



**Authorisation of complementary  
and herbal medicinal products  
2024**

## **Credits**

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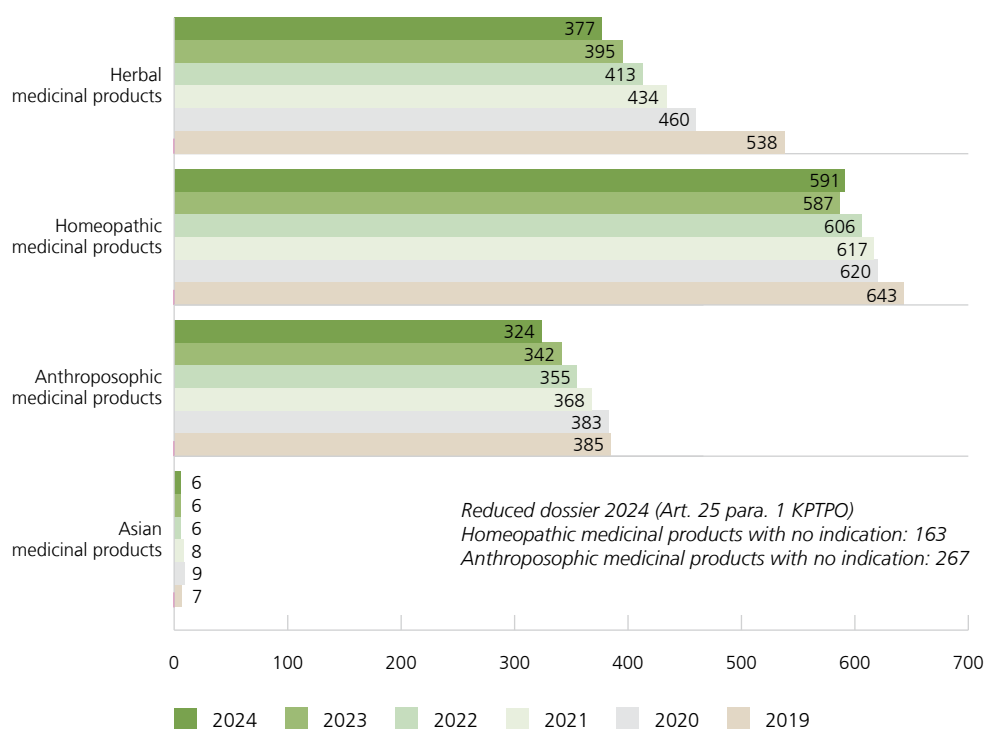
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## 1 Authorised complementary and herbal medicinal products without notification procedure



There was a further fall in the number of herbal medicinal products authorised during reporting year 2024 (377). The decline in authorisations of herbal medicinal products between 2019 and 2024 is striking. While authorisations of Asian medicinal products (6) and medicinal products used in other schools of complementary medicine remained stable, the number of homeopathic medicinal products authorised rose (591). Authorisations of anthroposophic medicinal products fell slightly (324). It should be remembered that the number of authorised homeopathic and anthroposophic medicinal products includes medicinal products with no indication in accordance with Art. 25 KPTPO (reduced dossier).

## 2 New authorisations of complementary and herbal medicinal products in 2024

Complementary and herbal medicinal products can be authorised using a simplified authorisation procedure in accordance with Art. 14 para. 1 let. b of the Therapeutic Products Act (TPA, SR 812.21) or Art. 14 para. 1 let. c<sup>bis</sup> TPA. A total of 18 complementary and herbal medicinal products were authorised in procedures of this type, while one medicinal product was authorised under the simplified procedure according to Art. 14 para. 1 let. a<sup>quater</sup> TPA and one further product was authorised under Art. 13 TPA (medicinal product authorised in another country). No applications under Art. 11 TPA (ordinary procedure, new active substance) were concluded during 2024.

### Overview of new authorisations of complementary medicinal products in simplified authorisation procedures in 2024

Authorisation number	Name	Indication	Type of treatment
67424	Hepasin liver and gall bladder drops, oral drops	According to homeopathic principles, helps relieve symptoms of liver and gall bladder disease or gall bladder disorders.	Homeopathic medicinal product
68992	Weleda Arnica Essence N, liquid for solution for application to the skin	According to the anthroposophic knowledge of humans and nature, for blunt trauma (such as bruises, sprains and contusions) and minor muscle and joint pain (muscle hardening, sore muscles, lumbago, tendinitis and musculoskeletal pain caused by overexertion).	Anthroposophic medicinal product
69142	Ceres complex remedy for colds, oral drops	According to homeopathic principles, for flu-like infections to alleviate symptoms of colds, including runny and blocked nose, cough, hoarseness, fever and chills.	Homeopathic medicinal product
69176	Similasan Graphites composite, eye drops, single doses	According to homeopathic principles, helps relieve symptoms of styes, including slightly inflamed, swollen areas of the eyelid.	Homeopathic medicinal product
69210	Similasan Tired Eye Relief, eye drops, single doses	According to homeopathic principles, helps relieve eye strain and tiredness from protracted reading, involving symptoms such as watering eyes and blurred vision.	Homeopathic medicinal product
69268	Allerino, spray for oral administration	According to homeopathic principles, for irritant and non-irritant clear nasal discharge and repeated sneezing attributable to allergic rhinitis.	Homeopathic medicinal product

Authorisation number	Name	Indication	Type of treatment
69269	Frissela, spray for oral administration	According to homeopathic principles, for symptoms of common cold, such as sore throat, blocked nose, sneezing and dry cough.	Homeopathic medicinal product
69270	Calmolla, spray for oral administration	According to homeopathic principles, for bruising and sprain-related muscle, ligament and tendon pain.	Homeopathic medicinal product
69273	Digestola, spray for oral administration	According to homeopathic principles, for digestion-related disorders such as feeling heavy or full, transient bowel transit disorders, bloating and flatulence.	Homeopathic medicinal product
69274	Calmozen, spray for oral administration	According to homeopathic principles, for agitation, irritability or slight anxiety accompanied by minor sleep disorders.	Homeopathic medicinal product
69327	Similasan Tired Eye Relief, eye drops	According to homeopathic principles, helps relieve eye strain and tiredness from protracted reading, involving symptoms such as watering eyes and blurred vision.	Homeopathic medicinal product
69328	Similasan Graphites composite, eye drops	According to homeopathic principles, helps relieve symptoms of styes, including slightly inflamed, swollen areas of the eyelid.	Homeopathic medicinal product
69619	Similasan Cerumen, ear drops	According to homeopathic principles, helps relieve a build-up of ear wax with the feeling that the ear canal is slightly blocked.	Homeopathic medicinal product
69654	Cocytal, oral liquid in single-dose container	According to homeopathic principles, for bloating and slight abdominal cramping caused by intestinal gas.	Homeopathic medicinal product
69774	Dulcamara / Lysimachia N, cream	Authorised with reduced dossier without indication according to Art. 25 para. 1 KPTPO (SR 812.212.24).	Homeopathic medicinal product

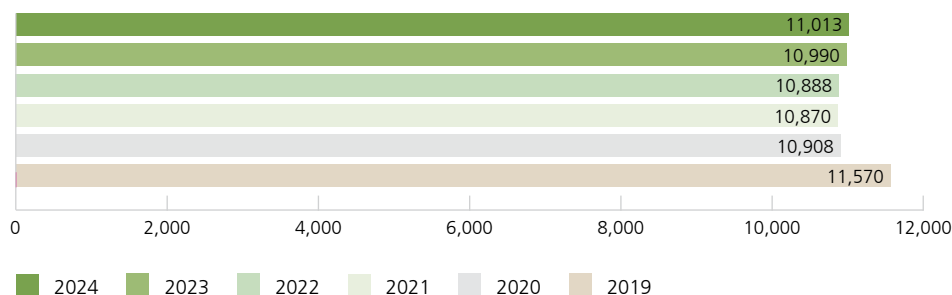
## Overview of new authorisations of herbal medicinal products in simplified authorisation procedures in 2024

Authorisation number	Name	Indication	ATC code
68497	Insadol, film-coated tablets	Traditional use in adults to help relieve the symptoms of mild inflammation of the gums and gum disease if a dentist does not think suitable dental and oral hygiene are sufficient on their own.	A01A
69025	Iberogast Stomach, oral drops	For upper abdomen problems in adults, such as stomach complaints, bloating, indigestion or minor cramps.  On medical prescription for functional dyspepsia (irritable stomach) with stomach cramps and pain.	A03
69493	Sidroga Diarrhoea Tea, herbal tea	Sidroga diarrhoea tea is traditionally used in slight, non-specific acute diarrhoea.	A07X

## 3 Authorised complementary medicinal products with no indication under the notification procedure (Art. 37 et seq. KPTPO)

The number of authorised homeopathic or anthroposophic medicinal products and medicinal products for gemmotherapy with no indication under the notification procedure according to Chapter 6 of the Complementary and Phytotherapeutic Products Ordinance (KPTPO, SR 812.212.24) remained stable at a high level in 2024 (11,013 medicinal products).

Complementary medicinal products without indication under the notification procedure



## 4 Latest news from the CHM Division

### “List of naturopaths” (Art. 49 TPO)

No medicinal products for use in traditional Chinese medicine (TCM) with no indication have been authorised under the notification procedure since 2024. As a result, naturopaths with a federal diploma who specialise in TCM have not been able to dispense these medicinal products.

### Orphan drug status

An application for orphan drug status has been approved for the first time in the CHM Division (active substance: dry extract of birch bark) for the treatment of the rare disease “epidermolysis bullosa”.

### CHM breakout session - information from medicinal product authorisation

A breakout session on complementary and herbal medicines was held at the [Regulatory & Beyond event](#) in Bern on 26 November 2024. It looked at the subjects of pharmaceutical equivalence and proof of tolerability in herbal medicinal products, the applicability of HMPC monographs to authorisation applications in Switzerland, best practice for the authorisation of complementary and herbal medicinal products and product life cycles, as well as the impending digitalisation of the HOMANT notification procedure for complementary medicinal products. The presentations from the event are available on the Swissmedic website.



