Health Canada Santé Canada

Summary of Results
Dispute Resolution (DR) Stakeholder Survey

Health Canada's Health Products and Food Branch (HPFB) is committed to increasing the range and flexibility of options available to prevent and resolve disputes with stakeholders, while continuing to put the health and safety of Canadians first. HPFB's long-term objective is to provide the Branch and its stakeholders with options appropriate to the nature of each dispute, while enhancing consistency and transparency across the Branch.

As part of this commitment, last year HPFB commissioned COMPAS Inc. to conduct an online survey of stakeholders such as industry, industry associations, consumer and public interest groups who had dealings with the Branch in the past five years. Our main goal was to gather information about the nature of your interactions with us -- including the types of disputes your organization may have had, and how these were resolved. Three hundred and twenty-two surveys were completed. Based on this sample size, the results are considered accurate within +/-5%, 19 times out of 20 (most conservative estimate).

The following is an overview of the key findings. The full COMPAS Inc. report is available on the Branch's Office of Consumer and Public Involvement web-site. (URL to be added.)

Nature of dealings with HPFB

- Over the past five years, most survey respondents have had dealings with two directorates: the Therapeutics Products Directorate and the Health Products and Food Inspectorate.
  - 76% Therapeutic Products Directorate
  - 53% Health Products and Food Inspectorate
  - 18-21% Marketed Health Products Directorate, Food Directorate, Natural Health Products Directorate
  - 15% Biologics and Genetic Therapies Directorate
  - 12% Veterinary Drugs Directorate

- Disputes with HPFB are not evenly distributed. Slightly more than half (53%) have had no disputes with the Branch in the past five years, while 41% indicated one or more -- two-thirds have had more than one, and one-quarter five or more. Given the higher number of interactions with the Therapeutic Products Directorate and Health Products and Food Inspectorate, disputes were more likely to occur with these organizations (66% and 30% respectively).

Types of disputes

Many disputes have involved pre-market assessments (45%), product categorization (30%), inspections, and decision timelines (28% each). In terms of nature of disputes, these were often interpretative[1] (54%), scientific/technical[2] (46%), quality-of-service[3] related (41%), as well as factual[4].

Experience with HPFB Dispute Resolution

Respondents were generally satisfied with HPFB employees and their willingness to resolve issues. In particular, of those respondents who had had one or more disputes with HFPB, 21% said that what they liked best about the dispute resolution processes was the helpfulness and competence of HPFB personnel, followed by the openness of communication (16%), and the informal nature of the discussions (12%).

Responses to the survey indicate general dissatisfaction with the Branch's dispute resolution processes and outcomes. 25% identified lack of timeliness as the factor they liked least about HPFB dispute resolution. 6% to 10% identified other issues such as lack of consistency. The survey also indicated a clear tendency among those who have been in dispute with the Branch to have had multiple disputes.

88% said their dispute was resolved through informal negotiation and discussion while 31% identified a formal appeals process. While respondents do not seem opposed to informal DR processes per se, the low levels of satisfaction with current DR processes suggest that informal means are not working as effectively as they could and that alternatives are needed. We will work towards increasing the range of both formal and informal mechanisms to deal more effectively with disputes.

81% agreed that disputes should be addressed initially at the level at which they arise before being allowed to escalate to higher decision-making authority.

Recommendations for change

The stakeholder community supports HPFB's intent to review and improve its DR processes. 76% said it would be a good idea for the Branch to develop improved dispute mechanisms, with 53% describing it as a very good idea. Respondents recommended applying DR measures in a variety of areas including compliance and enforcement, pre-market assessment, product categorization, decision timelines, policy development and others.

Respondents rated as important a full range of factors in developing DR mechanisms, the most important being timeliness (17%), fairness (16%), and clear procedures and guidelines (16%). This was followed by open communication (13%), transparency (11%), clear timelines (9%), ease of access and involvement of all relevant parties (6% each).

Respondents also told us that they are generally uninformed on the dispute resolution mechanisms available to them. Our intent with this consultation, and with the DR project as a whole, is to change this situation and to clearly make available dispute resolution options to anyone dealing with the Branch.

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[1] Concerning interpretation of policy and/or regulatory requirements.

[2] Concerning scientific data and/or opinion.

[3] Concerning issues such as timeliness, consistency, transparency, courtesy, fair treatment, knowledge/competence of staff or respect.

[4] Concerning the facts surrounding whether something has or has not been done in compliance with regulatory requirements.