To marketing authorisation holders / manufacturers of medicinal products distributed in Switzerland

Bern, 15.11.2023

**Declaration of consent**

**to sharing information on nitrosamines with partner authorities**

Please complete, sign and return the following declaration of consent to the following address:

Swissmedic

Market Surveillance

Hallerstrasse 7

3012 Bern

E-mail: market.surveillance@swissmedic.ch

**Declaration of consent to sharing information on nitrosamines with partner authorities**

The marketing authorisation holder / manufacturer (*delete as applicable, insert name*) hereby consents to Swissmedic sharing information compiled by Swissmedic during market monitoring on nitrosamine impurities in the medicinal products it manufactures / for which it holds marketing authorisation *(complete if the consent only applies to specific medicinal products*: namely: product name(s) marketing authorisation number(s)) as part of Swissmedic's involvement in the Nitrosamine Strategic Group (NISG) and the Nitrosamine Technical Working Group (NITWG) with international partners, for the purpose of exchanging information and as support for forming opinions.

This exchange is based on the following agreements ([www.swissmedic.ch/informationsaustausch](https://www.swissmedic.ch/swissmedic/en/home/about-us/international-collaboration/bilateral-collaboration-with-partner-authorities/agreements-on-information-exchange.html)). Swissmedic is thus authorised to provide its assessments to partner authorities1. These assessments may be used as part of a cumulative compilation of evidence, including for the assessment of comparable products or active ingredients. Any decisions on further administrative activities or potential administrative proceedings are made independently of any exchange of information with Swissmedic.

1 *Such assessments may include confidential data such as business secrets, experimental and analytical data on nitrosamine impurities as well as both positive and negative assessments by authorities.*

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Date, signature of Responsible Person(s)