living materials be covered? Animal by-products? Are these drugs unapproved for use in Canada?
- The permit process supports accelerated drug review times.
- The suggested timeline for implementation is too short.

Extra-Label Drug Use (ELDU) Policy

Health Canada Proposed Option: Recognizing the value of ELDU when used judiciously, efforts will be made to maximize the advantage and minimize the disadvantages of ELDU. Results of the ongoing Survey on Drug Use on Animals are expected before the end of 2003. The outcome of this survey will determine amongst other things, Health Canada's future policy on ELDU. This issue will be discussed at a future consultation focussing on ELDU.

Organizations Responsible for Implementation: Health Canada, Canadian Food Inspection Agency, industry, producer groups, veterinary medical associations and individual veterinarians.

Timeline for Implementation: Fall/Winter 2004.

Summary of Discussion

There was general support for developing a policy on ELDU, and for having a clear picture of how widespread the ELDU practice is. Participants felt that more data is needed on the use of all animal drug use, not just ELDU. It will also be important to define the advantages of the policy for stakeholders (pharmaceutical companies, veterinarians and producers).

It was noted that ELDU increases the liability and responsibility of veterinarians and decreases the incentive for pharmaceutical companies to get approvals.

Some participants felt that the survey results and additional consultation are needed before final recommendations can be made, while others felt that it is more important to move ahead immediately. Health Canada should ensure that the terminology in the Survey on Drug Use on Animals is clear, so that everyone is working from a common understanding of ELDU. A distinction is needed between off-label and extra-label use.

Some participants commented that antimicrobial resistance is a consequence of extra-label use, and that all extra-label use should be by prescription only. Labels should be written to prevent extra-label use and to limit a drug's use to certain species, ages, circumstances.

Other suggestions and comments included:

- Producers should not be able to use extra-label drugs. It should remain a veterinarian's right to recommend ELDU. Acceptable professional practice standards need to be in place.
- Any policy that Canada applies should be harmonized with the policy of trading partners, particularly with the U.S., so that we don't put our own industry at a disadvantage.
- Extra education is required for veterinarians on ELDU.
- Provinces/territories should be consulted on this issue and included in the list of organizations responsible for implementation.

- Canada's approval process is long and expensive. Health Canada should consider a minor use program, such as the program available for pesticides, with the participation of pharmaceutical companies.
- Don't abandon science-based risk assessment.
- Pharmaceutical companies should invest in animal drugs as they do for human drugs.

Harmonization Issues

Health Canada Proposed Option: Health Canada is committed to harmonization with other international regulatory agencies, wherever appropriate and feasible to address a wide range of issues regarding AMR (recommendations 2, 3, 4, 5, 14, 16, 17, 26, 28, 31, and 35). Steps have been taken to action this commitment.

Organizations Responsible for Implementation: Health Canada in collaboration with regulatory agencies such as: FDA Center for Veterinary Medicine (USA), Codex Committee on Residues of Veterinary Drugs in Foods, International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), World Health Organization (WHO), Office International des Epizooties (OIE), Quadrilateral Group (Australia, New Zealand, USA and Canada) on Food Safety, as well as with drug sponsors, producer groups, and veterinary medical associations.

Timeline for Implementation: Ongoing.

Summary of Discussion

Participants noted that harmonization discussions with other jurisdictions and organizations provides the opportunity for scientific dialogue, the sharing of information and experiences and the identification of appropriate approaches and mechanisms. In terms of the marketplace, harmonization is "a must in a global environment." Participants noted that "harmonization must be based on science, not just on what we think consumers are comfortable with." Concern was expressed that Canada is a "backbencher at Codex" and that, due to their nature, international committees move very slowly.

Clarification is needed around what is being harmonized. For example, does it include product data requirements, processes for regulatory review, etc.?

Suggestions and comments included:

- Review data from other countries (for example, the U.S. FDA Guidance Document) and adapt to Canadian regulations and conditions.
- Risk assessments must be transparent and fill all data gaps.
- Establish MOUs to provide for the sharing of proprietary information.
- There should be two streams – bilateral with major trading partners (U.S., Japan, Mexico, Korea and Australia) and multilateral, with concentration on the bilateral stream.

- The economic implications (on trade, for example) of harmonization need to be considered.
- Better coordination is needed between Health Canada and CFIA.
- Maximum residue limits (MRLs) don't address antimicrobial resistance.

Part 2
MANAGEMENT OF ANTIMICROBIAL RESISTANCE RISKS

Risk Analysis of Veterinary Antimicrobials

Health Canada's Proposed Option: Risk analysis of new and existing antimicrobials will be conducted according to the OIE guidelines and on priority basis. Health Canada will seek expert advice on specific risk assessment data provided by drug sponsors to evaluate the health risks and benefits of antimicrobials. An Expert Panel on Antimicrobial Resistance consisting of some members of the Advisory Committee, scientists from academia, as well as Health Canada's risk assessors will be formed to provide expert advice on risk assessment. The Expert Panel will consider input from various sources including drug sponsors and producer groups with respect to risk assessment issues. Proposed option is based on Advisory Committee's recommendations 14, 15, 16, and 17.

Organizations Responsible for Implementation: Health Canada in collaboration with drug sponsors and producer groups.

Timeline for Implementation: Review of existing antimicrobials will commence in Fall 2003.

Summary of Discussion

The proposed option was generally seen to be a positive, proactive approach. Participants noted that risk analysis would be science-based, help to maintain the effectiveness of antimicrobials, enhance public trust, increase international credibility and establish direction on priorities. It would give end-users confidence that the antimicrobials they select won't be increasing resistance and harm to human health.

Participants recognized the need to be aware of all global regulatory activities, to agree with other jurisdictions on a risk management/analysis process and to "harmonize to the greatest degree possible." As one group noted, "antimicrobial resistance is a global problem – we must harmonize our approach to it." However, Health Canada should have final responsibility to ensure the safety of Canadians. For example, Health Canada should have the ability to put a "stop use" order on an antimicrobial product.

Participants suggested that the expert panel for risk analysis should be knowledgeable, experienced and science based, and include microbiologists, pharmacologists, statisticians, epidemiologists and others who could contribute to the specifics of risk assessment. The role and responsibility of the panel needs to be clearly defined in terms of evaluation of data and risk assessment results, selection of priorities, etc. The communication of results will be important. Stakeholders should be provided with results and given the opportunity to be involved, including veterinarians, livestock producers, associations, non governmental organizations, consumer groups, and drug companies.

Some participants noted that the proposed option "is not sufficiently tangible to ascertain what is good or bad about it." For example, how will the capacity of an antimicrobial to create resistance be assessed? Will all points of view be considered in the risk analysis process – from farm to fork? Participants observed that the science required to properly assess the potential for an antimicrobial to contribute to resistance is not fully developed – such risk assessment methodology could be expensive to develop.

Participants felt that the proposed option would ensure the updating of existing drug labels to reflect current situations and eliminate any existing "bad" antimicrobials. However, participants cautioned that the option could cause some of the older approved antimicrobial drugs, which don't have sufficient financial backing or data, to be removed from the marketplace. Some of these drugs could be potentially lost.

Participants felt that risk analysis should consider resistance in terms of both food safety and human health, and not be restricted to food production animals. Antimicrobial use on companion animals should also be subject to risk analysis. There should be a prioritization of antimicrobials posing human health risks.

Some participants felt that the risk analysis option would make drug evaluation and approval more complicated and slower, and would increase the cost of antimicrobials. In addition, there is a fear that new drugs may not be developed. The cost of registering a product in Canada is high compared to potential Canadian sales. As one group noted, "the current system is already very lengthy and expensive – putting another layer of evaluation in place

may be prohibitive." It was suggested that a procedure for appealing a decision of the risk assessment panel be part of the proposed option.

What is acceptable risk and how do we manage it? Participants questioned whether there would be sufficient capacity to manage the scope of risk assessment suggested by the proposed option, in terms of both personnel and funding. Are there sufficient human resources? Participants noted that the backlog of risk analysis of human drugs is "huge." It is not clear how much will be paid to conduct these risk analyses?

It was suggested that Health Canada accept data and results from other countries, if the information has been compiled under recognized international standards/guidelines. For example, risk analysis data is available in the U.S. on two drugs: Fluoroquinolone and Virginiamycin. Heath Canada should consult with the U.S. and develop a model of risk analysis based on this data.

It was suggested that the word "transparency" be added to the proposed option and that efforts be undertaken to ensure that drug manufacturers know exactly what evaluation process will be used to assess the potential for an antimicrobial drug to increase the incidence of resistant bacteria. However, participants questioned how a process could be both transparent and confidential. In terms of the timeline for implementation of this option, participants were informed that Health Canada would, in all likelihood, establish the rules for review of existing antimicrobial drugs in the fall of 2003 and that the commencement of the actual reviews would likely be in the winter of 2003 or early 2004.

Other comments and suggestions included:

- Animal health must remain protected – the use of antimicrobials cannot be eliminated because of risk of the development of resistance.
- Risk assessment may be science based, but risk management becomes political.
- Instead of focussing on pre-market testing (risk assessment), increase post market surveillance.
- Add a public interest component.
- The suggested timeline for implementation is "impossible."
- Why waste money evaluating growth inhibitors? Support for recommendation 16, not for 17.

Antimicrobial Growth Promotants (AGPs)

Health Canada's Proposed Option: The risk analysis strategy should include the issue of efficacy to determine the fate of antimicrobials that are being used as growth promotants. Policy changes with respect to AGPs depend on the outcome of risk analysis. Initial focus of risk analysis will be on penicillin, tetracycline, tylosin, virginiamycin, and bacitracin.

Organizations Responsible for Implementation: Health Canada, Canadian Food Inspection Agency, in collaboration with drug sponsors and producer groups.

Timeline for Implementation: Review of AGPs will commence in Fall 2003.

Summary of Discussion

Some participants questioned the appropriateness of Health Canada's role in determining the "efficacy" of antimicrobial growth promotants. Health Canada should be focussing on safety issues, not efficacy. Some participants felt that antimicrobial growth promotants is a management issue to be handled by the food animal production industry, and some participants felt that the marketplace would dictate continued use or elimination of antimicrobial growth promotants. "Let the marketplace sort it out," was how one group put it.

Health Canada noted that it is not the intention of the proposed option to ban the use of antimicrobial growth promotants. Any decision must be based on evidence of risk to animal and/or human health. Health Canada has a role to play in determining the efficacy, so that the use of drugs that do not demonstrate efficaciousness is discontinued.

Some participants felt that antimicrobial growth promotants should be banned entirely for food safety and "public perception" reasons. Conversely, there was concern that there is not a clear enough link between the use of antimicrobial growth promotants and antimicrobial resistance to support banning or phasing out their use.

Some participants felt that Health Canada should take a risk assessment approach to antimicrobial growth promotants and the risk analysis should include the issue of efficacy. The focus should be on the "risks" as well as the "benefits" provided through the use of antimicrobial growth promotants. If it is determined that there is a health risk, stakeholders will need to be involved in a full debate to determine the level of acceptable risk before a generic ban is introduced.

Some participants felt that efficacy can be demonstrated for most antimicrobial growth promotants (increased feed/gain ratios and increased health status). They cautioned that a ban could have negative impacts, such as poor meat quality, increased use of antimicrobials for therapeutic purposes, increased costs for producers and consumers, and trade implications. For example, without antimicrobial growth promotants animals may get sick and require antibiotics. Participants observed that when Denmark and Sweden banned antimicrobial growth promotants there was an increase in disease in weaner pigs and broilers, which resulted in an increase in the therapeutic use of the same drugs.

Although producer costs would increase if antimicrobial growth promotants were banned, education on alternative/enhanced production practices could help offset this effect. Research on the economic impacts of the use of antimicrobial growth promotants is needed.

There was some concern expressed that Health Canada's involvement in determining efficacy could strain resources/capacity. Funds and resources would possibly be better spent on the research and development of improved production and animal management practices. Risk analysis on antimicrobial growth promotants that are not used or that are rarely used in human therapy should be considered by Health Canada but given low priority. This would help "lighten the load."

Other comments and suggestions included:

- Efficacy assessment is one of the most difficult tasks for regulators.
- Antimicrobial growth promotants should be reclassified as prophylactic, not therapeutic.
- Efficacy depends on the drug, dosage, organism and host species.

Part 3

PRUDENT USE OF ANTIMICROBIALS, RESEARCH & EDUCATION

Health Canada's Proposed Option: Health Canada proposed to establish a joint Committee with stakeholders to develop a communications strategy, tools, and messages aimed at promoting prudent and judicious use of antimicrobials, as well as addressing the need for developing educational programs focussing on antimicrobial resistance.

Organizations Responsible for Implementation: Health Canada, and other federal authorities, provincial/territorial authorities, veterinary medical associations, producer groups, drug sponsors, veterinary colleges, as well as the Canadian Committee on Antibiotic Resistance.

Timeline for Implementation: First meeting to be held in the Winter 2003/2004.

Summary of Discussion

There was agreement that education on the prudent use of antimicrobials is needed. The idea of a joint committee was supported by participants, but it was emphasized that Health Canada needs to take the lead by ensuring standards are in place, that an auditing mechanism is established and that there is full involvement of provinces and territories – "a national focus with regional input" was how one group put it. The committee could help track data from regional labs, help evaluate and interpret health and economic outcomes of using non-traditional medications, communicate instances of significant pathogens and which antimicrobials are available to treat region-specific incidents of infection, and serve as a forum for discussion of key issues as they arise.

Some participants felt that education on the prudent use of antimicrobials should be under the authority of the Canadian Veterinary Medical Association (CVMA), not Health Canada, as the CVMA is the national body that the veterinary profession looks to on educational issues.

However, Health Canada could play a role in funding the CVMA's educational efforts and helping to develop tools that will support delivery of a common message across the country. Species-specific guidelines, like those used in the United States, would be useful.

As well as the veterinarian community, producers also need to be educated on the prudent use of antimicrobials. Participants supported the idea that producers be reached through a partnership with the commodity On-Farm Food Safety Programs (OFFS). Partnership roles could include education development, delivery, information sharing and tracking of results.

There should be an assessment component to any education that is done in order to evaluate if it is working. For example, private veterinarian practices could be audited to ensure they are giving clients best practice information on antimicrobial use. Other indicators of success would be decreased use of antimicrobials and reduced resistance.

Participants noted that education and outreach are extremely expensive. It will be important to set priorities, target what needs to be done quickly and what can be done later, in order to make the best use of limited resources.

It is important to distinguish between and separate "education" and "research." While Health Canada is positioned to take a leadership role in education, it should leave research to other organizations such as the Canadian Institutes of Health Research, Aquanet, national/provincial centres of excellence, etc.

Participants felt it is important to "beef up" the infrastructure of laboratories and supporting science to veterinarians to help them change their prescription practices. Without research that clarifies how much the antimicrobials in use are affecting resistance, it is difficult to counsel on prudent use.

Other comments and suggestions included:

- Consider the development of a research strategy, with input from a stakeholder committee.
- Share prudent use guidelines with the U.S.
- Consider a consumer education component, particularly on safe handling practices.
- Build on existing committees – "no new committees."

CLOSING COMMENTS & KEY MESSAGES

Diane Kirkpatrick thanked participants for their contributions and insights. She noted that she has a greater appreciation for the issues and impacts of the different options and approaches on different stakeholders. She reviewed the key messages:

- *Prescription Status Issues:* The proposed option demonstrates transparency and will enhance consumer and international confidence in Canadian animal food products. There may be increased costs associated with the option – an assessment of the economic impact should be undertaken. There are concerns about the availability of veterinarians.

- *Importation of Antimicrobials:* It is important and necessary to take steps to close the regulatory loophole around own-use provisions. Strengthened enforcement mechanisms and penalties will need to be in place to ensure Canadians are protected.

- *Extra-label Drug Use Policy:* Health Canada needs to work closely with the provinces and territories, veterinarians, and producers to build understanding of the issues and to identify areas where extra-label drug use may be increasing human health problems and affecting animal welfare. There are cross-over issues related to this option, such as the availability of veterinarians, updating of labels for dosage, etc., that must also be considered in the development of extra-label drug use policy.

- *Harmonization Issues:* Harmonization initiatives are important and will provide the opportunity for the sharing of expertise and information across jurisdictions. Canada has an important role to play at the international table to move issues forward.

- *Risk Analysis:* Setting priorities is crucial – we must hone in on those antimicrobials that carry the greatest risk of selecting resistance. Risk analysis will enhance public trust, increase international credibility and give end-users confidence that the antimicrobials they use are not increasing resistance. Risk analysis should include antimicrobials used by food and companion animals. Risk assessment should look at both sides: the risks of using antimicrobials, and the risk of not using them.

The use of an expert panel for risk analysis, comprised of experts in the area of microbiology, pharmacology, statistics, epidemiology, etc., was supported.

- *Research and Education:* Rather than creating a new committee, let's look to existing committees and stakeholder organizations, such as the Canadian Veterinary Medicine Association and producer on-farm food safety programs, to build communication and education mechanisms. Limited resources will need to be prudently spent – so we should target efforts based on short-, medium- and long-term goals.

Ms. Kirkpatrick noted that a shadow of doubt lingers when the animal use of antimicrobials is discussed: some say there is no real proof that the use of antimicrobials is increasing antimicrobial resistance. But the reality is, the evidence is equivocal and our challenge is "keeping it in the box".

In closing, Ms. Kirkpatrick told participants that the dialogue begun at this consultation will continue. The views and input of stakeholders are of vital importance to the shaping of policy on antimicrobial use and risk management strategies for dealing with this significant human health issue. Health Canada will seek stakeholder views and keep stakeholders informed as the policy development process moves forward. "Let's keep talking."

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