

Health Canada's Task Force on Own-Use Importation (OUI) Final Report – August 5th, 2008

Outline of Report

Executive Summary

Background

1. Introduction

2. Analysis of Pivotal Issues

3. Task Force Results

1) Restricted Import Product Program (RIPP)

2) Regulatory Reform

4. Implementation

Appendix I – Preliminary RIPP Characteristics as Discussed by the OUI Task Force

Executive Summary

The Own-Use Importation (OUI) Task Force was struck by Health Canada (HC) in December 2006 with the mandate of examining a new, more restricted approach to OUI of animal drugs. The new approach was intended to help address availability of competitively priced products while maintaining safety for Canadians. It was also important to be mindful of trade concerns, due to use of non-Canadian regulated product and to maintain our ability to meet international obligations¹. These factors were all addressed along with support for a fair market economy² while maintaining the tenets that the food supply needed to be safe, overall competitiveness of the animal health sector had to be considered and regulatory public policy objectives had to be met by citizens and organizations³.

Issues with the current OUI Policy were identified by various stakeholders, including federal and provincial governments, the animal pharmaceutical industry, veterinarians and some producer groups. The Task Force reviewed all of these issues. A key concern regarding the current OUI Policy administered by Health Canada was the fact that it appears to compromise the integrity of the Canadian regulatory process for animal drugs since product could potentially be imported without having to demonstrate that it meets Canadian safety and environmental standards. This leads to concerns about safety as well as concerns relative to trade since most developed countries in the world do not have the same or similar regulatory provisions.

Canadian beef and pork producers are faced with competitive challenges due to the recent rise in the Canadian dollar and rapid increase in the price of feed. The cost of the

¹ North American Free Trade Agreement, Chapter Seven, Agriculture and Sanitary and Phytosanitary Measures, 2 a and b and WTO (GATT) Agreement of Application of Sanitary and Phytosanitary Measures, Article 4, Equivalence, 1.

² Cabinet Directive on Streamlining Regulation, April 2007.

³ Regulation, www.regulation.gc.ca, 'What is regulation?'

veterinarian component⁴ (veterinary fees, animal medications, genetics and breeding) amounts to 1.9% of the cost of production. While this may seem like a small component of the overall cost of production for livestock producers, lower priced U.S. product can help to reduce producer losses by lowering the cost of some animal health products. This is particularly the case for certain types and stages of productions e.g. beef and pork finishing, which may see animal health product costs in the 5% cost of production range.

This Report addresses all the issues raised during the Task Force meetings. The recommendations of the Task Force are as follows:

- ▶ That a Restricted Import Permit Program (RIPP) be piloted to determine program feasibility. At the same time a regulatory amendment process would be initiated that would result in closure of the current OUI provisions, to be replaced by a permanent RIPP program. Program implementation would occur within the usual regulatory amendment timeframe of up to 3 years.
- ▶ That a subcommittee be established in the Fall of 2008 with the mandate of negotiating details, further to preliminary discussions outlined in Appendix 1 of the Report, of a Restricted Import Permit Program (RIPP) for implementation by Health Canada.
- ▶ That regulatory reform in the area of veterinary drugs and biologics be recognized as essential to ensure timely availability and access to products that benefit livestock and our producers and that support innovation and the development of new animal health technologies by the animal health sector. The Task Force acknowledges that the Canadian Animal Health Product Regulatory Advisory Committee was initiated in early 2008 and has begun to examine the current regulatory systems for animal medications. They are making recommendations in cooperation with the Veterinary Drugs Directorate (VDD) and the Veterinary Biologics Section (VBS), designed to improve regulatory efficiency and cost effectiveness relative to animal medications, while ensuring Canadian standards for human, animal and environmental safety and product efficacy are met.

Representatives on the OUI task force that produced this report included:

Canadian Cattlemen's Association (CCA) - Dr. Louis Desautels and alternate Rob McNabb;

Canadian Pork Council (CPC) - Clare Schlegel and alternate Morgan Radford;

Canadian Animal Health Institute (CAHI) - Jean Szkotnicki;

Dairy Farmers of Canada - Rejean Bouchard;

Consumer Interest Alliance, Inc. - Jenny Hillard;

Canadian Veterinary Medical Association (CVMA) - Dr. Gordon Dittberner and Dr. Conrad L'Ecuyer;

Provincial veterinary body - Dr. Christianne Gagnon;

Provincial governments - Dr. Ron Clarke;

⁴ Agriculture and Agri-Food Canada, Farm Net Operating Expenses and Depreciation, 2006.

Ex-officio and/or Secretariat

VDD - Dr. Siddika Mithani and their lawyers;

Agriculture and Agri-Food Canada and Foreign Affairs and International Trade - Steve Lavergne;

Pest Management Regulatory Agency (PMRA) - Trish MacQuarrie;

Health Canada Inspectorate -James Bellis and alternate Jenny McLaughlin;

Veterinary Biologics Section, Canadian Food Inspection Agency (CFIA) - Dr. Glen Gifford;

Other groups were asked to attend but were unable to participate.

Background

The Own-Use Importation (OUI) Policy was established to permit individuals to import a 90 day supply of most drugs, for their own personal use or the use of another individual in that person's care or guardianship, based on the directions for use or reasonable intake, unless prohibited by law. Determination of a 90 day dosage supply or single course of treatment would be made by referring to the directions for use on the imported product. It should be noted that livestock producer access to non-prescription pharmaceuticals through OUI provisions pursuant to existing legislation is inferred by default through the “non-inclusionary” wording of existing regulations rather than through a recognized program.

Livestock producers in Canada have been purchasing animal health products utilizing the OUI Policy, in order to give them access to less expensive drugs and generic product not available in Canada. This is primarily a price driven phenomenon: there are reported cases of prices in the U.S. at 30% or less of the Canadian product. It is recognized though that this price differential does not apply to all products and that indeed there are some products that are cheaper to purchase in Canada than in the U.S., such as, a number of feed additives. The focus by livestock producers on OUI as an issue is largely based on the narrowing of production margins due to the rising Canadian dollar against that of the U.S.

The U.S. does not have a similar OUI Policy that would give its producers access to Canadian product that could be less expensive. Further, it is recognized that the OUI Policy is not restricted to importation from the U.S. Beef and pork industry representatives focused their discussion on OUI from the U.S. but it was recognized that other specie producers were importing animal health products from countries other than the U.S. The current OUI provision permits importation of product from both developed and developing countries. Health Canada’s Veterinary Drugs Directorate (VDD) has initiated a regulatory consultation that would prohibit the importation for own use of animal drugs intended for use in food animals due to potential safety concerns.

1. Introduction

Health Canada (HC) assembled a stakeholder Task Force to consider the issues surrounding the OUI Policy and identify possible solutions. The membership was chosen

by Health Canada with input from the Canadian Cattlemen's Association (CCA) and other groups to incorporate a representative, balanced perspective from a range of interested external parties. The Task Force has participation from producer groups, Pest Management Regulatory Agency (PMRA), consumer non-governmental organizations as well as appropriate government departments (see Appendix I).

The OUI Task Force started by establishing and agreeing on terms of reference. The group then began the process of identifying the issues that required further discussion and analysis. The PMRA had just recently participated in an OUI Task Force addressing similar issues and they were a resource for the VDD Task Force.

There was an overriding principle guiding consideration of a proposal for a system to address the issues identified. It was that the Veterinary Drugs Directorate's (VDD) mandate; of protecting human and animal health and the safety of Canada's food supply could not be jeopardized. Furthermore, the shared mandate of monitoring post marketing compliance (e.g. adverse event reporting) and environmental health as it relates to pharmaceutical use was to be respected.

2. Analysis of Issues

The major issues that were identified by the Task Force as needing to be addressed included price differentials and regulatory reform. While trying to ensure continued access to less expensive animal health products from other jurisdictions (e.g. the U.S.), the Task Force also wanted to enhance the registration process for innovative and generic products and improve the system for extension of label claims for existing products. The Task Force believes that regulatory reform would help to encourage investment in new animal health technologies in Canada and improve availability of competitively priced products in a timely manner.

One of the goals of the producer groups e.g. the Canadian Cattlemen's Association (CCA) and the Canadian Pork Council (CPC) is to keep their membership competitive in world markets. Canada is an exporting nation, as are the beef and pork industries, with a large percentage of products being exported. Producers must therefore consistently produce a safe, high quality product at a competitive price. To do this, they must use the latest technology and high quality animal health products that they can access at competitive prices. Producers cannot risk the loss of export markets or their ability to be competitive in these markets.

The issues identified during the meetings were twofold:

i. *Product price differentials between Canada and the U.S. had not seen a downward adjustment in Canadian pricing to reflect the rapid rise in the Canadian dollar. One OUI imported product was reported to be 300-600% higher for one active ingredient, however, this comparison was obtained by comparing a Canadian generic licensed product with the same U.S. generic licensed for sale in Canada.*

ii. *There is a need for regulatory reform.* A 2007 report⁵ prepared by the International Federation for Animal Health (IFAH) found that the pre market review for innovative animal drugs in Canada took about 6 years longer than the same review done in the European Union and Australia. Furthermore, the review process was unpredictable and Canadian reviewers were considered more risk averse. These factors, along with importation and use of OUI product and Active Pharmaceutical Ingredients (API), were a disincentive for investment in new and existing animal health products or in expanding existing product labels. As a result, veterinarians and animal owners do not have timely access to modern, safe animal health medications that would benefit animal well being and producer competitiveness. The Task Force recognized that food animal producers and the animal health industry were codependent: a healthy livestock industry depended on a healthy animal health industry and vice versa.

The Canadian beef and pork industries export up to 50% of production; they are also heavily integrated with the U.S. market and much of the product from these commodities is exported into the U.S. Producers also compete directly for global export markets with other countries, countries within the EU and South America and countries such as the U.S. and Australia. They need access to competitively priced animal health products to compete. Timely access to innovative and generic products would help address the technology gap and price differences that currently exist with our competitors, helping producers to remain competitive in export markets.

3. Task Force Results

The OUI Task Force highlighted two distinct issues that needed to be addressed: product pricing and regulatory competitiveness. Access to lower cost, new, reduced risk and generic products was identified as a key concern for livestock producers. The issue of price setting of drugs by the animal health industry was found to be linked to regulatory competitiveness, market size, market concentration and buying power. Canada is a small market representing approximately 2% of global animal health sales. In setting animal drug prices, Canadian firms are required to meet Patented Medicines Act requirements. Although the OUI Policy was originally established to assist with human health by permitting individuals to import a 90-day supply of a drug in dosage form for their own personal use, unless prohibited by law, the OUI Policy is currently also being used as a tool to import lower cost animal health products and to gain access to generic products not currently available in Canada.

The Pest Management Regulatory Agency OUI and newer Grower Requested Own Use (GROU) Importation Programs were reviewed by the Task Force. The pesticide programs were discussed as the Task Force searched for a resolution to the issues surrounding the OUI animal products. Fundamental historical differences between OUI pesticide programs and Health Canada's OUI Drug Policy are identified in the table below. The PMRA program was designed to give producers easier access to U.S.

⁵ Benchmarking the Competitiveness of the Canadian Animal Health Industry, International Federation for Animal Health, 2007.

product, while ensuring product met Canadian safety, efficacy and environmental standards. The Task Force concluded that a VDD Health Canada Restricted Import Permit Program would put greater discipline on importation of product by providing assurances that product being imported into Canada met Canadian standards.

Pesticide and Veterinary Drug OUI Comparison

Elements for Comparison	PMRA OUI/GROU Program	VDD/Health Canada OUI Current Status
Historical Perspective Pre-Permit Program	OUI program difficult to access by pesticide users	OUI program openly accessible to animal owners
Goals	To benefit producers and enable access to lower priced U.S. product meeting Canadian standards.	To ensure Canadians access to human medical treatments not licensed for sale in Canada. Animal drugs come under the same provision.
OUI/GROU Permit Programs Risk Assessment	PMRA conducts risk assessment and certifies the products that can be imported.	No risk assessment or certification is conducted by VDD for imported products.
Labelling	Canadian label on product	No Canadian label on product
Other	Support for container management program	No pharmacovigilance or container management requirements, in appropriate situations

1) Restricted Import Permit Program (RIPP)

A Restricted Import Permit Program (RIPP) was identified as a means of providing Health Canada oversight on the animal health products that would be permitted for import. The desired outcome would be one where benefits to livestock producers are optimized while minimizing negative safety and trade impacts on the food animal sector and bringing greater equivalency and responsibility in the regulatory burden between OUI product importers and firms marketing Canadian licensed product.

It is understood that many details remain to be worked out for the RIPP initiative, however, the Task Force objective is to have an interim measure to enable producers continued access to less expensive animal health products while longer term initiatives are undertaken to facilitate regulatory reform that would improve the registration process and, ultimately, the availability of licensed animal health pharmaceuticals.

The Task Force further recommended discussions with AAFC regarding mechanisms for the establishment of an on-going price monitoring program.

2) Regulatory Reform

The Task Force did not limit its recommendations to price differentials, it also discussed another issue, that of regulatory reform. The Committee recommended and is pleased to acknowledge that a Canadian Animal Health Product Regulatory Advisory Committee (CAHPRAC) was struck in early 2008 with the mandate of providing strategic advice to the CFIA and HC on ways of improving regulatory efficiency and effectiveness that would result in the timely availability of animal health products and support innovation and development of new animal health technologies.

Situations exist whereby Canadian producers are at a competitive disadvantage when compared to the U.S. due in part to our unpredictable regulatory system, market size, market concentration and buying power. The current Canadian regulatory system tends to discourage pharmaceutical companies from attempting to register new molecules, additional label claims and/or generic products. Our registration process needs to be enhanced so more innovative and generic products can be available sooner. The longer term goal of the CAHPRAC is implementation of the necessary changes to ensure Canada has a safe, reputable and competitive regulatory system, which looks towards closer harmonization with the U.S. and the EU.

4. Implementation

The Task Force agrees that the implementation of two previously outlined points should result in significant benefits for livestock producers and for reducing health risks to consumers, if the current OUI regulatory loophole was closed. It is also recognized that livestock producers have benefited from the current OUI Program, and that there is a need for ongoing access to an effective competitive pricing mechanism with the U.S. There is also a need to ensure that the major issues raised with the current OUI Program by the various stakeholders are adequately addressed.

Recommendations

The OUI Task Force concluded its deliberations and has the following recommendations:

- ▶ That a Restricted Import Permit Program (RIPP) be piloted to determine program feasibility. At the same time a regulatory amendment process would be initiated that would result in closure of the current OUI provisions, to be replaced by a permanent RIPP program. Program implementation would occur, within the usual regulatory amendment timeframe of up to 3 years.
- ▶ That a subcommittee be established in the Fall of 2008 with the mandate of negotiating details, further to preliminary discussions outlined in Appendix 1 of the Report, of a Restricted Import Permit Program (RIPP) for implementation by Health Canada.

- ▶ That regulatory reform in the area of veterinary drugs and biologics be recognized as essential to ensure timely availability and access to products that benefit livestock and our producers and that support innovation and the development of new animal health technologies by the animal health sector. The Task Force acknowledges that the Canadian Animal Health Product Regulatory Advisory Committee was initiated in early 2008 and has begun to examine the current regulatory system for animal medications. They are making recommendations, in cooperation with the Veterinary Drugs Directorate (VDD) and the Veterinary Biologics Section (VBS), designed to improve regulatory efficiency and cost effectiveness relative to animal medications, while ensuring Canadian standards for human, animal and environmental safety and product efficacy are met.

Lastly, the Task Force understands that it is Health Canada's Veterinary Drugs Directorate that will have the final authority on deciding what products are eligible for the Restricted Import Product Program (RIPP) and future regulatory reforms.

Appendix 1. Preliminary RIPP Characteristics as Discussed by the OUI Task Force

I. Pilot Project

It was initially proposed that the RIPP initiative be operated as a 2 - year pilot program. However, there was no agreement that a pilot project should be implemented. The CCA representative wanted to ensure that producers had access to drugs through the current OUI Policy until review of the RIPP pilot program was complete. CAHI, CVMA and the consumer representative did not think producers would engage in the pilot project if they still had continued access to OUI product without the regulatory burden of the restricted use program.

II. User Eligibility

It was generally thought that the program should be limited to animal owners. However, the CVMA thought that consideration should be given to expanding the program to include veterinarians. Currently, veterinarians cannot legally import product for resale. The products being considered for the RIPP initiative would be over the counter finished products that are generally sold through lay outlets other than in the province of Quebec.

III. RIPP Identified Products

A Committee represented by the CAHI, livestock producers from major food animal sectors (beef, dairy and pork), CVMA and others as deemed appropriate would, by consensus, recommend products eligible for inclusion on a list of potential drugs for import under OUI provisions. The list would be reviewed annually by the Committee at which time additions and deletions of eligible products could be made. Only OTC, off patent, finished drugs could be nominated for the RIPP while VDD would ultimately decide which products were eligible for RIPP.

Products under patent protection and/or data protection remain under protection and would be ineligible for the permit list as are Schedule F, Part 1 prescription drugs.

IV. RIPP Product Eligibility

There was no consensus on product eligibility for the Program. CCA thought that the active medical ingredient with any non prescription animal drug claim on the “list” must currently be licensed for sale in Canada. CAHI thought product eligibility should be limited to same brand, same manufacturer as the product licensed in Canada. Sponsors of product not eligible for the program but with the same active and formulation as an approved Canadian product would be encouraged to submit a product registration with VDD for assessment.

The Task Force recommended that the VDD accept products listed as “same product from the same company” as being functionally equivalent with no further documentation required. However, the VDD could request an attestation from the Animal Health

company that the product (e.g. U.S.) imported by the producer is the same as that currently sold in Canada. If that request was refused then another route to listing would be pursued by the committee. The PMRA solution as per their website is to revert back to the existing OUI Policy, which is more restrictive than Health Canada's OUI Drug Policy.

CCA also said that products eligible to be listed must be from an OECD country with which the VDD has a Memorandum of Understanding (MOU) &/or a Mutual Recognition Agreement (MRA).

V. Application Process, Container Management and Pharmacovigilance and Product Labelling

There was general agreement that a VDD type 3011 form be used by applicants. An importation permit would be requested by an individual. Within seven (7) days of receiving the request, the VDD would issue a response by fax or e-mail i.e. electronic permits and product labels.

The products could only be used for label indications approved in Canada or used extra label under veterinary prescription. The VDD would require that distribution be the responsibility of the foreign manufacturer/distributor or importer and that product label application be the responsibility of the importer.

The liability would be with the importer and there would be mandatory Adverse Drug Reaction (ADR) reporting by the producer and the veterinarian should s/he sign the import permit. Compliance with the container management program would also be a requirement.

An individual can only import enough product to meet his/her needs for one treatment or production cycle as per the permit and the amount of product requested and verified by a Canadian veterinarian, notary public or other official yet to be named.

There will be no fee to the livestock producer for the import permit.

VI. 3rd Party Involvement

The RIPP initiative would be a voluntary program for producers whereby they must agree that only individuals or their veterinarians are eligible to import products. For profit organizations are not eligible for the program and there is no redistribution allowed, i.e. no commercial resale of imported product to other individuals. CPC and CCA asked that importation be similar to the PMRA's GROU program where individual permits are issued to an importer and the product is imported solely for the importer's own use. The government's interpretation of the OUI Policy does not preclude the use of third parties to facilitate the importation of OUI product. This facilitation for pesticide products has included the use of commercial carriers to ensure safe transport, and assistance with logistical or regulatory matters related to the importation process.

The following table is a summary of the RIPP discussions. It identifies areas where there was consensus among participants and where there was no consensus.

RIPP Discussion Summary Table

Characteristics	CCA	CPC	CAHI	CVMA and other
Pilot Project	Supported by CCA until such time as regulatory reform was complete.	CPC quality assurance program already prohibits use of OUI product	Did not think the pilot project would be a good tool to assess program feasibility due to poor producer engagement with the OUI provisions continuing to be status quo.	Did not think the pilot project would be a good tool to assess program feasibility due to poor producer engagement with the OUI provisions continuing to be status quo.
User Eligibility	Producers	Producers	Producers since legislation would not permit veterinary eligibility & products were OTC already (except for Quebec).	Veterinarians want to be eligible for the program for clients in a Veterinary Client Patient Relationship (VCPR).
RIPP Identified Products <ul style="list-style-type: none"> ▶ Licensed product ▶ Non patented product ▶ VDD decides 	There was agreement that producers, CVMA and CAHI would, by consensus, nominate products for the RIPP.			
RIPP Product Eligibility	<ul style="list-style-type: none"> • Same active and formulation as an approved Canadian product. • Countries with which Canada has a 		Limited to same brand, same manufacturer. Encourage non licensed product sponsors to seek registration in Canada –	

	regulatory MRA or MOU.		consider expedited review process.	
Application	<ul style="list-style-type: none"> • Use 3011 type form • VDD requests information from producers e.g. ingredient list 			
Container Management & Pharmacovigilance	Equivalency for RIPP product and licensed Canadian product			
Labelling	Canadian label, bilingual, no resale (except by veterinarians in VCPR)			
3rd Party Involvement	Designed solely for individuals; for profit ineligible			