

21 Jul 2023 | News

# German Switch Committee Rejects Sildenafil And Tadalafil, Ball Now In Ministry's Court

by [David Ridley](#)

Germany's Expert Committee on Prescription has gone against the wishes of the country's health ministry in rejecting Rx-to-OTC switch applications for sildenafil and tadalafil. The BMG could, in theory, ignore the SVA's recommendation, however, such a move would be unprecedented.

Germany's Expert Committee on Prescription, the SVA, has rejected applications to switch from Rx to OTC status erectile dysfunction drugs sildenafil (25mg) and tadalafil (10mg).

In doing so, it has gone against the wishes of the German Ministry of Health, the BMG, which in October last year announced to industry's surprise that it would like to see the entire group of PDE-5 inhibitors switched to non-prescription status. (Also see "[German Government Wants Sildenafil, Tadalafil OTC](#)" - HBW Insight, 6 Oct, 2022.)

The BMG could, in principle, ignore the SVA's recommendation. Such a move would be unprecedented, but legally acceptable, the German medicines manufacturers' association's managing director for scientific affairs Elmar Kroth told HBW Insight in October last year. "Should a switch be implemented against the recommendation of the switch committee, this would be a unique process," he commented at the time. "We will see whether this step will be taken, or not."

## More Rejection

Rejecting the two applications by a majority – indicating that the decisions were not unanimous (the full minutes are not yet published) – the SVA on 11 July also turned down nasal spray combinations of azelastine and fluticasone propionate (no strength given). (Also see "[Sildenafil, Tadalafil Among Big Hitters On Upcoming German Switch Committee Agenda](#)" - HBW Insight, 15

Jun, 2023.)

We do not know the name of the applicant, but in Germany, an Rx version of azelastine and fluticasone propionate in combination is marketed by Viatris. Both azelastine and fluticasone are widely available as single substance OTC nasal sprays in Europe and elsewhere, usually in 0.1% (1mg/ml) and 0.05% (0.5mcg/ml) strengths.

Interestingly, the application was described in the medicines regulator BfArM's short minutes as "not finding the required majority of the voters present in the expert committee," also indicating dissent, perhaps even more so than with sildenafil and tadalafil.

### **Triptan Unanimous**

The SVA was, however, unanimous in its recommendation to make migraine drug rizatriptan (5mg) available OTC.

According to data from the Association of the European Self-Care Industry, AESGP, rizatriptan is only available OTC in New Zealand, Sweden and Switzerland (also 5mg).

In a 2019 survey, the BAH found that roughly one in two Germans would like to see more migraine drugs accessible without a prescription. The SVA answered this call the same year with a recommendation to reclassify sumatriptan (50mg) – a switch that had been previously blocked by the German Federal Council on formal grounds.

While there are many effective OTC medicines available for migraine, triptans are the "drug of choice" for moderate to severe attacks, the BAH's Kroth has previously told HBW Insight. (Also see "[One In Two Germans Want More OTC Migraine Medicines, BAH Survey Finds](#)" - HBW Insight, 5 Sep, 2019.)

Of the five triptans available OTC elsewhere in the world, German migraine sufferers only have access to three: sumatriptan, almotriptan and naratriptan.