Food and Drugs Act Liaison Office

Report on Activities 2011–2012

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. *We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.*

Published by authority of the Minister of Health.

Food and Drugs Act Liaison Office • Report on Activities 2011–2012
is available on Internet at the following address:
www.healthcanada.gc.ca/fdalo

Également disponible en français sous le titre :
Bureau de liaison pour la Loi sur les aliments et drogues • Rapport sur les activités 2011–2012

This publication can be made available on request in a variety of alternative formats.

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Cat.: H1-9/28-2012E-PDF
ISSN: 1927-6605 (Online)
Pub.: 120162

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Message from the Director

In March 2012, the Food and Drugs Act Liaison Office (FDALO) of Health Canada completed its fourth year of work addressing inquiries and complaints related to the *Food and Drugs Act*. As required by the Treasury Board Secretariat, the publication of this annual report captures trends in complaints and service improvements that stakeholders brought to FDALO's attention during that time. It also details some accomplishments FDALO made as it strives for program maturity, provides statistical data on our workload, and describes some example cases which illustrate the practical work we do.

Relative to the thousands of regulatory transactions completed each year by Health Canada staff who administer the *Food and Drugs Act*, FDALO receives complaints or inquiries about only a very small proportion. We work with stakeholders to solve specific problems, and we also provide feedback to the department to assist in optimizing relationships with stakeholders.

In 2011–2012, Health Canada employees were called upon to implement significant recommendations made in reports from the Auditor General of Canada, the Regulatory Cooperation Council and the Red Tape Reduction Commission. The 2011–2012 period also saw the implementation of updated user fees for a number of Health Canada's *Food and Drugs Act* regulatory activities related to human drugs and medical devices.

Each initiative challenged Health Canada employees to work differently and seek ways to improve service delivery while staying true to the primary objective of maintaining the health and safety of Canadians.

During this time of change, our team was proud that stakeholders who came to us felt heard and well-served, and that we provided the department with unique information to support its on-going efforts for improved service and regulatory renewal.

Serena Siqueira
Director

FDALO in Brief

This section provides an overview of FDALO's mandate, background and services.

Mandate

To receive complaints, concerns or enquiries about alleged acts, omissions, improprieties, and/or broader systemic problems on matters pertaining to the Food and Drugs Act, and to listen, offer options, make recommendations, facilitate resolution, or otherwise examine the issues impartially.

The Food and Drugs Act Liaison Office (FDALO) was launched in 2008 as an impartial and neutral service that helps to facilitate and manage the relationship between Health Canada and the various stakeholder groups who communicate with the Department about *the Food and Drugs Act*.

FDALO responds to requests for service on issues or questions which are brought directly to it by external stakeholders, as well as issues brought to it by Health Canada staff who are facing challenges managing relations with a specific stakeholder.

The Office does not have authority to review regulatory decisions or impose solutions on troubled stakeholder relationships. However, it is mandated to provide voluntary informal dispute resolution services to stakeholders and staff through coaching, mediation, and facilitation. FDALO also trains Health Canada staff to effectively manage stakeholder relations.

Our case management process begins with an assessment of the file, including whether it falls with the Office's mandate and any relevant past contacts. In simple cases of information requests, FDALO provides the needed information. More complex dispute-resolution cases are dealt with through coaching and facilitation for both parties. In either case, FDALO follows up with stakeholders to ensure that a resolution has been achieved before closing the file. A ***case management process diagram*** is included in the notes section.

FDALO receives requests for assistance from stakeholders regarding issues outside the *Food and Drugs Act*, such as *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 other Health Canada directorates and senior management.

FDALO's external stakeholders include members of the general public, business owners, medical professionals, elected 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.

Improvements in Stakeholder Relations in 2011–2012

This section of the report discusses developments stakeholders have observed at Health Canada in 2011–2012 which improved stakeholder relations.

Communicating Recourse Processes

Stakeholders who disagree with a regulatory decision by Health Canada often have options within Health Canada to seek recourse. In the past, however, FDALO has received complaints from stakeholders that decision letters from the department did not specify that recourse processes were available or provide key information about recourse options, such as time limits.

Some decision letters included a lengthy website link to additional information about a recourse process, but were delivered in a format where the link could not be launched directly or copied into an internet browser. Recourse information was also sometimes difficult to find on the Health Canada website.

FDALO took these matters up with the relevant Directorates. Since then, FDALO has observed that decision letters communicate the availability of recourse processes and time limits much more clearly. Stakeholders have also noted this as an important improvement in openness and transparency in the regulatory system.

Explaining the Rationale for Post Market Decisions

Health Canada collects post market information on therapeutic products it licenses. Analysis of this data may lead Health Canada to direct the manufacturer or license holder to mitigate an emerging risk associated with the product.

Some companies have complained that they are not given easy access to all the information that underpinned the department's request for action, but must instead request that information through the *Access to Information Act.* Companies complain that this is unnecessarily complicated and time-consuming, depriving them of a clear understanding of the department's rationale or a fair chance to quickly address the concerns and discuss other viable mitigation actions.

When FDALO approached the Health Canada directorate involved in this issue, steps had already been taken to remedy the situation. The directorate now prepares a summary document that explains the basis of a decision, while protecting the commercial and individual privacy of people involved. The summary document can be released to the manufacturer or license holder upon request without an *Access to Information* application, so as to fully disclose the rationale for the department's post-market action in a more timely manner.

Opportunities for Further Improvements in Stakeholder Relations

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

Web Advisories

Health Canada posts advisories on its website when therapeutic products are found to pose a health and safety risk to Canadians. The department leaves past advisories related to a company or product in place indefinitely, believing that this information serves the public interest.

FDALO has received complaints from companies because the advisories affecting their products do not reflect actions they may subsequently have taken to remedy the situation. In other words, companies feel that a negative advisory on the Health Canada website damages their reputation indefinitely, even after the company takes corrective action. This issue tends to be of most significant importance to small companies who have limited product lines.

Affected stakeholders believe the advisories should more clearly indicate the date the notice was posted and highlight the fact that the advisories are not updated to reflect corrective action a company may have taken subsequently.

Scrutiny of Non-medicinal Ingredients

Some cosmetic and personal care product manufacturers have approached FDALO about difficulties they continue to encounter with Health Canada's "***New Drugs List***" (also referred to as *Listing of Drugs Currently Regulated as New Drugs*). This administrative list is used by the Therapeutic Products Directorate (TPD) as a screening tool or guide to determine the type of submission the manufacturer is required to make for a proposed drug product. The type of submission determines the complexity of the application, which requires the manufacturer to submit a corresponding level of safety and efficacy data.

Complainants from the cosmetic and personal care industry have taken issue specifically with having to submit extensive safety data for ingredients from the "New Drugs List" that they use as non-medicinal substances in topical products (products that are not ingested). Industry members indicate that specific ingredients on the list have been commonly used as non-medicinal, inactive substances in personal care products for many years and no longer merit the extensive scrutiny the department is still carrying out. They describe the impact of lengthy reviews as causing a disruption in their ability to secure timely licenses for product applications that should be routine and predictable. This leads to disruptions in their Canadian production and marketing plans.

FDALO has been instrumental in facilitating discussions between stakeholders and regulatory staff about what constitutes an appropriate level of data to help determine the benefit–risk profile of non-medicinal ingredients. As of March 2012, the Therapeutic Products Directorate agreed to examine the New Drugs List with a view to developing guidelines that might ease the regulatory burden for applicants using ingredients from the list solely as non-medicinal ingredients and for topical, cosmetic-like drugs.

Requirements for the Approval of Nanotechnology in Sunscreens

For several years, Health Canada has rejected license applications for sunscreens due to a lack of sufficient safety studies of the nano-sized particles of zinc oxide or titanium dioxide they contain.

Many companies complained that they could not meet these requirements because the time and cost required to conduct the studies individually were prohibitive. The industry association had only limited success finding an industry-wide solution because each license application is reviewed individually by the department on the merit of the product's specific formulation. Companies cited this situation as an example of red tape, noting that they are able to sell their products in other jurisdictions around the world such as the United States and Australia.

FDALO played a significant role in facilitating dialogue between industry and the department, as well as encouraging a harmonized approach to these ingredients within the department. Progress has been made. Some companies have met the department's required threshold for safety where zinc oxide is concerned. More progress on nano-technology is anticipated, especially with regard to titanium dioxide.

Awareness of Canada Vigilance

FDALO continues to receive calls from consumers and patients who want to report an adverse effect from a therapeutic or consumer product. We direct these individuals to the Canada Vigilance Program, Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada.

Many of these callers want to alert the department to their experiences so that it can take appropriate action for the benefit of others. Consumers often say that the program should be more widely promoted so that other Canadians know it exists and will use it to give the department important post-market information.

Clarified Processes for Medical Marihuana License Holders

The Food and Drugs Act Liaison Office continues to receive a high number of calls related to Health Canada's role in administering marihuana licenses for medical purposes. A common complaint from license-holders is difficulty when they change their address. They say the process for updating the department on the address changes frequently leads to delays and confusion in license renewal, causing a disruption in access to the product. License holders would like to see simpler, clearer guidelines for how to notify the department of an address change, and a clearer website overall.

Accomplishments at FDALO in 2011–2012

This section outlines key accomplishments of FDALO in 2011–2012.

The primary work of FDALO is responding to complaints or enquiries raised by external stakeholders and Health Canada staff. In 2011–2012, FDALO opened 162 cases, which was a marginal increase over the 158 cases received in 2010–2011.

As noted earlier, in 2011–2012 the Government of Canada emphasized improvements in serving Canadians and responding to the needs of stakeholders. FDALO's mandate and services are well-aligned with this direction. The Red Tape Reduction Commission's final report included ***two specific recommendations*** which relate to FDALO's role: Training and Feedback Mechanisms (see *Notes* section).

Training

"Making the Most of Difficult Communications with Stakeholders" is a training program designed and offered by FDALO to both Health Canada staff and other federal regulators invited through the Community of Federal Regulators. Since its inception in 2009, the program has served approximately 500 participants.

The program supports the attainment of "soft skills" as recommended by the Red Tape Commission, by teaching participants to:

- recognize the importance of building positive stakeholder relations;
- identify potential problems and opportunities when communicating with stakeholders;
- manage competing interests in a regulatory environment;
- demonstrate improved non-technical communications competencies; and
- demonstrate improved competency in dealing effectively with difficult stakeholder situations.

This program was offered 10 times in 2011–2012, including 3 sessions in the regions and 2 sessions through the Community of Federal Regulators. FDALO staff also customized 2 sessions for the specific needs of particular work units within Health Canada.

In addition, FDALO offered its staff expertise in preparing for the difficult conversations which took place under the Deficit Reduction Action Plan. One FDALO advisor trained about 240 managers and Human Resources advisors in a period of one month.

Feedback Mechanism

FDALO served as a feedback mechanism for stakeholders of Health Canada's food and drugs regulatory activities. It provided an informal and confidential process for dealing with complaints and provides the department with feedback on stakeholder issues to support the department's ongoing efforts to improve service and performance.

Furthermore, in 2011–2012 FDALO completed a Logic Model that forms part of a broader Performance Measurement Framework that identifies how FDALO can proactively obtain feedback about its own performance. This will permit FDALO to evaluate itself objectively and identify any areas for future improvements.

Planning for 2012–2013

This section highlights FDALO's key commitments for 2012–2013.

FDALO is committed to ongoing systemic improvements of its services, offering high quality client services and providing feedback to Health Canada. To meet these goals, the office will:

1. Engage and work with Health Canada stakeholders to strengthen dispute resolution processes for regulatory decision-making.
2. Use training, coaching and case interventions to build Health Canada's staff capacity for managing stakeholder interactions.
3. Continue implementing the performance measurement framework.

Appendix A: Case Statistics

This appendix provides a full detailed breakdown of 2011–2012 activities discussed earlier, including graphical figures.

Number of Cases

- FDALO opened 163 cases during fiscal year 2011–2012. This represents a small increase over the 158 cases opened in the previous fiscal year.
- In 95.6 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. In the 28 cases marked "unknown", stakeholders did not disclose their location or were received by email.

FIGURE 1.0: GEOGRAPHIC ORIGIN OF CASES RECEIVED

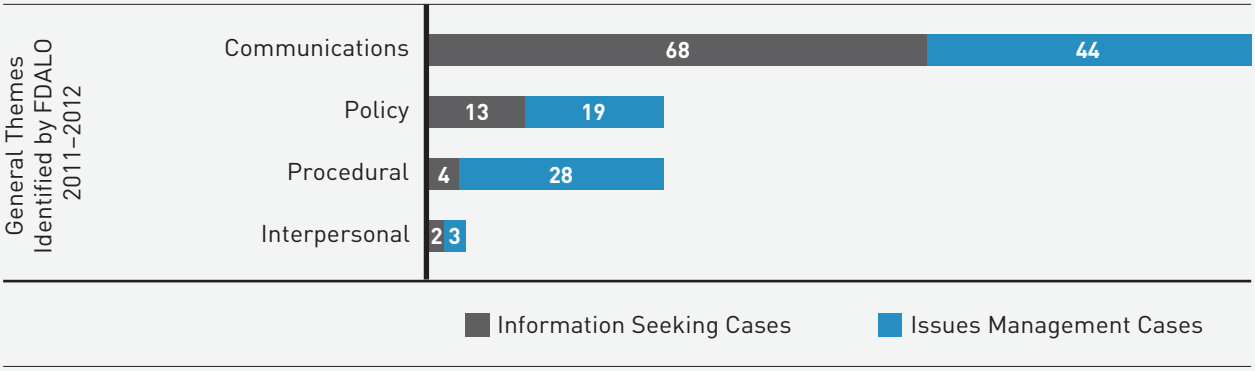
Nature of Issues

The 163 cases received by FDALO during the 2011–2012 fiscal year were categorized under two general types: *Information-seeking cases* and *issues management cases*. This categorization is based on the stakeholder's principle reason for contacting the office.

Information-seeking cases represented 55% percent of FDALO cases in 2011–2012, while the remaining 45% are issues management cases. This was consistent with the percentages in previous fiscal years.

Each case has been further categorized into **one or more** of the following four themes to capture the nature of the issues: Communications Issues, Policy Issues, Procedural Issues, and Interpersonal Issues. ***Examples for each theme*** are found in the notes.

FIGURE 2.0: GENERAL THEMES OF CASES RECEIVED



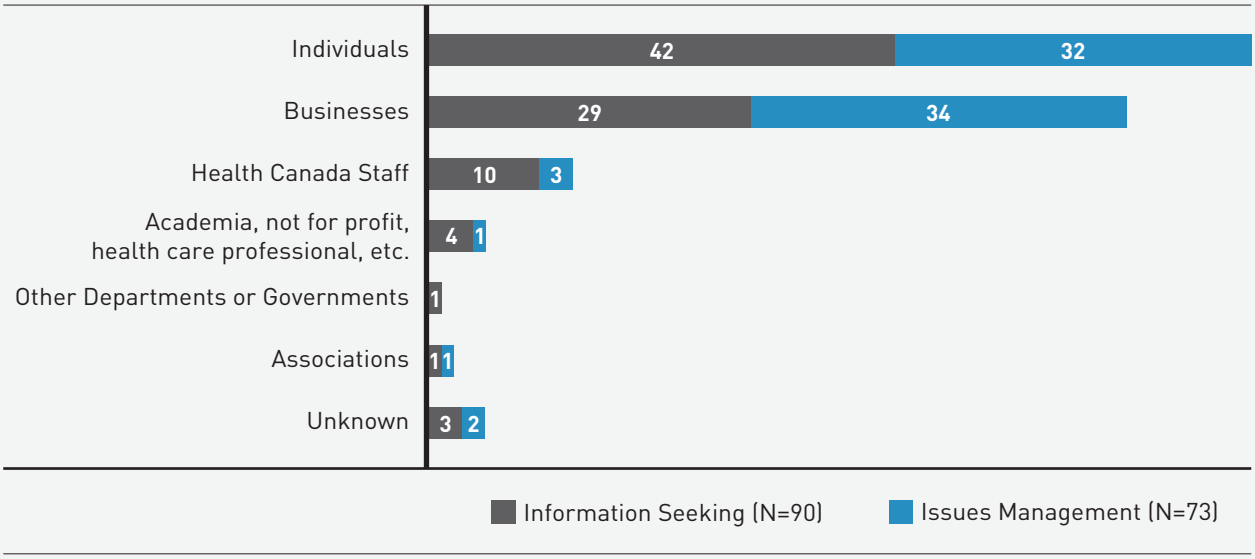
Note: Individual cases may fall into more than one theme.

A significant percentage of *information-seeking* cases have the potential to escalate into an *issues management* case. Through active listening and rapid response, FDALO works to minimize unnecessary conflict escalation.

Contact Type

FDALO dealt with a variety of stakeholders in 2011–2012. The following table highlights the types of stakeholders and the nature of the cases.

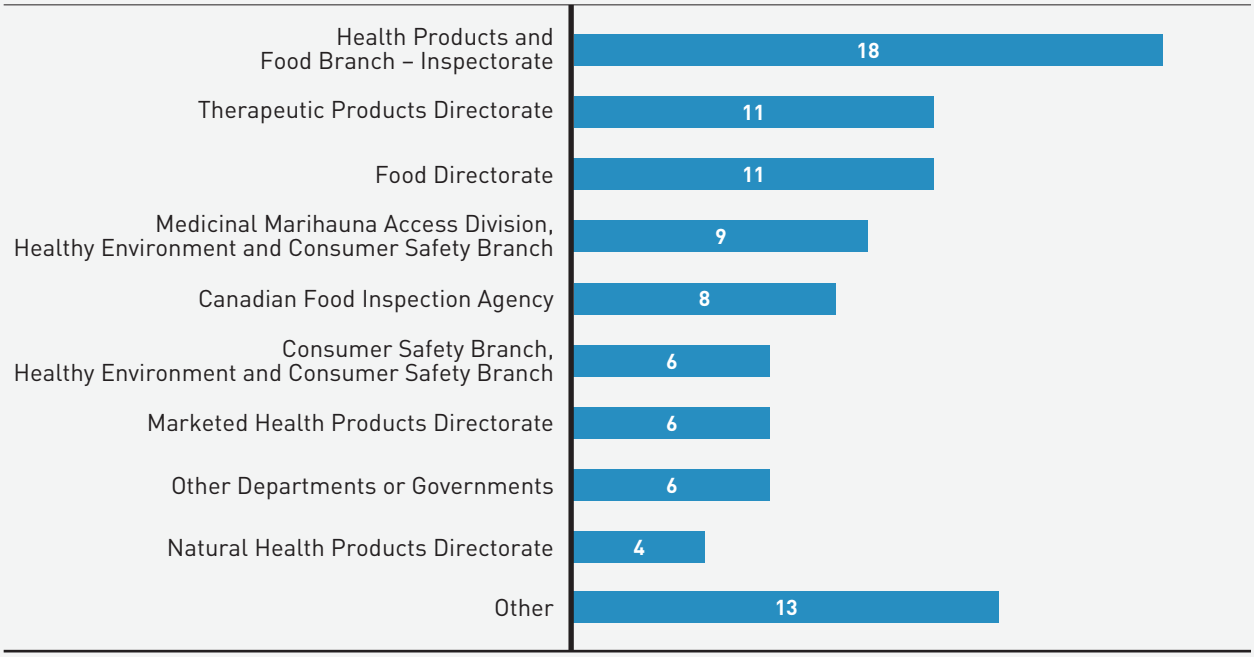
FIGURE 3.0: TYPES OF STAKEHOLDERS AND THE NATURE OF THE CASES



Referrals in Information-Seeking Cases

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

FIGURE 4.0: CASE REFERRALS IN INFORMATION SEEKING CASES



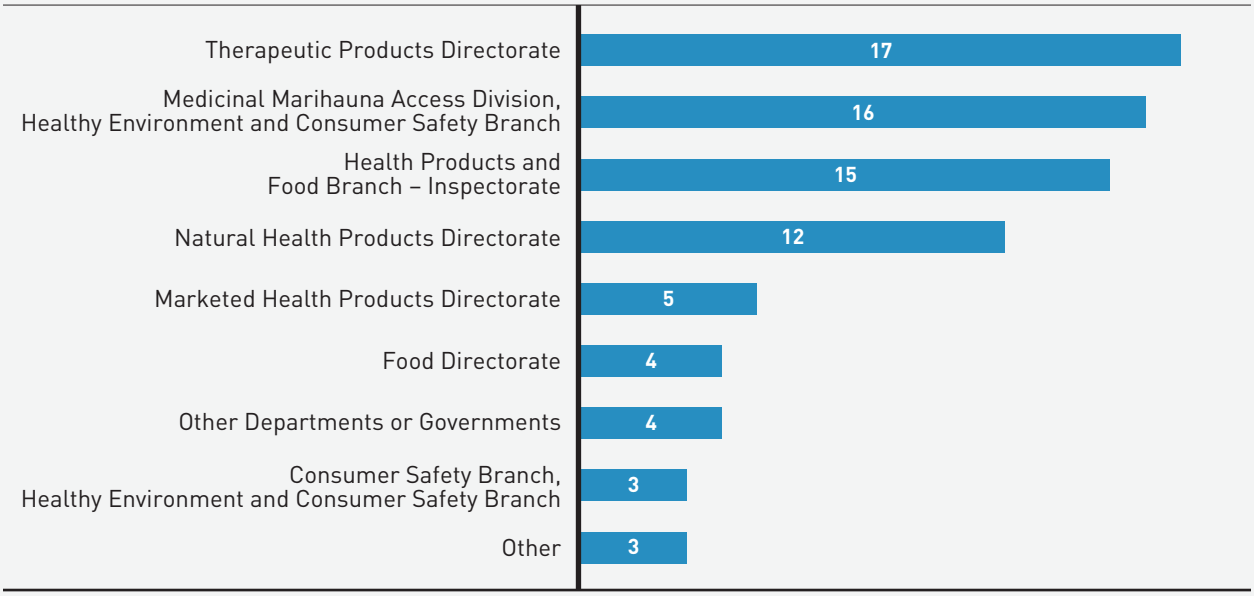
In 2011–2012, FDALO also made referrals to various outside organizations captured under "Other," such as Canadian Mental Health Association, the Procurement Ombudsman, and the Office of the Correctional Investigator. FDALO continues to help stakeholders find information on the Health Canada website as the site undergoes reconstruction to make it more user-friendly.

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.

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 figure also captures Health Canada work units who have contacted FDALO for proactive assistance in managing complex stakeholder files.

FIGURE 5.0: WORK UNITS IMPLICATED IN ISSUES MANAGEMENT CASES



Appendix B: Case Examples

This appendix provides examples of FDALO's work in 2011–2012. Every attempt has been made to protect the identity of individuals.

FDALO has chosen five examples from the 2011–2012 which demonstrate the daily work of the Office.

1. FDALO in Action: Ensuring Others Avoid Adverse Reactions

Issue	A stakeholder contacted FDALO to inquire why a specific drug was still available when it had caused her a serious adverse reaction two decades earlier. She felt that the department was acting irresponsibly in allowing this medication to remain on the market.
Intervention	FDALO listened to the stakeholder's concerns and was able to refer her to the Canada Vigilance Program to report the adverse reaction as there is no time-limit on the reporting period. Through this contact, the stakeholder learned that the product was now being used for other medical conditions and that changes had been made to the product label to address the type of adverse reaction she had experienced.
Outcome	The stakeholder felt she was listened to and was reassured that the department had taken measures to prevent others from experiencing the adverse reaction she had suffered.

2. FDALO in Action: Explaining the Rationale of a Decision

Issue	A company called FDALO to complain that an application for a post-DIN (Drug Identification Number) change submission was returned by Health Canada with a request that the company resubmit the application for a costlier, more extensive review process. It did not feel that a change to a non medicinal ingredient should require a more extensive review. Additionally, it was concerned that the department would take this approach with all its applications for post DIN changes.
Intervention	FDALO was able to act as an intermediary between the company and regulatory staff to shed light on how Health Canada arrived at its decision in this case. The formulation change in this particular product was in fact quite significant. The company had conducted studies to demonstrate that the product still maintained its efficacy. Health Canada's position was that the need to review these new studies justified a costlier and more extensive review process in this case.
Outcome	FDALO was able to facilitate communication between the company and regulatory staff to clarify the decision. As a result, the company understood that because its changes in this particular formulation had been so extensive, a longer review would be required by Health Canada. This would not necessarily be the case for minor formulation changes.

3. FDALO in Action: Reconsiderations and Impact on Future Decisions

Issue	A company consulted with FDALO about a license application which was rejected by Health Canada. The department did not agree that the company could treat a specific ingredient as a non-medicinal when present above a certain level. At that level of use, the department felt the ingredient had a therapeutic action which should be reflected in the indications for the product.
Intervention	FDALO determined that the issue was not a miscommunication or misunderstanding, but a scientific disagreement. The company was advised that it could request a reconsideration of the decision. It pursued this option and provided rationale for its position. The reconsideration decision was made in the company's favour. The company then sought assurance that the reconsideration decision would be considered in future similar license applications. FDALO assisted in having regulatory staff explain how the reconsideration decision might impact future regulatory decisions.
Outcome	FDALO was able to encourage the company and the department to work through a regulatory dispute in a transparent and predictable manner.

4. FDALO in Action: Clarifying the Expectations of Associations

Issue	An industry association called to express concern that the department issued a directive to several of its member companies without giving the association a warning about the directive. The association felt blindsided when its affected members called it for guidance and advice, but it was not aware of the reasons or rationale for the Department's directive.
Intervention	FDALO sought clarification from the Department about when it can communicate with associations. In this instance, a safety concern had come to the department's attention which required timely action by each company to mitigate the concern. In such scenarios, the regulator must communicate directly with the companies who hold market authorization for the products in question. It is not appropriate for the Department to contact an industry association about an issue pertaining to a specific company, even if several of the association's member companies are involved.
Outcome	Clarification of this point was reassuring for the association, especially when the Department confirmed that it would continue to communicate proactively with the association wherever possible and appropriate.

5. FDALO in Action: Supporting Staff with Letter Writing

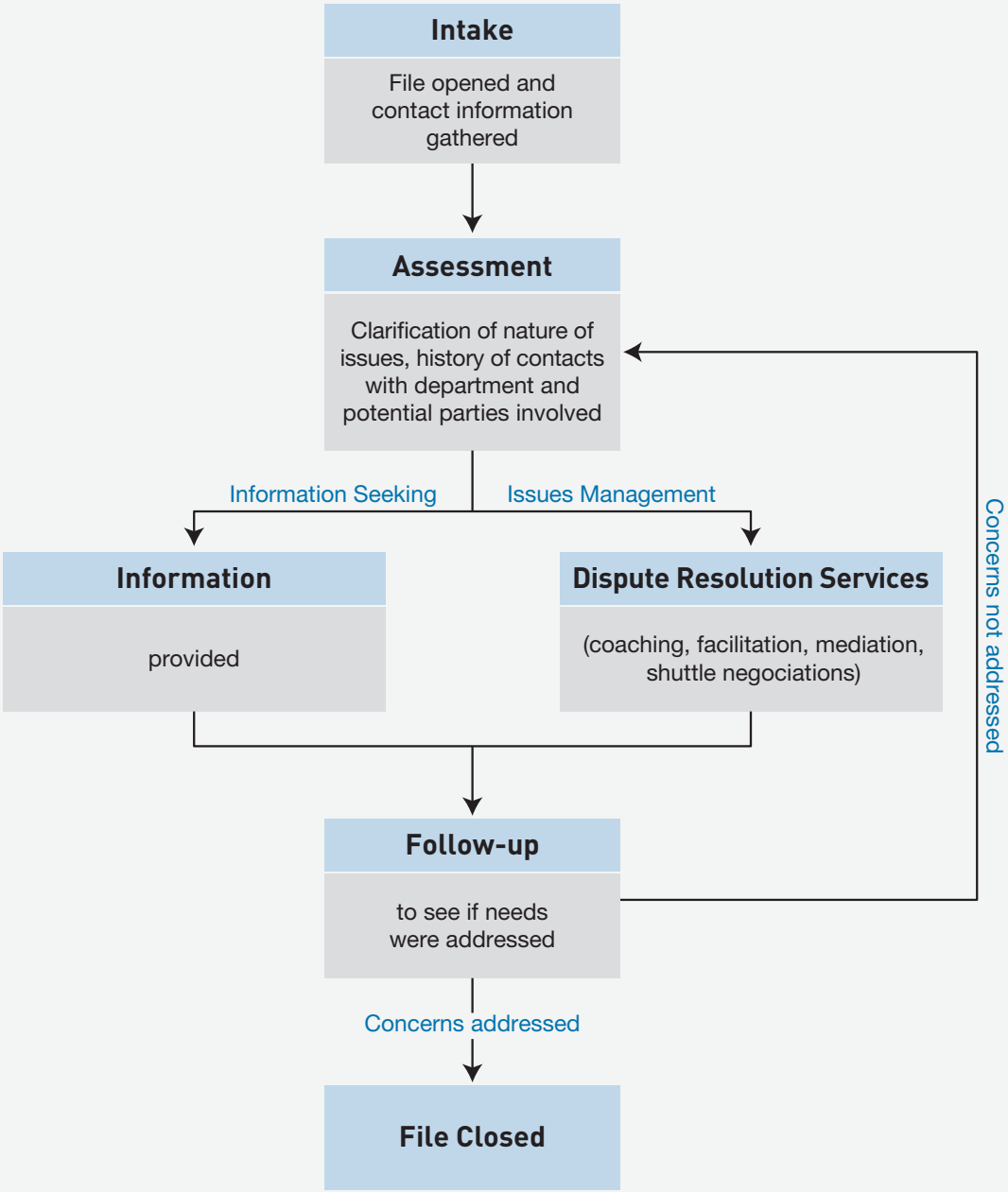
Issue	Health Canada staff are approaching the office more proactively for assistance in writing complex and sensitive correspondence. In its training program, FDALO emphasizes the importance of tailoring correspondence to the needs of the specific stakeholder. While the regulator may need to explain certain complex legal, regulatory or scientific concepts in its correspondence, this must still be done in a way that is understandable to the stakeholder.
Intervention	FDALO provides advice and guidance with letter writing to staff who request it. We work with staff to ensure that the stakeholder's concerns are addressed in the correspondence; that the use of technical jargon does not block understanding and that tone is respectful and appropriate.
Outcome	Staff who have utilized this feedback are becoming sensitised as to how to tailor correspondence to meet the needs of a vast array of stakeholders who differ in their knowledge and understanding of regulatory concepts.

Notes

Case Management Process Diagram

This diagram briefly illustrates the process we follow to manage the cases we receive.

FIGURE 6.0: THE FOOD AND DRUGS ACT LIAISON OFFICE'S CASE MANAGEMENT PROCESS



Recommendations from the Red Tape Reduction Commission:

1. The government should require all regulatory departments and agencies to develop a service charter by December 31, 2012, which would outline the principles of a strong service culture and ensure that employees understand their accountabilities for maintaining a service orientation and showing a high level of professionalism in their conduct. In responding to this recommendation, the government should consider the following:

   → ***Providing training courses for regulators*** *in order to build capacity, i.e., service-related "soft skills" in critical operational areas such as risk assessment, consultation, and compliance and enforcement procedures, and an understanding of the reality of the environment in which the businesses that must comply with their regulatory requirements have to operate.* These courses should be developed and incorporated into departmental learning plans and employee appraisals. The government should consider use of the Service Canada College model; and

   → Incorporating a commitment to a culture of service quality in the overall operations of regulatory programs and activities.

2. *All regulatory departments and agencies should* ***have a process for receiving feedback that will assist them to implement continuous improvements to their regulatory programs*** (i.e., complaints and compliments about service quality, recourse mechanisms to deal with contested decisions) by December 31, 2013. In responding to this recommendation, the government should consider the following:

   → Enabling businesses to provide feedback and suggestions anonymously and requiring departments and agencies to evaluate the complaints and compliments mechanism on a regular basis; and

   → Empowering regulators, through these recourse mechanisms, to reverse decisions or provide redress where appropriate.

Themes Present in Issues Management Cases

- **Communication issues** include: information-seeking inquiries, unreturned calls, unclear correspondence from Health Canada, or correspondence that does not address stakeholder concerns, etc.
- **Policy issues** include: disagreements with the interpretation or application of the law, policies or regulations, such as product classification.
- **Procedural issues** include: dissatisfaction with the processes used in regulatory decision-making, such as timeliness.
- **Interpersonal issues** include: stakeholder treatment by staff, or staff requests for assistance in dealing with stakeholder relations, etc.