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August 12, 2014

## Notice

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### **Release of draft revised: *Guidance Document: Reconsideration of Decisions Issued for Human Drug Submissions***

Health Canada is pleased to announce the release of the draft revised Guidance Document: *Reconsideration of Decisions Issued for Human Drug Submissions* for a 60-day consultation period. Once final, it will replace the 2006 *Guidance for Industry: Reconsideration of Final Decisions Issued for Human Drug Submissions*.

This document is intended to describe the appropriate mechanisms to address submission-related disputes and has been updated to reflect a redesigned Reconsideration Process with increased transparency and impartiality. At this time, we are not soliciting comments on the design of the Reconsideration Process, itself; but, rather, are interested in learning the impacts of the proposed revisions to the regulated industry.

The revised document includes administrative changes to increase clarity in the roles and responsibilities for the management of the Reconsideration Process. Specifically, responsibility for the management and administration of this process is being transferred to the Food and Drugs Act Liaison Office.

Additional procedural changes are also part of this revision. The rejection of a Priority Review Request under the *Priority Review Policy* or the Request for Advance Consideration under the *Notice of Compliance with Conditions Policy* will no longer be decisions for which a sponsor may submit a Request for Reconsideration. The individual review bureau/centres are best suited to understand the issues and grant decisions regarding the ability of a drug to meet an unmet patient need. As well, such decisions do not affect market access and can create unnecessary burden in the regulatory review process.

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The completion of a Summary Basis of Reconsideration Decisions (SBRD) has been removed from the Reconsideration Process. The intent of the SBRD was to inform stakeholders of reconsideration decisions; however, the writing of these documents is complicated by the possible disclosure of confidential business information for a submission that may not have received authorization. Health Canada is committed to communicating regulatory decisions and policy changes to stakeholders and will use the most appropriate mechanisms (as identified by the individual Directorates) to do so. As well, for applicable drugs, reconsideration decisions will continue to be described in Summary Basis of Decision documents as these processes form part of the rationale for a decision to issue market authorization.

The use of a Scientific Advisory Committee (SAC) as a mechanism to resolve a dispute under reconsideration will be removed from the process. These committees are not available for most reconsiderations due to the infrequency of their meetings. As well, SACs are not intended to provide adjudication on specific drug submissions.

This consultation is open for comment starting August 12, 2014 until October 11, 2014 (60 calendar days). Comments on this guidance document may be submitted in writing, by regular mail or electronically. If you are submitting your comments electronically, please use the words "Reconsideration Guidance Document" in the subject line of your email.

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# **GUIDANCE DOCUMENT**

## **Reconsideration of Decisions Issued for Human Drug Submissions**

Published by authority of the  
Minister of Health

<b>Adopted Date</b>	2005/11/30
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**Health Products and Food Branch**

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p style="text-align: right;"><i>Health Canada</i></p>	<p>The Health Products and Food Branch (HPFB)'s Mandate is to take an integrated approach to managing the health-related risks and benefits of health related to health products and food by:</p> <ul style="list-style-type: none"> <li>• Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and,</li> <li>• Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.</li> </ul> <p style="text-align: right;"><i>Health Products and Food Branch</i></p>
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***Également disponible en français sous le titre :*** Ligne directrice : Révision des décisions sur les présentations de drogues pour usage humain

## FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada's mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

<b>Document Change Log</b>			
<b>Version</b>	Guidance Document : Reconsideration of Decisions Issued for Human Drug Submissions	<b>Replaces</b>	Guidance for Industry: Reconsideration of Final Decisions Issued for Human Drug Submissions
<b>Date</b>	2014/07/08	<b>Date</b>	2006/03/01 and 2006/12/11

<b>Change</b>	<b>Nature of and/or Reason for Change</b>
Submission and Intellectual Property Division (SIPD) to Office of Submissions and Intellectual Property (OSIP)	Name change of the office
RAD to ORA	Name change of the office
Roles and responsibilities in managing/administering the Reconsideration Process	Requested by Industry
Change in the Process Map and Performance Targets	To reflect changes made within the Guidance Document
Changed “final decisions” to “decisions”	To properly reflect the reconsideration process *this change also affects the <i>Guidance for Industry: Management of Drug Submissions</i>
Removal of Summary Basis of Reconsideration Decision (SBRD)	Not the best vehicle for communicating the way forward in policy changes/revisions Poses a regulatory burden Health Canada is committed to notifying Industry on policy changes in the most appropriate form chosen by the Directorate
Re-organizing the layout of the Guidance Document	Better flow
Removal of reconsideration for the rejection of a Priority Review Request and the Request for Advance Consideration	Review bureaux/centres are best suited to make these decisions
Removal of Scientific Advisory Committees as a mechanism to review the Request for Reconsideration	Due to infrequency of their meetings.

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## ABBREVIATIONS

BGTD:	Biologics and Genetic Therapies Directorate
DG:	Director General <i>or</i> his/her delegate
FDALO:	Food and Drugs Act Liaison Office
IAS:	Issue Analysis Summary
NOD/W:	Notice of Deficiency - Withdrawal
NON/W:	Notice of Non-compliance - Withdrawal
Office:	Office of Science (TPD) <i>or</i> Office of Business Integration and Risk Management (BGTD)
RPMD:	Regulatory Project Management Division (TPD)
RR:	Request for Reconsideration
OSIP:	Office of Submissions and Intellectual Property
ORA:	Office of Regulatory Affairs (BGTD)
TPD:	Therapeutic Products Directorate

## **1 INTRODUCTION**

### **1.1 Policy Objectives**

To ensure that drug submission-related disputes that arise after the decision has been issued (see Section 1.3) are resolved effectively and efficiently.

### **1.2 Policy Statements**

The Reconsideration process is a formal dispute resolution process for decisions made on drug submissions. Refer to Appendix A for a map of the Reconsideration process.

If, at any time during the Reconsideration process, the sponsor files a Notice of Application to the Federal Court to resolve the issue(s) that are the subject of the Request for Reconsideration, the Directorate will terminate the Reconsideration process.

The information filed will be assessed for relevance to the issue(s) under dispute. The Reconsideration Process is not intended to circumvent the established processes for refiling submissions, thus new data will not be considered as part of the Request for Reconsideration (Section 3.2.1).

The sponsor and the review bureau/centre will have the opportunity to present their positions on the issues under dispute to the Director General or his/her delegate (hereafter referred to as “the Director General”), who will make the Reconsideration decision.

The assessment of the Request for Reconsideration will be completed by persons not involved in the original decision. To assist with the resolution of a Request for Reconsideration, the Director General may refer one or more issues under dispute to a Reconsideration Panel or for internal review (Section 3.3).

The Reconsideration decision will be issued by the Director General. For each issue(s) under dispute, the Director General may uphold or amend his/her original position, or refer the issue(s) back to the review bureau/centre for re-evaluation and preparation of a new decision letter reflecting the re-evaluation of the issue under dispute (Section 3.4).

### **1.3 Scope and Application**

A sponsor may file a Request for Reconsideration following the issuance of one of the following decisions:

- Screening Rejection Letter (SRL) (including New Drug Letter);
- Notice of Deficiency - Withdrawal Letter (NOD/W);
- Notice of Non-compliance - Withdrawal Letter (NON/W);

- Not Satisfactory Notice (NSN);
- Unacceptable Licence Application Letter;
- Unacceptable Licence Amendment Letter;
- Rejection of Accelerated Licence Amendment Submission.

## **2 ROLES AND RESPONSIBILITIES**

The following outlines the major responsibilities of each partner in the formal Reconsideration process.

### **2.1 Drug Submission Sponsor**

The drug submission sponsor is responsible for:

- filing a Letter of Intent and a Request for Reconsideration for eligible decisions;
- filing a Request for Reconsideration package within 45 calendar days of the receipt of the Eligibility Letter;
- ensuring no new data is included in the Request for Reconsideration;
- cross-referencing the information filed in the original submission (and/or the response to a Screening Deficiency Notice, Notice of Deficiency, or Notice of Non-compliance);
- providing nomination(s) for one member of a Reconsideration Panel, if formed;
- submitting draft questions to Food and Drugs Act Liaison Office (FDALO) to be posed to the Reconsideration Panel;
- providing background information for the Reconsideration Panel;
- making a presentation to the Director General, the Office of Science / Office of Business Integration and Risk Management (hereafter referred to as “the Office”), and the Reconsideration Panel.

### **2.2 The Office of Submissions and Intellectual Property**

The Office of Submissions and Intellectual Property, is responsible for the following:

receiving and acknowledging receipt of Letters of Intent and Requests for Reconsideration;

forwarding the Letter of Intent and the Request for Reconsideration to the FDALO with a copy to the Office, the Manager of the Regulatory Project Management Division [Therapeutic Products Directorate (TPD)] / Office of Regulatory Affairs [Biologics and Genetic Therapies Directorate (BGTD)], and the relevant review Bureau.

### **2.3 Food and Drugs Act Liaison Office (FDALO)**

The Food and Drugs Act Liaison Office is responsible for:

- responding to inquiries regarding the Reconsideration process;
- determining whether decisions are eligible for Reconsideration when a Letter of Intent is filed and informing the sponsor;
- responding to extension requests related to the Reconsideration process;
- coordinating and managing the Reconsideration meeting or Reconsideration Panel meeting.

### **2.4 Office of Science/Office of Business Integration and Risk Management**

The Office of Science and the Office of Business Integration and Risk Management are responsible for:

- preparing an Issue Analysis Summary with recommendations on the disposition of the Request for Reconsideration;

### **2.5 Food and Drugs Act Liaison Office (FDALO) in consultation with the Office of Science/Office of Business Integration and Risk Management**

The Food and Drugs Act Liaison Office in consultation with the Office is responsible for:

- responding to inquiries regarding the Reconsideration process;
- preliminary review of the issues presented in the Request for Reconsideration to recommending how each issue should be handled [that is (i.e.) review by the Office or by a Reconsideration Panel];
- making recommendations to the Director General regarding the membership of the Reconsideration Panel;
- liaising with the sponsor, review bureaux/centres and panel members;
- administering the reconsideration process;
- consulting with other areas of expertise as needed;
- reviewing draft questions to synthesize final questions to be posed to the Reconsideration Panel;
- forwarding all documents generated during the Reconsideration process to the Regulatory Project Management Division (TPD) or the Office of Regulatory Affairs (BGTD) for filing.

## **2.6 Regulatory Project Management Division/Office of Regulatory Affairs**

The Regulatory Project Management Division (TPD) and the Office of Regulatory Affairs (BGTD) are responsible for:

- responding to inquiries regarding the Reconsideration process;
- ensuring follow-up actions are taken on each submission after the Reconsideration decision has been made;
- ensuring Reconsideration decisions and recommendations for dispute prevention and early resolution are incorporated into the process for future submissions;
- communicating with the sponsor on follow-up actions of the Reconsideration decision, including time frames.

## **2.7 Review Bureau/Centre Directors**

The Directors of the review bureaux (TPD) or centres (BGTD) are responsible for:

- assisting FDALO by reviewing the Request for Reconsideration to ensure it does not contain new data. New data will not be allowed into the Reconsideration process;
- providing nomination(s) for one member of a Reconsideration Panel (if required);
- submitting draft questions to be posed to the Reconsideration Panel;
- identifying bureau/centre representatives to participate in the Reconsideration meeting;
- ensuring a presentation is prepared and presented to the Director General, the Office of Science or the Office of Business Integration and Risk Management, and the Reconsideration Panel;
- communicating with the sponsor on follow-up actions of the Reconsideration decision, including time frames;
- ensuring Reconsideration decisions, and recommendations for dispute prevention and early resolution are incorporated into the process for future submissions.

## **2.8 Reconsideration Panel**

The Reconsideration Panel is responsible for:

- listening impartially to each parties perspective;
- providing written answers to the questions posed.

## 2.9 Director General

The Director General or his/her designate is responsible for:

- deciding on the process for the disposition of the Request for Reconsideration;
- approving the membership of the Reconsideration Panel;
- attending the Reconsideration Meeting;
- making the Reconsideration decision.

## 3 GUIDANCE FOR IMPLEMENTATION

The Reconsideration process is a formal dispute resolution process for human drug submissions after the decision has been issued (see Section 1.3).

If, at any time during the Reconsideration process, the sponsor files a Notice of Application to the Federal Court to resolve the issue(s) that are the subject of the Request for Reconsideration, the Directorate will terminate the Reconsideration process.

Refer to Appendix A for a map of the Reconsideration process.

Appendix B outlines the performance targets for each step of the process. It is expected that issues referred for internal review will be fully addressed within 71 days of the receipt of the Request for Reconsideration from the Sponsor. Similarly, for issues referred for review by an external panel, the Reconsideration Process should be completed within 138 days of the receipt of the Request for Reconsideration. Sponsors should make every effort to respect specified timelines or risk having their Request for Reconsideration cancelled by the Directorate.

### 3.1 Filing of the Request for Reconsideration

Sponsors may file a Request for Reconsideration following the issuance of one of the decisions listed in Section 1.3.

#### 3.1.1 *Letter of Intent*

Within 30 calendar days of the date of the decision letter outlining the issues under dispute, the sponsor must submit a Letter of Intent clearly stating their intention to commence the formal Reconsideration process.

For both the TPD and the BGTD submissions, the Letter of Intent should be sent to the attention of the Office of Submissions and Intellectual Property (OSIP) at the address below. Note that sending the document to a location other than OSIP may result in delays.

For Electronic Common Technical Document (e-CTD) submissions, please refer to the Draft Guidance on *Preparation of Drug Regulatory Activities in Electronic Common Technical Document*.

Office of Submissions and Intellectual Property  
Therapeutic Products Directorate  
Finance Building, Address Locator # 0201A1  
101 Tunney's Pasture Driveway  
OTTAWA, Ontario  
K1A 0K9  
Facsimile: 613-941-0825

OSIP will acknowledge the receipt of the Letter of Intent and forward a copy to FDALO. In turn, FDALO will review the Letter of Intent to determine whether the decision under dispute is one for which a Request for Reconsideration can be filed (i.e., whether the decision is one listed in Section 1.3 and the Letter of Intent is submitted within 30 calendar days).

If the decision for which the Letter of Intent was filed is eligible for Reconsideration, FDALO will send an Eligibility Letter to the sponsor indicating that the decision is eligible for Reconsideration. FDALO will forward a copy of the Letter of Intent to the Office.

If the decision for which the Letter of Intent was filed is not eligible for Reconsideration, FDALO will ensure that the sponsor is contacted to explain the Reconsideration process and the mechanisms available for dispute resolution. The Request for Reconsideration will be refused by FDALO.

### **3.1.2 Request for Reconsideration**

The sponsor must submit a formal Request for Reconsideration addressed to the Director General within 45 calendar days of the date of the eligibility letter sent by FDALO. The Reconsideration package should be filed with OSIP at the address noted in section 3.1.1.

OSIP will acknowledge receipt of the Request and will forward it to FDALO for action, the Office and the Manager of Regulatory Project Management Division (RPMD)/Office of Regulatory Affairs (ORA) for information.

FDALO may grant requests for extension of the time allowed to file the Request for Reconsideration. Extension requests should be filed in writing to OSIP at the address given in Section 3.1.1, and should include a rationale for the request. The rationale will be evaluated and decisions will be made by FDALO on a case-by-case basis.

### **3.2 Format and Content of the Request for Reconsideration**

The Request for Reconsideration is expected to be filed in the prescribed format (see Appendix C) and contain the following information:

- a copy of the decision letter for which the Reconsideration is requested;
- statements, in numbered paragraphs, with the sponsor's definition of the issue(s) of dispute, linking closely with the points of the original decision;
- for each issue identified, the grounds of the dispute in numbered paragraphs.

If the Reconsideration package is not complete, FDALO will contact the sponsor to request additional information.

The information to support the Request for Reconsideration should be cross-referenced to the information filed in the original submission (and/or the response to a Screening Deficiency Notice, NOD, or NON). The Request for Reconsideration should be a brief, high-level summary of the issue(s) in dispute, and should not introduce new issues. Issues not contested will remain outstanding at the end of the Reconsideration process and will have to be addressed in a refilled submission.

#### ***3.2.1 Preliminary review of information filed for acceptable content***

FDALO in consultation with the review bureau/centre should assess the information filed in the Request for Reconsideration to ensure no new data is contained therein.

#### ***3.2.2 Preliminary review for issue processing***

FDALO, in consultation with the Office, will review the material presented and will recommend a process to be followed for the disposition of the Request. Options include the referral of all issues under dispute to a Reconsideration Panel (as described in 3.3.1), the review of all issues by the Office, or a combination of the two.

Issues that are eligible for referral to a Reconsideration Panel include:

- interpretation of available data;
- disagreement in applied methodology;
- relative weights given to data impacting on the risk/benefit assessment of the submitted information.

Issues that are not eligible for referral to a Reconsideration Panel include those that involve:

- interpretation of Regulations;
- submission of false information;
- allegations of bias;

issue(s) for which relevant expertise is available at Health Canada;  
issues which involve non-compliance in Health Canada Guidance Documents  
accessible online where the sponsor has not provided an acceptable rationale;  
Health Canada has received external advice on the issue(s);  
submission management process issue(s).

FDALO, in consultation with the Office, will make a recommendation to the Director General on the appropriateness of seeking external advice or using internal processes on one or more issues. The Director General will then make a decision, which will be communicated to the sponsor (in writing). The Invitation letter to the sponsor will contain the proposed process for disposition of the Request for Reconsideration, including details about the process and rationale for seeking external advice if applicable. If any data filed within the Request is deemed to be new, this will also be outlined in the letter. The sponsor will be asked if they wish to proceed with the Request for Reconsideration without the new data. The Invitation letter will also ask the sponsor to provide nominee(s) and draft questions to be posed to the Reconsideration Panel. The sponsor will be expected to submit the name(s) of their nominee(s) within 7 days of the date of the invitation letter. Concurrently, the sponsor and the review bureau/centre are required to provide their draft questions within 14 days of the date of the invitation letter.

### **3.3 Processing the Request for Reconsideration**

#### ***3.3.1 Review by the Reconsideration Panel***

If the Director General deems it appropriate to seek external advice, the sponsor and the review bureau/centre will have the opportunity to nominate a panel member with expertise relevant to the resolution of the matter. To ensure that the nominee can comply with conflict of interest requirements the sponsor must *not* contact the nominee, and must *not* provide them with any material for review. The nominees must *not* have been involved with the sponsor for the product in question and must not have expressed their views regarding the product in question. Both parties will be asked to provide nominee(s) in order of preference. Panel members will be chosen from these lists of nominees based on their experience, expertise, and/or analytical skills relevant to the review of a particular dispute issue(s). Panel members are contracted employees of Health Canada and are not volunteers. They are compensated for their contributions to the Reconsideration process. All costs associated with the panel meeting will be paid by the appropriate Directorate. All nominees will be contacted for interest and availability. FDALO is responsible for coordinating the Reconsideration Panel and managing its operations.

The membership of the Reconsideration Panel will be determined by the Director General as follows:

- one member selected from nominations by the sponsor;
- one member selected from nominations by the relevant Bureau/Centre Director; and
- one member nominated by FDALO and agreed to by the Director General will be appointed as Chair.

FDALO will contact all nominees to determine whether these individuals are interested and available to participate on the Panel. Nominees will be asked to provide a current *curriculum vitae* and must satisfy all conflict of interest and security clearance requirements. Any person who was involved with decisions related to the submission, or reviewed information related to the submission on behalf of the Directorate or sponsor will *not* be eligible as a member of the Reconsideration Panel. Detailed information on security and conflict of interest requirements is available from the FDALO. FDALO will then make a recommendation to the Director General on the membership of the Panel. Once the Panel members have been selected, a meeting date will be determined based on the availability of all panel members. This date is considered firm and both the sponsor and Health Canada representatives are expected to make themselves available.

The sponsor will provide a list of their representatives (up to 6 individuals) expected to participate in the reconsideration meeting indicating their titles and roles [for example (e.g.), presenter] as well as whether they will be participating via teleconference or in person. The sponsor's preference regarding order of presentation (e.g., preference to present first or second) will be solicited.

Advice will be solicited from the panel through one or more direct, un-biased questions. These draft questions should be submitted to FDALO by the sponsor within 14 days of the date of the invitation letter. The review bureau will also have 14 days to provide their draft questions. The questions should address the issue(s) highlighted in the Request for Reconsideration. FDALO, in consultation with the Office, will consolidate questions provided by the sponsor and review bureau/centre. The questions will be shared with both parties to provide minor revisions, if necessary. In addition, FDALO, in consultation with the Office, will ensure background material is provided to the Reconsideration Panel with enough time for review and consideration.

Formal presentations should be made to the Reconsideration Panel by both the sponsor and the review bureau/centre representatives. FDALO will set the agenda and allot an appropriate time for each speaker. A copy of the draft presentations will be required one-week prior to the meeting. Upon receipt of these presentations, FDALO will facilitate the exchange of presentations between the review bureau/centre and the sponsor. A copy of the final slide presentations is required two days prior to the meeting to allow for hard copies to be printed. Each presentation should consist of a brief overview of the salient points of the issue(s) under dispute, and will be followed by a question and answer period. The sponsor and the review bureau/centre representatives will each present their positions on the remaining issue(s) to the Director General and the Reconsideration

Panel members. The purpose of this meeting is to provide both parties the opportunity to be heard by the person who will make the Reconsideration decision. Both parties will be permitted attendance during both presentations and the corresponding question and answer periods that follow. The Director General, sponsor and review bureau/centre will then leave the Reconsideration Panel to its independent, closed deliberations and discussions of the specific questions to be considered by the Reconsideration Panel on the issue(s) identified.

The Chair of the Reconsideration Panel will submit a report capturing the response to the questions posed. The Office can ask the Panel for clarification on their responses if necessary.

### ***3.3.2 Review by the Office***

In the case of an internal review, both the sponsor and the review bureau/centre will be invited by FDALO to a meeting with the Director General and the Office. This meeting is intended to be non-confrontational and will allow both parties an opportunity to present their position(s) on the issue(s) under dispute to the Office and the Director General. Each presentation will be followed by a question and answer period where the Director General and the Office will have an opportunity to request clarification(s). Following the meeting, the Director General will provide a final ruling on the Reconsideration.

Where one or more issues will be referred to external Reconsideration Panel while others in the same Request will be reviewed by the Office, the meeting with the Director General will be held on the same day as the meeting of the Reconsideration Panel, if possible.

Following the meeting the Office may consult with areas of expertise within Health Canada as needed throughout its review.

### **3.4 Recommendation by the Office**

The Office will prepare an Issue Analysis Summary (IAS) describing the issues, analysis, and recommendations on the disposition of the Request. The IAS will include a summary of the process, information considered in the analysis, and detailed recommendations for follow-up actions to be taken.

The Office has several options for the disposition of Requests for Reconsideration. The Office can recommend that, upon Reconsideration, the Director General choose one of three options:

- to uphold his/her original position in the decision letter;
- to refer back to the review bureau/centre to amend his/her original position and ask that an amended version of the original decision letter be issued; or
- to refer the submission back to the review bureau/centre for re-evaluation of the issue under dispute and request that a new decision letter be prepared reflecting the re-evaluation of the issue under dispute.

### **3.5 Decision by the Director General**

FDALO will forward the recommendation to the Director General for a decision. The Director General will make a Reconsideration decision and will inform the sponsor; copies of the Reconsideration decision will be sent to FDALO, the Office, the review bureau/centre Director and the Manager of RPMD/Director of ORA.

### **3.6 Follow-up action by the Manager of Regulatory Project Management Division (RPMD)/Director of Office of Regulatory Affairs (ORA) and the Review Bureau/Centre Director**

Once the decision is issued and communicated to the Manager of RPMD/Director of ORA and the review bureau/centre Director(s), it is their responsibility to ensure appropriate follow-up actions are taken.

Specific follow-up actions related to the submission will depend on the nature of the Reconsideration decision. If the Directorate's position on one or more issues under dispute is amended, then an amended decision letter will be prepared for the Director General's signature.

If the Reconsideration decision was to refer the submission back to the review bureau/centre for re-evaluation, the Manager/Director and review bureau/centre Director(s) are responsible for ensuring that the appropriate process is followed, and/or the appropriate information is considered in the re-evaluation. In this situation, the submission will be placed in the queue based on its original target date (this will place the submission near or at the front of the queue). As the original target will likely have passed, the Manager/Director will ensure a new target date is set and communicated to the sponsor. The new target will be set on a case-by-case basis, depending on such factors as the number of issues involved, the quantity of data to be reviewed, the complexity of the issues and the data, etc.

After each Reconsideration Decision is made, FDALO will forward all documents generated during the Reconsideration process to RPMD/ORA. The Manager/Director and review bureau/centre Director(s) should ensure that the decision is integrated into the drug submission process and decision making framework, and therefore sets a precedent for future decisions as appropriate.

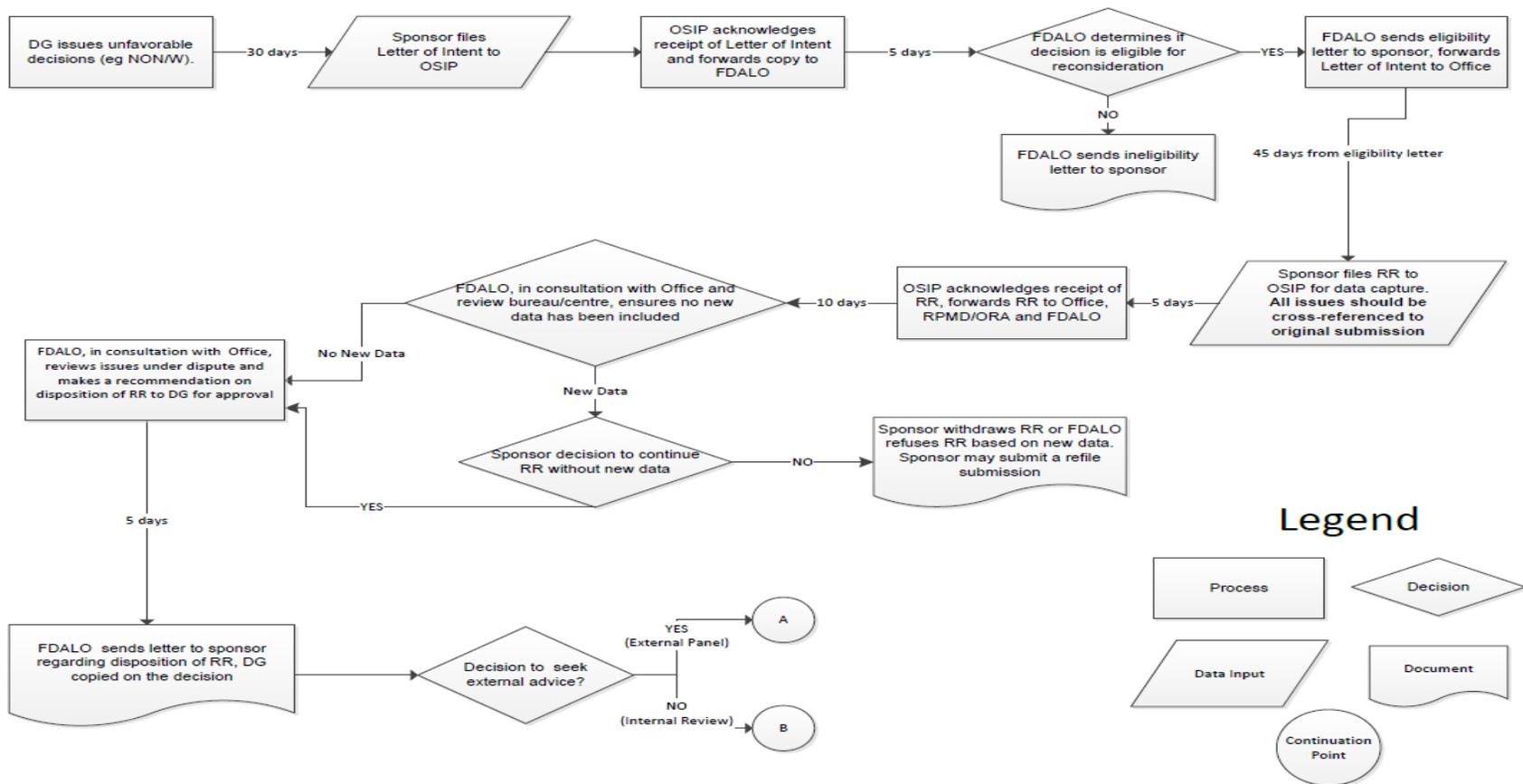
The Manager/Director and review bureau/centre Director(s) are also responsible for ensuring that any recommendations made by the Reconsideration Panel, and/or the Office, concerning dispute prevention or early resolution are appropriately communicated within RPMD/ORA and the review bureaux/centres, and are integrated into the submission process.

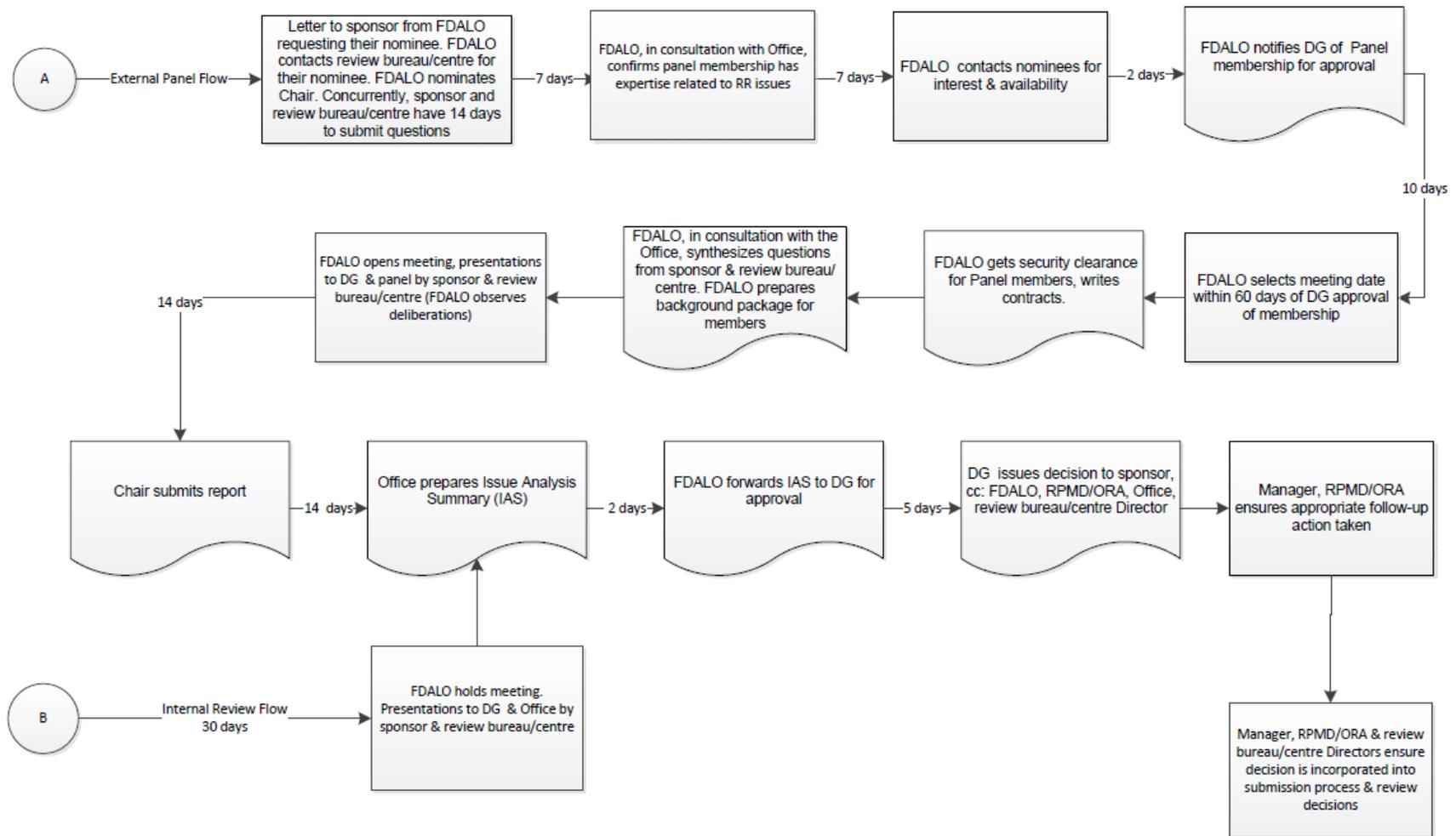
#### **4 EFFECTIVE DATE**

This guidance document is effective as of January 01. 2015.

**APPENDIX A: Reconsideration Process Map**

**Reconsideration Process Map**





**APPENDIX B: Performance Targets**

Section	Step in Reconsideration Process	Output of Step	Performance Targets (calendar days)
3.1.1	Sponsor files Letter of Intent	Letter of Intent filed to OSIP. Letter of Intent forwarded to FDALO.	30 (from decision issued by the Director General)
3.1.1	FDALO determines eligibility of decision for reconsideration	<i>If decision is eligible:</i> acknowledgement letter is issued. Letter of Intent forwarded to Office. <i>If decision is not eligible:</i> letter is issued and Request for Reconsideration is denied.	5 (from date of receipt)
3.1.2	Sponsor files Request for Reconsideration	Request for Reconsideration filed to OSIP	45 (from the date of the acknowledgment letter)
3.1.2	OSIP acknowledges and processes the Request for Reconsideration	Acknowledgement letter issued Request for Reconsideration forwarded to Office	5 (from date of receipt in OSIP)
3.2	FDALO (in consultation with the review bureau/centre) assesses the information and determines if new data is contained within the Request for Reconsideration. Prepares a recommendation on the disposition of the Request for Reconsideration	If information is relevant with no new data; recommendation made to DG on disposition of the Request for Reconsideration. If the information contains new data and the sponsor does not want to withdraw the data they can choose to refile the submission or can remove the new data and continue with the Reconsideration process	10 (from date of the acknowledgment letter)
3.2	FDALO sends invitation letter to sponsor with decision on the disposition of the Request for Reconsideration	Invitation Letter to sponsor is issued.	5 (from Director General decision on disposition of the Request for Reconsideration)

Section	Step in Reconsideration Process	Output of Step	Performance Targets (calendar days)
3.3.1	<i>Review by external panel</i> FDALO receives the sponsor and review bureau/centre nominees	Nominees received.	7 (from date of letter advising the sponsor on the disposition of the Request for Reconsideration)
3.3.2	FDALO (in consultation with the Office) ensures expertise is relevant to the Request for Reconsideration	Membership is reviewed and drafted for Director General approval.	7 (from receiving nominees from sponsor and bureau/centre)
3.3.2	FDALO contacts nominees for interest and availability	Members are polled.	7 (after consulting with the Office)
3.3.2	FDALO receives Director General approval on panel membership	Membership list approved.	2 (from when “draft” membership is completed)
3.3.2	FDALO contacts panel members to determine a meeting date	Meeting date is set.	10 (from the date of Director General approval)
3.3.2	Chair submits report	Report submitted to the Office.	14 (from the meeting)
3.3.2	Office reviews panel’s report	Office prepares Issue Analysis Summary and forwards it to FDALO.	14 (from date the report was submitted)
3.3.3	<i>Review by the Office</i> Office analyses issue(s) and prepares Issue Analysis Summary (IAS)	IAS forwarded to FDALO.	14 (from the meeting)
3.4	FDALO reviews IAS received from Office	FDALO forwards IAS to Director General	2 (from the date the IAS is received)
3.5	Director General makes a decision on the Reconsideration	Decision letter and IAS are sent to the sponsor.	5 (from receiving the IAS from FDALO)

**Note:** Every effort will be made to meet this target; however, unforeseen delays can occur as a result of conflict of interest and security clearance requirements, and the need to accommodate schedules of external experts. It is expected that issues referred for internal review will be fully addressed within 71 days of the receipt of the Request for Reconsideration from the Sponsor. Similarly, for issues referred for review by external panel, the Reconsideration Process should be completed within 138 days of the receipt of the Request for Reconsideration. Sponsors should make every effort to respect specified timelines or risk having their Request for Reconsideration cancelled by the Directorate.



Decision for which Request for Reconsideration is filed (check one) <i>(attach copy of decision letter)</i>	<input type="checkbox"/> Screening Rejection Letter (including New Drug Letter) <input type="checkbox"/> Notice of Deficiency – Withdrawal Letter <input type="checkbox"/> Notice of Non-compliance – Withdrawal Letter <input type="checkbox"/> Not Satisfactory Notice <input type="checkbox"/> Unacceptable Licence Application Letter <input type="checkbox"/> Unacceptable Licence Amendment Letter <input type="checkbox"/> Rejection of Accelerated Licence Amendment Submission
Date of issuance of decision for which Request for Reconsideration is filed	

**SECTION C – DEFINITION OF ISSUE(S) AND GROUNDS OF DISPUTE**

This section should be a brief, high-level summary of the issue(s) in dispute, and should not introduce new issues.

In this section the sponsor should include statements, in numbered paragraphs, with the definition of the issue(s) of contention, linking closely with the points of the original decision (attached). For each issue identified, the grounds of the dispute should be provided in numbered paragraphs. The grounds should be cross-referenced to the information filed in the original submission (and/or the response to a Screening Deficiency Notice, Notice of Deficiency, or Notice of Non-compliance). Issues not contested will remain outstanding at the end of the Reconsideration process and will have to be addressed in a refile.