swissmedic

Guidance document

Involvement of patient organisation in the review of Patient Information

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List of contents

1 Terms, definitions, abbreviations

1.1 Patient information

The Patient Information (PI) document required by therapeutic products legislation is produced by the marketing authorisation holder according to a predetermined structure[1] and is then checked and approved by Swissmedic in the context of authorisation applications (new authorisations and/or variations). In the PI, patients can find information – for example about administration and composition, contraindications and possible undesirable effects and interactions – in language that is understandable to a lay readership.

The PI must be produced in German, French and Italian and must be enclosed, in printed form, in the product packaging as a package leaflet.

All PIs approved by Swissmedic for human medicinal products authorised for the Swiss market can be viewed in the aforementioned languages at www.swissmedicinfo.ch.

1.2 Abbreviations

AI	Additional indication
APA	Administrative Procedure Act (SR 172.021)
CD	Calendar days
LoQ	List of Questions
MPI	Medicinal product information
MS	Milestone
NA	New Application/New Authorisation
NAS HMP	Human medicinal product (HMP) with New Active Substance (NAS)
PI	Patient Information
PORs	Representatives of patient and consumer organisations
PD	Preliminary Decision
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, SR 812.21)
TPLRO	Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (Therapeutic Products Licensing Requirements Ordinance, SR 812.212.22)
WL	Guidance document

2 Introduction, objective and scope

During a pilot phase (2018 – 2020), the involvement of representatives of patient and consumer organisations (PORs) in the review of PIs during the authorisation of medicinal products – primarily new authorisations of human medicinal products with new active substances (NA NAS HMP) or additional indications (AIs) – was tested.

The aim of involving the patient/consumer standpoint in the review of the PI is to optimise the PI in respect of comprehension, retrievability and weighting of the information and its completeness. The

[1] Requirements stated in Article 14 and Annexes 5.1 to 5.4 TPLRO (SR 812.212.22)

involvement is not intended to completely rewrite the Patient Information but rather, through targeted comments from the standpoint of the patient and/or the layperson, to improve the comprehensibility of the text.

This guidance document (WL) applies to human medicinal products in the context of authorisation.

A POR may be involved for the following applications:

- New authorisation of medicinal product with new active substances under the standard procedure (NA NAS)
- New authorisation of medicinal product with new active substances under the fast-track procedure (NA NAS FTP)[2]
- New authorisation of medicinal product with new active substances under the procedure with prior notification (NA NAS PPN)[2]
- Authorisation extensions (AEs) that involve a revision of the medicinal product information (MPI)
- Type II variations that involve a revision of the MPI, e.g. AI

The process for variations to the PI is not described in this WL.

3 Legal framework

For the procedure for authorising medicinal products in Switzerland in accordance with Article 84, para. 1 of the Therapeutic Products Act (TPA, SR 812.21), the Administrative Procedure Act (APA, SR 172.021) basically applies unless otherwise specified in the TPA. The TPA regulates the requirements relating to the handling of therapeutic products, particularly their manufacture and placing on the market. According to the APA, only the applicant and Swissmedic are involved in the authorisation procedure. There is no special provision in the TPA for any involvement of third parties in ongoing authorisation procedures. If PORs are to be involved in the review of PIs, this cannot take place in connection with an administrative procedure itself, but only in parallel, in a direct exchange between patient and consumer organisations and applicants.

A PI is basically required for all human medicinal products in dispensing categories A to D, excluding those pharmaceutical forms specified in Article 14, para. 2 of the Therapeutic Products Licensing Requirements Ordinance (TPLRO, SR 812.212.22), which are used exclusively by doctors or dentists (parenterals, for example infusions or injections).

For these products, the Information for Healthcare Professionals (IHP) is enclosed in the packaging.

The structure of the PI is regulated in Article 14 in conjunction with Annex 5.1 of the TPLRO. The WL *Product information for human medicinal products HMV4* provides further details on the specific requirements and provisions in the *Notes on the Patient Information* section.

[2] Applications under the fast-track procedure and applications under the procedure with prior notification are possible in consultation with Swissmedic and PORs if they can be processed within the specified applicant time limits.

4 Responsibilities

4.1 Swissmedic

Swissmedic assumes the role of a mediator between the applicant and the patient or consumer organisation/POR, but is not actively involved in the exchange between these two parties during pending applications.

Working with the patient and consumer organisations, Swissmedic creates and updates a List of PORs with the names and addresses of the organisations, first names and surnames and e-mails of the contact persons who are available for any review of PIs. The list also contains details of any special expertise and language skills (see the sample List of PORs for the PI Review in Annex 8.5). Swissmedic will supply the updated POR list to the applicant on request subject to the signing of a "Confidentiality agreement and use restriction" letter (see template in Annex 8.4).

Swissmedic is ultimately responsible for the definitive review and approval of a PI.

4.2 Applicant

The applicant undertakes to treat the List of PORs in confidence and, to this end, signs the "Confidentiality agreement and use restriction (to be signed by applicant)" letter (see template in Annex 8.4). On receipt of this signed letter, Swissmedic sends an updated list to the corresponding applicant.

The applicant is responsible for initiating and coordinating the exchange with the PORs.

When submitting the application, the applicant informs Swissmedic of its willingness to involve a POR in the review of the PI (ideally by means of a note in the cover letter to the application).

After submitting the application to Swissmedic, the applicant asks the POR whether it would be able to carry out a review. The applicant informs the POR that a preliminary decision may be issued by Swissmedic directly (without an LoQ) and that, as a result, the deadlines can be brought forward.

Where possible, the applicant will provide the POR with any feedback on its contributions.

4.3 Representatives of patient and consumer organisations

The PORs undertake to treat all information provided by the applicant in confidence and sign a corresponding confidentiality agreement and use restriction (see template in Annex 8.3).

The text manuscripts (PI / IHP) exist in the correspondence language of the applicant and can therefore be drafted in DE, FR or IT, which requires the PORs to possess the corresponding language skills.

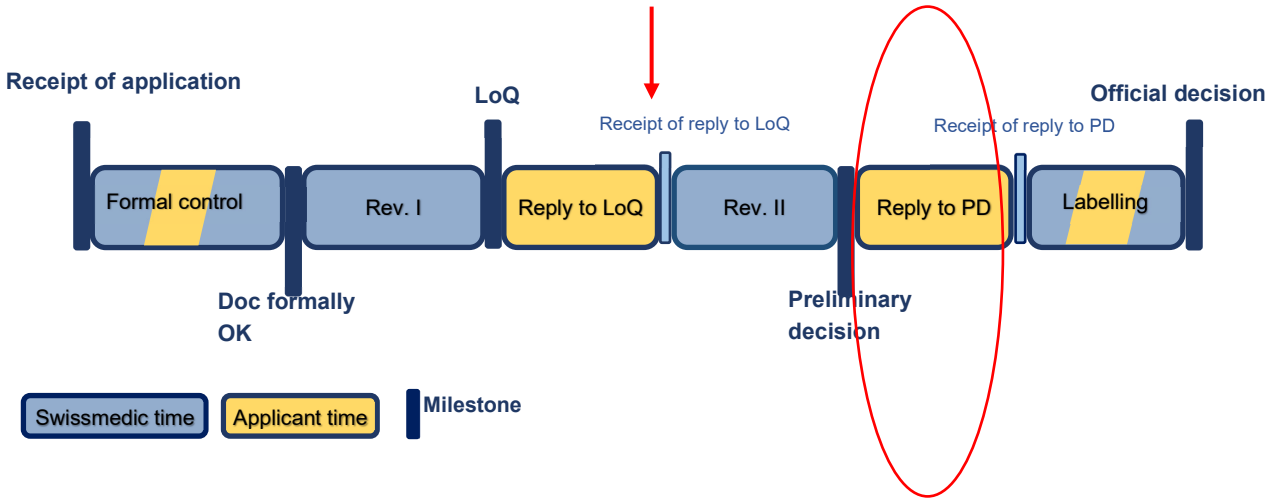
5 Process

5.1 General

The involvement of PORs in the review of PIs takes place in the following review phases:

- Applicant request to POR **at the latest** by the "Receipt of replies to LoQ" milestone (MS).
- Review of PI by POR during the "Reply to PD" procedure section

Request Review



5.2 Sequence

See also the flowchart in Annex 8.1

5.2.1 Step 1 – Request to patient organisation

At the latest by the "Receipt of replies to LoQ" MS, the applicant asks one POR (or several PORs) whether it (they) would be prepared to carry out a PI review. The selected organisation should preferably possess expertise in the indications of the notified medicinal products and the corresponding language skills. Applicants can obtain an updated List of PORs from Swissmedic at any time (see Annex 8.5). To this end, they sign the "Confidentiality agreement and use restriction (to be signed by applicant)" beforehand, as shown in Annex 8.4 by way of example.

If Swissmedic does not have any questions about the application, i.e. the "LoQ" is not necessary, the applicant must make sure to ask the POR in good time and point out that the review of the PI should ideally take place at an earlier stage.

Within 10 calendar days (CD), the corresponding POR answers the request and informs the applicant whether it will be able to review the PI at the scheduled time. By the PD at the latest, it should be clear whether a subsequent review of the PI by a POR will take place.

5.2.2 Step 2 – Review of the Patient Information

Swissmedic sends the LoQ and the corrected IHP to the applicant, followed by the PD and the corrected PI (possibly including an updated version of the IHP with the same status).

If the POR has agreed to the review (reply within 10 CD of the request at the latest), the applicant sends the revised version of the PI to the POR as soon as possible after the PD. The corresponding IHP (revised and with the same status) is also sent to the POR by the applicant as a supporting document.

The time limit for replying to the PD is 60 CD and corresponds to applicant time (shown in yellow in the diagram above, taken from the guidance document *Time limits for authorisation applications HMV4*). The POR must complete the review of the PI within this period, and deadline extensions

arising from the review of the PI by the POR are not possible. The POR has 7 CD (i.e. 5 working days) in which to review the PI.

The involvement is restricted to this one consultation round after the preliminary decision MS. No further consultation rounds take place.

Documents are exchanged in Word format, and applicants' secure e-mail transfer systems are used.

5.2.3 Sequence for a new indication, new dosage recommendation, new pharmaceutical form and variation of the medicinal product information (type II and authorisation extensions AEs)

For applications for authorisation, authorisation extension or extension of an indication, a new dosage recommendation or for applications for variation of the medicinal product information, only the specific section of the Patient Information that is affected by the change may be revised.

6 Criteria for the review

For the review of the PI by the POR, the criteria detailed in the following sections 6.1 to 6.3 are of primary relevance. The checklist in Annex 8.2 can serve as a guide.

6.1 Comprehensibility

The contents of the PI should be quickly and accurately fully understood by the reader. Since the PI involves written information, in addition to the readers' understanding of the content, the text structure and text layout should if possible be taken into account for ease of comprehension.

The **comprehensibility** of the PI can be characterised with the aid of the following four aspects:

1) Simplicity
- Simple sentences, not too long
- Common terms or short paraphrases
- Any foreign words or technical terms used should be explained

2) Structure and arrangement
- Logical structure according to the content (“a common thread is discernible”)
- Visual structure, e.g. with additional headings, paragraphs, lists

It should be noted, however, that the main headings (section titles) and their sequence are specified by law (TPLRO; SR 812.212.22) and may not be changed.

3) Brevity and conciseness
- No rambling sentences, but also not too short, "As long as necessary, but as short as possible"
- Wherever possible, address the patient directly

4) Additions to stimulate interest
- For example, illustrations are included, e.g. showing the correct use of the product

6.2 Retrievability

The review of **retrievability** ensures that the most important information for the patient/consumer can be retrieved quickly in the text without great effort. The structure and arrangement play a major role here.

The most important information for the patient/consumer includes:

- What the medicinal product is used for (indication)
- How, when and how often the medicinal product is taken
- Under what circumstances the medicinal product may not be taken and what precautions should be observed (in order to avoid possible serious side effects or identify them early enough, etc.)
- The possible side effects of the medicinal product
- What can be done in the event of a side effect, if a corresponding recommendation exists

6.3 Completeness

The review of **completeness** ensures that no questions are left unanswered in respect of the information that is most important for the patient/consumer.

If the correct administration of a medicinal product for inhalation is involved, for example, all the steps needed for correct administration should be described.

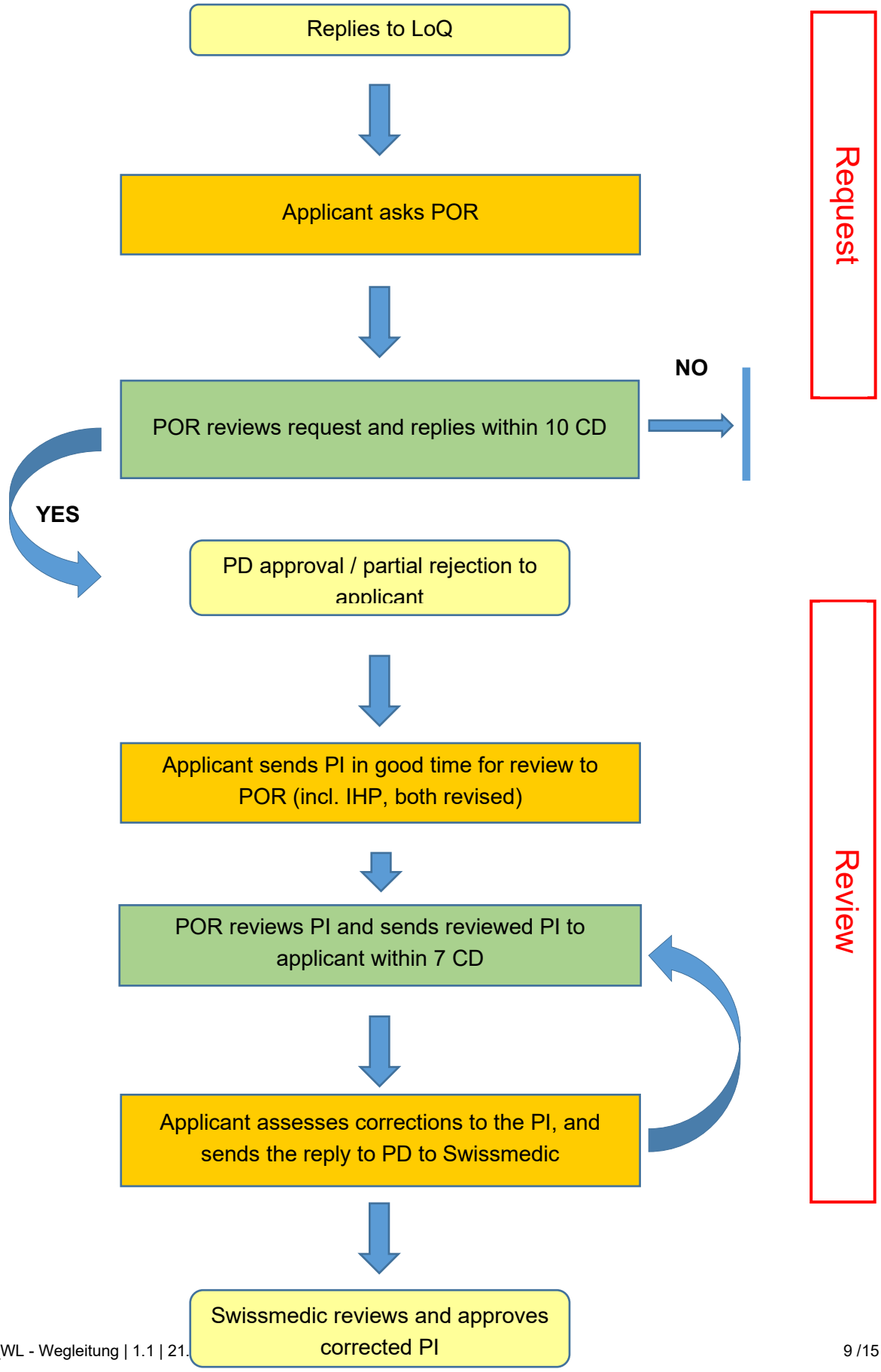
The review of completeness does not include other information of possible interest, e.g. on alternative treatment options or on the results of clinical trials. The Patient Information does not go beyond the information included in the Information for Healthcare Professionals.

7 Fees

The fees stated in FeeO-Swissmedic apply. The involvement of PORs in the review of the PI does not change anything in relation to the existing fees.

8 Annex

8.1 Procedural sequence (flowchart)



8.2 Further instructions and checklist for POR

The review of the PI by PORs focuses primarily on the main criteria, stated in section 6, of the comprehension, retrievability and completeness of the information. The checklist below can be used to document the PI review.

If the applicant has specific questions for the POR about a particular text section, it can highlight this text section in the document and insert its specific questions.

The POR inserts any comments and suggested changes directly in the document itself using “Track Changes” mode in the corresponding word processing program, so that all changes made to the document are visible as such. A general comment is inserted using the “Insert Comment” function. A specific proposed change, e.g. revised wording, should be made directly in the text using "Track Changes" mode. Comments and proposed changes should be entered in German or French, not in English.

If the POR's comments and inputs are not returned in time, it is left to the discretion of the applicant to determine whether these still need to be taken into account. Any failure by the POR to observe the deadline must not lead to delays in the process. Requests by the applicant to extend the deadline as a result of the involvement of a POR in the review of the PI are not possible.

Checklist for POR

Receipt of documents	Date:
Deadline	Date:
Confidentiality agreement	Exists ☐

Criteria for the review - Generally

1) Comprehensibility		**Remarks**
Simplicity	Are the sentences simple and clearly formulated?	
	Are the terms used in common parlance?	
	Are all the technical terms explained in a readily understandable way?	
Structure	Is the text structured and arranged appropriately within the specified sections?	
	Would additional headings in the text improve comprehensibility?	
	Would additional paragraph breaks improve comprehensibility?	

Brevity and conciseness	Are there any over-long text passages that could possibly be shortened?	
	Is the patient addressed directly?	
Additions to stimulate interest	Could a situation be made more comprehensible by means of an example?	
	Could a situation, e.g. the correct administration, be presented more clearly using an illustration / photo?	
2) Retrievability		**Remarks**
What is the medicinal product used for (indication)?	Retrievable without great effort Yes ☐ No ☐	
How, when and how often is the medicinal product taken?	Retrievable without great effort Yes ☐ No ☐	
What are the possible side effects of the medicinal product?	Retrievable without great effort Yes ☐ No ☐	
3) Completeness		**Remarks**
Is the correct method of administration adequately explained?	Yes ☐ No ☐	
Is any important information missing? If so, what?	Yes ☐ No ☐	

8.3 Template for confidentiality agreement and use restriction (to be signed by POR)

Before the PI to be reviewed is sent by the applicant, the defined POR(s) must have signed a corresponding confidentiality agreement, which is retained by the applicant. The following template can be used for this purpose.

Confidentiality agreement and use restriction

Administrative details

Name of the product: ……
Name of the applicant: ……

With the following declaration

…….....
(First name and surname of the patient/consumer organisation representative, POR)

.....
(Name of the represented organisation)

undertakes to preserve the confidentiality of all transmitted information.

Preamble

In connection with the involvement of patient and consumer organisation representatives (PORs) in the review of the Patient Information (PI), the applicant shall provide a patient or consumer organisation representative, during the ongoing authorisation procedure, with a – hitherto not officially approved – PI and with further information from the authorisation procedure (subsequently referred to as Confidential Information) for review and assessment of comprehensibility for a lay readership according to the separate process description.

By observing the following points, I shall ensure the confidential and designated treatment of the Confidential Information provided by *(name of applicant)*:

1. I undertake to keep secret all the Confidential Information provided to me.
2. I shall use all the Confidential Information transmitted to me exclusively for the purpose of reviewing and assessing the Patient Information provided to me.
3. I shall avoid any conflicts of interest in my activity connected with my involvement in this project.
4. I shall not forward any Confidential Information to third parties. If any involvement of other members of my organisation seems appropriate, and subject to the consent of the applicant, these individuals must also sign a corresponding confidentiality agreement before they are involved in the review and assessment of the PI.
5. I am aware and agree that all rights (particularly property/protective rights) to the Confidential Information made available to the patient and consumer organisation representatives under

this agreement shall remain with the applicant. All copies of the Confidential Information become the exclusive property of *(name of applicant)* and receive the same protection as the original.

6. I am aware and agree that the duty to maintain confidentiality shall continue for as long as the applicant has an interest in this.
7. This declaration is subject to Swiss substantive law. The sole place of jurisdiction is Bern.

Place, date: .....

Signature of patient/consumer organisation representative

.....

First name, surname Signature

8.4 Template for confidentiality agreement and use restriction (to be signed by applicant)

This "Confidentiality agreement and use restriction (to be signed by applicant)" letter is required both by Swissmedic before it sends the List of PORs to the corresponding applicant and then by the consulted POR.

The following template can be used for this purpose.

Confidentiality agreement and use restriction

Preamble

In connection with the involvement of patient and consumer organisation representatives (PORs) in the review of the Patient Information (PI), the applicant shall provide a patient or consumer organisation representative, during the ongoing authorisation procedure, with a – hitherto not officially approved – PI and with further information from the authorisation procedure for review and assessment of comprehensibility for a lay readership according to the process description.

For contacting the participating PORs, Swissmedic shall provide the applicant with a list including the following details:

- Name and address of the organisation
- First name and surname of the contact person
- E-mail of the contact person
- Special expertise of the contact person, including language skills

By observing the following points, (*name of company*) shall ensure the confidential and exclusively designated treatment of the data provided in the above-mentioned list (“Confidential Data”):

1. It undertakes to keep secret all the Confidential Data provided.
2. It shall use the Confidential Data transmitted to it exclusively in connection with the pilot project described above.
3. It shall not forward any Confidential Data to third parties or use the data for other projects within the company.
4. This declaration is subject to Swiss law. The sole **place of jurisdiction** is **Bern**.

The obligations stated above do not apply to such data, or parts thereof, which

a. (*name of company)* was aware of before receipt, or
b. are / were generally accessible.

Place, date: .....

Company XY/Applicant

Place, date:_____ Place, date:_____

_____ _____
Name Name
Title Title

8.5 Sample List of PORs for PI Review

Potential applicants should contact **networking@swissmedic.ch** for an updated List of PORs that can be involved in the PI Review.

Confidential document:
Involvement of PORs in the PI Review, Annex 9.5: List of PORs

Organisation	Contact person			Language skills		
Name, address	First name and surname	E-mail	Special expertise	DE	FR	IT

Change history

Version	Change	sig
1.1	Clarification in section 4.1.	stb
1.0	First version	stb