

Western Europe – UK

UK

Population: 65.6mn **OTC sales per capita:** \$38.48

Regulatory body: Medicines & Healthcare Products Regulatory Agency (MHRA)

Industry association: Proprietary Association of Great Britain (PAGB)

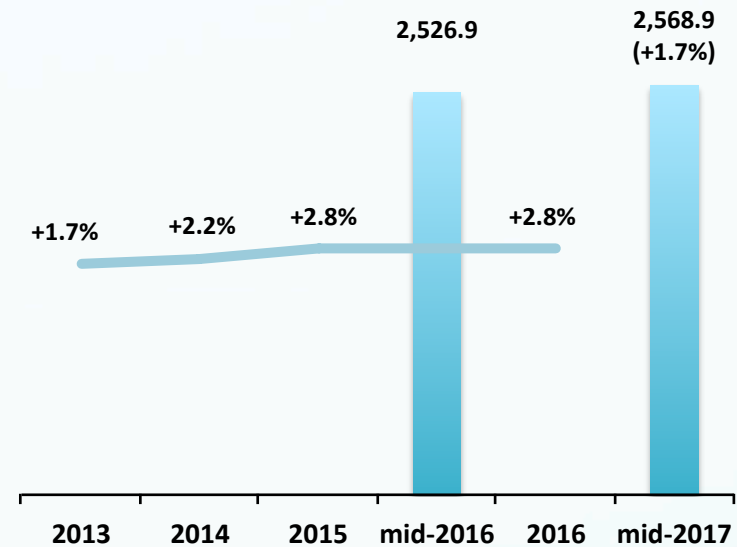
Ingredient or product led switch: Product

Pricing: Reimbursed OTCs are sold at the prescription price; non-reimbursed OTCs are freely priced

Reimbursement of OTCs: Many OTCs are available for reimbursement, mostly generics but also brands; same ingredients / products can be both reimbursable on the NHS and available pure OTC

Shared Rx & OTC branding: Allowed

UK OTC sales mid-2016 & mid-2017
(MSP, \$mn)



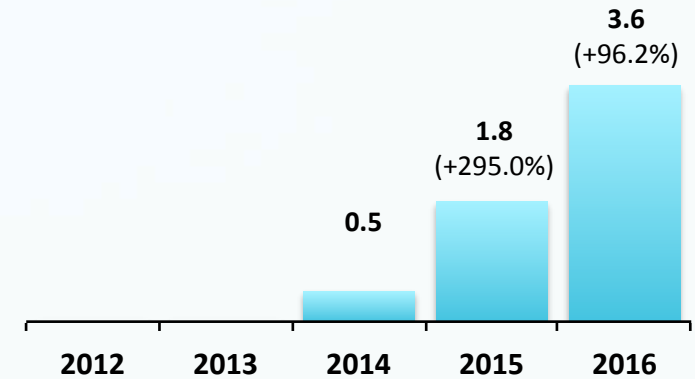
Overview

- One of the most liberal OTC markets in Europe, the UK has a high level of switched ingredients (often first switch worldwide) and an ongoing trend towards extending mass market (GSL) distribution
- The pace of switch has not let up, and 2017 saw further forward-looking reclassifications including the first OTC antimalarial and the UK's first erectile dysfunction treatment, Pfizer's Viagra Connect
- More switches are likely, with support from the NHS, which is committed to expanding the range of treatments available OTC

Silvasta (Douglas Pharmaceuticals)

Global OTC ranking: 2876 **OTC sales 2016:** \$3.6mn
Growth 16/15: +96.2% **CAGR 16/12:** n/a
Category: erectile dysfunction **Key market:** New Zealand
Market first switched: New Zealand

Silvasta OTC sales 2012-16
(MSP, \$mn)



- In October 2014 erectile dysfunction treatment sildenafil was approved by new Zealand’s Medsafe (following a recommendation by the Medicines Classification Committee) for reclassification from Rx-to-RM (Restricted Medicine – OTC, pharmacist-only), launched as Silvasta by Douglas Pharmaceuticals
- It can be sold to males aged 35-70 years, without a prescription, following a screening process with a trained pharmacist
- The switch represented a “first in world” OTC reclassification of an ED drug (leaving aside the Patient Group Direction scheme in the UK which allows for limited pharmacist prescribing of certain Rx medicines, including Pfizer’s Viagra – which is also to be available OTC in 2018)
- MCC previously rejected the switch, disputing the claimed benefit that there would be greater access to the medicine, stating that most men who are too embarrassed to talk to their GP would also be too embarrassed to talk to their pharmacist; in addition, a supporting cardiovascular screening tool was found to be inadequate
- However, authorities approved a new switch recommendation following new information provided by Douglas clarifying the purpose of the related screening tool and revising its focus; as a condition of switch, the MCC stipulated that the screening tool should require pharmacists to contact the patient’s GP, with the option for patients to opt-out

