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Alternative Smoking Cessation Drug Cytisine On 2023 German Switch Committee Agenda

by [David Ridley](#)

Low-cost alternative smoking cessation drug cytisine is under consideration by Germany's independent switch committee in January, alongside azelastine and fluticasone propionate in combination for intranasal use, olopatadine for ophthalmic use and bilastine (10mg) for oral use.

Natural nicotine replacement drug cytisine is up for Rx-to-OTC switch consideration at the next meeting of the German independent Expert Committee on Prescription, SVA, which takes place in January 2023.

A nicotine-like generic alkaloid that occurs naturally in the laburnum plant species, cytisine – which is being proposed at a dose of 1.5mg for oral use by an as yet unknown applicant – potentially offers a low-cost alternative cessation therapy for Germany's roughly 15 million smokers

Discovered as a nicotine alternative by smokers in the Balkans who couldn't access tobacco during World War II, cytisine was first authorized as a smoking cessation therapy in Bulgaria in the 1960s and is used in many other Eastern European countries.

With the entry of former socialist economy countries to the European Union, cytisine was withdrawn from the market in Czech Republic, Slovakia, Hungary and Romania.

Only in Bulgaria and Poland has cytisine been used continuously as a prescription-only or OTC medicine, manufactured by Pharmachim and later by Sopharma under the Tabex brand.

However, it was only when Pfizer launched varenicline-based Champix, inspired by and similar to Tabex, that these nicotine alternative alkaloids became more widely known.

Evidence Mixed

The first randomized placebo-controlled trials of Tabex were published in Eastern Europe in the 1970s, long before any smoking cessation medication was available in Western Europe or the US.

Since then, more RCTs of the drug which conform to the stricter Russell standard of reporting have been completed, providing good evidence that cytisine is an effective smoking cessation treatment, [according to a 2012 systematic review](#).

[A recent study](#) comparing cytisine to varenicline has called into question the former's efficacy as a smoking cessation aid. Nevertheless interest in the drug remains high.

Cytisine is relatively inexpensive compared to both nicotine replacement therapies and other smoking cessation treatments. [A 2016 report](#) by the Canadian Agency for Drugs and Technologies in Health estimated the cost of smoking cessation treatment in Canada with varenicline to be about \$350 per person per course, compared with \$56 for cytisine.

To seize this opportunity, Canadian start-up Zpharm launched in 2017 a cytisine-based OTC natural health product under the Cravv brand.

Azelastine And Fluticasone

Also on the agenda for the SVA is the proposed switch of azelastine and fluticasone propionate in combination for intranasal use.

Viartis currently has a combination prescription-only nasal spray approved in Germany – via its Meda Pharma subsidiary – under the Dymista brand.

Azelastine and fluticasone are widely available across Europe as single substance OTC products.

Germany's expert committee for prescription recommended the Rx-to-OTC switch of fluticasone in 2016, with GSK first to market with Otri-Allergie Nasenspray in early 2017.

According to IQVIA, the prescription-to-OTC switch of fluticasone and mometasone nasal sprays produced a "clear shift to self-medication" in Germany within the category, with sales of OTC nasal sprays tripling to 1.2m packs during 2017. (Also see "[German switch success rare](#)" - HBW Insight, 12 Jan, 2018.)

OTC Azelastine

According to the Association of the European Self-Care Industry, azelastine was switched in Germany in 1997. Currently, Dermapharm markets a German OTC azelastine nasal spray under the Azedil brand.

In the US, however, where azelastine and fluticasone in combination are also still Rx – and manufactured by Viatris as Dymista, and also as a non-branded generic – azelastine as a single substance OTC product was only approved last year. The US Food and Drug Administration gave the green light to Bayer Healthcare's Astepro Allergy as an OTC nasal spray indicated for seasonal and perennial allergic rhinitis in adults and children six years and older. (Also see "[OTC Allergy Switch Approved For Bayer In US](#)" - HBW Insight, 17 Jun, 2021.)

Launching Astepro Allergy in the US helped Bayer Consumer Health's Allergy & Cold category post a double-digit rise in sales in the third quarter of 2022. (Also see "[Astepro Launch And Strong Cold Season Boost Bayer In Q3](#)" - HBW Insight, 9 Nov, 2022.)

Olopatadine Proposal

The third Rx-to-OTC switch proposal to be discussed at the SVA's January meeting will be olopatadine for ophthalmic use.

In the US, olopatadine is available OTC indicated for the temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair or dander under Alcon's Pataday brand. (Also see "[US Proposed ACNU Rule Rings Bell About Rx Drugs Marketed After NDAs Eliminated With OTC Switches](#)" - HBW Insight, 30 Nov, 2022.)

Pataday Once Daily Relief Extra Strength, approved by the FDA for OTC sales based on a separate Alcon Labs' application, is the same formulation as prescription Pazeo marketed by Novartis AG.

Novartis markets an Rx olopatadine product under the Opatanol brand in Germany.

Bilastine Lower Strength

Also on the list for exemption from the prescription requirement is second-generation antihistamine bilastine (10mg) for oral use.

The active ingredient in Berlin-Chemie's Bitosen, and available without a prescription in Poland, Austria and the Czech Republic, bilastine in 20mg strength was recommended for reclassification as an OTC drug for the relief of symptoms of hay fever and other forms of allergic rhinitis, as well as hives or urticaria only last year. (Also see "[Stada Says Lemocin's OTC Status 'Vindicated' By German Switch Committee Decision](#)" - HBW Insight, 2 Feb, 2021.)