



# Operational Procedures (OP)

## Access Consortium New Active Substance Work-sharing Initiative (NASWSI)

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## Introduction

This document outlines operational procedures and recommendations for the planning and implementation of the New Active Substances Work-sharing Initiative (NASWSI) for the regulatory agencies within the Access Consortium:

- Therapeutic Goods Administration (TGA) – Australia
- Health Canada (HC) – Canada
- Health Sciences Authority (HSA) – Singapore
- Swissmedic (SMC) – Switzerland
- Medicines and Healthcare products Regulatory Agency (MHRA) – United Kingdom

As part of the NASWSI, a joint review may be considered for new chemical entity or new biological entity applications, or new indication applications that are submitted to two or more Access agencies.

For new chemical or biological entity applications, the application will be divided into modules, with each module, or in some cases designated sections within a module, reviewed by a specific agency. Other participating agencies conduct a peer review of the assessment reports for each module. Each agency is also responsible for the review of their relevant Module 1.

For new indications applications, generally one agency will evaluate Module 5. Other participating agencies conduct a peer review of the assessment reports and also evaluate their respective Module 1.

Each agency makes its own sovereign decision based on the recommendations contained in the assessment reports. Where during the process, it becomes apparent that there are insurmountable issues with the data that the participating agencies are unable to reconcile, the agencies have the option to seek additional information and undertake further review.

## Applicant and application selection

Applicants considering taking part in the NASWSI should initiate early communication with the Access agencies in the countries where they propose to submit their application to discuss the suitability of their application.

Potential applicants will be required to work collaboratively with the agencies throughout the procedure.

### Requirements for applications

Applications should be submitted simultaneously to at least two, but preferably more, of the Access agencies. The formal work-sharing procedure described in this Operational Procedures document will commence on submission of an Expression of Interest (EoI) form (see below).

A joint review may be considered for:

- new chemical entity or new biological entity applications
- new indication applications.

Applications submitted under the standard or priority review pathways may be eligible for the NASWSI. The same assessment pathway (standard or priority) must be used in all participating jurisdictions. Applicants are required to indicate the pathway they intend to use in the EoI.

A joint review will not be considered for:

- applications for provisional or conditional approvals
- variations to products previously authorised through the NASWSI procedure (other than new indications applications).

### **Dossier requirements**

The dossiers submitted should comprehensively address the requirements of all jurisdictions proposed for work-sharing.

It is expected that the applicant submits the same data set for Modules 2-5 to all agencies. However, if there are differences, the completed “Summary of Differences” table (included in the EoI form) should be submitted, outlining the differences in the information provided to each participating agency. The participating agencies will consider these differences to determine if the application is suitable for the NASWSI. It is acknowledged that Module 1 will continue to be different for the dossiers filed in the different Access jurisdictions (as per regional requirements).

Dossiers must be submitted in eCTD format to all agencies where eCTD is allowed.

### **Phase 1: Pre-procedure – confirmation of operational approach**

The pre-procedure covers the process steps and issues that will be considered before an application is accepted for the NASWSI. These steps need to be completed concurrently within the regulatory systems of the participating agencies.

#### **Technical (scientific) pre-submission meeting/teleconference**

A technical pre-submission meeting or teleconference with the applicant is recommended. The technical pre-submission meeting will usually be held with the Module 5 lead agency, although bilateral meetings with each jurisdiction may also be possible.. Joint meetings, with two or more regulators can be requested, but may not be granted due to operational and resource challenges.

Applicants are required to follow the usual procedure of their local agency when requesting a technical pre-submission meeting.

Note the technical pre-submission meeting can occur after the submission of the Expression of Interest (EoI).

#### **Submission of EoI form**

Interested applicants should submit an EoI at least 3 months in advance of their anticipated filing date to each agency proposed for work-sharing. Once an EoI form has been submitted, the participating agencies will discuss the suitability of the application for the NASWSI and the next steps via email and/or teleconference.

## **Pilot access request for priority review: Promise Pilot pathway**

Interested applicants should submit their EoI at least 6 months before filing their application for marketing authorization. (For timelines, please refer to Annex 2.)

The Access agencies understand that an applicant may not know until closer to submission that their application is suitable for priority. Where this is the case, applicants are encouraged to discuss the timelines with the proposed agencies and/or to submit an EoI 6 months before filing and note that they may withdraw their interest in the Promise Pilot pathway pending the outcome of ongoing clinical trials.

### **1) Determining eligibility for the pathway**

Expressions of interest for new active substances or new indication applications must meet the following criteria:

- diagnoses, treats or prevents a condition that is serious, life-threatening or severely debilitating; **and**
- for which no other treatment is currently registered and marketed in participating jurisdictions for the proposed indication

After receiving the EoI, participating agencies will determine whether the eligibility criteria have been met and, if so, send a confirmation to the applicant.

A lead agency is then determined.

The applicant and all agencies proposed for work-sharing may wish to hold a joint pre-submission meeting/teleconference (combined logistical and technical). Applicants should propose possible meeting dates in their EoI form.

### **2) Evaluating a priority review request**

For eligible EoIs, applicants should submit one scientific data package and justification which will allow Access agencies to assess the evidence of a significant therapeutic benefit to determine whether to grant priority review status. One agency will lead the assessment and peer review will take place by all agencies, with work being shared between the agencies.

The agencies will then seek to reach a consensus regarding the application's priority review status through the Promise Pilot pathway, however, in principle, an agency may still consider its national criteria for priority review/fast-track requests as part of its decision. Applicants may refer to each jurisdiction for more information. However, those national criteria are very similar and allow the applicant to prepare 1 data package.

If the Access agencies cannot agree, the applicant may continue to submit the application using the:

- Promise Pilot pathway for those agencies that accepted the request **or**
- standard Access procedure to all requested agencies

If priority review status is not granted, an applicant cannot use the Promise Pilot pathway. An applicant may still submit a national priority/fast-track request or a national reconsideration application, where applicable.

Note: There are no legal entitlements or appeal rights for the Promise Pilot pathway, as Access procedures are proposed in addition to national procedures.

For a target evaluation plan, please consult Annex 2.

We have provided key dates for submitting a marketing authorization application. Evaluation plans are always discussed with an applicant in advance.

## **Role determination for Access partners**

The Access agencies will consider their operational needs when allocating review responsibilities for the dossier.

There will be models for 2, 3, 4 and 5-way work-sharing. As an example, for a new chemical entity application involving three regulators the joint review could consist of one agency reviewing module 3 data, one agency reviewing module 4 data and another agency reviewing the module 5 data.

Responsibility for the review of aspects related to more than one module (e.g. impurities) or where the data is evaluated by different groups within the Access agencies (e.g. bioavailability) will be determined on a case-by-case basis. As an example, if a toxicological assessment of impurities is required, it will be directed to the agency that is responsible for the non-clinical review.

Note – The lead for the clinical review will coordinate the logistical pre-submission meeting on behalf of Access partners, where one is requested (see below).

## **Development of an evaluation plan and timeline**

Access agencies will develop an evaluation plan with specific milestones that allows each agency to meet their legislative obligations and/or performance standards.

In addition to the expected evaluation timeline, the Access agencies will also confirm the approach for agency questions raised during the assessment phase:

- For joint review of an application under the standard pathway, agency questions will generally be issued as part of a consolidated list of questions (LoQ) at the end of the round 1 evaluation (Milestone 3). Access agencies may, however, indicate a preference to issue evaluation questions throughout the evaluation period (via “rolling questions”) for the module they are responsible for.<sup>2</sup>
- For joint review of an application under the priority review pathway, agency questions will be issued as “rolling questions” throughout the evaluation period (i.e. during Phase 2).

## **Logistical pre-submission teleconference**

In addition to the technical discussions that may occur between each agency and the local applicant, the applicant may wish to hold a logistical pre-submission teleconference. This should be coordinated with the Module 5 lead agency..

The aim of the logistical pre-submission teleconference is to discuss and confirm the logistics and expectations related to the requirements, timelines and processes specific to work-sharing, and allow the agencies to respond to any queries from the applicant.

It is recommended that the teleconference takes place 1month prior to the filing of the application.

The applicant will be requested to:

- provide a list of queries for the Access agencies at least two weeks in advance of the pre-submission teleconference
- complete a meeting record summarising the agreed outcomes and actions arising within two weeks of the meeting.

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<sup>2</sup> Note the NASWSI does not allow rolling submission of data by applicants during the evaluation phase. Applicants must lodge a complete dossier at the time of submission.

## Phase 2: Application submission and assessment

All timelines described below should be interpreted as “calendar days”. If a milestone falls on a weekend or a national holiday, the milestone will be the preceding business day.

The evaluation timeframes outlined below are the default timeframes for a NASWSI application using the **standard pathway**. These are *target timeframes* that will allow all Access agencies to meet their legislative obligations and/or performance standards. Participating agencies may agree to modified timeframes in consultation with applicants.

If any changes to the evaluation plan are required during the evaluation, e.g. changes to applicant response times or delays to reviews, the Access agencies will correspond with the applicant to seek agreement.

### Milestone 1: Submission of the application

Applications should be submitted to each agency simultaneously or as agreed with the agencies.

### Milestone 2: Acceptance of Application

**Timeframe: 30 to 45 days**<sup>3</sup>

After receipt of the application, the agencies will:

- independently perform the technical and administrative screening of the application to ensure that their legislative and data requirements are met (e.g. application forms, user fees)
- inform the local applicants of the acceptability of the application for assessment following their usual procedure.

The day of acceptance of the application for assessment is “Day 0” of the NASWSI process.

Note – screening timeframe may vary between agencies, however the goal is to have the application enter review on the same date in all participating jurisdictions.

### Assessment of dossier

**Timeframe: 90 days**

Access agencies will review and prepare an Assessment Report (AR) and a List of Questions (LoQ) for the module(s) they are responsible for using their own national guidelines.

Each agency will follow their usual procedure for reviewing its respective Module 1.

Where an application (priority review pathway) or individual module is being reviewed using rolling questions rather than a LoQ:

- The Access agencies will issue rolling questions throughout the evaluation at set time points wherever possible. For example, one scenario could be, starting at day 60 and then once a month until day 150 (i.e. 4 rounds in total).
- Applicants are required to provide responses to rolling questions within 15 days.

### Peer review

**Timeframe: 25 days**

The Access agencies will conduct a peer review of the AR and LoQ:

- consulting the modules (as needed) and sharing additional questions on relevant modules

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<sup>3</sup> From filing to acceptance for assessment.

- with the reviewing agency
- undertaking any necessary supplemental evaluations of the relevant module(s) where there are additional country-specific requirements or guidelines that need to be considered.

Evaluator teleconferences will be scheduled to discuss aspects of the review as necessary. Feedback and any additional questions may be provided to the reviewing agency for consideration and discussion.

#### Finalisation of the ARs and LoQ

**Timeframe: 5 days**

Access agencies will finalise the consolidated LoQ on Modules 2-5 (excluding any questions issued by rolling questions) and their respective LoQ on Module 1 as applicable (including questions on product information and labelling).

#### **Milestone 3: Consolidated LoQ issued to the applicants**

Each agency will send to their local applicant:

- the consolidated LoQ
- a copy of the AR(s) they have prepared, where this is part of their usual procedure.<sup>4</sup>

The LoQ will be divided into a common set of questions (common to all participating agencies), and country-specific questions (relating to Module 1 as well as any country-specific questions for the other modules). The country-specific questions will be identified using prefix letters A (Australia), or C (Canada), S (Singapore), CH (Switzerland), UK (United Kingdom), e.g. A1, A2 etc.

Note that the agencies will not provide copies of assessment reports prepared by another agency.

#### **Milestone 4: Response to the consolidated LoQ**

**Timeframe: 30 or 60 days**

Applicants are required to send complete responses to the consolidated LoQ to each agency as follows:

- responses to all common questions should be submitted to each agency
- responses to country-specific questions for Modules 3-5 need only be submitted to the applicable agency, unless requested as an FYI.

The dossier must be updated in all jurisdictions to ensure that the application is complete. If required, a 'catch-up' sequence can generally be provided towards the end of the evaluation process that includes any updated data for Modules 3-5.

The time for the response to the consolidated LoQ will be either 30 or 60 days as nominated by the applicant in the EoI.

Note – participating agencies may agree to modify the LoQ response period in consultation with the applicant.

#### Assessment of responses to LoQ

**Timeframe: 25 days**

The Access agencies will:

- review the responses to the LoQ and update the ARs for the module(s) they are responsible for
- prepare an AR of responses to their respective LoQ on Module 1 and any supplemental

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<sup>4</sup> TGA and MHRA will share their AR at Milestone 3.

evaluations of the other modules.

#### Peer review

**Timeframe: 15 days**

The agencies will conduct a peer review of the AR of the responses.

#### **Milestone 5: Finalisation of the ARs**

**Timeframe: 5 days**

Where there are no outstanding issues the report(s) will be finalised and the agencies will proceed to follow Phase 3 National Steps.

If necessary, the agencies may prepare an additional (second) LoQ to seek further clarification on any outstanding issues, which each agency sends to their local applicant.

If the additional LoQ are country-specific, the other agencies may elect to proceed to follow Phase 3 National Steps.

#### Submission of responses to additional LoQ by applicant

**Timeframe: 15 days<sup>5</sup>**

If required, the applicant sends responses to any additional questions to all participating agencies via the respective local applicants.

#### Assessment of responses to additional LoQ

**Timeframe: 15 days<sup>5</sup>**

The reviewing agencies will review the responses to the LoQ and update the ARs as necessary.

Where relevant, Access agencies conduct a peer review of AR of the responses and provide feedback. Access agencies will finalise the AR(s).

#### **Milestone 6: Conclusion of formal work-sharing**

**Total maximum elapsed time from acceptance of the application to the start of the national steps:  
225-255 calendar days [180 days excluding applicant time/stop-clocks]**

The work-sharing process formally concludes at the end of the evaluation phase as the process enters into Phase 3 National Steps. Each agency will progress towards making a final decision (or seeking further clarification on issues separately before making a final decision) by undertaking necessary administrative steps to finalise the application process domestically.

### **Phase 3: National steps**

National steps may include expert advisory committee meetings, and the finalisation of product labelling. To ensure all agencies can follow their national steps in a timely manner, the agencies may customise the evaluation plan beyond Milestone 5.

During the national steps, the Access agencies may continue to share information, such as outcomes of expert advisory committee meetings, and discuss issues concerning the labelling and packaging material.

Note: While there may be discussions between regulators about product labelling during the evaluation phase, different laws and frameworks exist in each country which affects regulatory decisions related to product labelling. It is likely that product labelling will differ from one jurisdiction to another.

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<sup>5</sup> Depends on nature of unresolved issues.

## **Milestone 7: Separate sovereign decisions**

The Access agencies will:

- independently inform the local applicant of their decision to grant or refusal to grant market authorisation
- publish a public assessment report or similar document in accordance with their usual procedures.

These communications may not be simultaneous.

Market authorisation or refusal of market authorisation by one regulator will not affect the decision or the timing of the decision by the remaining participating regulators.

Where an application is not considered approvable by an Access agency, its national procedures will apply.

## Annex 1 Target evaluation plan of the Access NASWSI standard procedure

The following timelines should be interpreted as “calendar days”. This includes applicant time/stop-clocks (or calendar days excluding stop-clocks). If a milestone falls on a weekend or a national holiday, the milestone is the preceding business day.

Milestone	Timeframe	Action	Comments/agency-specific information
<b>Phase 1: Pre-procedure – confirmation of operational approach</b>			
	>3 months pre-submission	Submitting EoI	
	~3 months pre-submission	Technical pre-submission meeting	Between Access agency and applicant within each jurisdiction Can occur before EoI is submitted
		Determining roles and developing evaluation plan	Occurs between Access agencies
	~1 month pre-submission	Confirming agencies’ intention to participate in the work-sharing project and sharing evaluation plan with applicants	At the latest 1 month pre-submission, all Access agencies which received EoI inform their respective applicants
<b>Phase 2: Application submission and assessment</b>			
<b>Target timeframes for standard pathway – Calendar days (excluding stop-clocks)</b>			
<b>1</b>	Day -45 to day -30	Submitting application for screening	TGA: Applicant to also submit PPF before (timing can be negotiated) HC & HSA: 45 days for screening (standard submission)
<b>2</b>	Day 0	Accepting application/commencing evaluation	
	Day 60, 90, 120, 150	Issuing rolling Qs	If applicable for a particular module. Attempts will be made to develop a schedule for rolling questions where possible.
	Day 75, 105, 135, 165	Responding to rolling Qs	
	Day 90	Exchanging Rd 1 reports and start of peer review of reports by Access agencies	
<b>3</b>	Day 120	Finalising Rd 1 reports Consolidating Rd 1 LoQ issued to applicant	
<b>4</b>	Day 150/180 (120)	Responding to consolidated Rd 1 LoQs/commencing evaluation of response	Applicant nominates response time (30/60 days) in EoI All agencies except HC: Clock is stopped during response
	Day 175/205 (145)	Exchanging Rd 2 reports and start of peer review of reports by Access agencies	
<b>5</b>	Day 195/225 (165)	Finalising Rd 2 reports Issuing consolidated Rd 2 LoQs (if necessary)	SMC: Rd 2 LoQ corresponds to pre-decision

	Day 210/240 (165)	Responding to consolidated Rd 2 LoQ/commencing evaluation of response	All agencies except HC: Clock is stopped during response
<b>6</b>	Day 225/255 (180)	Concluding formal work-sharing	
<b>Phase 3: National steps</b>			
		Expert advisory committee meeting (except HC)	TGA: If required, meetings are held bi-monthly HSA: If required, meetings are held every 3 months SMC: If required, meetings are held monthly and are integrated into Phase 2 MHRA: If required, meetings are held monthly and are integrated into Phase 2
		Finalisation of labelling etc.	
<b>7</b>	Day 300	Separate sovereign decisions	MHRA: decision by day 255/285 (that is, 210 days excluding stop-clocks)
		Prepare, review and publish public assessment reports	MHRA: PAR published within 60 days of approval/refusal

## Annex 2: Target evaluation plan of the Access NASWSI Promise Pilot pathway

The following timelines should be interpreted as “calendar days”. This includes applicant time/stop-clocks. If a milestone falls on a weekend or a national holiday, the milestone is the preceding business day.

Milestone	Timeframe	Action	Comments/Agency-specific information
<b>Phase 1: Pre-procedure – Request for Promise Pilot pathway (recommended timelines)</b>			
	6 months before submission of MAA	Submitting EoI	EoI should include submission date(s) for the priority request and proposals for a pre-submission meeting
		Determining eligibility for pathway and role for Access agencies	
	5 months before submission of MAA	Acknowledging acceptance for Promise Pilot pathway	
	3 to 4 months before submission of MAA	Submitting priority review request	Filing same request package to each agency. Applicants should respect national requirements for submission and screening periods so all agencies may start the review on the same day.
	2 to 3 months before submission of MAA	Evaluating priority request	Includes possible questions to applicants with 2 days turnaround
	2 months before submission of MAA	Decision on priority request	
	~1- 3 months before submission of MAA	Technical pre-submission meeting	Between Access agencies and applicant for all jurisdictions
	1 to 2 months before submission of MAA	Confirming roles and evaluation plan	
<b>Phase 2: Application submission and assessment</b>			
<b>Target timeframes for pathway – calendar days. Key dates only. Individual evaluation plans are always discussed with the applicant in advance.</b>			
<b>1</b>	Day -25	Submitting application for screening	25 days for screening
<b>2</b>	Day 0	Acceptance of application/commencing evaluation	
<b>3</b>		Issuing rolling questions (alternative process: consolidated, batched LoQ)	If possible, a schedule for rolling questions is made. Response time: 15 calendar days for rolling Qs and maximum 30 days for consolidated LoQ
<b>4</b>		Responding to Qs	
<b>5</b>		Concluding formal work-sharing	
<b>6</b>	Day 180	Separate sovereign decision	