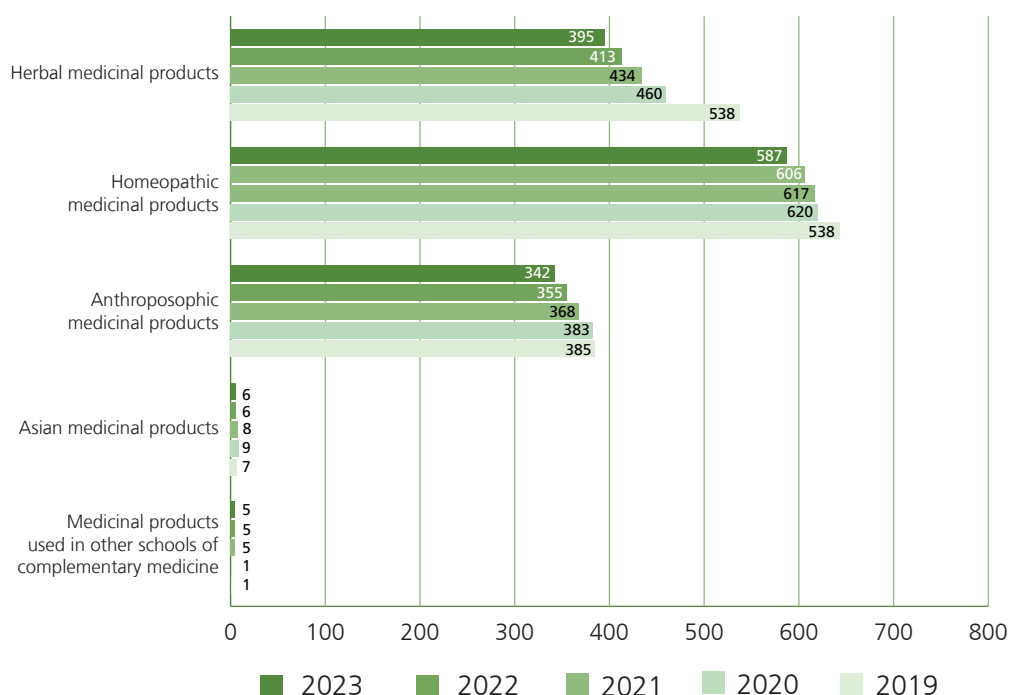




Authorisations of complementary
and herbal medicinal products
2023

Authorised complementary and herbal medicinal products, without notification procedure (2019 to 2023)



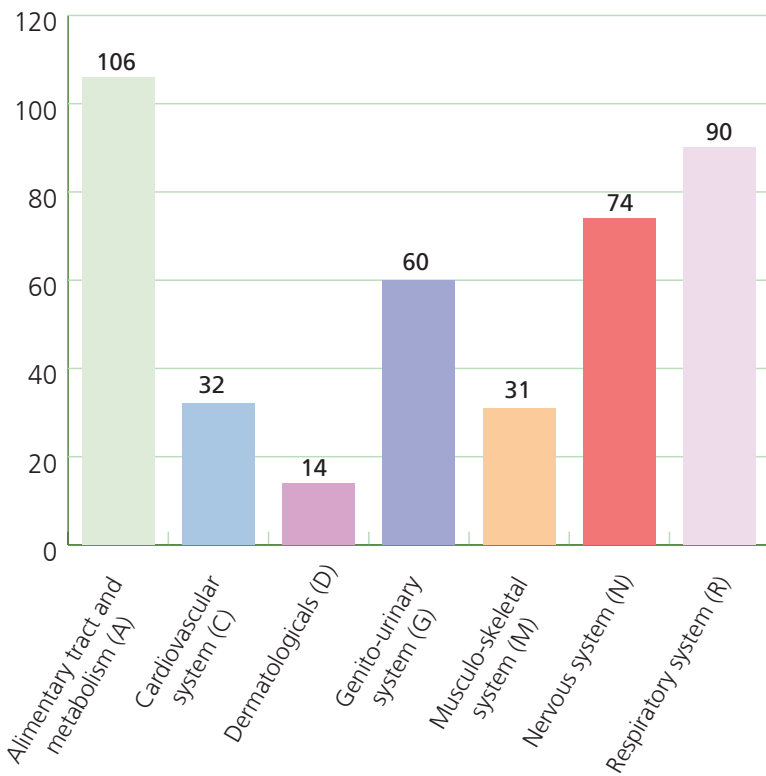
In the reporting year 2023, the number of authorised homeopathic medicinal products (587), anthroposophic medicinal products (342) and herbal medicinal products (395) decreased again. The mean reduction in authorised medicinal products, excluding Asian medicinal products (6) and medicinal products used in other schools of complementary medicine (5), has remained roughly constant over the last three years.

Classification of authorised herbal medicinal products in 2023

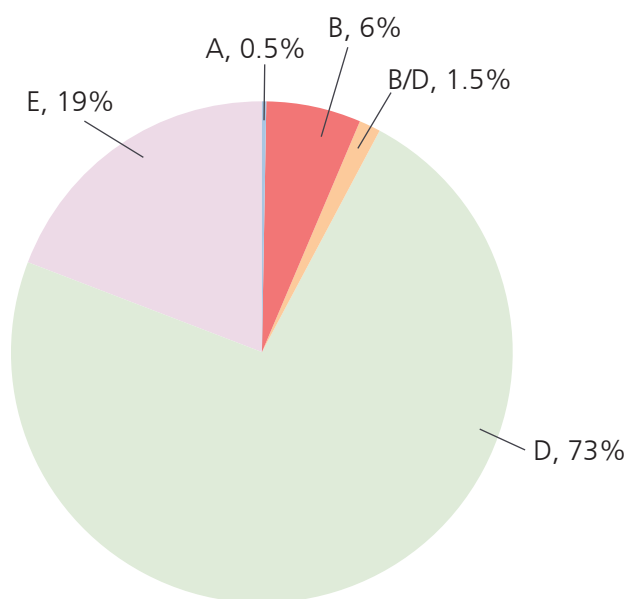
The authorised herbal medicinal products are subdivided into the following groups of the Anatomical Therapeutic Chemical classification system (ATC) and are categorised below based on the dispensing categories.

Most authorised herbal medicinal products are assigned to the ATC groups of Alimentary tract and metabolism (106), Respiratory system (90), Nervous system (74) and Genito-urinary system (60). In addition to the prescription-only drugs used in herbal medicine, the Swiss public can medicate themselves with a wide range of safe, high-quality herbal medicines, which are available without a prescription in dispensing category D (after expert advice) or in dispensing category E (over-the-counter).

Authorised herbal medicinal products by ATC group



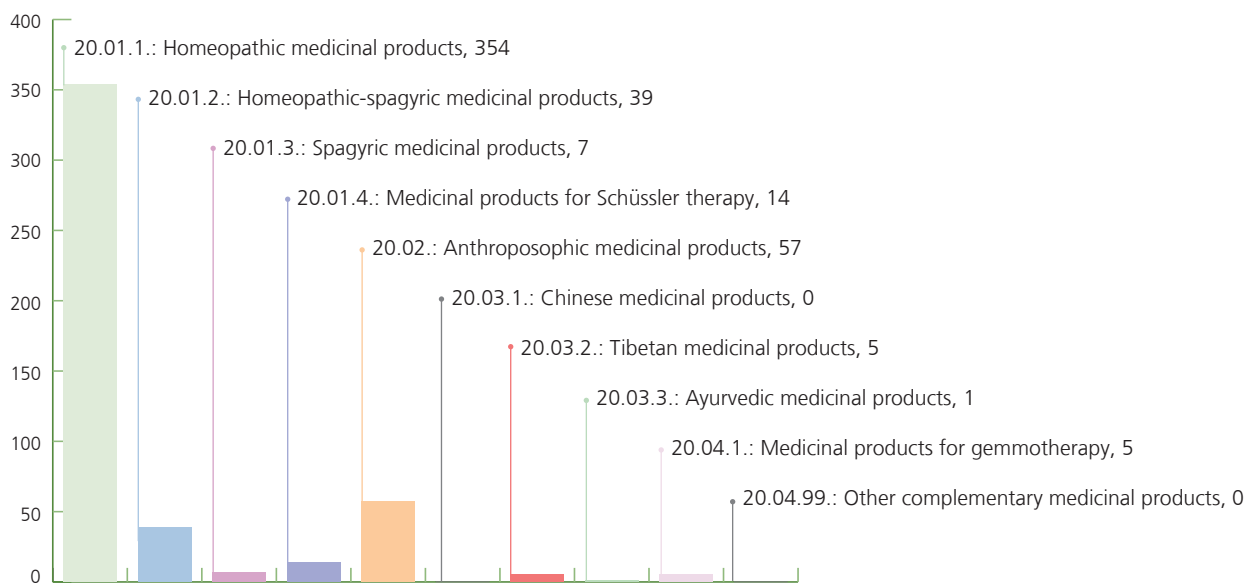
Authorised herbal medicinal products by dispensing category



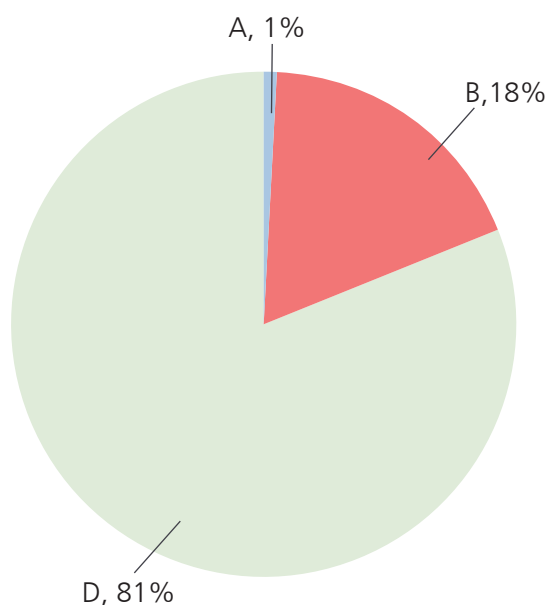
Classification of authorised complementary medicinal products with indication in 2023

The authorised complementary medicinal products with indication are subdivided into the following groups of the Index Therapeuticus (IT) and are categorised below based on the dispensing categories.

Authorised complementary medicinal products by IT Group



Authorised complementary medicinal products with indication by dispensing category



Complementary medicinal products with indication are dispensed on a prescription-only basis in dispensing categories A and B, and without a prescription in dispensing category D after expert advice.

New authorisations of complementary and herbal medicinal products in 2023

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^{bis} TPA. A total of 16 medicinal products were authorised in procedures of this type.

In 2023, one application submitted according to the procedure described in Art. 13 TPA (Medicinal products and procedures authorised in foreign countries) was approved. No procedures according to Art. 14 para. 1 let. a^{bis-quater} TPA were concluded in the year under review.

Overview of new authorisations of complementary medicinal products in simplified authorisation procedures in 2023

Authorisation number	Name	Indication	Type of treatment
68682	Infludoron N, globules	According to the anthroposophical knowledge of humans and nature, for influenza infections and colds. Based on anthroposophic principles, suitable for use at the first signs of illness, or following its outbreak, and can alleviate symptoms such as fever, runny nose, chills, muscle and limb pain, profuse sweating or signs of exhaustion.	Anthroposophic medicinal product
68702	Influenzinum N, globules/granules	Authorised with reduced dossier without indication according to Art. 25 para. 1 KPTPO (SR 812.212.24).	Homeopathic medicinal product
68743	Wala Aconit comp. Oil for pain, oil for use on the skin	According to the anthroposophical knowledge of humans and nature, stimulation of the warmth organism and integration of metabolic processes in painful illnesses originating from the nerve-sensory system, such as painful tension e.g. in the back, neck or shoulders, limb pain, joint pain resulting from arthritis.	Anthroposophic medicinal product
68745	Adler Juvebene, tablets	According to the biochemical therapeutic principle described by Dr. Schüssler, for limb and bone pain during the growth phase in childhood and adolescence.	Medicinal product for Schüssler therapy

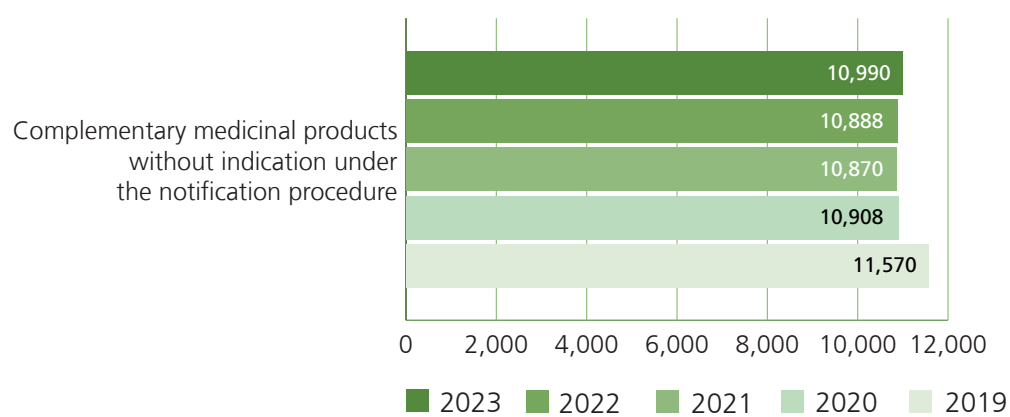
Authorisation number	Name	Indication	Type of treatment
68825	Visiodoron Euphrasia comp., eye ointment	According to the anthroposophical knowledge of humans and nature, for inflammatory eye disorders such as conjunctivitis, stye, chalazion and blepharitis.	Anthroposophic medicinal product
68893	Adler joint complex, tablets	According to the biochemical therapeutic principle described by Dr. Schüssler, for the alleviation of joint pain of varying origin, e.g.: mild, painful disorders of the musculoskeletal system, especially the joints; mild rheumatic joint pain; pain in mild degenerative diseases such as osteoarthritis, arthritis and joint swelling.	Medicinal product for Schüssler therapy
68970	Hyoscyamus/Valeriana N, oral drops	Authorised with reduced dossier without indication according to Art. 25 para. 1 KPTPO (SR 812.212.24).	Anthroposophic medicinal product
68982	Symphytum comp. N, oral drops	Authorised with reduced dossier without indication according to Art. 25 para. 1 KPTPO (SR 812.212.24).	Anthroposophic medicinal product
69071	Bryonia / Spongia comp., oral drops	Authorised with reduced dossier without indication according to Art. 25 para. 1 KPTPO (SR 812.212.24).	Anthroposophic medicinal product

Overview of new authorisations of herbal medicinal products in 2023

Authorisation number	Name	Indication	ATC code
68525	Valverde Intestomint, enteric-coated soft capsules	For mild cramp-like gastrointestinal complaints, for flatulence and abdominal pain, particularly in patients with irritable bowel syndrome.	A03AX15
68559	Perenterol Lyo-Sol, powder for oral suspension	For the symptomatic treatment of diarrhoea of varying aetiology.	A07FA02
68742	Valverde Magen-Darm, film-coated tablets	Traditionally for the symptomatic treatment for gastrointestinal complaints.	A03AX
69008	A.Vogel sore throat tablets, lozenges	Short-term treatment of acute inflammatory disorders of the mouth and throat.	R02AX
69381	Calefactor, gel	Painful injuries, rheumatism.	M02AX10
69393	Kytta med, cream	For rheumatic complaints and blunt injuries	M02AX
69593	Pulmex Efeu cough syrup, syrup	To promote expectoration in a productive cough.	R05CA12

Authorised complementary medicinal products without indication under the notification procedure (2019 to 2023)

The number of authorised homeopathic or anthroposophic medicinal products, medicinal products for gemmotherapy and Asian medicinal products without indication under the notification procedure according to Chapter 6 of the Complementary and Phytotherapeutic Products Ordinance (KPTPO, SR 812.212.24) increased slightly in 2023 (10,990 medicinal products).



Authorisation was withdrawn in 2023 for 20 suspended homeopathic medicinal products without indication authorised under the notification procedure.

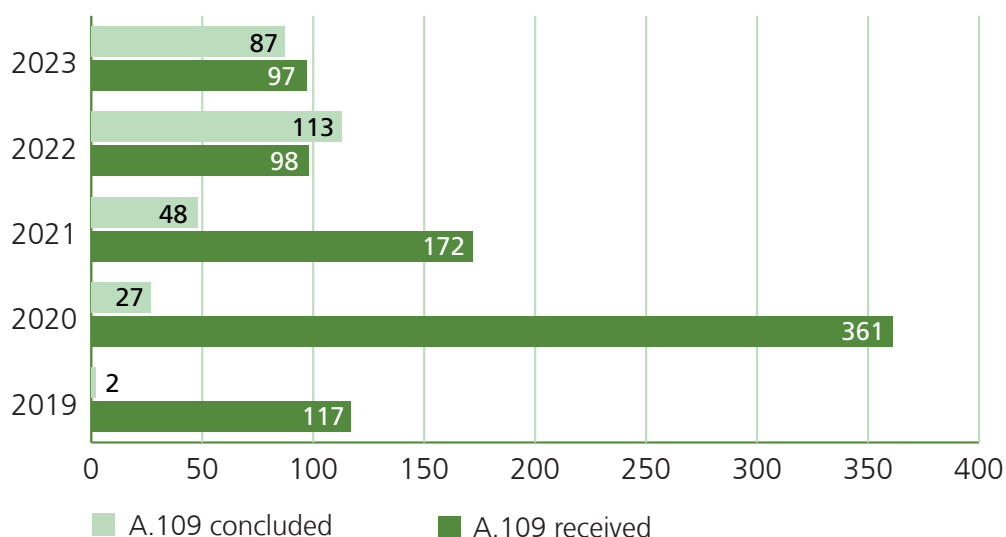
In 2023, 214 medicinal products used in Chinese medicine (TCM) without indication were converted from transitional authorisation (Art. 95 para. 3 HMG) to an authorisation under the notification procedure. The conversion of other medicinal products used in Chinese medicine is still outstanding.

A.109 regulatory changes (2019 to 2023)

Implementation of the new requirements in accordance with the revised TPLRO

Full declaration became mandatory for all medicinal products when the revised therapeutic products legislation came into force on 1 January 2019. These adaptations to the requirements are requested with an A.109 regulatory application. Single and multiple applications are considered below.

In 2023, 87 A.109 applications were concluded.



Since the revised therapeutics products legislation came into force on 1 January 2019 and a consequent increase in A.109 applications received, the annual number of newly submitted A.109 applications continues to decline. The number of A.109 applications concluded in 2023 fell slightly compared to the previous year, in contrast with all other applications (new authorisations, variation applications, authorisation extensions and safety-related applications).

Other activities

Updating of the list for naturopaths

The list of medicinal products designated by Swissmedic to be dispensed by specialists in complementary medicine with a Swiss diploma was supplemented in 2023 by the list of 234 Chinese medicinal products without indication authorised under the notification procedure.

IDMP

The term Identification of Medicinal Products (IDMP) covers a set of standards that make it possible to uniquely identify and describe medicinal products with consistent documentation and terminologies (for further information see the Swissmedic website, keyword IDMP).

Swissmedic will use the IDMP standards for the exchange of medicinal product data. The CHM Division is involved in the preliminary work for applying the IDMP standards to herbal and complementary medicines.

Transformation of Swissmedic platforms (TSP)

Swissmedic is working on the next step in digitalisation and over the next few years will build a digital corporate solution for core processes relating to licensing, authorisation and market surveillance (for further information see the Swissmedic website, keyword TSP).

Since 2023, the CHM Division has been involved with its own project for digitalising the notification procedure.

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