Information sheet
Archive access

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1 Objective

In accordance with the corresponding legal requirements, Swissmedic archives documents submitted by companies in connection with administrative procedures and new documents created during the course of procedures. On request, companies can gain archive access to view their company's own records of **concluded** procedures. For reasons of efficiency, archive access is provided by preparing the requested documents for the attention of the company in digital form. This service is chargeable.

2 Scope

This document regulates the practice and fees relating to requests for access to Swissmedic's archive material. This ruling does **not** apply to

- Requests for access to live records (pending proceedings),
- Requests for access to records according to the AA (Federal Archiving Act, SR 152.1) and
- Requests for access to records according to the FoIA (Federal Act on Freedom of Information in the Administration, SR 152.3).

The document is intended for all persons who are entitled to inspect the archive of Swissmedic and for Swissmedic personnel who carry out related tasks.

3 Description

3.1 Process description

3.1.1 Ordering and order clarification

Applications for archive access can be submitted to Swissmedic in writing or by e-mail (esubmission@swissmedic.ch). During the order process Swissmedic communicates with the applicant by e-mail.
The competent department at Swissmedic is Operational Support Services. For the purpose of order clarification, OSS checks the availability of the documents in the archive and resolves any uncertainties in consultation with the applicant.

3.1.2 Offer and declaration of consent

As soon as the volume of the ordered documents is ascertained (number of paper documents to be scanned, number of digital documents, number of medicinal product dossiers), Swissmedic prepares a cost estimate and provides the applicant with a corresponding upper cost limit. The applicant issues the order by e-mailing the declaration of consent.

3.1.3 Preparation, delivery and invoicing

Swissmedic then executes the order as follows: Paper documents are scanned, electronic documents are compiled, medicinal product dossiers (records relating to the business case) are edited so as to remove all internal Swissmedic information (i.e. internal administrative records of a non-evidential nature used exclusively for internal decision-making, such as notes or draft decisions).
If permitted by the data volume, the documents are delivered by electronic file transfer (service of the Federal Office of Information Technology, Systems and Telecommunication). Otherwise, the documents are sent on a data medium (CD/DVD) by post. On completion of the delivery, the service is billed by an invoice sent under separate cover.

3.1.4 Processing period

Since the provision of archive access is not a core task of Swissmedic, the processing periods are based on the size of the order and the currently available staff capacities. The applicant is informed of the processing period together with the offer (paragraph 3.1.2).

3.2 Costs

3.2.1 Basic information

The archive access according to this Information sheet is charged at a cost-covering hourly rate of 270 Swiss francs in accordance with Art. 4 para. 1 of the Therapeutic Products Fees Ordinance (FeeO, SR 812.214.5). Investigations that do not lead to a delivery of documents are not invoiced. No digitisation costs are charged for documents that already exist in digital form. Standardised time-based rates are charged for the digitisation of folders and loose-leaf binders and for the editing of medicinal product dossiers (paragraph 3.2.2).

3.2.2 Cost rates

The costs for preparing documents from the archive are calculated on the basis of the following rates:

Expense item	Labour
Digitisation of federal lever arch file and loose-leaf binder	0.2 hours (all-in rate)
Digitisation of medicinal product dossier	by time
Editing of already digitised medicinal product dossier	0.25 hours (all-in rate)
Specific follow-up enquiries and searches	by time
Administration (order processing, upload/delivery)	by time, max. 5 hours

The costs for order processing are calculated from the sum of the chargeable items multiplied by the hourly rate (paragraph 3.2.1). Only documents actually delivered/services actually provided are invoiced. However, the invoice shows a total sum without detailing the individual expense items. No charge is made for orders involving less than half an hour of work.

Change history

Version	Change	sig
2.0	New service fee based on revised FeeO	ni
1.3	Footer with telephone number and contact email address changed	ni
1.2	New layout, no content adjustments to the previous version	tsj
1.1	New address inserted in footer	dei
1.0	**New document**	**ni**