Contents

1 Introduction

Swissmedic, the Federal Food Safety and Veterinary Office (FSVO), the Federal Office of Public Health (FOPH) and one representative of each of the Association of Cantonal Pharmacists and the Cantonal Chemists ("authorities") meet regularly as a cross-agency Expert Panel for Delimitation Questions ("Expert Panel") to discuss questions relating to delimitation and, accordingly, competence. These meetings enable experts to discuss questions relating to the delimitation of products and/or substances and reach agreement in order to clarify competence (e.g. for measures that need to be taken) and pursue an approach that is as uniform as possible. The exchange of information also enables an early and appropriate response to signals indicating new trends on the market.

2 Purpose of the Expert Panel

The Expert Panel provides the participating authorities with a platform for exchanging information as well as experience and for agreeing on competence. The following aims in particular are pursued:

- Exchange of information and opinions and intra-agency comparison in order to classify products/substances which cannot a priori be clearly assigned to an item of legislation
- Strengthening and refinement of the existing delimitation practice
- Development of best practices, taking into account the established court rulings
- Information and guidance for market players on the classification according to the current state of science
- Publication of consolidated opinions, joint information sheets or guidance documents for placing products on the market in a legally compliant manner
- Guidance to clarify competence questions and coordination on cross-agency competence

3 Legal standards

The Expert Panel deals with questions on the basis of the following legal norms which fall within the scope of competence of the authorities involved:

- Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; SR 812.21)
- Federal Act on Foodstuffs and Utility Articles (Foodstuffs Act, FoodA; SR 817.0)
- Federal Act on Protection against Dangerous Substances and Preparations (Chemicals Act, ChemA; SR 813.1)
- Federal Act on Narcotics and Psychotropic Substances (Narcotics Act, NarcA; SR 812.121)
- Tobacco Ordinance (TabV; SR 817.06). In the future: Federal Act on Tobacco Products and Electronic Cigarettes (Tobaccoproducts Act, TabPG)

4 Out of scope

- The Expert Panel does not handle delimitation questions relating to veterinary medicinal products/animal feed.
- The Expert Panel is not an enforcement body. Its expert assessment is a scientific evaluation intended to clarify delimitation questions and to coordinate enforcement.
- Directive and enforcement powers remain with the authorities designated for the respective legislation. It's their responsibility to implement the findings and recommendations of the Expert Panel.
- The Expert Panel does not offer advisory services relating to external business activities.

5 Participants

The number and composition of the Expert Panel's members should ensure that the questions arising can be handled with the necessary expertise.
The participating authorities guarantee the resources required to perform the tasks.

5.1 Representation of Swissmedic

The participation of Swissmedic ensures the expertise regarding the classification of medicinal products, including complementary and herbal medicines, medical devices and the enforcement responsibility of Swissmedic (therapeutic products legislation).

5.2 Representation of the FSVO

The participation of the FSVO ensures the expertise regarding foodstuff and utility items.

5.3 Representation of the FOPH

The participation of the FOPH ensures the expertise regarding chemicals, prohibited narcotics, and tobacco substitutes.

5.4 Representation of the cantons

One participant of each, the cantonal pharmacists and the cantonal chemists, ensures that the expertise and concerns of the cantons are taken into account.

6 Nature and frequency of meetings

The Expert Panel generally meets three times a year. The meetings are organised and hosted by Swissmedic.
The dates for the meetings are agreed at the last meeting of the year for the following year.

7 Principles of collaboration

7.1 Meeting chair

The meeting is chaired by Swissmedic.

7.2 Single Points of Contact of the representatives (SPoC)

Swissmedic, the FSVO and the FOPH each designate a SPoC who is responsible for the timely preparation of the agenda, the provision of the preparatory documentation and the communication with the SPoC in the other authorities. The SPoC for the cantons is the person representing the cantons.

7.3 Organisation and reporting

- Agenda

Swissmedic coordinates the preparation of the agenda before the meeting via SharePoint. The agenda is finalised and sent to all participants at least one week before the meeting.

- Minutes

Swissmedic generally prepares the draft minutes within the two weeks following the meeting and initiates consultation with all participants. Once feedback has been received from the participants, the minutes are finalised, taking into account the amendments, and sent to the participants as a .pdf document within one month.

7.4 Participation of experts

The Expert Panel may call in additional experts for special topics. They participate as guests for the respective agenda items.

7.5 Recommendations

The Expert Panel forms a consolidated opinion taking into account the current state science. The recommendations are not legally binding, but support the enforcement by the responsible competent authorities. The Panel decides which topics and recommendations will be published (see 7.6).

7.6 Transparency

The present mandate of the Expert Panel will be published.
In addition, jointly prepared information sheets on special topics relating to delimitation questions as well as recommendations relevant for market players and classifications which support the legally compliant placing on the market of products, will be published in an appropriate form.

The minutes are confidential and for internal use by the authorities only.