Swissmedic

Pharmacovigilance

Hallerstrasse 7

3012 Bern

Switzerland

 dd.mm.yyyy

**Letter of intent to access the PV Gateway solution for reporting ICSR originated from Switzerland**

Dear Sir or Madam,

Company XY declares its intention to submit Individual Case Safety Reports (ICSR) electronically to Swissmedic. Our preferred date for initiating the process of the implementation of the Gateway solution would be dd.mm.yyyy.

* We agree to pay the external activation costs of CHF 10,000 ahead of the initiation process.
* We will allocate the necessary resources to enable the integration of the gateway solution within 3 months.
* We are technically able to exchange ICSR electronically via AS1 or AS2 protocols.

Mr. ABC will be the person responsible for coordination with the following contact details:

Mr.ABC, Safety Manager

Email:

Tel:

Yours faithfully,

Mr. Z