1 Formal requirements

1.1 Does the applicant need to possess the necessary licences in order to transfer the authorisation of a medicinal product, or is a Swiss delivery address sufficient?

On the date the application to transfer the authorisation is submitted, the future authorisation holder must satisfy the authorisation conditions specified in Art. 10 TPA (licence, registered office/branch in Switzerland).

1.2 We are a company based in a European country and plan to arrange for an authorised medicinal product to be transferred to our company. Is this possible, or do we need to have a branch in Switzerland?

On the date the application to transfer the authorisation is submitted, the future authorisation holder must satisfy the authorisation conditions specified in Art. 10 TPA (licence, registered office/branch in Switzerland).

1.3 Two medicinal products that are basic products with linked co-marketing authorisations are to be transferred to a new authorisation holder. Is the obligation stipulated in the originally submitted form for the new authorisation of a co-marketing medicinal product, i.e. that "the authorisation holder of the basic product, the authorisation holder of the co-marketing medicinal product and the person responsible for manufacture undertake to keep each other updated about the documentation and incidents relating to quality, efficacy and safety during use of both medicinal products" automatically transferred to the new authorisation holder, or does an updated form or some other document have to be submitted for this purpose.

A new form does not need to be submitted since the obligation is transferred automatically.

1.4 For eCTD authorisations, does the application for the transfer of authorisation also need to be submitted as an eCTD? What is the procedure if the current authorisation holder fails to provide the eCTD life cycle before the authorisation is transferred?

The application should be submitted as an eCTD if the medicinal product is subsequently managed in the eCTD format (which would be greatly welcomed by Swissmedic). If the eCTD life cycle cannot be provided by the current authorisation holder before or after a transfer of authorisation, the application can also be submitted on paper. Further details can be found in the *Formal requirements* guidance document, section 2.1 Submission formats (page 9 *"Life cycle following the transfer of authorisation"*).

1.5 We plan to transfer the authorisation for a medicinal product and would simultaneously like to change the name of the medicinal product and submit product information texts adapted to the reference product. Can we submit these applications as a multiple application?

No, multiple applications are not possible for a *transfer of authorisation*.

1.6 Can a co-marketing authorisation be transferred to another authorisation holder, or is the existing co-marketing terminated and a new one initiated with the other authorisation holder in this scenario?

The authorisation for the co-marketing medicinal product can be transferred to another company if the authorisation holder of the basic medicinal product consents to this procedure.
A new declaration of consent by the authorisation holder of the basic medicinal product will therefore need to be submitted.

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1.7 For the transfer of an orphan drug status (ODS), the consent of the existing holder of the ODS is required. In our case this is no longer possible because the holder has been deleted from the commercial register as a result of its merger with the company to which the ODS is to be transferred and therefore no longer exists.
In this situation can we apply for the ODS to be transferred without a declaration of consent and e.g. refer to the commercial register extract (merger) instead?

In this situation it is possible to submit a relevant extract from the commercial register relating to the legal successor instead of the declaration of consent.

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2 Regulatory questions

2.1 During a transitional period of 1 year it is permissible to refer to the new authorisation holder on newly released batches by way of a sticker affixed to the outer packaging. Does this sticker covering over the previous authorisation holder need to be affixed only to the secondary packaging (e.g. folding carton) or to the primary packaging as well (e.g. label)?

During the transitional phase of up to 1 year, the previous authorisation holder only needs to be covered over on the outer packaging. Affixing a sticker on e.g. the label is not necessary (see also the guidance document "Transfer of marketing authorisation", section 5.1.3.2).

2.2 What pharmacovigilance activities are needed, and if so when, in connection with a transfer of marketing authorisation? Does an application need to be submitted together with e.g. a "Summary of the PV system"?

Following a transfer of marketing authorisation, a separate application with an updated module 1.8.1 does not need to be submitted. The change can be taken into account during a future variation application when these documents need to be submitted.

2.3 We plan to take advantage of the transitional period in connection with the transfer of authorisation and affix a sticker. Does a GMP certificate need to be submitted for this purpose? Does the covered-over product need to be released again?

While Swissmedic does not consider a manufacturing licence to be necessary for affixing a sticker with the name and registered address of the new authorisation holder, the authorisation holder is responsible for ensuring that the affixing of the sticker does not adversely affect the quality or traceability of the labelled batches.

2.4 Section 5.1.2.3 of the guidance document *Transfer of marketing authorisation* states the following: "...After one year at the latest, the authorisation holder may only release and place on the market batches featuring the new authorisation holder...". We are not clear how the definition of "place on the market" should be interpreted. Are all released batches automatically considered to be "placed on the market"?

All medicinal products whose batches were released by the Responsible Person (RP) before the official decision to approve the transfer of authorisation was received are considered to be placed on the market. Therefore, these medicinal products do not need stickers to be affixed even if they are still in the warehouse of the authorisation holder. This also means that products with stickers may continue to be sold even more than 1 year after the transfer of authorisation, provided they were already released at an earlier time by the RP of the previous authorisation holder.

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3 Other questions

3.1 Our company is the legal representative for an authorisation holder of an orphan drug status (ODS). The holder intends to transfer the ODS to a future holder in accordance with the "Orphan Drug" guidance document.

Is any action on our part required in order to complete the transfer?

The function of the legal representative "lapses" with the transfer of the ODS. If the legal representative is to be retained, this should be notified by the future holder by including a power of attorney in the application for the transfer of the ODS. No further action is required.

3.2 We plan to transfer to our company the authorisation of a medicinal product that is stored and transported at refrigerator temperatures.
We would like to make use of the transitional period for modifying the packaging, information for healthcare professionals and patient information.
In view of the practical difficulties associated with affixing stickers onto refrigerated products, we wonder whether an alternative to a sticker would be admissible that would still allow us to place newly released batches on the market during the transitional period.

All products that are released for the market after the transfer must either have modified packaging or be provided with a sticker. Only those products that have already been released for the market do not require an adhesive label.
The requirements of the guidance document apply:
If the former authorisation holder has a permit for wholesale trading in medicinal products, it may continue – in its capacity as wholesaler – to sell those batches which it released for sale prior to the transfer of authorisation. If the new authorisation holder also has a permit for wholesale trading, it is possible that an agreement may be concluded between the former and the new authorisation holders for taking over batches already released for the market. Unless aspects relating to GDP are affected, however, such an agreement will come under private law.

3.3 How long does it take to process an application for the transfer of authorisation? In other words, how long is the period between application submission and the issuing of the approval decision?

The application must be submitted at least 3 months before the company's preferred date.
Provided the documentation is complete and satisfies the legal requirements, the transfer is subsequently approved by the desired date.

3.4 During a transfer of authorisation, a *change in the name* of the medicinal product concerned cannot be submitted as a combined multiple application.
When should the name change be submitted (at the same time, before, afterwards), and who should submit the application (new or old MAH)?
Since the corporate design and logo usually have to be changed as well, would the name change have to take place beforehand (with the "old" design) or at the same time (separate application for variation of a medicinal product name and simultaneously new design / logo in parallel with the transfer)?

The application can be submitted at any time.
If the application for a variation of the medicinal product name is submitted before, or in parallel with, the application for transfer, this can be done by the previous authorisation holder or the new authorisation holder with a corresponding power of attorney.
Ideally, the application for a variation of the name of the medicinal product should be submitted 60-70 days before the transfer date. The submitted transfer application and the application for a variation of the medicinal product name should each include a reference to the other application. Swissmedic will then be able to coordinate these two applications.

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The application for a variation of the medicinal product name is normally concluded on the day after your desired transfer date.
Naturally, the name of the medicinal product can also be changed by the new authorisation holder at a later date.

3.5 How can the future authorisation holder submit an application for transfer of the authorisation to Swissmedic via the eGov portal?

Section 5.2.13 of the information sheet on *Swissmedic eGov Portal standard functions* describes the procedure for submitting an authorisation transfer and states that the delivery type *Application for authorisation transfer* should be used. See the information sheet for further details on this procedure.

3.6 We have submitted a paper-based application for the transfer of authorisation. Unfortunately, I have not received a confirmation of receipt, nor is anything to be seen on the portal.

Swissmedic does not issue a confirmation of receipt for paper-based submissions. Registered mail can be tracked by the sender via the postal service.
The (still) current authorisation holder can view the application on the portal. The new authorisation holder can view its (future) medicinal products only after the transfer has been officially approved.

3.7 We have submitted an application for the transfer of authorisation with a desired date of 1 August 2022. However, according to the timeline on the portal, the date for Evaluation I is not until 24 March 2023. Can we nevertheless expect the application to be concluded with our desired date, since it was submitted on time at least 3 months before the planned date?

The deadlines shown on the portal for the transfer of authorisation are theoretical values. As soon as your application is processed, the conclusion date will be changed accordingly. If the application for transfer is not submitted at least 3 months beforehand, Swissmedic will contact the applicant.

3.8 When the authorisation is transferred to a new authorisation holder, does the authorisation number also change?

The authorisation number does not change when the authorisation is transferred.

3.9 We plan to transfer the authorisation of a medicinal product. Several variation applications relating to this medicinal product are being processed by Swissmedic. If the authorisation has been transferred, who will receive the corresponding official decisions when the variation applications are concluded?

After transfer of the authorisation, all correspondence (including that regarding ongoing variations submitted by the former authorisation holder) will be sent to the new authorisation holder.

3.10 Is it possible for a medicinal product that is still being processed in an ongoing first authorisation procedure to be transferred to another company/authorisation holder?

Yes, a change of applicant during an ongoing first authorisation procedure is possible.
The requirements of the guidance document *Transfer of marketing authorisation* apply, apart from the fact that the medicinal product may not be distributed until it is authorised and the packaging elements are modified in the actual authorisation procedure.

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3.11 Section 5.2.12, Submission of an authorisation transfer, of the information sheet on "Swissmedic eGov Portal standard functions" states the following on page 18: ***"Please note: During the 5 days prior to the submission of the authorisation transfer, no other application may be submitted by the existing authorisation holder. Only after the re-registration is complete may the new authorisation holder submit new applications."*** **We are not sure about this statement. Please can you explain it in other words?**

The waiting period of 5 days prior to the submission of the application for the transfer of authorisation relates to application submissions by the currently valid authorisation holder. Once the application for the transfer of authorisation has been submitted by the future authorisation holder, the currently valid authorisation holder can continue submitting further variation applications up to the date of the transfer. As of the date of the official approval of the transfer, only the newly valid authorisation holder may submit applications.

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