

Guidance document
Project Orbis

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List of contents

Guidance document	1
1 Terms, definitions, abbreviations	3
1.1 Abbreviations	3
2 Introduction	3
2.1 Legal framework	4
3 Objective	4
4 Scope	4
5 Description	5
5.1 Requirements	5
5.1.1 Formal requirements	5
5.1.2 Document protection	5
5.1.3 Time limits	5
5.1.4 Fees	5
5.2 Process	6
5.2.1 FDA Selection Process	6
5.2.2 Types of Project Orbis submissions	6
5.2.3 Determination of Orbis type by Swissmedic	7
5.2.4 Submission of the application	7
5.2.5 Swissmedic assessment	8
5.2.5.1 Meetings	8
5.2.5.2 List of Questions / Information Requests	8
5.2.5.3 Preliminary decision	9
Annex 1 – Flow Chart	10

1 Terms, definitions, abbreviations

1.1 Abbreviations

AAid	Assessment Aid
ANVISA	Agência Nacional de Vigilância Sanitária
FDA	U.S. Food and Drug Administration
GSP	Global Submission Plan
HSA	Health Sciences Authority
IMOH	Israel Ministry of Health
MHRA	Medicines and Healthcare products Regulatory Agency
IR	Information Requests
LoQ	List of Questions
POP	Project Orbis Partner
RMP	Risk Management Plan
SAL	Sponsor Authorization Letter
SMC	Swissmedic
TGA	Therapeutic Goods Administration
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPLRO	Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)

2 Introduction

Project Orbis is a program coordinated by the US Food and Drug Administration (FDA) to promising oncology treatments. It provides a framework for the concurrent submission and review of applications for oncology products among international partner authorities (POPs). It aims to deliver faster patient access to innovative treatments with potential benefits over existing therapies.

It involves the regulatory authorities of:

- Australia (TGA)
- Brazil (ANVISA)
- Israel (IMOH)
- Canada (Health Canada)
- Singapore (HSA)
- Switzerland (Swissmedic)
- United Kingdom (MHRA)

The FDA is responsible for coordination and verifies that applications fulfil the acceptance criteria for Project Orbis. Initial enquiries should therefore be addressed to the FDA. However, each participating country retains autonomy as regards the final authorisation decision and labelling.

2.1 Legal framework

The procedure for the authorisation of medicinal products with new active substances is based on the following legislative texts in particular:

TPA

Art. 9	Marketing authorisation
Art. 10	Conditions for granting a marketing authorisation
Art. 11	Application for a marketing authorisation
Art. 14 para. 1 f	Important medicinal products for rare diseases

TPO

Art. 7	Fast-track authorisation
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TPLRO

Art. 2	General preconditions
Art. 3	Documentation on the analytical, chemical and pharmaceutical tests
Art. 4	Documentation on the pharmacological and toxicology tests
Art. 5	Documentation on clinical trials
Art. 6	Special requirements for fixed combinations of medicinal products

The procedure for the authorisation of new indications of medicinal products is a type II major variation and based on the following legislative texts in particular:

TPO

Art. 23	Major variations
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TPLRO

Art. 22a	Classifications of the variations
Annex 7	List of amendments according to Articles 21-24 TPO

3 Objective

This guidance document describes the marketing authorisation process for medicinal products with medical applications in oncology within the framework of Project Orbis.

Swissmedic uses this guidance document first and foremost as a resource for applying the legal provisions on authorisation in a uniform and equitable manner. Publication of the guidance document is intended to provide transparency for third parties on the requirements that have to be fulfilled under Swissmedic practice. It is also intended to provide a description of the requirements for obtaining authorisation of human medicinal products under Project Orbis in Switzerland.

4 Scope

This guidance document applies to the authorisation of human medical products with new active substances and new indications (type II variations) that are assessed under Project Orbis.

5 Description

5.1 Requirements

The requirements for the authorisation of medicinal products with new active substances are described in the guidance document *Authorisation of human medicinal product with new active substance*. The requirements for the authorisation of new indications are described in the guidance document *Variations and extensions HMP*.

Project Orbis procedure is a special service offered by Swissmedic in collaboration with the FDA.

Requests for a fast-track procedure, temporary authorisation procedure or procedure with prior notification must be submitted on deadline prior to application submission. Applications that involve a request for review under Project Orbis can be combined with these procedures. This also applies if it is not yet known, at the time of submission, that the FDA will accept the request for review under Project Orbis.

The following documents outline specific criteria and requirements for the procedures of the same name:

- Guidance document *Fast-track authorisation procedure*
- Guidance document *Temporary authorisation for human medicinal products*
- Guidance document *Procedure with prior notification*

5.1.1 Formal requirements

The formal requirements are based on the guidance document *Formal requirements* and the associated directory of *Documents to be submitted*.

5.1.2 Document protection

Information on documentation protection is provided in the guidance document *Document protection*.

5.1.3 Time limits

The time limits are based on the guidance document *Time limits for authorisation applications*.

The time limits may vary depending on the type of application (NAS, IE) and Orbis type (see section 5.2.2 Types of Project Orbis submissions). Type A Orbis applications and fast-track Type B Orbis applications are always subject to the Orbis procedure time limits, irrespective of whether the application was initially submitted under a different procedure (e.g. FTP).

5.1.4 Fees

The fees specified in the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-SMC; SR 812,214.5) apply.

5.2 Process

5.2.1 FDA Selection Process

Once topline results are available from the registrational clinical trial(s), the US applicant can make a request for review under Project Orbis to the FDA. In principle, applications that qualify for Project Orbis satisfy the conditions for FDA Priority Review. The decision on whether to accept submissions in Project Orbis lies entirely with the FDA. Applications for inclusion in Project Orbis cannot therefore be submitted to either Swissmedic or the other POPs.

5.2.2 Types of Project Orbis submissions

Type A

Applications that are sent to Swissmedic within 30 days of submission to the FDA (submission gap) are classified as Orbis Type A. Orbis Type A permits parallel assessment, which maximises cooperation between the FDA and the POPs involved in the application and ensures that regulatory decisions are made concurrently or within a short period of each other. Orbis applications submitted as Type A will always be accepted as such by Swissmedic. The time limits for Orbis Type A are shorter than the standard time limits (see guidance document *Time limits for authorisation applications*). Questions take the form of Information Requests (IRs).

Type B

Applications that are sent to Swissmedic more than 30 days after submission to the FDA (submission gap) but before the FDA issues its decision are classified as Orbis Type B. They provide the possibility of cooperation with the FDA on the ongoing assessment process. Depending on the submission gap, available resources and the progress of the FDA's review, Orbis Type B applications may be fast-tracked (fast-track Orbis Type B) in a similar way to Orbis Type A applications. Otherwise the standard assessment timelines will be applied to Orbis Type B applications (non-fast-track Orbis Type B), in a similar way to Orbis Type C applications (guidance document *Time limits for authorisation applications*). The applicant will be notified no later than the start of the procedure.

Type C

Applications on which the FDA has already made a decision and has submitted the unredacted assessment reports to the participating partner authorities are classified as Orbis Type C. Concurrent assessment with the FDA is not possible for Orbis Type C. The standard time limits, as set out in the guidance document *Time limits for authorisation applications*, apply and a List of Questions (LoQ) is sent to the applicant in line with customary practice.

Table 1: Types of Project Orbis submissions (as per general FDA template)

Orbis Type	Submission Timeline	Submission overlaps with FDA	Sharing of FDA reviews	Multi-country review meetings (POP TCONs)	POP Attendance at FDA review meetings	Concurrent review with FDA	Near concurrent action with FDA
Type A	Application submission to POPs ≤ 1 month of FDA submission	Expected	Yes	Yes	Yes	Expected	Possible ¹
Type B	Application submission to POPs > 1 month of FDA submission	Expected	Yes	Yes	Yes	Possible	No ¹
Type C	Any time after FDA submission ²	Permitted ²	Yes	No	Unlikely	Unlikely	No ¹

5.2.3 Determination of Orbis type by Swissmedic

Swissmedic determines the Orbis type according to the criteria above (section 5.2.2) and on the basis of the submission dates for the USA and Switzerland given in the Global Submission Plan (GSP). The GSP must be submitted to the FDA by the US applicant when applying for a Project Orbis procedure. As soon as Swissmedic has determined the Orbis type and reported back to the FDA, the FDA will notify the US applicant. The latter must then notify the applicant in Switzerland of the planned submission and instruct it to contact Swissmedic (e-mail: projectorbis@swissmedic.ch).

5.2.4 Submission of the application

As a rule, submissions should be made electronically using the Common Technical Document format (i.e. eCTD) with all documents in English, with the possible exception of the country-specific Module 1. Marketing applications should comply with the specific requirements for submissions to Switzerland (see also guidance document *Formal requirements*).

In order to allow the exchange of information between Swissmedic and the participating Project Orbis partners over the course of the assessment, the Swiss applicant must consent to information

¹ Regulatory action in other jurisdictions is unlikely to occur immediately after FDA action and will follow respective health authority timelines.

² Dependent on Project Orbis Partner (POP) guidelines. Contact specific POP(s) regarding optimal timing for submission of Type C dossier.

exchange (see form *New authorisation of human medicinal products* or *Variations and authorisation extensions HAM*).

In addition, the following documents should be submitted in Module 1: the FDA 'Sponsor Authorization Letter' (SAL) and the FDA 'Assessment Aid' document (Aaid).

5.2.5 Swissmedic assessment

5.2.5.1 Meetings

For Orbis Type A and fast-track Type B applications, the FDA organises and coordinates several online meetings with the authorities involved in the application to discuss various aspects of it (mid-cycle meeting and other application-specific meetings). The application-specific meetings include discussions of specialist issues such as efficacy, safety and clinical pharmacology and a general benefit-risk assessment is made. In the case of non-fast-track Orbis Type B and Orbis Type C applications, the FDA's assessment is already at an advanced stage or has been completed, and it is therefore generally no longer possible to take part in FDA meetings.

5.2.5.2 List of Questions / Information Requests

Type A and fast-track Type B applications make no provision for Lists of Questions (LoQs). During Evaluation phase I, questions will be asked on an ongoing basis (rolling procedure) in the form of Information Requests (IRs). Swissmedic's IRs are shared with the FDA and POPs and sent to the applicant in Switzerland. Questions are sent in English with a response deadline of 10 calendar days (see guidance document *Time limits for authorisation applications*).

Where IRs concern the medicinal product information texts, Swissmedic may also send the revised manuscripts. The local subsidiaries submit the responses to the IRs to the FDA and all POPs except where the responses are to FDA IRs concerning raw data analyses and IRs concerning country-specific labelling. These do not have to be submitted to Swissmedic.

For Switzerland, responses to the IRs have to be uploaded as a "communication" to the Swissmedic eGov Portal. A covering letter referencing the relevant IR(s) and mentioning that the application is being reviewed under Project Orbis should be enclosed with the submission.

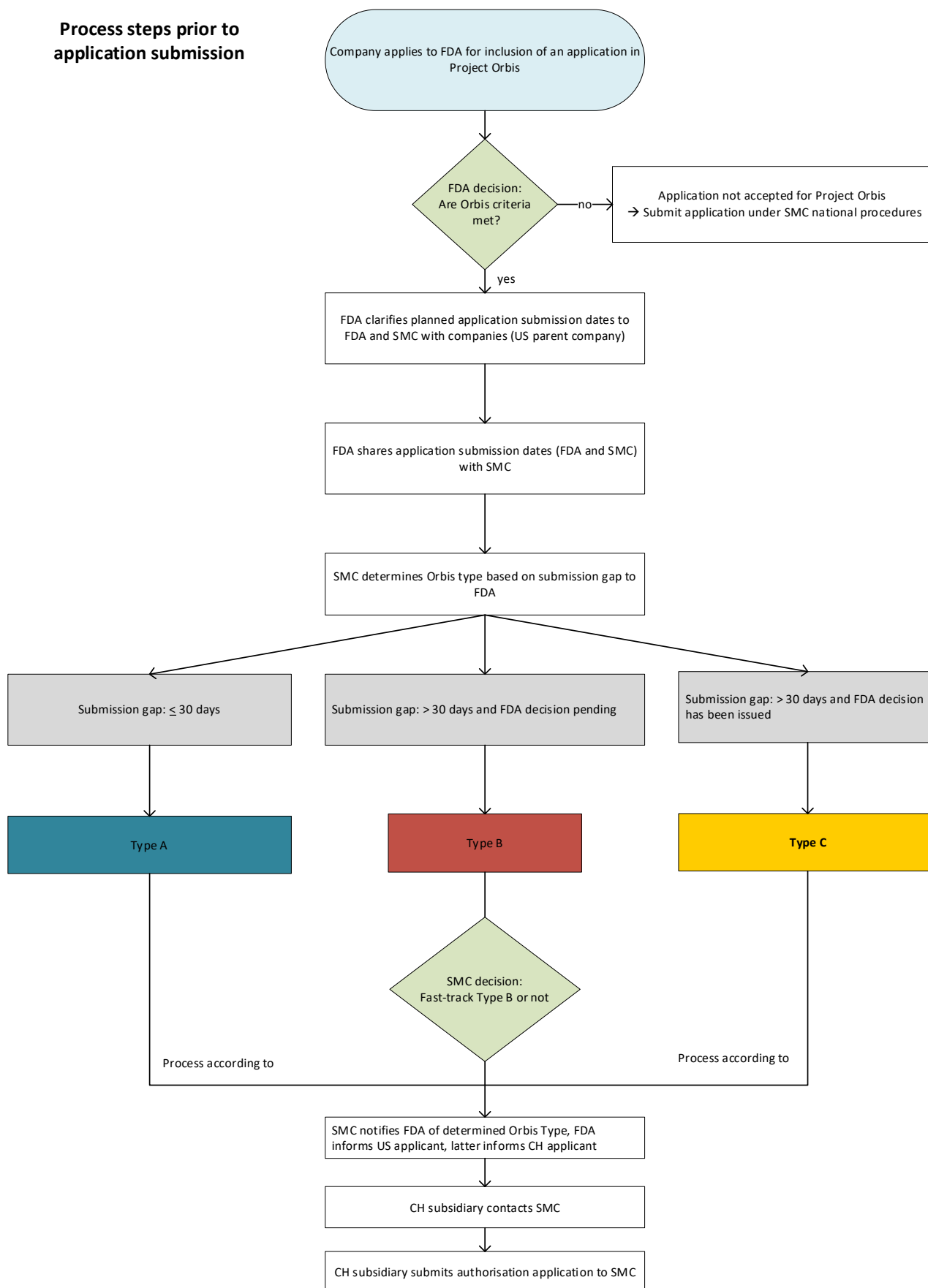
The responses must be submitted to all authorities involved with the application as concurrently as possible. The responsible Regulatory Manager and projectorbis@swissmedic.ch must be notified by e-mail of the upload. For non-fast-track Type B and Type C applications, Evaluation phase I generally concludes with a LoQ.

5.2.5.3 Preliminary decision

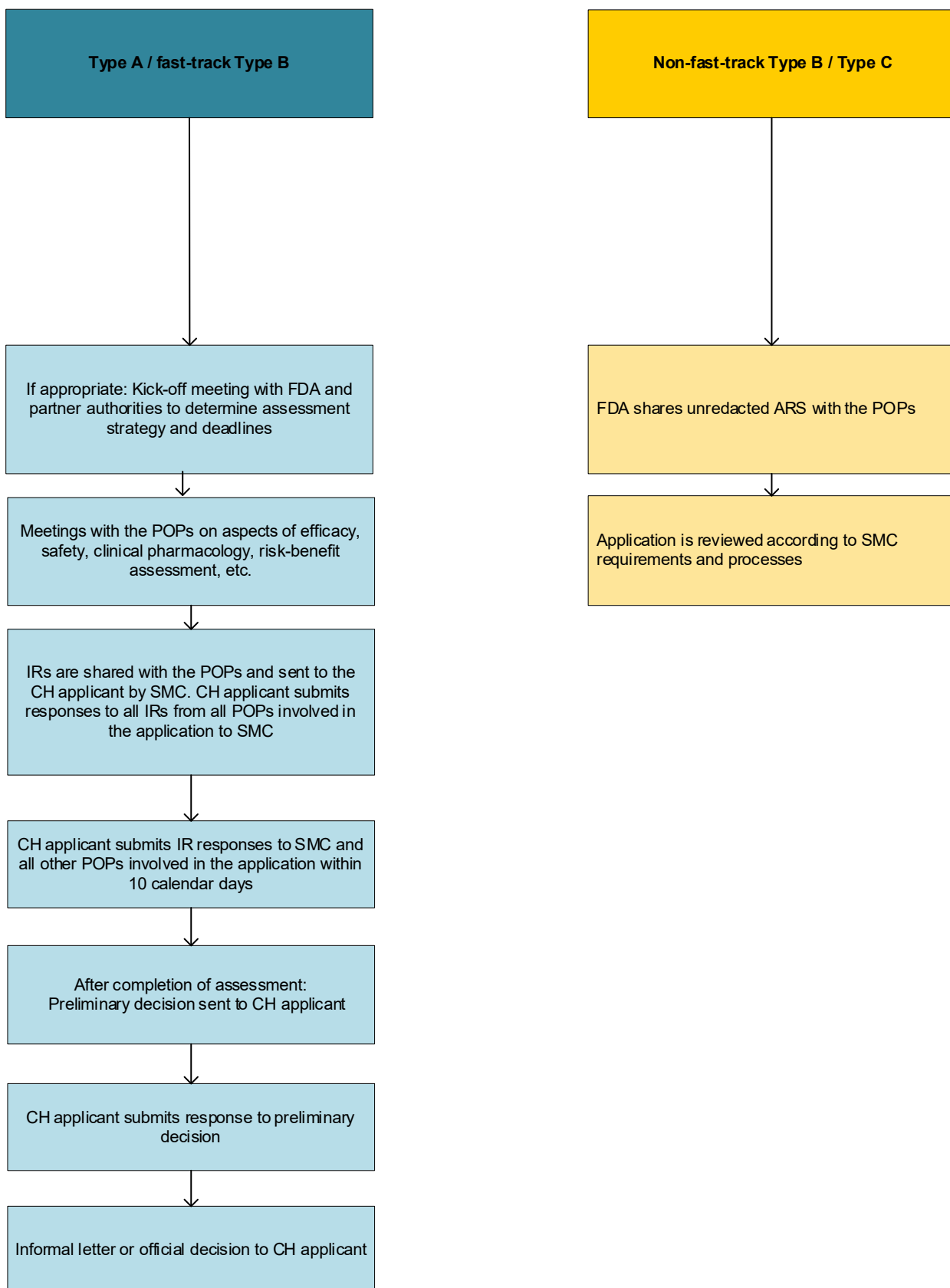
For Type A and fast-track Type B applications, Swissmedic sends a preliminary decision to the applicant in Switzerland at the end of Evaluation phase I (the IRs having replaced the LoQ). For eCTD submissions a consolidated eCTD sequence containing all responses to the IRs made by all authorities has to be submitted with the response to the preliminary decision. Swissmedic will also consider responses to IRs received up to the date of the decision. Type C and non-fast-track Type B applications are subject to the standard procedure.

Annex 1 – Flow Chart

Process steps prior to application submission



Process steps after application submission



Change history

Version	Change	sig
4.0	Editorial changes, Orbis Type A and fast-track Type B processes clarified	fg, cuf, ate
3.1	New layout, no content adjustments to the previous version.	dei
3.0	Clarification in section 6.2: Notification of the Information Request directly to the applicant in Switzerland	rim, ru, wph, fg
2.0	Section 2: Israel new partner authority in Project Orbis Linguistic clarifications New Annex 1 with flow chart	rim, ru, dts
1.0	New document	rim, ru, wph, dts