1 Information for marketing authorisation holders on the introduction of the E2B(R3) format in Switzerland

Currently, Swissmedic accepts only E2B(R2) format for individual case safety reports (ICSRs) submitted by marketing authorisation holders (MAHs) via the B2B gateway (MAH I) and the Electronic Vigilance System (ElViS; MAH II), respectively. Following necessary modifications of its database system, Swissmedic has now started to plan the changeover of the reporting process for ICSRs from E2B(R2) to E2B(R3). This transition is currently expected to begin by the end of September 2024. The transition will be implemented in a step-by-step process. It is expected to take at least approximately 1.5 years to convert all MAHs to the new format, that already submit ICSRs via the gateway.

The Electronic Vigilance System (ElViS) cannot be adapted to the R3 format. Therefore, all MAHs that submit ICSRs via ElViS and are capable of exchanging ICSRs in E2B(R3) are recommended to migrate to the B2B gateway. For MAHs that use the “Direct insert” function of ElViS or have not yet been able to generate E2B(R3) files of their ICSRs, a front-end solution of the Swissmedic database will be provided for the exchange of ICSRs to R3 format. We currently expect that this front-end solution will be available in the course of 2025.

The changeover to E2B(R3) in Switzerland will be adapted as far as possible to the recommendations and procedures of the European Medicines Agency with regard to data elements and message specifications. Differences in the requirements between the EMA and Swissmedic will be addressed in a Swiss implementation guide.

2 Specific information for MAHs that already exchange ICSRs with Swissmedic via the B2B Gateway (MAH I)

These MAHs are requested to contact Swissmedic via pvgateway@swissmedic.ch until 1st July 2024 to express their interest in transitioning to R3 format. The request should include precise and binding information on time windows as of autumn 2024 in which resources are available for the test process as shown in the figure below. Following an internal planning process, Swissmedic will inform these MAHs of the exact timing of the test phase. As the respective MAHs already have a functional B2B gateway connection to Swissmedic, only compatibility checks in E2B(R3) format in a test environment are necessary before the go-live of the exchange of ICSRs in the new format. The duration of the process for a single MAH is expected to be approximately three months.

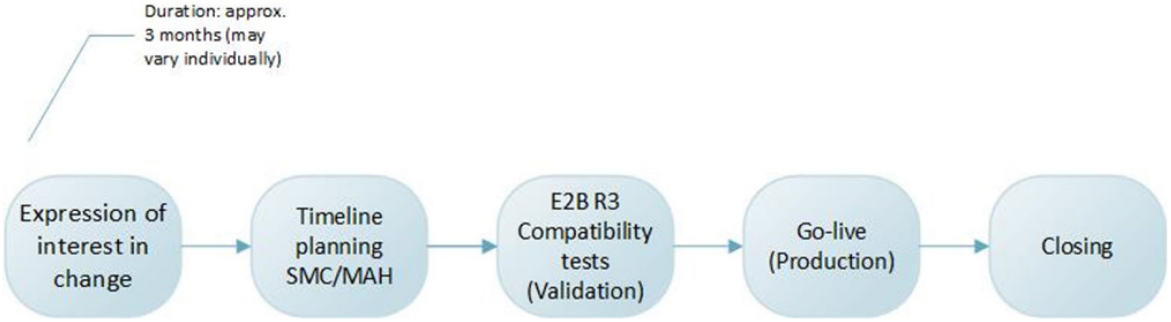

Figure 1 Procedure of the test phase for marketing authorisation holders that already exchange ICSRs with Swissmedic via the B2B Gateway

3 Specific information for MAHs that currently exchange ICSRs with Swissmedic via ElViS (MAH II) and are capable of and interested in exchanging ICSRs in E2B(R3)

Electronic reporting in E2B(R3) requires MAHs to have an ICH-E2B-compliant pharmacovigilance system. MAHs that now transmit ICSRs via ElViS must implement a gateway connection with Swissmedic as a first step. We recommend to send a letter of intent until the 1st July 2024 to facilitate the further planning process. See the instructions in the following factsheet
https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/mu/mu101_20_001e_mbguidanceforindustryelectronicexchangeoficsrsthro.pdf.download.pdf/mu101_20_001e_mbguidanceforindustryelectronicexchangeoficsrsthro.pdf
In parallel to the connectivity tests, compatibility for exchange in R3 format will be tested (Fig.2). The duration of the process for a single MAH is expected to be approximately three months.

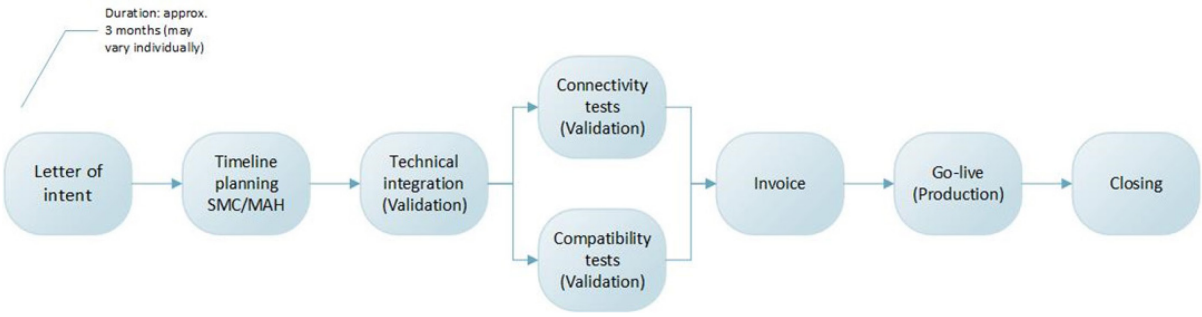

Figure 2 Procedure of the test phase for marketing authorisation holders that currently exchange ICSRs with Swissmedic via ElViS but are capable of exchanging ICSRs in E2B(R3)

4 Specific information for MAHs that use the “Direct insert” function of ElViS or have not yet been able to generate E2B(R3) files of their ICSRs

No specific actions are required at present. Swissmedic will provide information on when a front-end solution with E2B(R3) compatibility will be available in due course.

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