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Food and Drugs Act Liaison Office

Report on Activities 2010–2011



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Message from the Director

On behalf of the Food and Drugs Act Liaison Office (FDALO) team, I am presenting this report to Health Canada representatives and external stakeholders. The report serves a dual purpose. The first is to share our observations, based on interactions with both stakeholders and Health Canada representatives, on past improvements and future opportunities for improving stakeholder relations. The second purpose is to report on FDALO's accomplishments in the past year. The report will be published on the FDALO webpage of Health Canada's website.

Having completed its third year of operations, FDALO continues to expand its impact on stakeholder relations at Health Canada. On a weekly basis, the staff at FDALO are putting stakeholders in touch with key personnel in the department who can address their issues, helping to manage conflicts, and providing feedback to the department about the state of stakeholder relations. They are also reaching out proactively to stakeholders and Health Canada staff as well as providing training for staff who want to improve their relationship management skills. They are solving problems and preventing conflicts.

While a certain degree of tension between the Regulator and the Regulated will always exist and is perhaps desirable, FDALO's work has contributed to the efforts that are currently underway at Health Canada to address many of the administrative and service delivery irritants that stakeholders have complained about. These efforts aim to provide stakeholders with clear, responsive and reliable communications, as well as greater openness and transparency in decision making processes.

The year 2010–2011 saw some significant improvements in stakeholder relations at Health Canada. Stakeholders and staff are increasingly taking advantage of FDALO's assistance and expertise to defuse, deescalate and rebuild troubled stakeholder relationships.

Meanwhile, FDALO staff have analysed the trends in complaints received from stakeholders in the past year to identify potential areas where they would like to see further improvements in stakeholder relations.

This Annual Report details FDALO's activities and accomplishments in 2010–2011. I encourage you to read it and to contact us for information or assistance.

Serena Siqueira

Director

Summary

The following pages provide a brief overview of this Annual Report.

FDALO in Brief

The Food and Drugs Act Liaison Office (FDALO) is a neutral and impartial work unit holding expertise in dispute resolution that was launched in 2008. It facilitates and manages the relationship between Health Canada and the various stakeholder groups who communicate with the Department on regulatory matters. Its primary roles are to help manage challenging stakeholder relationships, to provide information and referrals to stakeholders, and to provide feedback and advice to Health Canada. In 2010–2011, FDALO managed 158 cases.

Improvements in Stakeholder Relations in 2010–2011

In the last year, stakeholders noted there have been a number of promising improvements in stakeholder relations at Health Canada.

- Changes to the Health Canada website and better contact mechanisms have created **better access** to information for stakeholders.
- Within Health Canada, there is increasing **proactive use of FDALO's assistance** to de-escalate difficult situations and defuse potential problems.
- The licensing of Natural Health Products, which has traditionally been a source of stakeholders complaints, has seen **significant improvements** including, the implementation of performance targets, the publication of licensing progress reports, the continued development of electronic tools and the disclosure of reviewers notes. Positive feedback is being received from stakeholders.

Stakeholder Suggestions for Further Improvements

By virtue of its unique perspective, FDALO is able to make observations and share what improvements stakeholders have told us they would like to see at Health Canada.

- Stakeholders experience frustration caused by waiting times of unpredictable length, and would like to see more **predictable response times** for their inquiries.
- Stakeholders sometimes experience delays or miscommunications related to files which require coordination of multiple units within Health Canada. They suggest a more **coordinated approach to managing complex cases**.
- Stakeholders who challenge a specific regulatory decision, especially with regard to compliance and enforcement, have asked for **additional recourse opportunities** within Health Canada.
- Stakeholders would like greater automation within the **Special Access Program (SAP)**, which provides access to non-marketed new drugs. FDALO also notes that more communication and outreach by SAP would help to ensure that users understand the mandate, rationale and requirements of the program *before* they must interact with it under urgent circumstances.

Accomplishments at FDALO in 2010–2011

FDALO continues to **reach out to stakeholders** through its link on the Health Canada web site, through email, and through presentations.

This year saw ten more sessions of FDALO’s training program “Making the Most of Difficult Communications with Stakeholders” delivered to Health Canada staff. This program, introduced in 2009, responds to the need for **specific training in managing difficult communications with stakeholders** in a complex regulatory environment. Post-session evaluation surveys confirm participants’ appreciation and satisfaction with this learning program.

FDALO is building **operating procedures** in consultation with regulatory staff, in order to foster a shared understanding of when and how to use the program, and when its involvement would not be appropriate.

A key achievement in the past year has been the expanding contact between FDALO and **senior managers** at Health Canada.

Who We Are



The following paragraphs describe FDALO in terms of age and organizational placement.

The Food and Drugs Act Liaison Office (FDALO) was launched in 2008 as an impartial and neutral service that facilitates and manages the relationship between Health Canada and the various stakeholder groups who communicate with the Department. Its staff consists of dispute resolution professionals.

FDALO forms part of the Consultation and Management Services Directorate (CMSD) of the Public Affairs, Communications and Consultation Branch (PACCB) of Health Canada.

What We Do



This section of the report briefly explains the overall mission and mandate of FDALO, as well as the benefits FDALO brings to Health Canada.

FDALO responds to requests for service on issues or questions which are brought directly to it by stakeholders, as well as issues brought to it by Health Canada staff that are facing challenges managing relations with a specific stakeholder. FDALO's scope extends to regulatory matters pertaining to the *Food and Drugs Act*. The Office does not have authority to review regulatory decisions or impose solutions on troubled stakeholder relationships. Its neutral and impartial position allows it to provide voluntary informal dispute resolution services to stakeholders and staff as it has no vested interest in how disputes are settled. FDALO's services include coaching, mediation, facilitation and training for staff.

As the Clerk of the Privy Council said in his 2010–2011 Annual Report, “Excellence in regulation is a matter of understanding and balancing stakeholder interests... It also means being transparent in decision-making and communicating effectively with stakeholders and citizens.” FDALO's role, both in principle and in practice, is to help stakeholders and staff achieve such clarity in communications and transparency in processes.

FDALO strives to be much more than a *reactive* organization based on a belief that *proactive* attention to stakeholder relations can prevent many relationships from becoming contentious. It is widely agreed that the potential cost in time and goodwill created by a failure in stakeholder relations more than justifies the resources that Health Canada devotes to preventing these situations from escalating.

The mandate of FDALO is aligned with that of the **Red Tape Reduction Commission**¹ insofar as FDALO is also seeking ways to simplify and expedite the interactions which stakeholders have with Health Canada. It is noteworthy that in the course of fulfilling its mandate, FDALO addresses many of the administrative and service irritants identified by stakeholders to the Commission.

As the only informal dispute resolution mechanism for Health Canada's regulated stakeholders, FDALO receives request for assistance from stakeholders concerned with the *Canada Consumer Product Safety Act* and the administration of the *Marihuana Medical Access Regulations*. The Office responds to these requests for service on a case-by-case basis in consultation with senior management.

¹ As announced in Budget 2010, the Government of Canada established the Red Tape Reduction Commission with a mandate to promote effective and efficient government that enables growth, innovation, competitiveness and productivity, while safeguarding the environment, health, safety and security of Canadians. The Red Tape Reduction Commission is working with regulators such as Health Canada, to provide specific recommendations on how to reduce compliance burden due to federal regulation, so that business—especially small business—can focus on investment and creating jobs.

Stakeholders include members of the general public, business owners, medical professionals, representatives, patients, law enforcement officials, and industry associations. They share a common desire for clear, reliable information on Health Canada's programs, policies and regulatory processes.

FDALO by the Numbers

- In 2010–2011, FDALO opened 158 cases or three new cases every week. 98.6 percent of inquiries received acknowledgement by FDALO within 24 hours.
- About 57 percent were cases where stakeholders were **seeking information**. The remaining 43 percent were cases where an existing stakeholder relationship with regulatory staff had deteriorated to a point where either the stakeholder or Health Canada staff sought FDALO's intervention to **manage issues**. All cases shared one or more of the following themes: misunderstandings, interpersonal conflicts, procedural issues, policy issues, or a desire for a better understanding of FDALO's services.
- Based on feedback and comments by stakeholders, FDALO estimates that approximately 20% of cases where stakeholders sought information had the *potential* to escalate into more serious situations requiring relationship management. In all cases, **conflict escalation was avoided** because FDALO was able to arrange for stakeholders to obtain the requested information in a timely way.

Relationship Management

Stakeholder relationships may break down for many reasons. In many of the cases FDALO encounters, there are misunderstandings between stakeholders and Health Canada regarding policies or regulatory decisions. In other cases, there is a mismatch of expectations regarding what Health Canada will do and how quickly that will occur. Finally, there are inevitable interpersonal issues which can arise, especially when a stakeholder feels they are being ignored or treated unjustly. In these situations, FDALO plays an impartial role to manage the relationship and de-escalate the situation. Timely, transparent and reliable information is often enough to resolve these situations. While Health Canada's regulatory functions will inevitably lead to some intractable conflicts, FDALO works with regulatory units to provide clarity, restore trust and rebuild relationships.

Information

As a key point of entry for stakeholders, especially those unfamiliar with Health Canada, FDALO receives a significant number of information requests each month. Some of these inquiries fall within Health Canada's area of responsibility and some do not. FDALO staff refer these stakeholders to the appropriate contact point within Health Canada or outside as required. By expediting referrals, FDALO reduces stakeholder frustration and improves outcomes by enhancing communication and streamlining administrative processes.

Observation and Feedback

In executing its role as a liaison office, FDALO is uniquely placed to relay improvements that stakeholders observe in overall stakeholder relations at Health Canada and to identify further opportunities for improvement. Providing feedback to the department about the strengths and weaknesses in stakeholder relations is central to FDALO's mandate and the value it brings to Health Canada.

Improvements in Stakeholder Relations in 2010–2011

This section of the report discusses developments stakeholders have observed at Health Canada in the last year which have improved stakeholder relations.

Better Access to Information

In the past, stakeholders have reported difficulty obtaining basic information about the department's activities and regulatory processes from the website. Furthermore, the website did not offer a toll-free telephone line or a general inquiry email box for questions or concerns. This resulted in a high volume of information inquiries to Service Canada and FDALO. The process of referrals from the website, through Service Canada, FDALO and on to a specific unit of Health Canada often led to understandable frustration.

FDALO raised this issue in the 2009–2010 Annual Report. Since then, the department has launched two initiatives over the past year to make service improvements.

First, the department reinstated a departmental toll-free and email service on its website, thereby giving the public direct access to the department when the website does not suffice. As a result, the department's general inquiry staff are responding to an average of 373 inquiries every day, and there has been a corresponding reduction in routine inquiries coming to FDALO. This has allowed the Office to focus on more complex and mandate-related inquiries and complaints.

Second, the department has also begun an overhaul of its external website to make it easier to navigate, better organized, and focussed on providing relevant and timely resources to the various stakeholder groups it serves. All program areas at Health Canada are being called upon to help ensure that web content is relevant, reliable, and accessible.

Proactive Use of FDALO

Health Canada staff and stakeholders are increasingly using FDALO's dispute resolution services in a proactive way to manage issues to keep and prevent escalations into costly and more adversarial conflicts. This is, in part, due to FDALO's extensive outreach activities with staff and stakeholders.

As FDALO becomes better known, staff and stakeholders whose interests extend beyond the *Food and Drugs Act* are increasingly seeking its services to address complaints expediently and with an emphasis on constructive dialogue to resolve issues. These interests include Health Canada's other regulatory functions such as medicinal marihuana, consumer product safety, and pest management.

Progress in the Licensing of Natural Health Products

Feedback from stakeholders indicates growing satisfaction with the licensing of natural health products (NHP) in three specific areas.

1. The Natural Health Products Directorate (NHPD) has implemented performance targets and made progress in **addressing the backlog** of NHP license applications that was created since 2004 when the regulations were introduced. The Directorate also now posts detailed quarterly progress reports on the Health Canada website.
2. Stakeholders say NHPD's **electronic tools facilitate** the application process, especially for products comprising of pre-approved substances.
3. **The disclosure of reviewers' notes** clarifies the threshold a sponsor must meet in order to obtain licensing authorization, especially when the sponsor desires more than the limited information provided in the licensing decision letters. These notes are available upon request.

During the last year, FDALO has received positive feedback from stakeholders about each of these improvements.

Opportunities for Further Improvements in Stakeholder Relations

Based on the cases received by FDALO in this reporting period, this section discusses four specific areas stakeholders have identified for further improvements.

1. More predictable response times for inquiries and requests;
2. Improved coordination of cases which require input from more than one work unit of Health Canada
3. Additional recourse options for stakeholders who disagree with compliance and enforcement decisions;
4. More proactive communication about the Special Access Program, as well as implementing a more automated system for SAP applicants.

Predictable Response Times

Stakeholders note that greater predictability in response times to their inquiries could prevent a key source of frustration. Predictable response times would likely reduce the escalation of these situations, thereby decreasing the additional investment of time and resources required by both Health Canada and the stakeholders involved.

Departmental staff, who must deal with competing priorities and issues that vary in complexity and urgency, are sometimes not able to address a stakeholder's concern within a timeframe the stakeholder considers reasonable. Stakeholders note that the department often does not give them any timeframe in which a response will be available. As a result, stakeholders perceive the wait to be open-ended and unpredictable. Frustration and anger may grow, sometimes fuelled by the perception of being ignored or dismissed, which lead to conflict escalation.

Currently, FDALO helps manage stakeholder expectations by liaising with staff about their progress and conveying updates to stakeholders.

Coordination on Complex Files

An integrated case management process for stakeholder inquiries could significantly improve service, reduce conflicts, and create efficiencies in regulatory decision-making that involves several areas of the department.

Stakeholders report difficulty with the coordination of responses to inquiries or requests involving more than one directorate or branch in the department and/or one of the regional offices. Sometimes stakeholders become confused, frustrated and unsure of who is the key decision-maker. They would like to see a more coordinated approach to managing these more complex cases.

Additional Recourse Opportunities in Compliance and Enforcement

FDALO has encountered a number of small and medium sized businesses who would like access to a recourse process within the department to deal with their objection to a compliance and enforcement decision. Despite FDALO's informal dispute resolution services to enhance communication and understanding between parties, in these cases the stakeholder continues to object to the merits of the decision. At this point, the issue is no longer that the stakeholder does not understand the decision or the rationale for it; they simply do not agree with it. These stakeholders have asked for access to a formal reconsideration process within the department as an alternative to judicial review or federal courts, which they feel is neither affordable nor expedient enough to be a viable option for their small operations.

Special Access Program

Stakeholders require more proactive communication to understand the scope of the Special Access Program (SAP). Furthermore, stakeholders would like to see the SAP application process more fully automated.

SAP provides access to non-marketed drugs for health care practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable.

FDALO has received complaints from hospital pharmacists, on behalf of physicians and other front line medical staff, in part related to actual or potential global drug shortages. The complaints revealed that the expectations of this stakeholder group go far beyond the mandate of SAP. FDALO facilitated a dialogue between SAP staff and a group of pharmacists and physicians in one particular region of the country to foster understanding on both sides. Two central themes related to SAP's processing of applications emerged from the discussions.

First, explanations by SAP staff regarding the scope and limitations of SAP mandate can be perceived by applicants as a challenge to their medical judgement or to their professional authority to make therapeutic choices for their patients. Explanations given by staff in the rush of an urgent application may not be well-received. While many past efforts have been made to communicate the intent and limitations of the program, SAP staff has recognized the need for further communication and are planning to consult with key stakeholders across Canada in the coming year.

The second perception to emerge from discussions with stakeholders is that the SAP application process may create frustration because it is labour intensive and may require numerous phone calls to sort out administrative details. The process relies on forms which are often completed by hand and transmitted by fax. SAP applicants would like to see a more automated application process that would improve efficiency and accuracy.

Accomplishments at FDALO in 2010–2011

The following pages outline the key accomplishments of FDALO in the past year.

Outreach

The ongoing success of FDALO depends on awareness of FDALO and its role among staff and stakeholders. The population of potential stakeholders – anyone with an interest in Health Canada's administration of the *Food and Drugs Act* – is huge. The available time and resources are limited. In the past year, a number of outreach accomplishments stand out.

1. A link to the FDALO program is now located on the main page of Health Canada's web site under the heading "How to Get Involved." This prominent location has been useful to many stakeholders who were unaware of FDALO's existence but seek fair, timely and cost effective assistance to their concerns on regulatory matters.
2. In 2010, FDALO completed two electronic mail-outs to approximately 10,000 stakeholders registered in a departmental database of known stakeholders with an interest in the *Food and Drugs Act*. This mail-out reached individuals and groups in sectors including academia, industry, patient and consumer associations. The first notice informed stakeholders of the program, while the second provided information about the 2008–2010 Report on Activities.

3. FDALO presented to the Community of Federal Regulators regarding of “The Fairness Triangle”, a practical tool for evaluating fairness in administrative decision-making which is the foundation for FDALO’s training program. This well-received presentation was attended by 166 employees from various regulatory departments and agencies in Ottawa. This has led to other invitations to present to workgroups in various regulatory departments, as well as an invitation to present to the Community of Federal Regulators in Montreal.

FDALO is becoming known as a best practice within the federal government for dealing with stakeholder complaints informally and expediently.

Training

This year saw ten more sessions of FDALO’s training program “Making the Most of Difficult Communications with Stakeholders.” This program, introduced in 2009, responds to the need for specific training in managing difficult communications with stakeholders in a complex regulatory environment.

The program has been delivered fourteen times across Canada in both official languages. In this past year, the program reached over 193 staff across several directorates and branches in the department, and helped staff make connections with each other.

Designed for regulatory staff communicating with external stakeholders, the training program includes learning tools and case studies to help staff deepen their thinking on such topics as:

- what does client service mean within a regulatory context;
- how to listen for what matters;
- approaches to managing conflict and escalated emotion;
- communication skills; and
- best practices.

Post-session evaluation surveys confirm participants’ appreciation and satisfaction with this learning program. From the responses collected, all respondents felt they learned something new in the course; and almost all (96%) agreed or strongly agreed that the content was useful to their work. Comments included:

“This is the first time in collective memory that we’ve had a communications course for dealing with external stakeholders. It is excellent – should be mandatory and needs to be an orientation course. I’ve realized that there is a very big gap for our organization and this needs to be addressed for training and retention.”

“Valuable in all aspects of dealing with difficult stakeholder situations, diffusing these, and building ‘trust’ relationships.”

“I found it to be very helpful, useful and enlightening. Made me aware of my own behaviours and how I can consciously improve myself.”

As a result of the training’s success, FDALO has begun to receive requests for customized training from specific groups in other regulatory areas inside and outside the department.

Formalizing Processes

FDALO is building operating procedures in consultation with regulatory staff, in order to foster a shared understanding of when and how to use the program, and when its involvement would not be appropriate. There have been significant advances in identifying cases where FDALO services would be useful, and it has been agreed that FDALO will not become involved in cases where litigation is underway. There is also agreement that stakeholders will not be turned away by FDALO simply because their issue falls outside of its mandate, especially if their complaint is about a poor service experience. Each case will be considered by FDALO on its own merit.

FDALO had limited resources to dedicate to formalizing and communicating its operating procedures over the past year, opting to concentrate on case management and training instead. Work will continue on these procedures in the coming year, in consultation with regulatory staff.

Senior Management Liaison

A key achievement in the past year has been the expanding contact between FDALO and senior managers at Health Canada.

A member of the Health Products and Food Branch's (HPFB) management team has been assigned to the role of FDALO Senior Champion. This has improved FDALO's ability to communicate quickly and effectively with senior management in that branch. The Senior Champion has also played an important role in promoting the use of FDALO's services among HPFB management team and staff.

FDALO also met with all of the directors general and key staff members of HPFB to communicate the role and observations made by the program. These presented opportunities to build stronger relationships so that FDALO can call directly on staff in different program areas as it receives stakeholder inquiries. Of equal importance is the opportunity to discuss the important issues and service improvement opportunities with management teams.

HPFB invited FDALO to present on how the office could strengthen and improve existing dispute resolution processes. As the branch looks for opportunities to strengthen and improve existing systems as well as address any gaps, FDALO has been able to offer insights into stakeholder perspectives and experiences.

Conclusion

The forgoing pages have described in brief the work of FDALO in the past year. Barely three years since its launch, FDALO is fulfilling a significant role in helping Health Canada and stakeholders work more efficiently and constructively through regulatory matters. FDALO staff are helping to build relationships with stakeholders and to respond quickly and impartially when relationships deteriorate. Equally important, FDALO is providing Health Canada with a broad perspective on the strengths and weaknesses of the way the department currently relates to stakeholders, and making suggestions about how the relationship may be improved in the years to come.

Appendix A: Case Statistics

This appendix provides a full detailed breakdown of 2010–2011 activities discussed earlier, including graphical figures.

The following data provides a more complete picture of FDALO’s caseload, emerging trends, and key statistics describing the cases and caseload.

Number of Cases

- FDALO opened 158 cases during fiscal year 2010–2011.
- In 96.8 percent of cases, FDALO responded to inquiries within one business day.

Geographic Origin of Cases

The following chart illustrates the geographic origin of cases received. The 17 cases marked “unknown” did not disclose their location.



Nature of Issues

The 158 cases received by FDALO during the 2010–2011 fiscal year have been tracked under two general categories: *information-seeking cases* and *issues management cases*, based on the stakeholder’s principle reason for contacting the office.

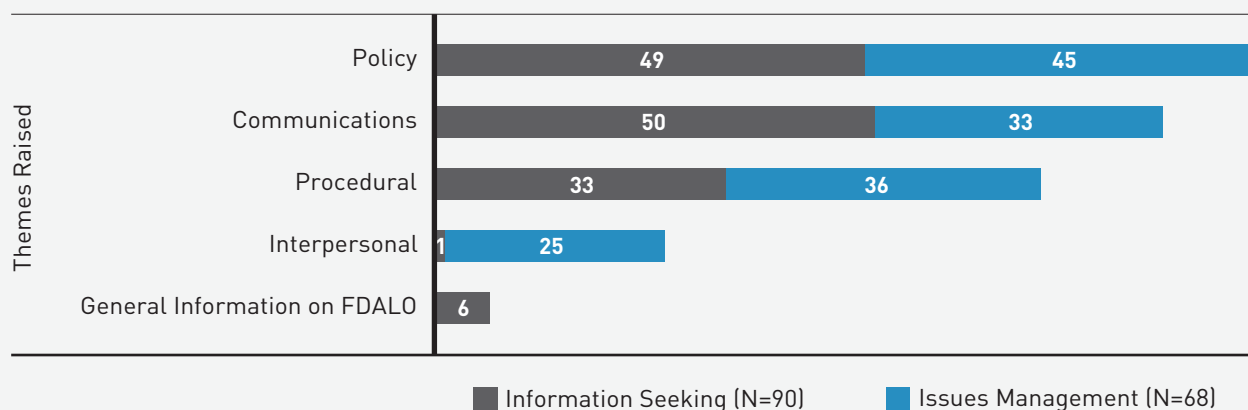
Information-seeking cases represent 57% percent of FDALO cases, while the remaining 43% are issues management cases.

Each case has been further categorized into **one or more** of the following five themes to capture the nature of the issues:

- **Policy issues** (For example, disagreements with the interpretation or application of the law, policies or regulations, such as product classification, etc.)
- **Communication issues** (For example, information-seeking inquiries, unreturned calls, unclear correspondence from Health Canada, or correspondence that does not address stakeholder concerns, etc.)
- **Procedural issues** (For example, dissatisfaction with the processes used in regulatory decision-making, such as timeliness, etc.)
- **Interpersonal issues** (For example, stakeholder treatment by staff, or staff requests for assistance in dealing with stakeholder relations, etc.)
- **General questions/inquiries** about the Food and Drugs Act Liaison Office and its services

While a case has been tracked as either “information-seeking” or “issues management”, it may contain more than one theme.

GENERAL THEMES IDENTIFIED BY FDALO



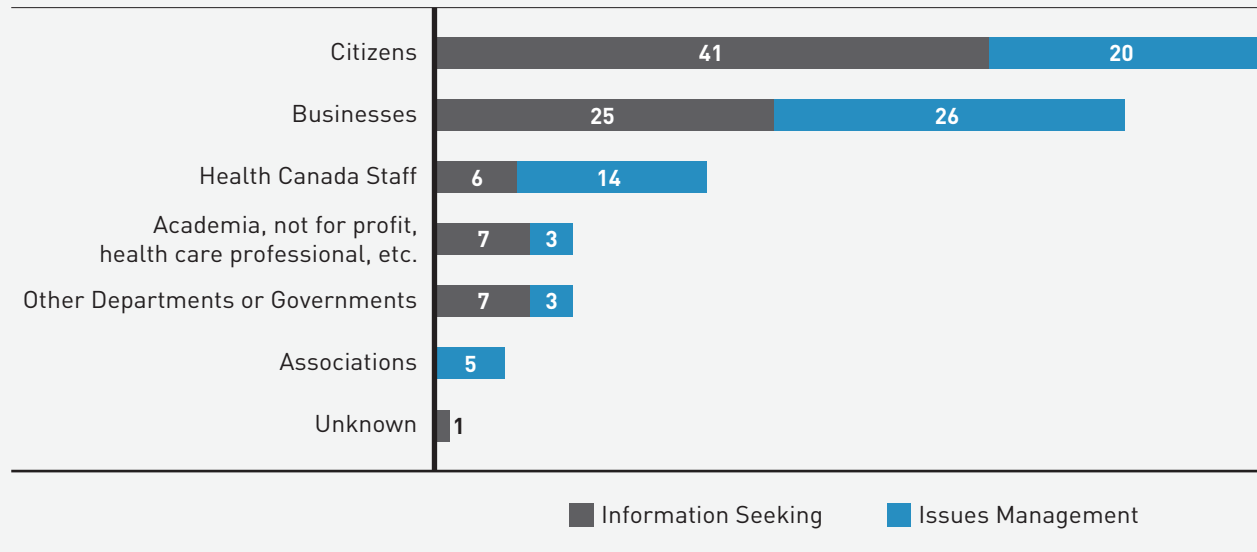
Note: A single case may include several themes

Approximately 20 percent of information-seeking cases had the potential to escalate into issues management cases. Through active listening and rapid response, FDALO addressed the stakeholders’ concerns to minimize conflict escalation and maximize service satisfaction.

Contact Type

FDALO dealt with a variety of stakeholders over the past year. The following table highlights the types of stakeholders and the nature of the cases.

CONTACT AND ISSUE TYPE

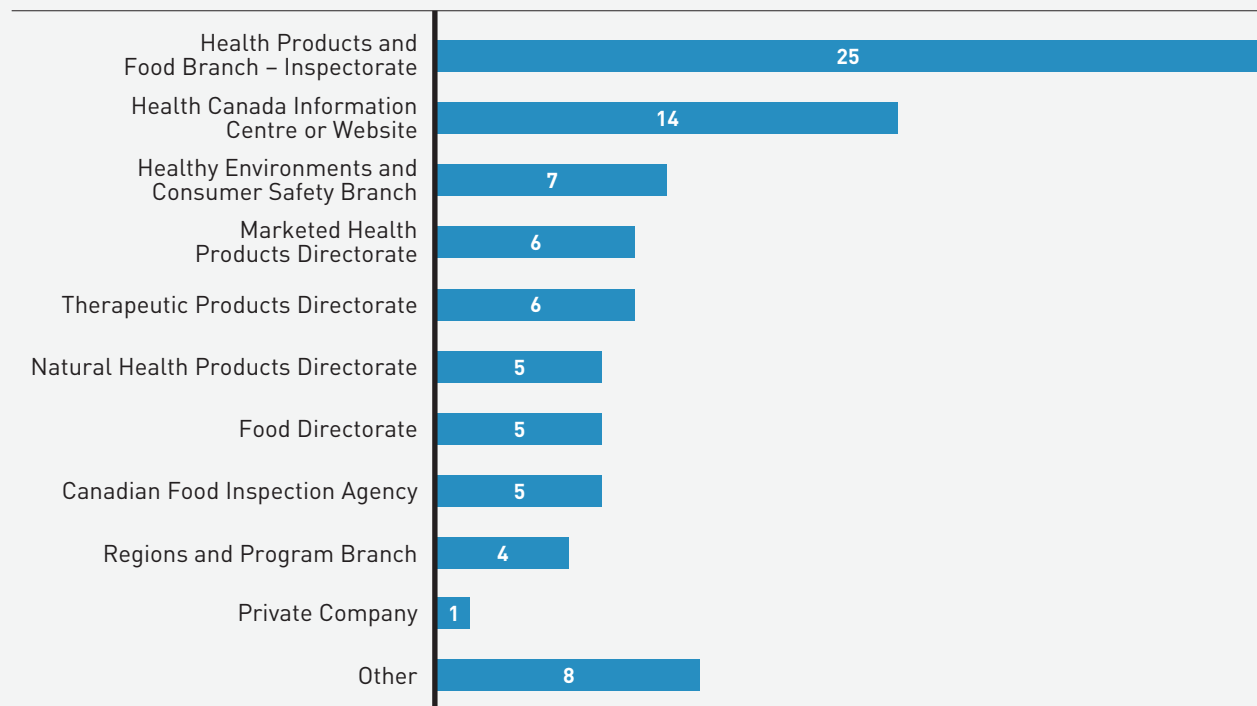


Referrals in Information-Seeking Cases

Those seeking information or a contact person within Health Canada were often referred to work units. The following chart illustrates the referrals. A single case may have been referred to more than one work unit.

CASE REFERRALS BY FDALO

Information Seeking Cases

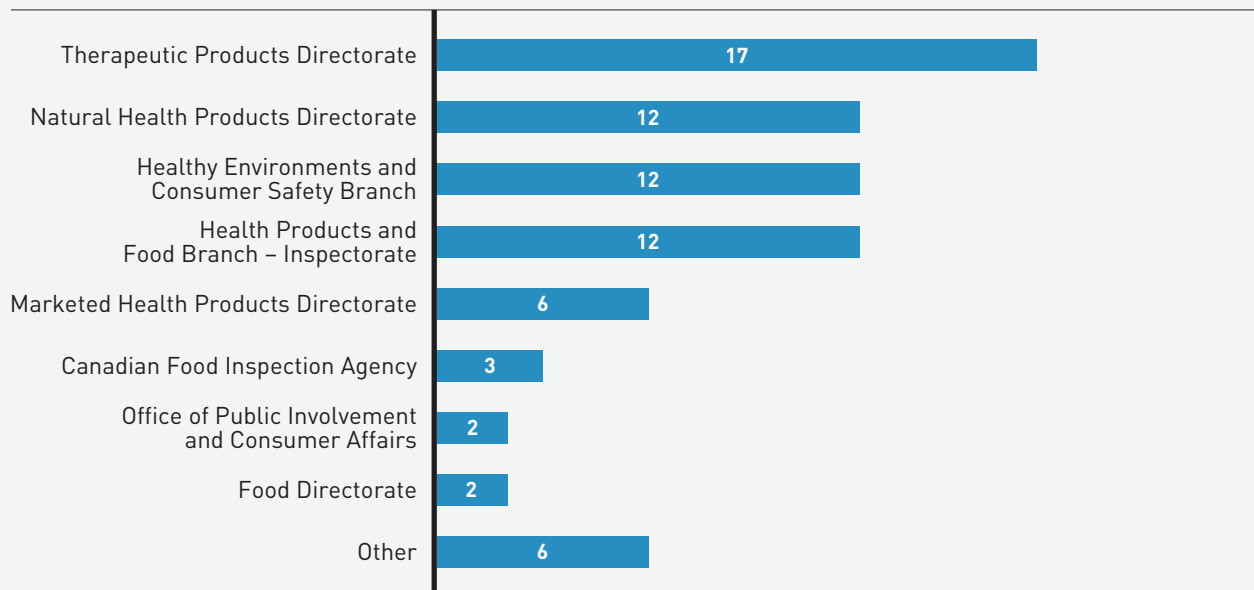


FDALO continues to help stakeholders find information on the Health Canada website as it undergoes reconstruction to make it more user-friendly. FDALO also made referrals to various outside organizations captured under “Other,” such as Canadian Mental Health Association, the Procurement Ombudsman, and the Office of the Correctional Investigator.

Work Units Implicated in Resolving Issues Management Cases

The following chart highlights the work units involved in complaint resolution. Some cases may involve more than one work unit. It should be noted that FDALO sometimes receives inquiries from stakeholders concerning a certain work unit, and after providing information or guidance to the stakeholder on options for dealing with the issue, the stakeholder may choose to pursue the matter directly with the work unit without FDALO involvement. The work units about whom the inquiry was made have still been captured below. This graph also captures Health Canada work units who have contacted FDALO for proactive assistance in managing complex stakeholder files.

WORK UNITS IMPLICATED Issues Management Cases



Appendix B: Case Studies

This appendix provides examples of FDALO's work in 2010–2011. Every attempt has been made to protect the identity of individuals.

FDALO in Action: Fostering Openness and Transparency in Decision Making

Issue	Health Canada's Inspectorate stopped the importation of a product by a Canadian company on the grounds that it did not conform to the Regulations, and in fact, posed a health risk to Canadians. The company was unhappy as it disagreed with the assessment that the product was unsafe. The company felt that Health Canada had made an error and said it did not understand the rationale used by the department to arrive at its decision. However, the company was not able to get further information or satisfactory clarification of the decision from Health Canada. It requested FDALO's assistance.
Intervention	FDALO inquired with Health Canada as to how it had arrived at the conclusion that the product was unsafe. The response was that the department had conducted laboratory tests that validated a significant safety risk to the public. FDALO requested that the test results be disclosed to help the stakeholder understand the evidence on which the decision had been based. After some consideration, the department released the results to the company.
Outcome	Through inquiries and active listening, FDALO was able to identify a critical issue that was unnecessarily causing conflict escalation. Once the documentation was released, the stakeholder understood the rationale used by the department and could respond in a meaningful and factual way. Since this intervention, many work units are more readily disclosing critical information to stakeholders in a timely way to help them understand the rationale for a decision without resorting to the <i>Access to Information Act</i> .

FDALO in Action: Preventing Needless Conflicts

Issue	<p>A company hired a consultant to prepare a critical regulatory report for Health Canada. The Health Canada employee who reviewed the report found it lacking in certain requirements and informed the company and the consultant of this conclusion. While the consultant agreed that some parts of the report needed attention, he found the tone of Health Canada's feedback to be condescending and felt that it called into question his professionalism. He took offense to this especially as the feedback was shared with the company that hired him. He noted that he had decades more experience of working in the field of food and drugs regulations than the employee who had responded to his report.</p> <p>The consultant contacted FDALO to request that his complaint be escalated to the highest officials in the department.</p>
Intervention	<p>After listening to both parties, it became apparent that the Health Canada employee had no intention of discrediting or disrespecting the consultant and, in fact, fully acknowledged the consultant's experience and expertise. This did not change the fact that the consultant's report was lacking in certain respects. Working with the parties, FDALO facilitated an intervention where they gained a better understanding of each other's perspectives. FDALO also offered coaching to the employee and manager on how to give feedback on such reports in a more objective, neutral and factual way, staying away from potentially inflammatory adjectives. Finally, management agreed to write a letter to the consultant to acknowledge his concerns and committed to reminding staff to provide feedback in a more constructive way.</p>
Outcome	<p>FDALO was able to assist the staff and the stakeholder in addressing their concerns at the lowest levels possible and prevented the issues from escalating unnecessarily to the highest levels of the organization. From the stakeholder's perspective, he felt that his concerns were acknowledged. For Health Canada staff, FDALO facilitated an internal dialogue on best practices and helped management and staff become more mindful of using constructive feedback to convey negative decisions.</p>

FDALO in Action: Ensuring a Fair Hearing

Issue	A small business owner was hospitalised with a serious medical condition for several months causing him to miss the deadline to apply for a cost reduction of a medical device licence his company holds. The business owner felt that his extenuating circumstances should have been taken into consideration, and that his delayed revenue submission should have been accepted. He was not successful in negotiating this matter directly with the staff involved. He therefore contacted FDALO for assistance.
Intervention	FDALO does not have the authority to overturn a regulatory decision. However, it agreed to obtain further clarification of the decision from Health Canada. The FDALO advisor contacted the employee involved to obtain a detailed understanding of the process and to explore options that might be acceptable to the department. The solution reached was that the business owner would substantiate with a medical note from his physician, the length of time he was incapacitated, and on this exceptional basis, his delayed revenue submission would be reviewed.
Outcome	The business owner was pleased that FDALO was able to have the department consider his exceptional circumstances to arrive at a fair and just decision to review his delayed submission. This early intervention from FDALO permitted the business owner and Health Canada to arrive at an acceptable solution for both parties.

FDALO in Action: Reassuring a Worried Parent

Issue	A parent called a Health Canada official after learning her child's medication for a chronic and serious illness was temporarily unavailable due to a regulatory issue between the manufacturer and the department. The parent was very upset as there were no other viable treatment options for her child. She felt she was getting the "run around" from the department and the company. A Health Canada official and the company both contacted FDALO for assistance on how they could address the parent's concerns.
Intervention	As FDALO discussed the issue with both parties, it became clear that while they were working to resolve the regulatory issues, their communications with the parent may have been blaming each other for the delays. Through coaching, FDALO was able to encourage the Health Canada official and the company convey the spirit of co-operation that they had already embraced, and explain to the parent their respective roles and responsibilities to bring the medication into compliance.
Outcome	The communications approach recommended by FDALO helped to calm the parent's frustration and anxiety while the regulatory review was completed.

FDALO in Action: Preventing Escalation Through Communication

Issue	A lawyer representing a multi-national company called FDALO for a confidential consultation. The company was contemplating legal action because it was denied authorization to use an ingredient in their product. The ingredient had apparently been accepted in other jurisdictions where this company operated.
Intervention	Through active listening, FDALO learned that the company was not satisfied with the rationale for why the ingredient could not be used in Canada. The lawyer felt that the company was not being given adequate attention and that the Health Canada employee with whom it was dealing lacked sufficient expertise on the issue. FDALO worked with the lawyer to clarify the company's expectations. FDALO was then able to contact a senior Health Canada decision maker and arrange for both parties to speak on this issue.
Outcome	By using FDALO services, the lawyer did not have to resort to adversarial conflict escalation to have the company's concerns addressed. The company was able to engage in further dialogue with senior operational staff to work through the issues in a constructive and expedient way.

FDALO in Action: Sharing Industry Perspective

<p>Issue</p>	<p>Several industry stakeholders from the cosmetics sector have contacted FDALO to express concern about the administrative burden and regulatory complexities they face in obtaining licensing approval for what they consider to be low risk products. Depending on the ingredients contained in a formulation, products from this sector can fall under three different regulatory frameworks administered by three separate areas in the department. In some cases, product classification and sorting out the correct regulatory area of responsibility have been challenging. From the perspective of industry, this framework often brings to light inconsistencies in how the different Health Canada work units deal with products containing the same ingredients.</p> <p>Companies have complained that cosmetic-like drugs do not lend themselves easily to the drug regulation framework, resulting in over regulation of low risk products. They note that similar products with similar risk profiles are regulated as natural health products by Health Canada and do not have such burdens placed on them. Labelling regulations of cosmetics containing drug ingredients such as those in sun screens has created much concern for companies. This includes the requirement for dosage labelling on products, and the fact that phrases such as “make-up,” “foundation” or “lip colour” are not permitted for these products. Companies say these labelling requirements are needlessly disrupting global marketing initiatives.</p> <p>Companies would like a more integrated approach to the regulation of cosmetics and non-prescription drugs within the department. They hope the <i>Food and Drugs Act</i> will soon be updated to allow for more effective risk management given the range of complexity and diversity of all products presently under the <i>Act</i>.</p>
<p>Intervention</p>	<p>FDALO has received the comments from industry and has facilitated meetings between Health Canada representatives and industry members to find solutions within the existing regulatory framework. It has provided an avenue for the association and its individual members to have specific concerns addressed on a case-by-case basis.</p>
<p>Outcome</p>	<p>FDALO has helped to address specific cases and also brought this systemic issue to the attention of senior management for consideration in future regulatory modernization.</p>

FDALO in Action: Lending a Hand to Other Regulated Stakeholders

Issue	As FDALO becomes known to stakeholders, it has begun to receive enquiries and complaints that fall outside of its mandate. These include complaints pertaining to Health Canada’s other regulatory areas of responsibility, namely consumer product safety and medical marihuana. Over the 2010–2011 reporting period, FDALO received 9 complaints from patients and growers regarding the status of their medical marijuana licenses.
Intervention	FDALO has approached senior management in these other regulatory areas, and has been given permission to intervene on a case-by-case basis. The Marihuana Medical Access Division (MMAD) has accepted FDALO intervention. FDALO has provided a forum for stakeholders to address their service delivery concerns and has followed up with MMAD to have these complaints addressed. FDALO has also offered to management in MMAD to train all staff interacting with stakeholders.
Outcome	FDALO has successfully helped to resolve many medical marihuana cases on an individual basis and will continue to work with the other regulatory components of Health Canada to manage and resolve similar stakeholder concerns.

FDALO in Action: Resolving Longstanding Cases

Issue	Health Canada staff have started using FDALO services to manage longstanding and highly escalated complaints from stakeholders. These are situations where the department has made numerous attempts to resolve a stakeholder concern, but the stakeholder remains dissatisfied. Some of these complaints have been ongoing for months or years, and have involved countless person-hours of effort. In several cases, staff have turned to FDALO for new approaches in managing the stakeholder’s complaint.
Intervention	Once the stakeholder has accepted the referral for FDALO’s intervention from Health Canada staff, FDALO has offered its neutral and impartial perspective to examine the complaint. It has listened to why stakeholders feel the issue has not been adequately addressed by the department. Common gaps perceived by stakeholders include issues with the process used to make a decision, how the decision was communicated or the treatment they received in the interactions with staff. In each of these cases, FDALO has assisted stakeholders to clarify their expectations. Where gaps are noted, FDALO made recommendations to staff for remedial action. This might include additional correspondence with the stakeholder to clarify a specific issue that has not been addressed to their satisfaction. This role has allowed FDALO to ensure the issue has been thoroughly and thoughtfully addressed from the stakeholder’s perspective. In some cases, FDALO’s assessment is that the department has addressed all of the stakeholder’s concerns and that the situation is such that the stakeholder must “agree to disagree” with the regulator.
Outcome	While the outcome in each of the cases is different, FDALO has helped to bring each of these recurring compliant cases to closure while minimizing the use of scarce departmental resources. Its neutral and impartial perspective allows it to communicate its assessment to stakeholders as to whether or not the department has adequately addressed their concerns.

FDALO in Action: Making Connections

Issue	Health Canada and the Canadian Food Inspection Agency (CFIA) have related responsibilities and their respective roles are often confused by stakeholders. For example, FDALO has received questions, concerns and complaints regarding animal feed products and veterinary drugs. The issue is the classification and licensing of these products and which organization has jurisdiction over them.
Intervention	In each case, FDALO carried out a thorough examination of the issues to make appropriate referrals not only to the correct organization, but to a specific contact person within the organization. In some cases, FDALO helped to make connections between Health Canada and CFIA to promote communication over matters that are interrelated for both organizations.
Outcome	Our ability to help clarify the issues and bridge communication between both organizations results in stakeholders getting access to the appropriate decision makers in a timely way. In addition, FDALO provides feedback to both organizations when it observes systemic problems or issues that are causing confusion for and conflict escalation among stakeholders.