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What We Heard ~ *Key Findings from the 360° Assessment of Stakeholder Relations*

Marketed Health Products Directorate (MHPD) 2008



2008

Catalogue: H164-95/2008E-PDF (PDF version)

ISBN: 978-1-100-10617-5 (PDF version)

THE 360° ASSESSMENT	3
The Purpose.....	3
The Overall Approach.....	3
THE RESULTS.....	4
An Assessment of the Findings.....	4
Conclusion	5
The Challenge	6
NEW APPROACH.....	6
Our Stakeholder Relations' Vision	6
Our Commitment to our Stakeholders	6
Working Together	7
Building on Our Strengths	7
HPFB Bilateral Meeting Program.....	7
Ad Hoc Meetings	8
Multi-Stakeholder Forums	8
Other Forums	8
TOWARDS GREATER WORKING RELATIONSHIPS	8

The 360° Assessment

The Purpose

The Marketed Health Products Directorate (MHPD) was created in 2002 as a horizontal body to coordinate the post-market surveillance activities of the Health Products and Food Branch (HPFB). In five years, MHPD has tripled in size and has taken a stronger leadership role in post-market surveillance.

The MHPD recognizes the important role that many must play in post-market surveillance activities. Therefore, as a first step, it was important to assess the quality of our stakeholder relationships. A formal exercise called a 360° Assessment is a feedback mechanism used to improve business processes; it focuses on existing strengths, yet highlights areas for improvement. This mechanism collects multi-directional feedback which means feedback from within and outside of the organization, on a given subject area. This report presents the key findings from the 360° Assessment of MHPD's Stakeholder Relations and sets out MHPD's resulting stakeholder relations vision and commitment.

The Overall Approach

Persons from within MHPD, HPFB as well as various external stakeholders were invited to participate.

Various representatives from the sectors below were invited to participate:

- Health Care professionals including, physicians, nurses, pharmacists, other health professional groups, and others who prescribe, administer or develop guidance pertaining to marketed health products;
- Health consumer and patient groups;
- Industry, Health product businesses, market authorization holders;
- Non-governmental health related organizations;
- Academia; and
- Other regulating bodies.

The four main steps of this 360° Assessment (the Assessment) were:

1. Conduct a web-based survey
2. Conduct telephone interviews
3. Assess the findings to identify opportunities for improvement
4. Prepare a report detailing the key findings and suggestions for achieving improvements.

The Results

An Assessment of the Findings

This section presents an assessment of the key findings from the survey and interviews. The assessment considered the main messages, or themes, that appeared throughout the findings, from the perspective of an independent observer. The following eight themes emerged from the survey and interview findings.

Theme 1: MHPD has people who are good, committed and knowledgeable.

Many stakeholders recognize MHPD's expertise in post-market surveillance. Nearly 60% of MHPD's regulatory staff is comprised of biologists, epidemiologists, scientific and clinical evaluators, pharmacists, and practicing physicians – M.Sc., Ph.D., and M.D's all dedicated to the health and safety of Canadians. Our stakeholders recognize that MHPD employees are good, committed and knowledgeable.

Theme 2: MHPD has an enormous job.

As of January 2008, more than 22,000 pharmaceutical products, 42,000 natural health products, and 50,000 medical devices are available on the Canadian market. MHPD's job is to monitor the safety and effectiveness of all these products – after they have reached the marketplace. From information collection, signal detection and evaluation, and risk management, MHPD stakeholders recognize that post-market surveillance is an enormous job.

Theme 3: MHPD has a low profile among external stakeholders.

External stakeholders made comments such as:

- MHPD has no presence among stakeholders.
- MHPD has seemingly not yet found its place and made its mark.
- MHPD needs to be more proactive and visible.
- Some persons stated they did not know enough about MHPD to complete the survey.

These findings indicate that not all stakeholders have a solid understanding of the scope of work and responsibility falling to MHPD. Therefore, MHPD needs to focus on reaching out and communicating better.

Theme 4: MHPD's relations with external stakeholders need to be improved.

All stakeholders surveyed suggested that MHPD needs to improve its stakeholder relations. The challenge for MHPD is to understand and manage the competing interests and varying expectations of its many stakeholders. MHPD will have to consider, and where feasible utilize better mechanisms for engaging the various stakeholders in ways that are meaningful and appropriate to each.

Theme 5: MHPD's performance is not meeting external stakeholders' expectations.

MHPD has a diverse group of stakeholders, each with a different view and role within post-market surveillance and the broader Canadian Healthcare System. While the Assessment focussed mainly on stakeholder relations, some findings suggest that stakeholder expectations are not being met. Some reasons given are: MHPD has not been innovative; is slow to act; and is inconsistent with follow-up.

Other findings suggested that some stakeholders unknowingly expect MHPD to deliver on aspects that are not within its mandate to deliver.

These findings, closely resembling those of theme 3, indicate that MHPD has work to do in communicating better the scope of its mandate, and applying a more collaborative approach to post-market surveillance.

Theme 6: Stakeholders have concerns about the lack of transparency.

The Assessment found that stakeholders want sound and transparent processes that are applied systematically and consistently, based on all the knowledge and wisdom that can be brought to bear.

It is noteworthy to mention that stakeholder comments concerning transparency were blurred between being directed at MHPD versus HPFB. Nonetheless, this is still indicative that MHPD needs to increase transparency in the course of its work.

Theme 7: Despite criticism, external stakeholders want MHPD to provide leadership and want to work with MHPD.

Notwithstanding a number of challenges, internal and external stakeholders regard MHPD as a leader for post-market surveillance in Canada. All stakeholders expressed the desire to work with MHPD more collaboratively.

Theme 8: MHPD's performance and impacts would improve with better stakeholder relations.

The findings suggest that MHPD's performance would benefit greatly, and the positive impact of its work increase, by adopting a more collaborative approach to post-market surveillance.

Without a doubt, the success of any post-market surveillance program depends on the efforts and knowledge of many. MHPD relies on external stakeholders for many reasons, such as: reporting adverse reactions, communicating risks to health care professionals and consumers, and for their contribution to the development of our marketed health products policies and guidelines.

Conclusion

The above findings indicate clearly that while stakeholders recognize that MHPD has committed, knowledgeable staff, work needs to be done to strengthen existing and secure future relationships. The following sections set out MHPD's vision, commitment and approach to strengthening its stakeholder relationships.

The Challenge

MHPD has a wide range of stakeholders, each with differing perspectives and competing interests. Exercising our role as a regulator can create differences of opinion among our various stakeholders, create challenging situations, and, at times, the need to have difficult conversations. Learning to effectively manage competing stakeholder interests and expectations while enabling the important contribution each organization can make towards post-market surveillance is a must.

New Approach

MHPD recognizes that its stakeholders have expert knowledge and important contributions to make towards post-market surveillance. MHPD is looking to advance collaborative work with our stakeholders, improve mechanisms for input and expand our dissemination strategies to better reach out to those who benefit from our programs.

We are moving from passive to proactive in our approach to engaging our stakeholders. We want to encourage meaningful involvement and participation. And we want to engage the right stakeholders, at the right times, in the right ways.

Building strong relationships with our stakeholders is an ongoing process, one that will require continued effort and commitment. MHPD is using the findings of the Assessment to determine how best to move forward with our stakeholders in the next five years.

Our Stakeholder Relations' Vision

To foster a stakeholder environment where trust and respect flows between all parties, where expectations are clearly communicated, where relationships are mutually beneficial and where proactive collaborations result from ongoing stakeholder engagement activities.

Together, we can build a world class post-market surveillance program trusted by all Canadians!

Our Commitment to our Stakeholders

MHPD is committed to strengthening its stakeholder relationships by better engaging them in meaningful ways. MHPD will strive to:

- foster open and transparent communication;
- consult stakeholders during the development of key post-market surveillance policies, regulatory change, strategies, guidance documents;
- meet with stakeholders regularly to discuss issues of interests or concerns;

- look for opportunities for input into direction and scope - not only the details;
- provide timely responses to issues of concerns;
- supply stakeholders with post-market surveillance strategic and business plans as well as annual reports of activities;
- provide clear and simple MHPD contact information;
- Develop internal capacity to work more effectively across all stakeholder groups.

Repeat Assessments

MHPD is committed to repeating a 360° Assessment of our stakeholder relations in 2009. We will be working to see a measurable improvement in the quality of our stakeholder relationships.

Working Together

As MHPD moves forward into its next five years, we invite our stakeholders to help us build strong relationships.

Engaging our stakeholders in meaningful ways will take time, commitment, transparency, communication, and a willingness to work collaboratively by all parties. It will require an understanding, appreciation and respect for each party's mandate. This is an opportunity for all to learn and appreciate the contributions that all parties can make towards post-market surveillance.

Building on Our Strengths

The Health Products and Food Branch has existing policies and processes to facilitate stakeholder engagement. MHPD is working to fully utilize these opportunities as well as build others. The following briefly describes some of the current ways in which MHPD interacts with its various stakeholders.

Assistant Deputy Minister's Stakeholder Strategy

The Assistant Deputy Minister proactively meets with key stakeholders each year. The list of stakeholders and agenda items change from year to year, as the issues and priorities of the Branch and its stakeholders evolve.

MHPD participates in these meetings when post-market surveillance issues arise.

HPFB Bilateral Meeting Program

The Health Products and Food Branch's Bilateral Meeting Program enables stakeholders to regularly meet with appropriate Directorates at the same time to discuss their issues and concerns. By meeting with various Directorates at the same time, the Program aims to reduce duplication of effort and increase efficiencies. Typically, meetings are scheduled twice per year. Since post-market surveillance encompasses the four main health product business lines, MHPD regularly participates in HPFB bilateral meetings led by other Directorates. In addition, MHPD will lead

the coordination of meetings with stakeholder organizations that focus on post-market specific agenda items. In keeping with the Branch bilateral approach, MHPD will invite the other HPFB Directorates to participate.

Ad Hoc Meetings

Ad hoc meetings allow for more in-depth discussion on topics relating to post-market surveillance. With MHPD and the stakeholder at the table, there is greater opportunity to build collaborative participation, find solutions to shared issues and work toward common goals.

Multi-Stakeholder Forums

MHPD has a diverse group of stakeholders with varying perspectives and competing interests. Multi-stakeholder forums give stakeholder groups the benefit of hearing a range of viewpoints, allowing for robust discussion, fulsome understanding, and meaningful contributions. Of all the ways to engage stakeholders, multi-stakeholder forums require the greatest commitment of resources, time and planning.

For example, MHPD held a successful *Roundtable Discussion on Consumer Advertising Guidelines for Non-Prescription Drugs in June 2006*. The overall objective was to enhance the dialogue with key stakeholders with respect to the communication of risk information in advertising for non-prescription drugs including natural health products and to ultimately implement viable options in the interest of Canadians.

In 2007, MHPD created the Expert Advisory Committee on the Vigilance of Health Products (EAC-VHP). The mandate of the EAC-VHP is to provide on-going external expert broad strategic policy advice on the safety and therapeutic effectiveness of marketed health products for human use. It will also provide a mechanism to involve the public, providing them with a forum to have their views heard by experts who can discuss their input and incorporate it into the advice provided.

MHPD will look to engage stakeholders on other post-market surveillance topics through multi-stakeholder forums in the coming years.

Other Forums

MHPD participates with our stakeholders in post-market surveillance related committees, advisory boards, and working groups across Canada. MHPD will strengthen this network and improve information sharing and collaboration.

Towards Greater Working Relationships

Over the next several years, MHPD is committed to building internal capacity to work more effectively and meaningfully with its stakeholders. MHPD will reach out to its stakeholders to forge and strengthen relationships important to the creation of a comprehensive post-market surveillance system.

The feedback provided will be used to guide the development of a Stakeholder Relations Strategy. In line with the *Planning for our Future: Federal Regulatory Post-Market Surveillance Strategy 2007-2012*, the Stakeholder Relations Strategy will help set the direction for stakeholder engagement.

MHPD would like to thank all persons who participated in this Assessment. For any further information on this 360° Assessment, or for any additional questions or concerns relating to stakeholder engagement, please contact:

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