

Food and Drugs Act Liaison Office (FDALO)
Summary of
2015 – 2016 Report on Activities
Presented by Serena Siqueira



Polling Question

Which of the following 4 descriptions accurately describes FDALO's mandate:

- 1) We overturn decisions by annoying regulators
- 2) We advocate tooth and nail for your interests
- 3) We are scientific and regulatory experts who can unilaterally change policy
- 4) We are an impartial and confidential resource for individuals, business and organizations when they experience problems with how Health Canada administers the *Food and Drugs Act*.



Purpose

- To provide highlights of the Food and Drugs Act Liaison Office's (FDALO) [2015-2016 Annual Report](#)
- To demonstrate how FDALO's work can assist you, your business and your association

Full Report: <https://www.canada.ca/en/health-canada/corporate/publications/food-drugs-act-liaison-office-report-activities-april-2015-march-2016.html>

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Launched New Reconsideration Process

- In April 2015, FDALO took over management of the reconsideration process for prescription drug submissions
- 7 reconsideration requests received in 2015-2016
 - 6 cases went through the process
 - 1 was deemed ineligible for being outside the 30-day time limit

	Internal Process		External Panel	
	Original decision upheld	Original decision modified and sent for further review	Original decision upheld	Original decision modified and sent for further review
Innovator	-	-	2	1
Generic	2	1	-	-
Total	2	1	2	1

New Reconsideration Process - Improvements

Based on feedback from the parties and our observations, FDALO is making the following improvements:

- A “Frequently Asked Questions” sheet for participants
- A code of conduct explained at each meeting
- Tips for internal and external panel members on managing the reconsideration meeting
- Preparatory assistance for companies and staff who require guidance for the process
- Standardizing reports for clarity and consistency, and
- Updating and streamlining forms

Case Management

135 cases received from April 2015 – March 2016

- 35% increase in number of cases over previous year
- Due in part to our improved web presence and increased outreach activities

Types of Cases

- 63 cases or 47% were complaints
- 72 or 53% were inquiries

Who Contacted Us

- 64% of our cases involve industry stakeholders
- The rest are patients, consumers, health care practitioners, other government departments and Health Canada staff who want assistance in managing a challenging stakeholder relationship.

See Case Statistics section at the end of this presentation for additional quantitative data.

Polling Question

Among the following themes, which do you think generates the most cases:

- 1) **Communications** – lack of rationale or clarity of decisions; unclear or contradictory communications; insufficient or no acknowledgment of stakeholder concerns.
- 2) **Policy** – disagreement with the application of a law, policy or guideline – product classification, risk assessment during a submission review; importation rules; policy coherence.
- 3) **Procedural** - process used by the decision-maker. Openness and transparency; predictability; chance to respond to concerns before a negative decision is rendered; application of guidance that hasn't been finalized or published.
- 4) **Interpersonal** - client service experience (timeliness, responsiveness, courtesy)



Case Management – Individual Cases

- Helping Citizens Navigate a Complex System
- Public Advisory to Manage Risk to Canadians
- Helping Small Business Understand Regulations
- Ensuring Administrative Fairness

Case Management – Systemic Trends

From an impartial perspective, FDALO gathers stakeholder feedback on Health Canada's administration of the *Food and Drugs Act*

Positive Feedback

- Multilateral Engagement Session Across Sectors

Requested Improvements

- A new Consumer Health Products Framework
- Professional use category or 'Special Access Program' for natural health products
- Better understanding of and access to redress processes for compliance and enforcement actions
- Predictability and transitional period before new Guidance is implemented

Priorities - 2016-2017

- FDALO will continue to gather feedback from a cross-section of stakeholders on the reconsideration process for human drugs to make further changes and improvements to enhance transparency, openness, fairness and efficiency
- FDALO is applying lessons learned and currently piloting a new reconsideration process for products regulated by the Natural and Non-prescription Health Products Directorate (NNHPD)

Polling Question

Following this presentation, how comfortable are you using FDALO's services

- 1) I wish I knew about FDALO's services before!!!
- 2) Pretty Comfortable
- 3) Eh – not so sure...
- 4) Don't call me; I'll call you.



Our Contact Information

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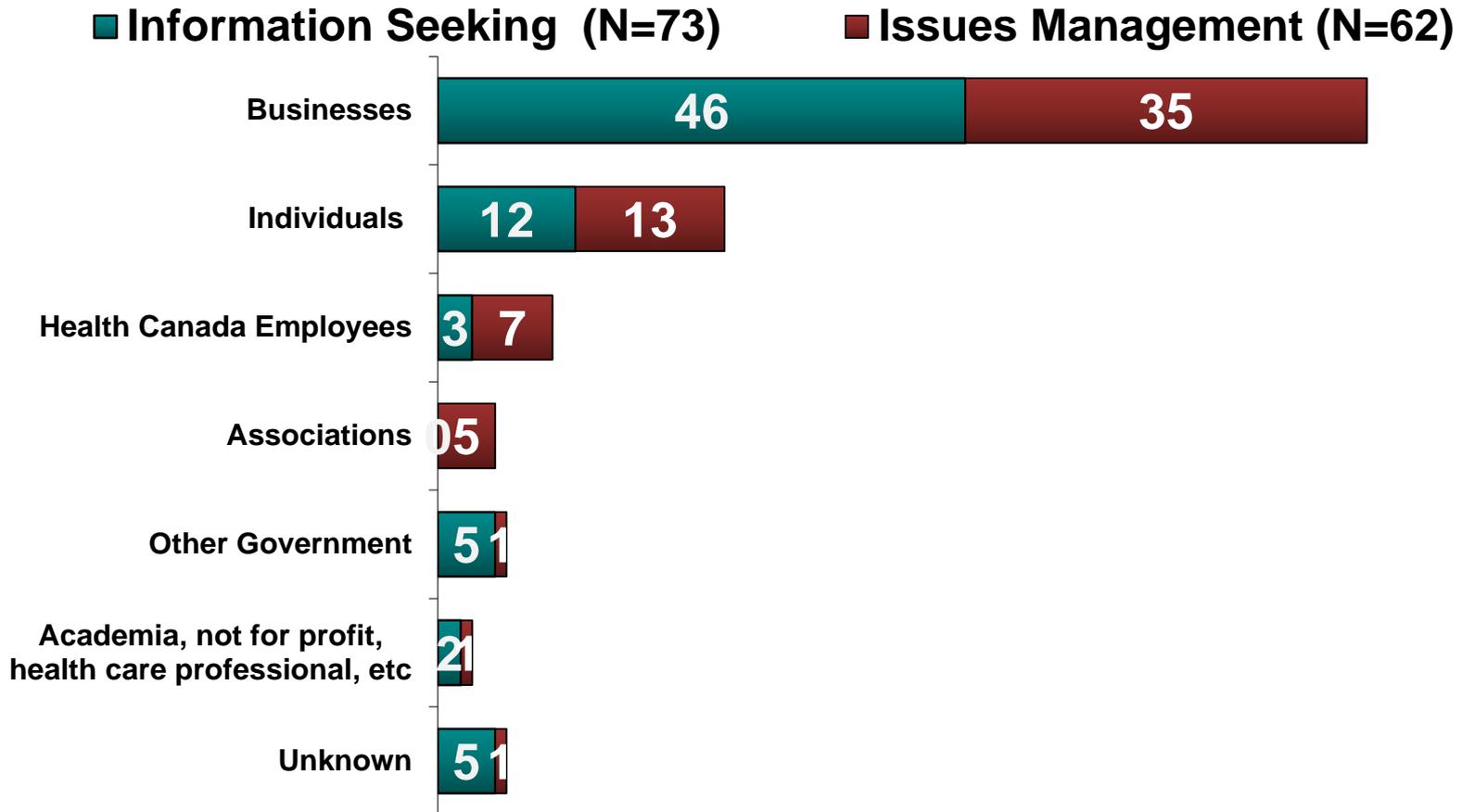
Toll free: 1-866-339-4998

APPENDIX

CASE STATISTICS

Who Contacted Us?

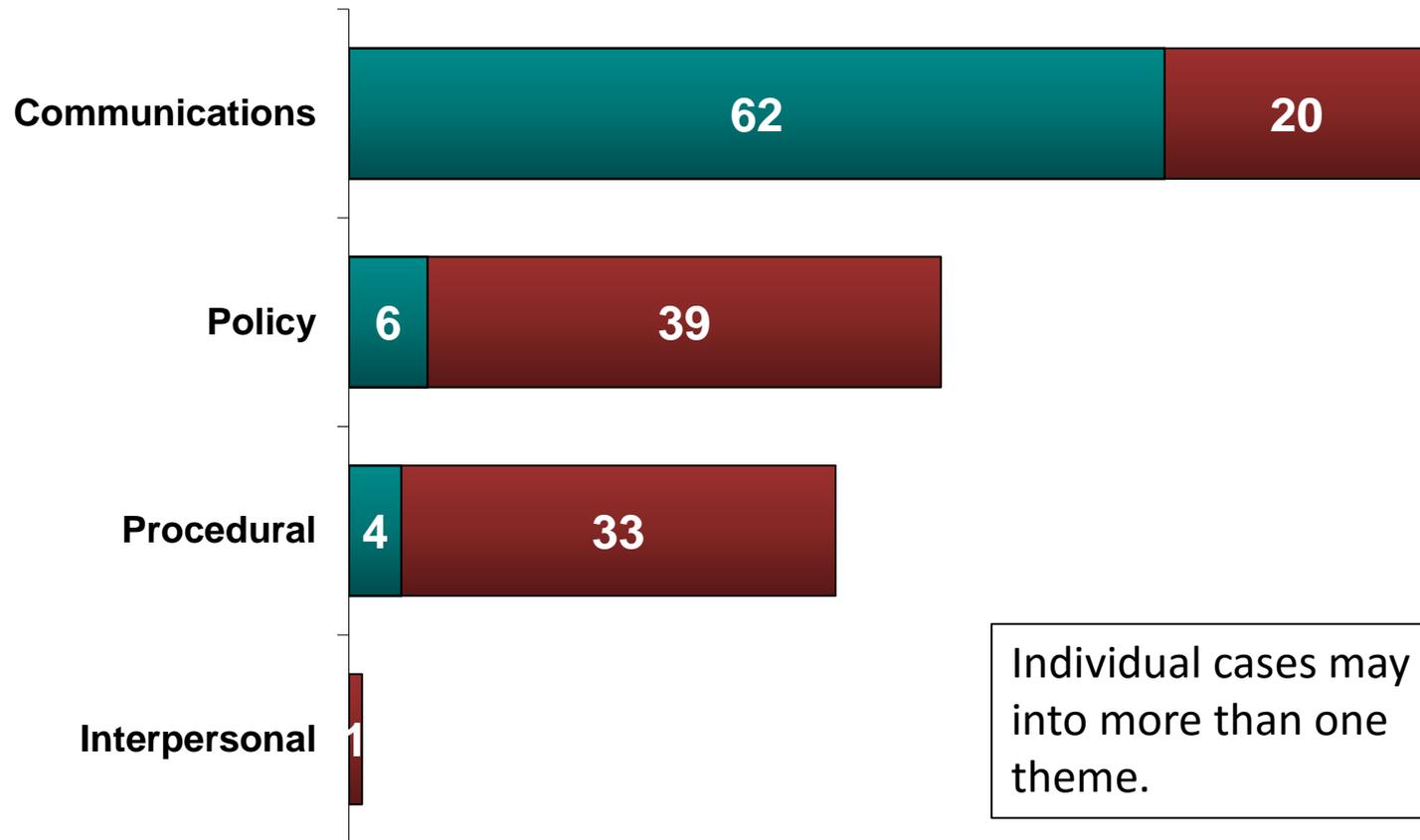
FDALO received 135 cases during 2015-2016



General Themes Identified by FDALO, 2015-2016

■ Information Seeking Cases (73)

■ Issues Management Cases (62)

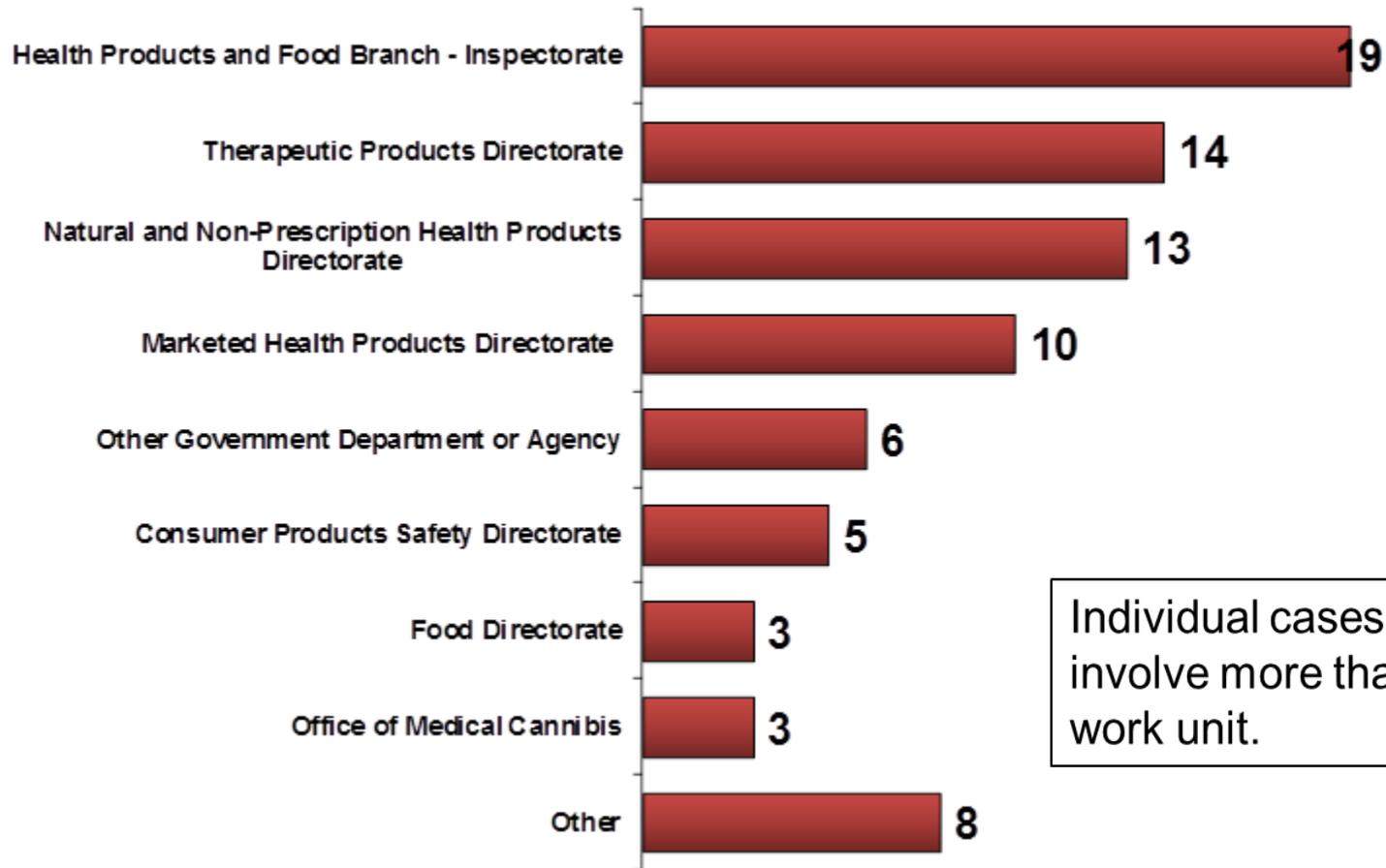


Individual cases may fall into more than one theme.

Information Seeking: Referrals by FDALO



Issues Management Cases: Health Canada Work Units Involved 2015-2016



Individual cases may involve more than one work unit.

Geographic Origin of Cases

