Food and Drugs Act Liaison Office

Report on Activities

April 2016 to March 2017

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada ‘s people and to making this country’s population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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Message from Deputy Minister

At Health Canada, our top priority is protecting the health and safety of Canadians. As a regulator under the *Food and Drugs Act* (FDA), we play an important role in ensuring that health products on the Canadian market are safe and effective.

Canadians count on us to make fair, evidence-based regulatory decisions that protect the public interest. Industry, consumer advocates and other stakeholders need to know how and why we arrive at these decisions. For this reason, openness and transparency are guiding principles of our work.

The ***Food and Drugs Act Liaison Office*** (FDALO) strives to make the regulatory process open, understandable and accessible to Canadians. It is a neutral body charged with fostering effective communication between Health Canada and external parties interested in the administration of the FDA. As such, it works to resolve disputes and enhance client service experiences.

Over the past year, Health Canada has worked to make regulatory decision-making practices more open and transparent. We have, for example, improved the reconsideration processes for pre-market licensing activities under the FDA. As a result, all stakeholders now have enhanced opportunities to engage with Health Canada.

This report contains insights into the feedback received by FDALO over the past year and highlights lessons learned from the more than 300 cases processed during that time. Health Canada will continue to innovate and enhance the way it carries out and communicates its regulatory work.

Simon Kennedy

Summary of Accomplishments

In fiscal year 2016–17, the Food and Drugs Act Liaison Office (FDALO):

- processed more than double the number of cases as in the previous year—315 compared to 135 in 2015–16;
- trained 117 employees to better manage communications with stakeholders; and
- implemented lessons learned from managing the human drug and natural health product reconsideration processes.

What is FDALO?

Health Canada's Food and Drugs Act Liaison Office (FDALO) provides impartial dispute resolution services to help resolve complaints and inquiries between external stakeholders and regulatory staff who administer the *Food and Drugs Act* (FDA).

The Department's Health Products and Food Branch, Healthy Environments and Consumer Safety Branch and Regulatory Operations and Regions Branch administer the FDA.

FDALO aims to settle cases fairly and quickly. It also champions improvements to regulatory services based on lessons learned.

Year in Review

Health Canada's FDALO marked its ninth year of operations in 2016–17.

Over the past year, FDALO increased its outreach and communications efforts and achieved major accomplishments in two areas:

- acting on lessons learned while managing reconsideration processes available to companies that disagree with a regulatory decision by Health Canada; and
- processing more than double the volume of cases in 2016–17 compared to 2015–16, representing a 240% increase in the number of complaints and information-seeking cases handled.

Health Canada is committed to regulatory openness and transparency. This annual report offers feedback and insights into what mattered to stakeholders who used FDALO's services in 201617.

The reconsideration process

The reconsideration process is a redress mechanism for companies. If companies disagree with a decision made during Health Canada's review process for licensing therapeutic products, they can request that it be reconsidered.

In 2015, FDALO began managing reconsideration requests for prescription human drug submissions. Previously, Health Canada's Therapeutic Products Directorate (TPD) and Biologics and Genetic Therapies Directorate (BGTD) had managed their own reconsideration processes. Some stakeholders expressed concerns about the potential conflict of interest, given that the same directorates that made the decisions ran the reconsideration process. FDALO assumed this role in 2015 to enhance transparency and impartiality. Since FDALO is not part of the regulatory directorates, it has no vested interest in the outcome of the reconsideration process.

FDALO is now responsible for convening a reconsideration panel and meeting to resolve the objection in each case. The reconsideration process results in a recommendation to the Director General responsible for the Health Canada drug review.

Since FDALO began managing the prescription human drug reconsideration processes, it has worked with Health Canada review directorates to enhance transparency, impartiality and predictability. FDALO:

- Ensures that the individuals selected for the reconsideration process have the necessary expertise for the issue in dispute and have not been involved in the original review of the submission.
- Works with parties to select and enter into a contract with an external panel when no qualified impartial reviewers are available from Health Canada or the Public Health Agency of Canada.
- Explains the reconsideration process to both the company and review bureau staff.
- Ensures that all relevant information is fully disclosed to the company, including a clear rationale for the decision so that the company can prepare a thorough rebuttal.
- Works with the parties to resolve any procedural issues before the reconsideration process results in a final decision by the Director General to ensure credibility and buy-in for the process from the companies and from Health Canada staff.

FDALO can address procedural issues in many ways, including:

- explaining the rationale for selecting specific impartial reviewers
- clarifying the scope of issues under dispute, and
- helping to settle differences of opinion between parties about what constitutes "new information," as new information cannot be introduced in the reconsideration process.

By managing procedural issues, FDALO helps to minimize conflict between parties. This also allows the parties to focus on the substantive issues under dispute during the reconsideration meeting. Building agreement on the reconsideration process helps boost the acceptance and credibility of the final decision.

Prescription drug reconsiderations

Eight prescription drug reconsideration requests were filed in 2016–17. Seven of these requests related to the TPD and 1 to the BGTD. Table 1 shows the outcomes of these 8 requests.

TABLE 1: BREAKDOWN OF PRESCRIPTION DRUG RECONSIDERATION REQUESTS IN 2016–17

	Requests received		Requests withdrawn		Requests completed by internal process		Requests completed by external panel	
	Eligible	Not eligible	Withdrawn by review bureau/ submission returned to review	Withdrawn by company	Original decision upheld	Original decision amended	Original decision upheld	Original decision amended
TPD	7	-	5	1	1	-	-	-
BGTD	1	-	-	-	1	-	-	-
Total	**8**	**-**	**-**	**-**	**2**	**-**	**-**	**-**

TPD—Therapeutic Products Directorate; BGTD—Biologics and Genetic Therapies Directorate.

Of the eight requests, only two cases advanced to a full reconsideration meeting. In cases that did not proceed with the full process, FDALO—as intermediary—prompted further dialogue between parties. In five cases, the parties agreed that the negative decision letter would be withdrawn and the review bureau would return the submission to the review process, and in one case, a company withdrew its reconsideration request.

The cases that Health Canada returned to the review process were resolved with parties using informal approaches. To date, no further reconsideration requests have been filed on these cases.

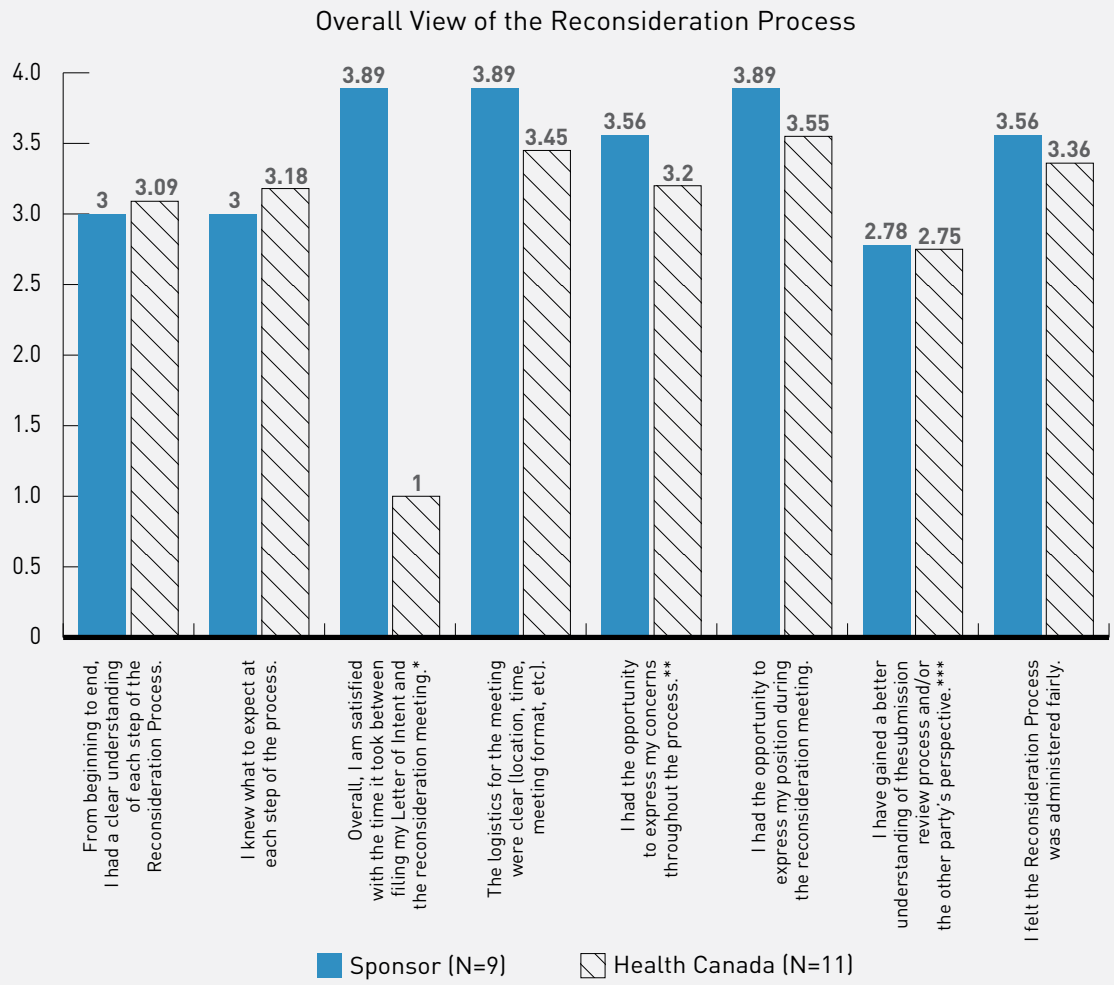
For each case that proceeds with a full reconsideration meeting, FDALO sends a confidential survey to those who attended on behalf of the company and the drug review bureau. FDALO uses that survey to ask participants to share their views on the reconsideration process. FDALO sends the survey immediately following the meeting, before the reconsideration decision is issued. The deadline to complete the survey is set before the decision is issued. The purpose of the survey is to collect feedback on the process, and not the decision.

Attendees can answer the survey anonymously. The only demographic information requested is whether the respondent is from the company or the review bureau. There are usually several participants from each group.

The responses to some key survey questions are presented in Figure 1, based on the two cases that advanced to a full reconsideration meeting. In total, there were 9 respondents from companies and 11 respondents from Health Canada.

The survey measured responses to various statements, with answers ranging from “strongly agree” (4 points) to “strongly disagree” (1 point). Respondents also had the option to reply “don’t know/ not applicable.”

FIGURE 1: SATISFACTION SURVEY FOR PRESCRIPTION DRUG RECONSIDERATIONS IN 2016 TO 2017



N = total number of participants

*10 responses by Health Canada staff were “don’t know/not applicable.”

**1 response by Health Canada staff was “don’t know/not applicable.”

***3 responses by Health Canada staff were “don’t know/not applicable.”

Respondents generally indicated overall satisfaction with the process.

Natural and non-prescription health product reconsiderations

In 2016–17, FDALO began work with Health Canada's Natural and Non-prescription Health Products Directorate (NNHPD) to revamp its reconsideration process. FDALO is building on the experience it has acquired managing the prescription drug reconsideration process.

The NNHPD reviews submissions for all non-prescription human drugs, including hard-surface disinfectants, and natural health products.

From February to November 2016, FDALO ran a pilot project for the reconsideration process in the NNHPD. The pilot offered two choices to companies that filed a reconsideration request. They could select either the new process managed by FDALO, or the previous process managed by the NNHPD.

Companies filed six reconsideration requests during that period. Two applicants chose the previous process. In both cases, the original decision was upheld. Four applicants chose the new process managed by FDALO. The outcomes are recorded in Table 2.

TABLE 2: BREAKDOWN OF RESULTS FOR PILOT NNHPD RECONSIDERATION REQUESTS RUN BY FDALO IN 2016–17

	Requests received		Requests withdrawn		Requests completed by internal process		Requests completed by external panel	
	Eligible	Not eligible	Withdrawn by review bureau/ submission returned to review	Withdrawn by company	Original decision upheld	Original decision amended	Original decision upheld	Original decision amended
Natural health product	2	-	-	-	1	1	-	-
Over-the-counter product	2	-	-	1	1	-	-	-
Total	**4**	**-**	**-**	**1**	**2**	**1**	**-**	**-**

FDALO uses the same survey process for natural health products as it uses for prescription drugs. For each case that proceeds with a full reconsideration meeting, FDALO sends a confidential survey to those who attended on behalf of the company and the review bureau. FDALO uses that survey to ask participants to share their views on the reconsideration process. FDALO sends the survey immediately following the meeting, before the reconsideration decision is issued.

Given that there were fewer than five respondents from each group who participated in the NNHPD reconsideration pilot survey, the results are not reported here because the sample group is too small.

Respondents have an opportunity to provide comments as part of the survey. This allows them to express thoughts that are not captured through the survey questions. One company offered compelling comments about improvements that it noted in the new process managed by FDALO.

> *"We very much appreciated the flexibility in this process to introduce information to respond to new issues that were raised in the rejection letter. Allowing post-meeting clarifications/ answers to questions raised by the panel also gave us the impression that there was a sincere effort to adequately air out complex issues."*

Feedback from the NNHPD pilot has helped to shape a revision of the ***Guidance Document: Reconsideration of Decisions Issued for Human Drug Submissions*** so that it incorporates natural health products and disinfectants. FDALO will send the draft to stakeholders for consultation in 2018 and will take the resulting feedback into account in finalizing the document

FDALO will keep working with the NNHPD to design an appropriate redress mechanism while Health Canada moves forward with a new regulatory framework for self-care products.

Lessons learned from managing reconsideration processes

FDALO has learned important lessons from managing human drug and natural health product reconsideration processes. The office, in turn, has shared these lessons with the review directorates involved. Here is some of what was learned.

Rejection letters must contain clear and thorough explanations

Health Canada needs to ensure that its rationale for rejecting a submission is clearly and thoroughly explained in the decision letter. This allows the company to fully understand the reasons for the rejection, including Health Canada's legal authority to reject a submission. It also gives the company an opportunity to prepare its arguments for a reconsideration process.

A clearly explained rejection letter can help a company make an informed decision about the best course of action to take next. Choices include:

- collecting missing data or evidence to support regulatory requirements and resubmitting an updated application;
- filing a reconsideration request, and preparing a clear and comprehensive rebuttal to each point in the rejection letter; or
- abandoning the submission.

FDALO has played an important role in seeking clarification, on behalf of companies, from Health Canada review bureaus on rejection letters. Some FDALO inquiries have led to further communication between the review bureau and the company. In some cases, this avoided the need for a formal reconsideration process.

Applying "No new information" policy to support procedural fairness

Companies cannot submit new information at the reconsideration stage of the submission review process. This rule is set out in the guidance document on reconsideration requests for human drug submissions. During the reconsideration process, impartial reviewers must examine the same evidence that the review bureau considered in making its decision.

However, companies have pointed out that Health Canada's rejection letter occasionally contains a new rationale for a rejection. Companies will not have had a chance in the review process to respond to this new rationale. In these instances, FDALO ensures that the company has an opportunity to respond to the new rationale.

The review bureau may return the file to the review process so that the company can respond. At other times, a company can make rebuttals during the reconsideration process. Those rebuttals are not treated as new information. Before the reconsideration meeting happens, FDALO helps to broker discussions on what constitutes new information between the company and the review staff.

Information disclosed between parties in advance of the reconsideration meeting ensures procedural fairness

During the reconsideration process, FDALO manages proper and advance disclosure of information between parties. This ensures procedural fairness. The company and review bureau each prepare a presentation with the information that they deem necessary to support their respective positions. Impartial reviewers see these presentations before the reconsideration meeting.

Neither party can give the impartial reviewers information that has not been shared with the other side. Information cannot be submitted at the last minute since this would deny the other side enough time to respond. FDALO upholds this important principle to ensure a fair and transparent reconsideration process.

FDALO can solve conflicts between parties when deadlines loom for performance targets

Submissions that are charged fees to be processed also have performance standards that Health Canada must meet. If timelines are not met, the Department pays a financial penalty.

This situation can create conflict between parties. A company may need more time during the review process to respond to Health Canada's request for additional information. The Department has informed some companies that it would close their submissions, if the company could not provide the information on time. Some companies report feeling that Health Canada would not consider a request for extension because of requirement for the Department to meet performance timelines.

A reconsideration meeting is usually not the right avenue in which to resolve these situations. In these cases, FDALO acts as a neutral third party between Health Canada and the company. It tries to help them reach a mutually acceptable resolution.

Reconsideration decisions based only on written submissions speed up priority reviews

Health Canada has a policy called the ***Priority Review of Drug Submissions***. It explains how a company can request an expedited review of certain products that treat serious and life-threatening conditions. These products include new drug therapies, and preventive or diagnostic agents.

Should Health Canada reject the request for a priority review, a company can file a reconsideration request. FDALO has managed one such request. FDALO discovered, however, that there is no provision to run an expedited reconsideration process. Cases follow the same process for all issues that are eligible for reconsideration. The standard reconsideration process does not operate quickly enough to meet a company's need for a priority review.

Submissions that fail to qualify for a priority review stay in the review stream under the usual review timelines. This differs from other reconsideration requests where the submission is closed after the rejection letter is sent. When a reconsideration decision cannot be made in a timely way for a priority review file, the process becomes moot as the normal review process might be nearing completion.

There is only one way to run an expedited reconsideration process. The company can elect to have the reconsideration decision made based on a review of written submissions. This means forgoing a reconsideration meeting and the opportunity to be heard in person that comes with it. This is the element of the reconsideration process that takes the most time to organize. FDALO can offer this option to companies, but cannot compel them to use it.

Case management

In addition to managing formal reconsideration processes, FDALO provides other services. It offers informal complaint resolution services related to various aspects of Health Canada's administration of the FDA. The office also ensures that external stakeholders receive responses to general inquiries for matters that fall under the Act.

Case management in brief

FDALO managed 315 cases in 2016–17.

- The number of cases received represented a 240% increase over the 135 cases received in 2015–16. It was FDALO's highest number of cases in the 9 years the program has been in operation.
- Of the 315 cases, 222 were general inquiries, representing 70.5% of all cases.
- The remaining 93 cases were complaints, representing 29.5% of all cases.

The significant increase in volume of cases is due to FDALO's concerted outreach and communications efforts.

Here are a few examples.

- FDALO presented its annual report to members of major industry associations that have an interest in the FDA.

- FDALO increased its presence on the new Government of Canada website, Canada.ca. It did so on pages related to the FDA, such as *About Natural Health Product Regulation in Canada*. As with other such web pages, information about FDALO appears under "Additional resources."
- FDALO encouraged Health Canada employees to approach its office with difficult cases. It also encouraged staff to refer dissatisfied stakeholders to FDALO.

Anecdotally, new clients have said that they were referred by companies and individuals who had good experiences using FDALO's services.

What we heard

In 2016–17, FDALO received both positive feedback and suggestions for improvement on various regulatory activities carried out by Health Canada under the FDA, as follows:

- Positive feedback:
  - Notice to Stakeholders for the Cosmetics Ingredient Hotlist
  - reduced regulatory burden for some U.S.-made sunscreens
  - mandatory reporting of drug shortages and discontinuations in Canada
- Requests for improvements:
  - disclosure of review reports for refusals of natural health products
  - shorter, clearer process needed for switch submissions
  - more flexibility for border issues

Positive feedback

Notice to Stakeholders for the Cosmetic Ingredient Hotlist

Health Canada informs manufacturers and the public about ingredients that are considered prohibited or restricted for use in cosmetic products. It uses an administrative tool, the *Cosmetic Ingredient Hotlist*, to communicate information about substances on the list. Health Canada continually reviews and updates the list as new scientific data become available on new risks.

FDALO has helped handle several cases where industry and Health Canada disagreed on how the Department manages new or amended entries to the Hotlist.

In the past, industry did not find Health Canada's timeframes and process for updating the Hotlist entirely clear or predictable. As a result, companies had problems complying with changes in a timely and responsible way. Some companies complained that Health Canada's expectations were unclear and unpredictable.

In 2016–17, Health Canada made some changes to the way it manages the Hotlist that were welcomed by industry. The Department now posts a Notice to Stakeholders to provide information on the substances being reviewed for possible prohibition or restriction in the next Hotlist update. Health Canada then posts a consultation document proposing updates to the Hotlist on its website. This document sets out the Department's planned course of action with supporting rationale. Stakeholders have 60 days to provide any safety information or other considerations about the proposed substances to Health Canada.

All stakeholders who wish to take part in these reviews should subscribe to the ***Cosmetics Mailing List***. This mailing list keeps subscribers up to date on consultations and other relevant information.

The new process offers all stakeholders—industry and consumer advocates alike—a better chance to engage with Health Canada on proposed changes. The new process also allows changes to be made in a more open, transparent and predictable way.

The changes to the Hotlist process come with a caveat. Industry is still legally required to take corrective action as soon as it knows that an ingredient poses harm to human health. It must not wait for an ingredient to be added to the Hotlist before taking action.

Reducing regulatory burden for some U.S.-made sunscreens

Over the 9 years that FDALO has existed, industry has complained about the regulatory burden imposed on some low-risk non-prescription drugs. This includes certain sunscreens classified as "drugs," based on active ingredients that are used to make them.

Part of the regulatory burden relates to the import of these products. Sunscreens classified as drugs must be quarantined and re-tested for compliance with Good Manufacturing Practices before being sold in Canada. This practice applies to all imported therapeutic drugs.

In February 2017, Health Canada introduced a 1-year pilot project to help partly reduce the regulatory burden with the understanding that the differences between U.S. and Canada on health and safety were not significant. The pilot applies to sunscreens classified as drugs that are also manufactured and packaged in the United States. Canadian importers who apply to and qualify for the pilot can import the sunscreens for direct shipment to retailers without having to re-test the product.

This pilot is a significant step forward in harmonizing trade between Canada and the U.S. It has helped to reduce the regulatory burden while working to ensure that there is no additional risk to the health and safety of Canadians. And while the industry reaction to this initiative was largely positive, some companies that had not applied for the pilot said that they hope this initiative is permanently adopted. They indicated that it is too onerous to change their business practices for a pilot if they may have to revert to previous screening requirements after the pilot.

Mandatory reporting of drug shortages and discontinuations in Canada

When FDALO first launched as a program in 2008, the lack of predictability and knowledge of drug shortages ranked among the most pressing concerns. Health care providers, specifically hospitals experiencing difficulty sourcing critical drugs for patient care, brought these concerns to FDALO's attention.

In its 2010–11 annual report, FDALO outlined how unexpected shortages leave health care practitioners scrambling to find alternatives. Practitioners often have to apply to Health Canada's Special Access Programme because of these shortages. This program considers requests for access to drugs that have not received market authorization in Canada for patients with serious or life-threatening conditions.

In 2012, Health Canada led the establishment of the Multi-Stakeholder Steering Committee on Drug Shortages to address drug shortages. The committee comprised industry representatives, federal, provincial and territorial government leaders, and representatives of health care professional associations. Committee members were charged with identifying potential solutions to the issue of drug shortages. Solutions that were based on voluntary reporting by manufacturers proved ineffective.

In June 2016, Health Canada proposed a regulatory amendment to the *Food and Drugs Regulations* requiring drug makers to report drug shortages and discontinuations in Canada. The Shortages of Drugs and Discontinuation of Sale of Drugs amendment was passed in the spring of 2017. This led to a new website in March 2017: ***www.drugshortagescanada.ca***. All of these steps have been important in addressing this critical issue for patient care in Canada.

Requests for improvements

Disclosure of review reports for refused product licence applications for natural health products

Some companies have complained to FDALO about refusal letters sent for natural health product applications. They feel some letters don't contain enough detail. To properly understand the decision, companies wish to receive the complete review report, as well as the decision letter. Although reviewer's reports are available to applicants upon request, companies feel the delays in receiving the report hamper their ability to make timely decisions about next steps.

FDALO heard similar concerns a few years ago with regard to the review of prescription drug submissions. The directorates that review prescription drugs are the TPD and the BGTD. They now release review reports with all negative decision letters. NNHPD is currently examining this issue.

Shorter, clearer process needed for switch submissions

Health Canada has a process to assess whether a health care product can be moved from the prescription drug list to non-prescription status. This is known as a "switch" submission.

A ***guidance document*** is available that helps companies determine what evidence should be submitted to Health Canada when applying to switch a medicinal ingredient from prescription to non-prescription status. Certain industry associations and companies have contacted FDALO to convey their concerns regarding the lack of clarity in the review process.

One of the main concerns expressed by companies is the absence of timelines in the guidance document. This lack of predictability gives rise to several questions for the companies, in particular, the status of their submission and the expected date for the decision.

Another concern that the companies raised is that once a decision is issued, the rationale provided is not always robust. Companies say that they are often not given the name of a contact person who can address their concerns with the decision. Companies would like to know what information the Department considered during the review of their submission, so that they can have a comprehensive understanding of how the decision was made.

Companies would like more transparency and predictability for this type of submission.

More flexibility for border issues

Individuals and small and medium-sized enterprises often encounter problems with regulations and laws that apply to their imports, which they don't realize until they are subject to compliance and enforcement action at the Canadian border.

These companies have asked Health Canada to use more discretionary authority in the compliance and enforcement action taken. Stakeholders feel this is especially important for products they consider low risk.

Imported products, such as cosmetics, have to meet applicable Canadian regulatory standards before they can be sold in Canada. These standards include proper manufacturing and labelling.

In some cases, provisions exist that help companies overcome these challenges. A company may advise Health Canada of its plan to import a product manufactured and labelled according to another jurisdiction's standards. Then it "over-labels" the product to meet Canadian requirements. (This involves re-labelling the product to make it compliant with Canadian regulations.)This declaration has to be made before importing the product or the product will not be allowed entry into Canada.

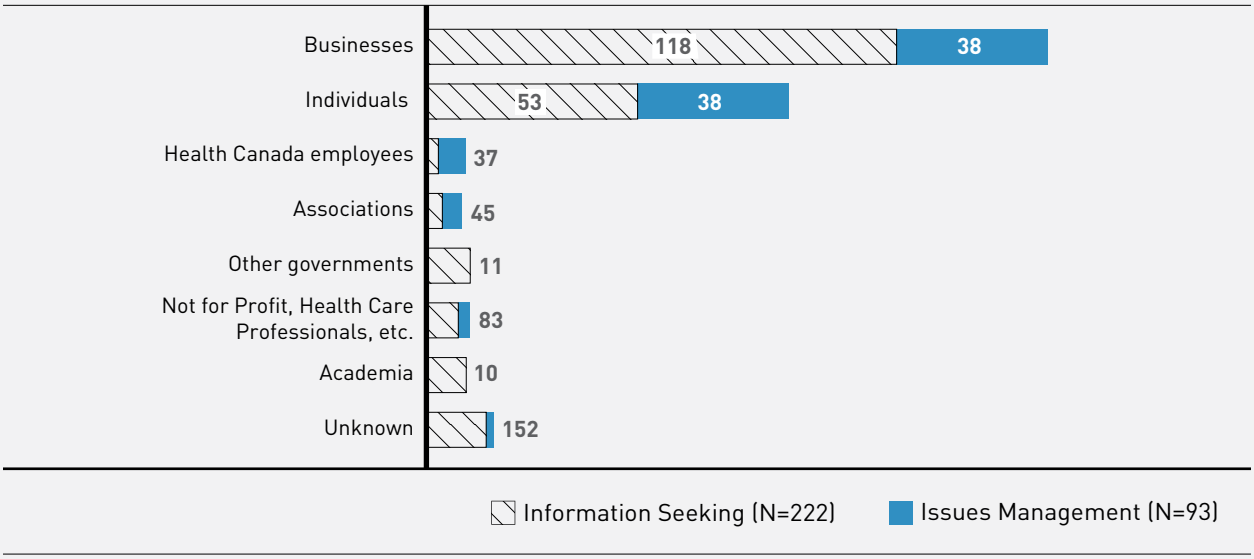
From 2016–17, three companies asked FDALO for help when labelling issues prevented them from bringing certain cosmetic imports into Canada. One company attempted to import a cosmetic product with a label that referenced a foreign website that indicated the product "eliminates age spots." According to Health Canada's regulatory authorities, this therapeutic claim requires an over-the-counter drug review with supporting data.

The company was prepared to over-label the website address with the claim "reduces the look of age spots." This would have been acceptable to Health Canada without a pre-market licensing review. However, because the company failed to declare this issue before importing the cosmetic product, the imports were refused entry.

Case statistics

Figure 2 details the type of inquiries that FDALO received in 2016–17, and who contacted the Office with these inquiries.

FIGURE 2: WHO CONTACTED FDALO



FDALO has grouped the analysis of cases under these four themes:

- communication issues, such as:
  - information-seeking inquiries,
  - calls not returned by the reviewing bureau, and
  - unclear correspondence or correspondence that does not address the stakeholder's concerns.
- policy issues, such as:
  - disagreements with the interpretation or application of the law,
  - interpretation of policies or regulations, such as product classification, and
  - evaluation of risk assessment.
- procedural issues, including dissatisfaction with the processes used in regulatory decision-making, such as:
  - timeliness,
  - openness,
  - transparency,
  - predictability, and
  - advance notice of changes to rules.
- interpersonal issues, such as:
  - treatment of stakeholders by Health Canada staff, and
  - requests by Health Canada staff for assistance in dealing with difficult stakeholder communications.

Figure 3 details the themes under which stakeholder cases fell in 2016–17. Figures 4 and 5 list the entities involved in complaints and general inquiries cases, respectively. These figures also indicate the number of cases in which various entities were involved. Lastly, Figure 6 displays the geographic origin of cases.

FIGURE 3: HOW CASES WERE CATEGORIZED BY THEME

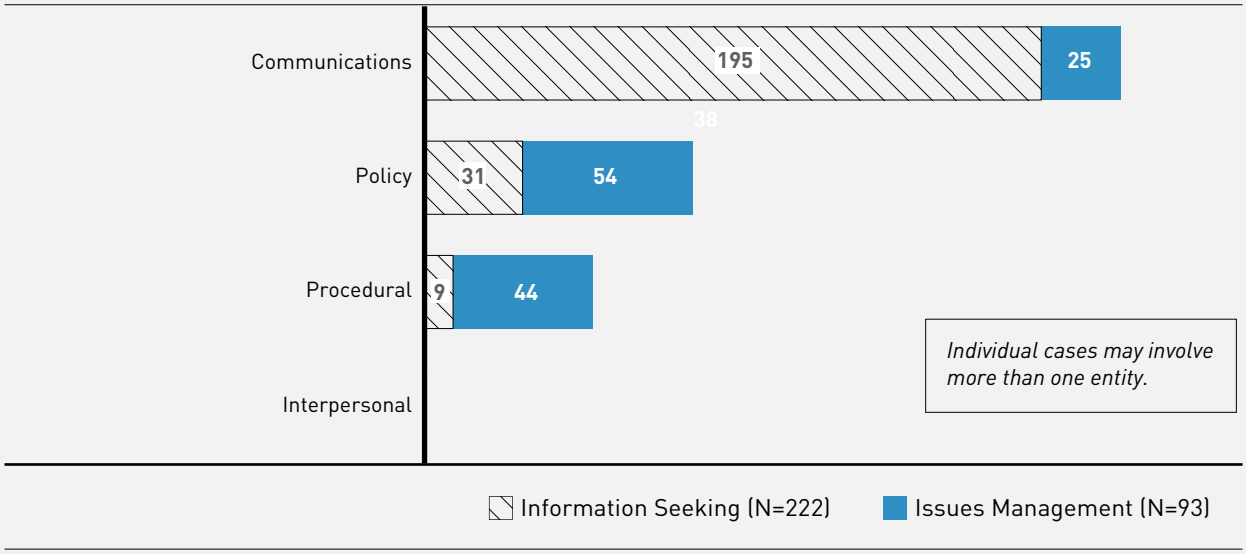


FIGURE 4: ENTITIES INVOLVED IN ISSUES MANAGEMENT CASES

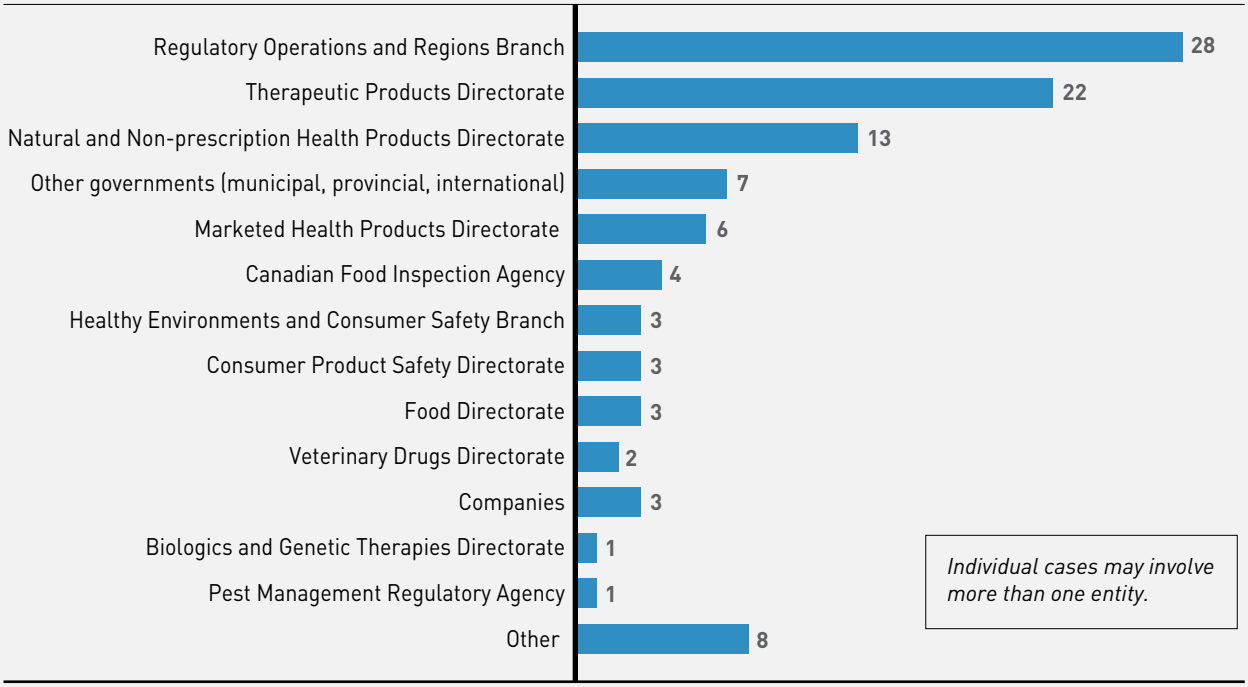


FIGURE 5: ENTITIES INVOLVED IN INFORMATION-SEEKING CASES

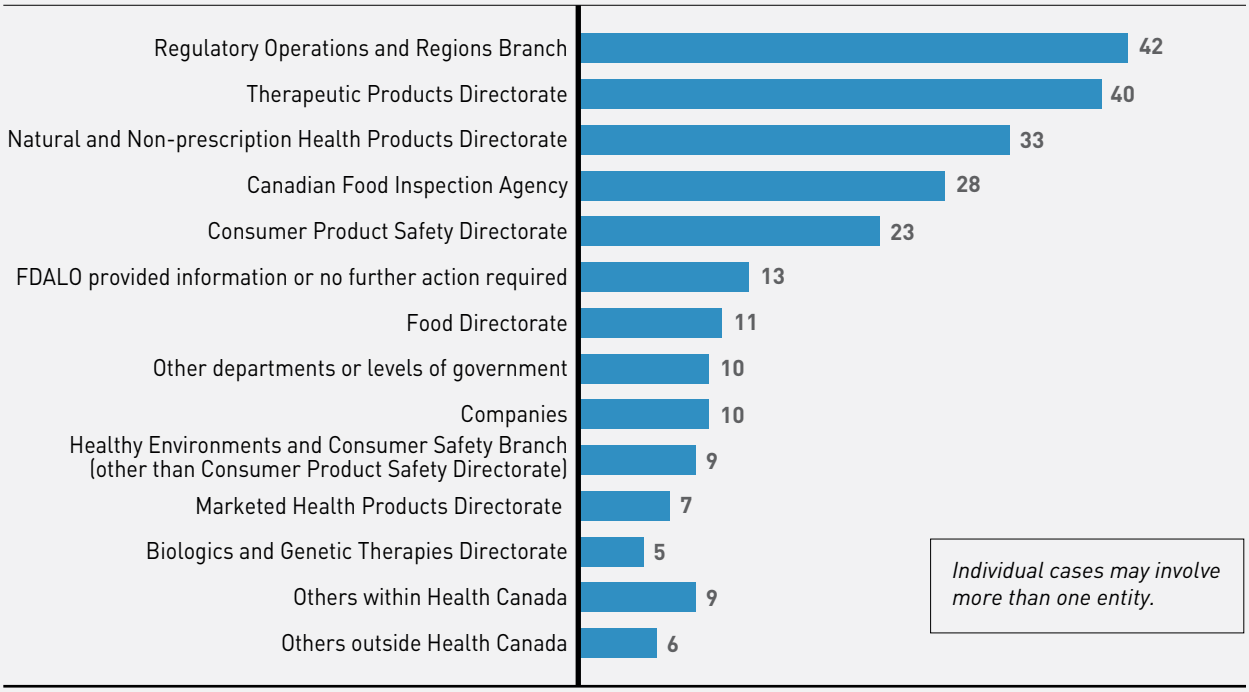


FIGURE 6: GEOGRAPHIC ORIGIN OF CASES

Building competencies

Between 2016–17, FDALO:

- hosted seven sessions of its flagship training session Making the Most of Difficult Communications with Stakeholders, with 102 attendees in total. This session is open to members of the Health Portfolio and other federal employees through the *Community of Federal Regulators*;
    - ran one mini-workshop, entitled *Stories We Tell Ourselves*, for 15 attendees;
    - trained staff from two non-regulatory departments, as they requested FDALO's unique expertise in managing stakeholder relations.

Making the Most of Difficult Communications with Stakeholders is a unique training session that allows departmental representatives to network and learn best practices. It also gives them a chance to reflect on how to offer responsive services and to acknowledge high emotions. The feedback on this training remains extremely positive.

Over the next year, FDALO will continue to promote its mini-workshops in Health Canada. These workshops are designed to be used during staff retreats or as team-building exercises. They offer a way to bring teams together to enhance their ability to effectively respond to stakeholders.

Moving ahead

In 2017 to 2018, FDALO will advance its core work of the past 9 years—resolving disputes and improving stakeholder relations. Its three key tasks will be:

- managing complaints and issues between external stakeholders and regulatory staff,
- managing reconsideration processes, and
- enhancing staff capacity to have challenging conversations.

FDALO will continue to help regulatory staff resolve stakeholder complaints and inquiries efficiently and fairly. This gives Health Canada vital insight into and feedback from stakeholders on how it administers the FDA. Stakeholders and Health Canada staff appreciate FDALO's important work in resolving informal complaints.

With regard to reconsideration processes, the office will expand its efforts from 2017–18. FDALO will begin its third year of managing the reconsideration process for prescription human drug submissions. It does this on behalf of Health Canada's TPD and BGTD. FDALO will continue to track and implement lessons learned.

As well, FDALO will finalize and implement a revised reconsideration process for natural health products, non-prescription human drugs, and disinfectants. During 2017–18, FDALO will assume the responsibility of managing all reconsideration requests filed by NNHPD's clients.

In the coming year, FDALO will again offer its mini-workshops and its Making the Most of Difficult Communications with Stakeholders sessions. This training and coaching encourages dialogue and insight into Health Canada's continuing efforts to enhance communications with stakeholders.