# THE FOOD AND DRUGS ACT LIAISON OFFICE: REPORT ON ACTIVITIES

A retrospective look on the office's evolution and recent activities (2008–2022)

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# 1. INTRODUCTION

In any regulatory environment, the management of potential conflicts and disagreements with stakeholders is a key component to fulfilling a commitment to greater regulatory transparency and openness. This is no different for Health Canada (HC) and its stakeholders in improving and understanding health regulatory decision-making. Successful management of disagreements makes for a stronger regulatory environment where Canadians can have access to the health products they need while having confidence that these products meet the safety and efficacy requirements to be sold on the Canadian market. Positive regulatory relationships contribute to the satisfaction of stakeholders, benefit all Canadians and support trust in the reputation of HC as a regulator.

The Food and Drugs Act Liaison Office (FDALO) is a key component of HC's commitment to resolving potential conflicts and disagreements surrounding the *Food and Drugs Act*. The effectiveness of the Office since 2008 and its ongoing liaison with stakeholders and HC have demonstrated value in the positive outcomes that can occur when fair conflict management and resolutions are a part of the regulatory process. Experience has shown that many of the regulatory conflicts and resolutions can be addressed through respectful and active listening to different perspectives and demonstrating transparency about processes and decisions. More generally, FDALO has played a pivotal role since its inception in working to make the regulatory process open, understandable, and accessible to Canadians.

In 2022, FDALO quietly celebrated fourteen years of service to HC's stakeholders. This Report on Activities provides a retrospective of the Food and Drugs Act Liaison Office's work since its inception. It also provides a more detailed report of activities since 2017.

# 2. THE FOOD AND DRUGS ACT LIAISON OFFICE: THE FIRST FOURTEEN YEARS

The story of FDALO unfolds in three phases:

- Establishing the Program – 2008–2012
- Developing Program Strengths – 2013–2016
- Expanding the Program– 2017–2022

## 2.1. Establishing the Program – 2008–2012

HC launched FDALO in 2008 to facilitate and manage its relationship with stakeholders. FDALO was to provide an alternative, impartial avenue for stakeholders with concerns about the regulatory process. The creation of FDALO was championed in 2001 by the Assistant Deputy Minister of the Health Products and Food Branch following an examination of ways to improve the range and flexibility of dispute resolution options available to deal with conflicts arising from the Branch's regulatory activities. FDALO reported administratively to the Public Affairs, Consultations and Communications Branch, which later became the Communications and Public Affairs Branch.

During the initial years, FDALO identified opportunities to cultivate conversations and develop networks with both external stakeholders and HC staff. Through dialogue and casework, FDALO laid the groundwork of what would become its core services:

- Consulting with staff and stakeholders on challenging and complex files;
- Reporting on trends and systemic issues;
- Encouraging program integration through supporting regulatory directorates in refining work practices to streamline case management approaches;
- Offering training for staff to better manage stakeholder relationships.

FDALO became known as a forum for stakeholders to voice their concerns or disagreements with HC over the interpretation or decisions on the administration of the *Food and Drugs Act*. FDALO brought these concerns to HC staff, worked towards resolution, and were effective in liaising with stakeholders to help them navigate the regulatory process and to have their concerns heard by the Department.

During these years, HC listened and responded to the requests of stakeholders. Specifically, HC:

- implemented improvements in the application and review process;
- introduced changes to provide more timely responses to concerns and complaints;
- made changes to its website to provide easier access to HC information, responding to stakeholder requests to be transparent in informing them on the regulatory process;
- implemented performance targets, the publication of licensing progress reports, and electronic tools to support the application and review process at the Pharmaceutical Drugs Directorate (PDD)[1] and the Natural and Non-Prescription Health Products Directorate (NNHPD)[2]; and
- provided reviewer notes to stakeholders containing the information they needed to understand the rationale for evidence-based decisions.

## 2.2. Developing Program Strengths – 2013–2016

By the five-year mark, FDALO had solidified its role as an impartial and confidential resource for individuals, businesses and organizations who have questions, challenges, or complaints regarding how HC administers the *Food and Drugs Act*. FDALO staff developed their skills in shuttle negotiation, in facilitated conversations, and in mediation. Working from a position of impartiality, they identified the scope of concerns, encouraged positive dialogue, and helped develop alternate solutions.

In 2013, the Office defined its services in four distinct areas:

- Dispute Resolution;
- Trend Identification & Analysis;
- Outreach & Engagement;
- Capacity Development.

[1] Formerly known as the Therapeutic Products Directorate

[2] Formerly known as the Natural Health Products Directorate

## Dispute Resolution

FDALO offered a dispute resolution alternative to stakeholders and HC staff. This role comprised more than 75% of FDALO's work. The Office received complaints, concerns or enquiries about alleged errors, omissions, and improprieties as well as broader systemic problems on matters pertaining to the administration of the *Food and Drugs Act*. FDALO advisors listened, offered options, facilitated communications, and examined issues impartially. The Office acted as an intermediary to help parties arrive at a mutually agreed resolution. In 2015, after an internal assessment on the effectiveness of the role of FDALO, it was determined that it could build on its success and expand its offering to include the management of reconsideration requests for human drug submissions.

## Trend Identification & Analysis

FDALO provided continuous feedback to HC senior management on trends in cases and issues to assist with the continuous improvement of the regulatory process. FDALO also summarized trends and observations in its *Report on Activities*[3], which it made available to HC and external stakeholders.

## Outreach / Internal Engagement

FDALO relied on outreach and internal engagement to build relationships with internal decision makers and external stakeholders. The intent of this outreach and engagement was to increase stakeholders' awareness of FDALO services, encourage the use of these services, and ensure FDALO was perceived as a trusted and impartial program. FDALO's outreach and internal engagement efforts included:

- attending stakeholder association bilateral meetings as an observer or a presenter;
- attending stakeholder association meetings and conferences;
- attending stakeholder events held by the Department;
- facilitating intradepartmental meetings on "hot issues" and "lessons learned";
- publishing its *Report on Activities;* and
- increasing its visibility in relevant sections of HC and Government of Canada websites.

## Capacity Development

FDALO offered training courses to enhance the communication and conflict resolution skills of HC staff who work with stakeholders. FDALO also offered case management assistance and coaching to develop the skills of HC staff. The Office actively followed complex cases and helped HC staff respond constructively to stakeholder concerns. FDALO also helped HC staff charged with communicating non-regulatory decisions.

[3] For copies of the Report on Activities from 2013 to 2016, contact the Food and Drugs Act Liaison Office.

### Improvements

During this period, HC implemented a number of additional initiatives to respond to stakeholder feedback. The transfer of the review of non-prescription drugs and disinfectants submissions from the PDD to the NNHPD streamlined the regulatory process. PDD eliminated the backlog of generic drug submissions and initiated multi-sector engagement meetings to encourage dialogue among stakeholders and identify areas of divergence and agreement.

In response to stakeholder requests for transparency in reconsideration processes, FDALO undertook the management of the reconsideration process on behalf of PDD and Biologic and Radiopharmaceutical Drugs Directorate[4] (BRDD). The intent of this change was to increase the impartiality and the transparency of the reconsideration process.

## 2.3. Expanding the Program – 2017–2022

Since 2017, FDALO has strengthened and expanded its service offerings in the areas of dispute resolution and capacity development.

### Dispute Resolution

In 2018, FDALO's role in managing reconsideration requests for PDD and BRDD was widened to include NNHPD. Coordinating the reconsideration process expanded FDALO's network and credibility in this sector.

HC staff and stakeholders came to recognize FDALO as a valuable resource for alternative dispute resolution, connecting stakeholders to appropriate people around a specific issue and creating options for a satisfying outcome, with the goal of avoiding lengthy and expensive litigation. The Office's dispute resolution expertise has helped stakeholders and HC to clarify their request or rationale, resulting in a deeper understanding of the issues stemming from stakeholders and from HC.

### Capacity Development

Requests for assistance and coaching across HC directorates and programs have increased, as have requests from Senior Management for support with complex cases that involve multiple directorates.

In addition, FDALO continues to offer training workshops to refine and deepen the skills and expertise of HC program staff who work with stakeholders. FDALO has diversified its training offerings with a series of mini workshops that targeted specific skill areas. The Office also receives requests from staff for customized training focused on particular challenges and dilemmas they face.

[4] Previously known as the Biologics and Genetic Therapies Directorate (BGTD)

### Improvements

During this period, HC made improvements in response to stakeholder feedback. These improvements included increased clarity in decision letters from NNHPD and PDD, as well as greater specificity in reconsideration letters, which resulted in clearer communication between the applicant or sponsor and the relevant directorate.

# 3. FIVE YEAR REVIEW: APRIL 2017 – MARCH 2022

FDALO has undergone several changes, including changes in long standing leadership and integration of current leadership which have both helped shape the direction of FDALO since 2018. Furthermore, there have been modifications to the reconsideration process within NNHPD, an increase in the complexity of cases, and finally, like many globally, a requirement to adapt to the realities of advancing work during the COVID-19 pandemic.

This section provides an overview of FDALO's work in the areas of dispute resolution, outreach and internal engagement, and capacity development.

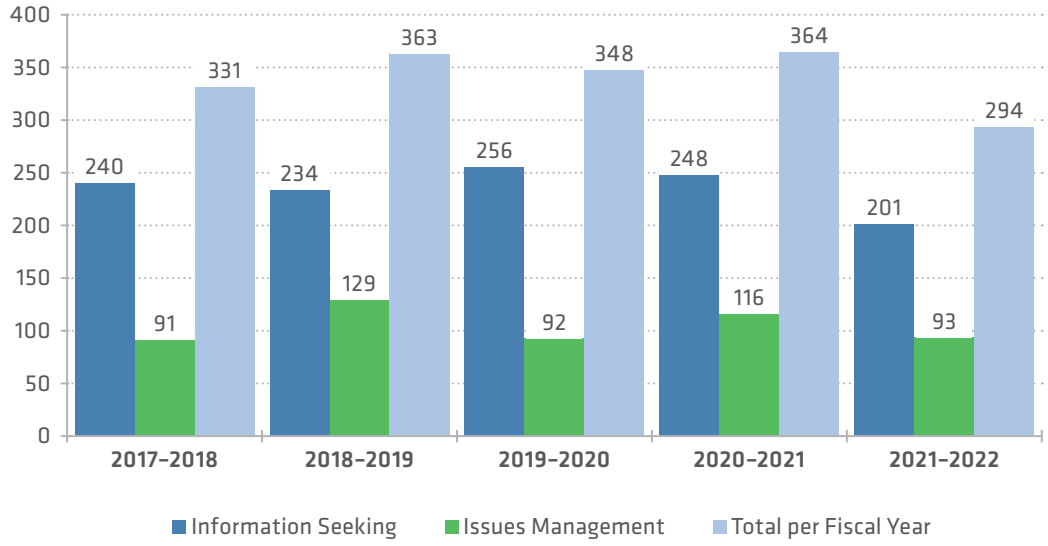
## 3.1. Dispute Resolution

### Case Management

Between 2017 and 2022, FDALO managed 1,700 cases, typically between 300 to 364 cases per year. These consist of all incoming enquiries, concerns, or complaints received from regulated parties such as individuals or businesses. Cases are categorized as either *Information Seeking* or *Issues Management.* Information Seeking cases generally require FDALO to connect stakeholders with appropriate information and regulatory resources within the Department or answer general questions about the administration of the *Food and Drugs Act* as we do not provide legal interpretations of the *Act*. Issues Management cases usually involve a complaint from a third party and require FDALO's intervention and facilitation between HC and the stakeholder to achieve a positive outcome. Cases related to Issues Management have represented approximately one-third of all cases. Some example cases are provided in the Appendix.

In the 2021–2022 fiscal year, changes to the departmental naming conventions to email addresses meant that FDALO inquiries submitted via webforms were not received by the office. Once this change was noted, the problem was rapidly fixed; however, those inquiries were not able to be recovered or responded to.

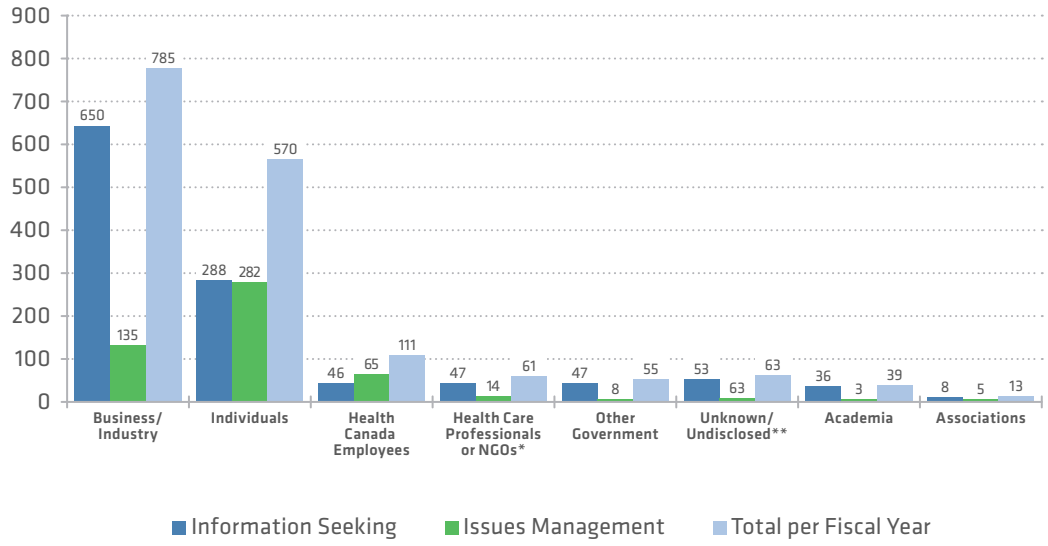
**Total Cases Received from April 1, 2017 to March 31, 2022**




## *Who Contacted Us*

FDALO was contacted predominantly by businesses and individuals from within the regulatory environment, usually with a request for information. Year over year there was a steady increase in requests by private individuals for help with issue management.

**Who Contacted FDALO from April 1, 2017 - March 31, 2022**

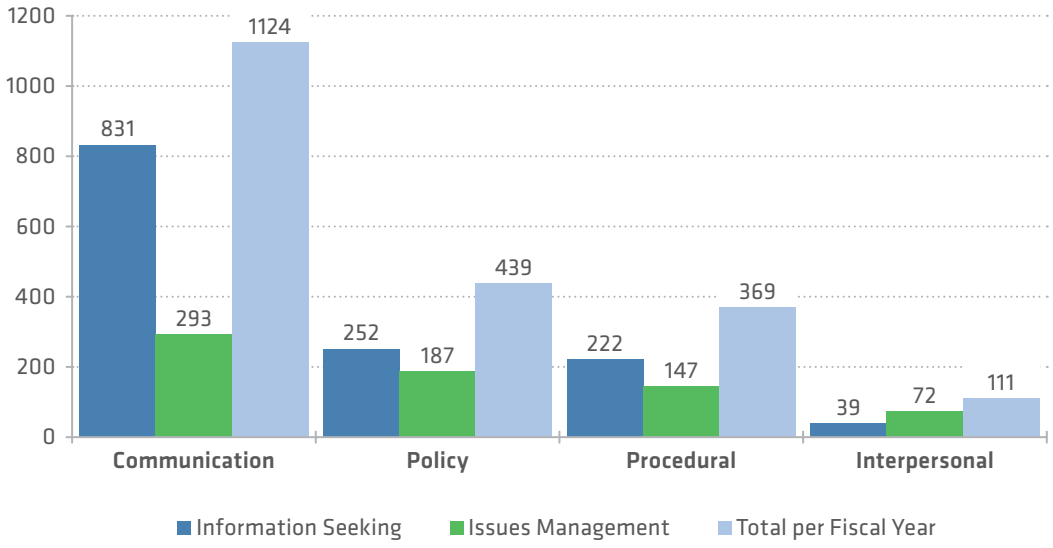


## *Nature of Issue*

FDALO cases fall under four themes: communication, policy, procedure, and interpersonal issues. Of these, communications issues – which include information-seeking – are the most common. Some cases present more than one issue and may therefore appear under more than one theme.

| Case Theme | Proportion | Examples |
|---|---|---|
| **Communication issues** | 66% | Information-seeking inquiries, unreturned calls to HC, unclear correspondence or correspondence that does not address the stakeholder's concerns. |
| **Policy issues** | 26% | Disagreements with the interpretation or application of the law, regulations, or policies such as product classification, risk assessment, policy coherence. |
| **Procedural issues** | 22% | Dissatisfaction with aspects of the regulatory decision-making process such as timeliness, openness, transparency, predictability, and advance notice of changes to policies. |
| **Interpersonal issues** | 7% | Stakeholder treatment by staff, or staff requests for assistance in dealing with difficult stakeholder communications. |

**Nature of Issue Identified by FDALO April 1, 2017 to March 31, 2022**




## *Directorates Involved in Cases*

FDALO works with other components of HC and outside organizations to resolve cases. About two-thirds of FDALO's cases involve the Regulatory Operations and Enforcement Branch, NNHPD, PDD, and the Canadian Food Inspection Agency.

| Work Units Involved in Cases 2017–2022 | Issues Management Cases | Information Seeking Cases | All Cases |
|---|---|---|---|
| **REGULATORY OPERATIONS AND ENFORCEMENT BRANCH** | | | |
| Health Product Compliance Directorate | 99 | 153 | 252 |
| Medical Devices and Clinical Compliance Directorate | 9 | 16 | 25 |
| Consumer Products and Controlled Substances Directorate | 3 | 17 | 20 |
| Other Regulatory Operations and Enforcement Branch | 14 | 31 | 45 |
| | **125** | **217** | **342** |
| **HEALTH PRODUCTS AND FOOD BRANCH** | | | |
| Natural and Non-prescription Health Products Directorate | 69 | 165 | 234 |
| Pharmaceutical Drugs Directorate | 42 | 181 | 223 |
| Medical Devices Directorate | 18 | 80 | 98 |
| Food Directorate | 14 | 78 | 92 |
| Other Health Products and Food Branch* | 89 | 53 | 142 |
| | **232** | **557** | **789** |
| **OTHER BRANCH AND ORGANIZATIONS** | | | |
| Healthy Environments and Consumer Safety Branch | 34 | 15 | 49 |
| Canadian Food Inspection Agency | 49 | 109 | 158 |
| Other health portfolio** | 83 | 120 | 203 |
| Other Government (municipal, provincial, other federal and international government departments) | 57 | 105 | 162 |
| Company | 20 | 29 | 49 |
| | **243** | **378** | **621** |
| **Total** | **600** | **1152** | **1752** |

* For example: Biologic and Radiopharmaceutical Drugs Directorate, Marketed Health Products Directorate, Policy, Planning and International Affairs Directorate, and Veterinary Drugs Directorate, etc.

** For example: Pest Management Regulatory Agency, Public Health Agency of Canada, etc.

## Reconsideration

As noted earlier, FDALO manages the reconsideration process in accordance with the **Guidance Document for Reconsideration of Decisions for Human Drugs and Natural Health Products Submissions**.

The statistics collected between 2017 and 2022 underline the annual trends and patterns for human drug and natural health product reconsiderations.

Not all applications meet the criteria for proceeding to the formal reconsideration process and may be ineligible if they exceed the 30-day deadline or are outside the scope of what is outlined in the reconsideration guidance document.

Between 2017 and 2022, FDALO received 24 reconsideration requests for **human drug submissions,** of which 23 met the criteria for proceeding to the formal reconsideration process. Of the eligible reconsideration requests, 21 were related to decisions made by the PDD while the remaining two were related to decisions made by the BRDD.

| Human Drug Reconsideration Requests from 2017 to 2022 | | 2017–2018 | 2018–2019 | 2019–2020 | 2020–2021 | 2021–2022 | Total |
|---|---|---|---|---|---|---|---|
| | Number Of Eligible Cases | 3 | 5 | 6 | 2 | 7 | **23** |
| **Final Decision** | Original Decision Upheld | 1 | - | 1 | 2 | 1 | **5** |
| | Original Decision Partially Amended | - | 1 | - | - | 1 | **2** |
| | Original Decision Amended | 2 | 1 | - | - | - | **3** |
| **Withdrawn, cancelled, or sent back into review** | Withdrawn By Company | - | 2 | 4 | - | - | **6** |
| | Sent Back into Review | - | 1 | - | - | - | **1** |
| | Cancelled | - | - | 1 | - | 5 | **6** |

Between 2017 and 2022, FDALO received 65 reconsideration requests for **natural health products**, of which 48 met the criteria for proceeding to the formal reconsideration process described in the Guidance document. When a submission is not eligible for the FDALO-led reconsideration process, it may still be eligible for an "opportunity to be heard" from NNHPD. For cases that fall outside of our scope, FDALO refers the file to NNHPD so that NNHPD can determine the next steps for the opportunity to be heard.

| Natural Health Products Reconsideration Requests from 2017 to 2022 | | 2017–2018 | 2018–2019 | 2019–2020 | 2020–2021 | 2021–2022 | Total |
|---|---|---|---|---|---|---|---|
| | Number Of Eligible Cases | 1 | 8 | 9 | 11 | 19 | **48** |
| **Final Decision** | Original Decision Upheld | - | 1 | 2 | 5 | 11 | **19** |
| | Original Decision Partially Amended | - | - | - | - | - | **0** |
| | Original Decision Amended | - | - | 1 | - | 1 | **2** |
| **Withdrawn, cancelled, or sent back into review** | Withdrawn by Company | - | 3 | - | 4 | 2 | **9** |
| | Sent Back into Review | - | 1 | - | 1 | 5 | **7** |
| | Cancelled | 1 | - | - | - | - | **1** |
| | Outside FDALO scope | - | 3 | 6 | 1 | - | **10** |

## Participant Feedback on the Reconsideration Process

FDALO treats each reconsideration as a learning opportunity for all parties.

FDALO invites participants in reconsideration processes which involve a panel meeting to share their feedback anonymously and in confidence to help improve services. A survey is sent to the stakeholders and HC staff who attended. As the purpose of the survey is to collect feedback on the process, and not the decision, these surveys are sent before the final decision is released.

The survey feedback is used to improve the reconsideration process. In response to constructive feedback from participants, FDALO has:

- proactively communicated key next steps to applicants, sponsors, or HC staff;
- shared more information about the format and expectations for the panel meetings;
- clarified the process and practice for information sharing before and during panel meetings;
- started sharing more details about the panel member's areas of expertise to all participants in response to comments from companies, and to ensure credibility of the reconsideration process; and
- looked for ways to ensure we reliably meet our timelines while remaining flexible and adaptable.

What we've heard from stakeholders:

- *FDALO was very helpful along the process ensuring what was expected of all parties.*
- *FDALO staff has been transparent, approachable, and collaborative during the reconsideration process.*
- *The FDALO staff were very accessible via email and provided timely responses.*
- *I truly believe that all of our concerns were not only expressed by us, but properly received by Health Canada.*

## 3.2. Outreach and Engagement

FDALO's outreach and engagement activities include information presentations explaining FDALO's role and services at association meetings and to HC staff. Specifically, FDALO works to ensure that staff and external stakeholders have a clear understanding of the role and function of the reconsideration process.

FDALO works to understand the challenges currently experienced by internal and external stakeholders. FDALO regularly reaches out for informal conversations internally and externally to stay abreast of changes within HC and emerging trends within the industry. From 2017 to 2022, FDALO attended numerous association meetings to support communications between different directorate staff and associations. This permitted FDALO to have a broad understanding of key issues that are important to staff and associations in ensuring access to quality products on the Canadian market.

## 3.3. Capacity Development

FDALO has offered support and training to HC staff to refine their skills in managing stakeholder relations within a complex and ever-changing regulatory environment and system. FDALO offers training workshops and provides HC staff with support in developing responses to specific stakeholder issues. With the arrival of the COVID-19 pandemic, FDALO modified its training and began to deliver virtual sessions to staff. Staff responded positively to these offerings.

What we heard from participants:

- *The checklist shared during the training and some of the other resources are extremely helpful and relevant to what we do.*
- *This workshop provided valuable information to help with effective communication skills as it pertains to conversations that may lead to conflict.*
- *The strategies presented are very good and I am planning to put them into practice.*

Prior to the COVID-19 pandemic, FDALO continued to offer the two-day interactive workshop "Making the Most of Communications with Stakeholders" and a series of custom mini workshops, reaching 455 HC staff and 87 members of the Community of Federal Regulators. This workshop was developed by FDALO in 2008 and has undergone several revisions. The office has introduced other workshops focused on maintaining and enhancing stakeholder relations in a regulatory context. Since the start of the pandemic, FDALO has focussed on its shorter workshops that can be delivered virtually, thereby allowing participants from regional offices and National Capital Region to attend the same sessions.

Since 2017, FDALO has experienced a slight but steady increase in requests for support in responding to challenging situations with stakeholders. There was also a growth in demand for customized training. FDALO was invited by HC directorates to facilitate learning conversations where employees could reflect on their practices and identify improvements.

# 4. MOVING AHEAD IN 2022–23

In 2022–23, FDALO will increase supports in engagement and capacity Development for the department. The Office will pursue outreach activities with internal and external stakeholders' though a series of informal and formal meetings and/or presentations to raise awareness of FDALO's services, to hear about their concerns and to ensure that FDALO is adapting to meet their needs. In addition, FDALO will focus on training and coaching with HC staff to develop staff capacity to lead and navigate challenging conversations with stakeholders. FDALO will continue to manage reconsideration processes and advance its core work of facilitating the resolving of disputes and improving stakeholder relations.

## 4.1. Requested Changes from Stakeholders

Internal and external stakeholders have come to FDALO with various suggestions for systemic improvements. FDALO's role in receiving these requests is to offer feedback to senior management for their consideration.

### Expanded Dispute Resolution Processes for all Regulatory Decisions

FDALO has heard, throughout the years, that stakeholders would like expanded dispute resolution processes for all decisions that have a direct impact on their ability to do business in Canada. While FDALO continues to offer informal dispute resolution services and advocates for openness and transparency in all of HC's interactions, some companies expressed concerns that there are regulatory decisions that, once made, cannot be appealed through formal or informal means. The result is that their only recourse is costly and time-consuming court cases. They feel this option is not accessible for smaller companies or for products with tight profit margins. The feedback is that it may be making their businesses less competitive and may be restricting Canadian's market access to products that may be available elsewhere.

### Flexibility in Light of Business Consequences

As shown in the first case study in the appendix, regulatory decisions can have profound impacts on the sustainability and survival of businesses affected. This includes the regulated parties but also related businesses such as business support, wholesale and retail which depend on the regulated product. In cases not involving imminent risks to the public, stakeholders have asked that HC take these business consequences into account when rendering decisions so as to balance the scope and timing of compliance requirements against the potential economic damages and disruption.

# 5. CONCLUSION

Fourteen years of experience has shaped FDALO's commitment to the values of respect and responsiveness and of creating a space for stakeholders and HC regulatory officials to be heard. FDALO has learned the critical importance of being responsive and clear in communications, however small or large in scope the request may be. In some cases, this may require active listening and words of encouragement. In other cases, however, we help the stakeholder clarify the issue, connect with people who can provide relevant information, facilitate clarity of communications on regulatory decision making and find viable options to inform a more positive outcome. FDALO's effectiveness has been in its ability to build and maintain understanding and trust between HC and its stakeholders, even when interests diverge, and there is an impasse. This approach will continue to guide the work of FDALO in being a valued impartial and confidential resource for individuals, business, and organizations when they disagree with how Health Canada administers the *Food and Drugs Act*.

# 6. APPENDIX: CASE STUDIES

### Case # 1:

**Issue:** A small business owner received a notification for a stop sale of a product that they were selling for several years. The small business owner was very upset as it would result in significant financial losses for their business. They considered taking legal actions but decided to reach out to FDALO for assistance first.

**Intervention:** FDALO met with the stakeholder to provide them with a listening experience and to document their concerns. With the business owner's permission to speak to the department, FDALO reached out to the relevant teams within HC. The HC staff member explained the rationale for the decision, the measures they took to notify the stakeholder and the options available for getting the product back on the market. As the follow-up action, FDALO met with the stakeholder to convey this information using plain language and to give them the time to process what they heard. Through active listening and taking the time necessary, FDALO was able to confirm that the stakeholder understood the issues and the potential remedies.

FDALO provided feedback to the HC staff regarding what the stakeholder felt could have been done to clarify early communications. The HC staff accepted and acknowledged this feedback. With the HC staff's permission, FDALO shared this acknowledgement with the stakeholder.

**Outcome:** The stakeholder was not pleased that the issue was not resolved in their favour. They did appreciate FDALO's effort and time in helping them and agreed to pursue the steps with HC to get the product back on the market. Through active listening, asking questions and taking time to be present, FDALO provided a service to a stakeholder that helped de-escalate a situation that could have potentially resulted in a more adversarial and costly dispute. FDALO's intervention helped to repair and preserve the relationship between HC and the stakeholder.

### Case # 2:

**Issue:** An individual contacted FDALO and was very upset because of the severe and ongoing adverse reactions they experienced from a medication. The individual had several concerns and wanted to find out if the drug was approved in Canada and what actions they could take so that this does not happen to anyone else. They also wanted medical advice to help them with this severe adverse reaction.

**Intervention:** FDALO met with the individual and took the time to listen to them and express empathy. FDALO then guided them to the **Drug Product Database** website to find more information about the drug's approval status in Canada. FDALO provided them with information on how to make a voluntary report to the **Canada Vigilance Program** with respect to the adverse reactions they had experienced. Finally, FDALO clarified that it does not have the mandate to give medical advice and encouraged them to seek advice from a health professional.

**Outcome:** The stakeholder was grateful for the service provided. They shared how they found it difficult to navigate the machinery of government and having someone walk them through it helped to demystify the process. FDALO was able to acknowledge the impact of this adverse reaction on their quality of life, refer the stakeholder to the appropriate services within HC and to provide them with a satisfactory client service experience.

### Case # 3:

**Issue:** A company contacted HC with questions they hoped would enable them to classify their product. They wanted to reference a similar product that has been licensed by a competitor. The directorate had provided the company with general information, but not a definitive classification for their product, nor would the directorate provide information on the competitor's product. The company was dissatisfied with this information and continued over the next few months to correspond and call the directorate to obtain the classification designation.

On the suggestion from the bureau, the company approached FDALO with a request to obtain the desired information.

**Intervention:** After reviewing the correspondence between HC and the company, FDALO held several conversations with the staff working on this file. Through these conversations FDALO began to appreciate the stakeholder's expectations for the help they thought they should be receiving. The staff at the bureau realised that, in their effort to be of assistance to the company, they never stated the limits and the scope of help they could provide.

The company was hoping for specific and detailed information that can only be assessed and provided within a product application. This information cannot be shared with a third party as it would be considered confidential business information. FDALO worked with the staff handling this request to summarize the approach they had taken with the company and to provide rationale for restricting the disclosure of further information. FDALO then communicated with the company the explanation regarding the limits of information that the bureau was able to provide.

**Outcome:** In this instance, FDALO utilized tactful communication skills to manage expectations on the part of stakeholders. FDALO's impartial review of the file helped identify the misunderstandings and the Office's ability to name the issues causing conflict thereby helping to create clarity. HC staff were appreciative of the assistance in managing the tense relationship and being offered the opportunity to address the stakeholder's concerns. The company was satisfied with the information provided and understood the reasoning behind it.