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Authorisation of complementary and herbal medicinal products 2025

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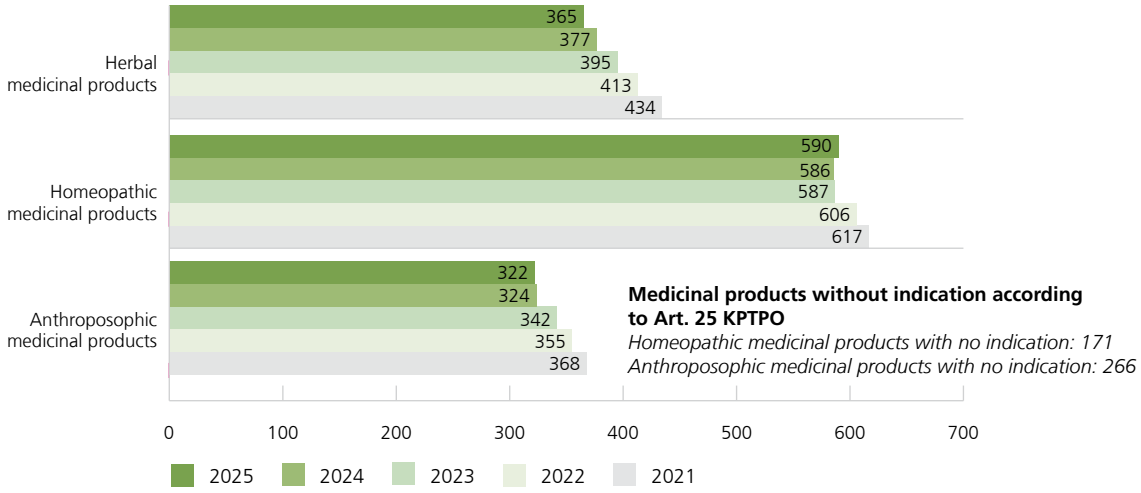
1 Authorised complementary and herbal medicinal products excluding those in the notification procedure



The downward trend for the number of herbal medicinal products authorised continued during reporting year 2025, falling to 365. By contrast, the figures for authorisations of homeopathic (590) and anthroposophic (322) medicinal products remained largely stable compared to the previous year. It should be noted in this context that the number of authorised homeopathic and anthroposophic medicinal products also includes those without indication in accordance with Art. 25 of the Complementary and Phytotherapeutic Products Ordinance (KPTPO, SR 812.212.24), and these are also included in the diagram. No change has been reported over the past few years in the number of authorisations of Asian medicinal products (5) and medicinal products used in other schools of complementary medicine (5), neither of which are shown in the diagram.

The number of herbal medicinal products authorised in recent years has fallen significantly, although the regulatory framework conditions have remained largely unchanged. Key influencing factors include medical devices and the growing importance of herbal dietary supplements. In light of the above, many manufacturers have decided to focus on these product categories, with a consequent reduction in the variety of herbal medicines available.

2 New authorisations of complementary and herbal medicinal products in 2025

Complementary medicinal products with indication 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 as complementary medicinal products without indication under Art. 25 of KPTPO. Herbal medicinal products can be authorised using either the ordinary authorisation procedure under Art. 11 TPA or the simplified authorisation procedure under Art. 14 para. 1 let. c^{bis} TPA.

A total of 11 complementary and herbal medicinal products, including 5 with indication, were authorised according to these procedures during 2025. For the first time, an application was submitted for the authorisation of a herbal medicinal product under Art. 11 TPA (ordinary procedure, new active substance) with the application of Art. 13 with orphan drug status, and authorisation was granted for the Swiss market.

Overview of new authorisations of complementary medicinal products in 2025

Authorisation number	Name	Indication	Type of treatment
69519	**Digestodoron N, oral drops**	According to the anthroposophic knowledge of humans and nature, Digestodoron N can be used for disturbed digestive rhythms (e.g. of secretory and motor function) and resulting gastrointestinal symptoms such as heartburn, flatulence, constipation and diarrhoea (including their alternation), abdominal pain or cramps. Thanks to its rhythmic action, Digestodoron N harmonises digestion.	Anthroposophic medicinal product
69741	**Viburcol, tablets**	According to homeopathic principles, Viburcol can be used for restlessness and irritability in children aged 2 years and older with or without fever (e.g. during teething, mild abdominal pain, sleeplessness) and for common infections.	Homeopathic medicinal product

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Authorisation number	Name	Indication	Type of treatment
69844	**Adler die heisse Sieben ["the hot seven"], powder in sachets for oral solution**	According to the biochemical therapeutic principle of Dr. Schüssler, Adler die heisse Sieben can be used for acute cramp-like symptoms, e.g. • Mild colic and mild cramps of the smooth muscles of the digestive tract (e.g. stomach cramps, gastro-intestinal symptoms, constipation, flatulence) • Mild menstrual cramps and mild labour pains and cramps accompanying childbirth Functional symptoms, e.g. • Mild incipient migraine or migraine-like headaches • Mild nerve pain • Mild nervous tension, such as stage fright and stress.	Medicinal product for Schüssler therapy
70049	**Pollen (Dactylis glomerata ex polline), oral drops**	Authorised with reduced dossier without indication according to Art. 25 para. 1 KPTPO (SR 812.212.24).	Homeopathic medicinal product
70050	**Pollen (Dactylis glomerata ex polline), globules**	Authorised with reduced dossier without indication according to Art. 25 para. 1 KPTPO (SR 812.212.24).	Homeopathic medicinal product
70134	**Vaccinotoxinum, globules/ granules**	Authorised with reduced dossier without indication according to Art. 25 para. 1 KPTPO (SR 812.212.24).	Homeopathic medicinal product
70149	**Arnica comp. / Formica N, cream**	Authorised with reduced dossier without indication according to Art. 25 para. 1 KPTPO (SR 812.212.24).	Anthroposophic medicinal product
70172	**Hamamelis comp., cream**	Authorised with reduced dossier without indication according to Art. 25 para. 1 KPTPO (SR 812.212.24).	Anthroposophic medicinal product
70279	**Antimonite D1, cream**	Authorised with reduced dossier without indication according to Art. 25 para. 1 KPTPO (SR 812.212.24).	Anthroposophic medicinal product

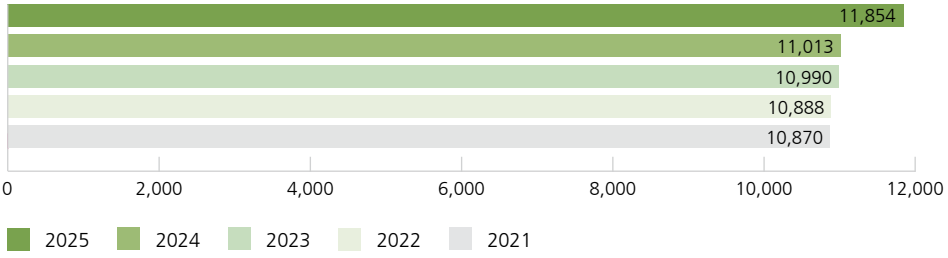
Overview of new authorisations of herbal medicinal products

Authorisation number	Name	Indication	ATC code
69715	**Beroseren, coated tablets**	Beroseren is traditionally used to improve well-being in nervous tension and to promote sleep.	N05C
70069	**Filsuvez, gel**	Filsuvez is used to treat superficial wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients aged 6 months and older.	D03AX13

3 Authorised complementary medicinal products without indication under the notification procedure

In addition to the authorisation procedures described above, medicinal products without indication can also be authorised under the notification procedure according to Chapter 7 KPTPO. These are homeopathic and anthroposophic medicinal products, as well as medicinal products for gemmotherapy. The number of complementary medicinal products without indication authorised under the notification procedure – both single and combined products – rose in 2025 (11,854 medicinal products) compared to the previous year as a result of an authorisation transfer. The number of medicinal products without indication authorised under the notification procedure also includes 78 veterinary medicinal products. No medicinal products for use in traditional Chinese medicine (TCM) without indication were authorised under the notification procedurein 2025.

Complementary medicinal products with no indication under the notification procedure



4 Latest news from the CHM Division

Herbal medicinal product authorised with orphan drug status

On 25 July 2025, Swissmedic authorised the medicinal product Filsuvez under Article 13 TPA on the basis of the assessment results of the European Medicines Agency (EMA). Filsuvez contains as its active substance a dry extract from the bark of various species of birch and is used to treat wounds in patients with two types of epidermolysis bullosa (EB) - dystrophic or junctional. Epidermolysis bullosa is a rare genetic disease that makes the skin extremely sensitive. As a result, it blisters and tears easily. This often leads to chronic wounds that do not heal easily and that considerably impair patients' lives. Since these are rare, life-threatening diseases, the medicine has been authorised as an orphan drug.

10. CHM Round Table: CHM in dialogue with stakeholders

The 10th CHM Round Table, in which Swissmedic (SMC) exchanges views with CHM associations and industry, was held on 2 July 2025. For years this platform has been promoting the dialogue and mutual understanding between SMC and the stakeholders from the complementary and herbal medicines sector.

Digitalisation at Swissmedic

Swissmedic is investing in the digitalisation of its systems and processes. The CHM Division is working on the phased digitalisation of the notification procedure for complementary medicinal products without indication, i.e. replacement of the HOMANT software and integration in the new Swissmedic Portal. In 2025, the initial phase involved in-house preparatory work designed to enable external stakeholders to be involved next year.

Company meetings

To support companies, and in the interest of optimising the authorisation procedure, Swissmedic organises meetings for applicants for the mutual exchange of information and to clarify questions relating to content and procedure.Over the past year, the Division held 5 meetings with CHM stakeholders. Swissmedic recommends that stakeholders take advantage of these meetings.

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