

Why is Rx-to-OTC switch an imperative?

Pathway to industry growth
and improved public health

Non-prescription access to treatment for non-communicable disease and risk factors will reverse inequities and enable a new generation of consumer-driven health, contributing to optimal outcomes for individuals and populations

1



DELIVER

Long-term CHC
growth

2



LEAD

In health equity

3



UNLOCK

The power of
interoperability

Achieve a “Triple Aim” for Consumer Health with Rx-to-OTC switch

COVID-19 spotlights health inequities

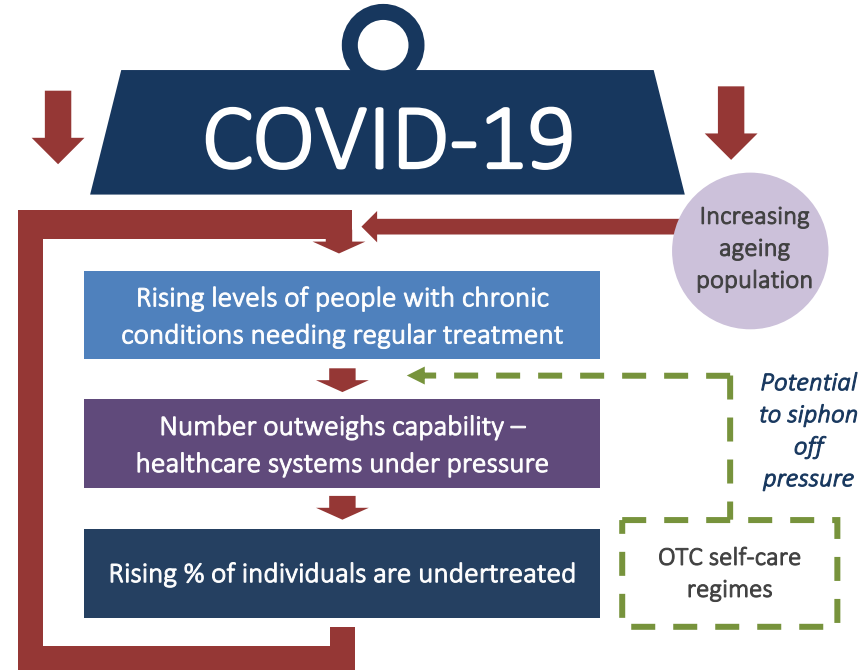
Undertreated correlates with higher risk of severe COVID-19

COVID-19 – the disease that hit the undertreated hardest

- When COVID-19 swept the globe beginning end-2019, the **cost of no treatment or undertreatment of chronic conditions hit hard**
- The older population (60+ years) and those with chronic conditions have been identified to be more at risk of severe illness from COVID-19²⁴; identified high-risk chronic conditions include²⁵:
 - Severe lung conditions (COPD, asthma)
 - Obesity & overweight
 - Type II diabetes
 - Hypertension
- **Health systems globally have been pushed to breaking point** – the system has been trying desperately to cope with the urgent needs: existing disease, rising infection levels and are now racing to vaccinate entire populations

The need for a revolution in self-treatment and in access to medications that have previously only been available from the doctor has never been greater

COVID-19 has killed 3.4mn people²⁶ – data suggests ~1/3 of COVID-19 survivors with severe or critical disease suffer long-term impairment²⁷

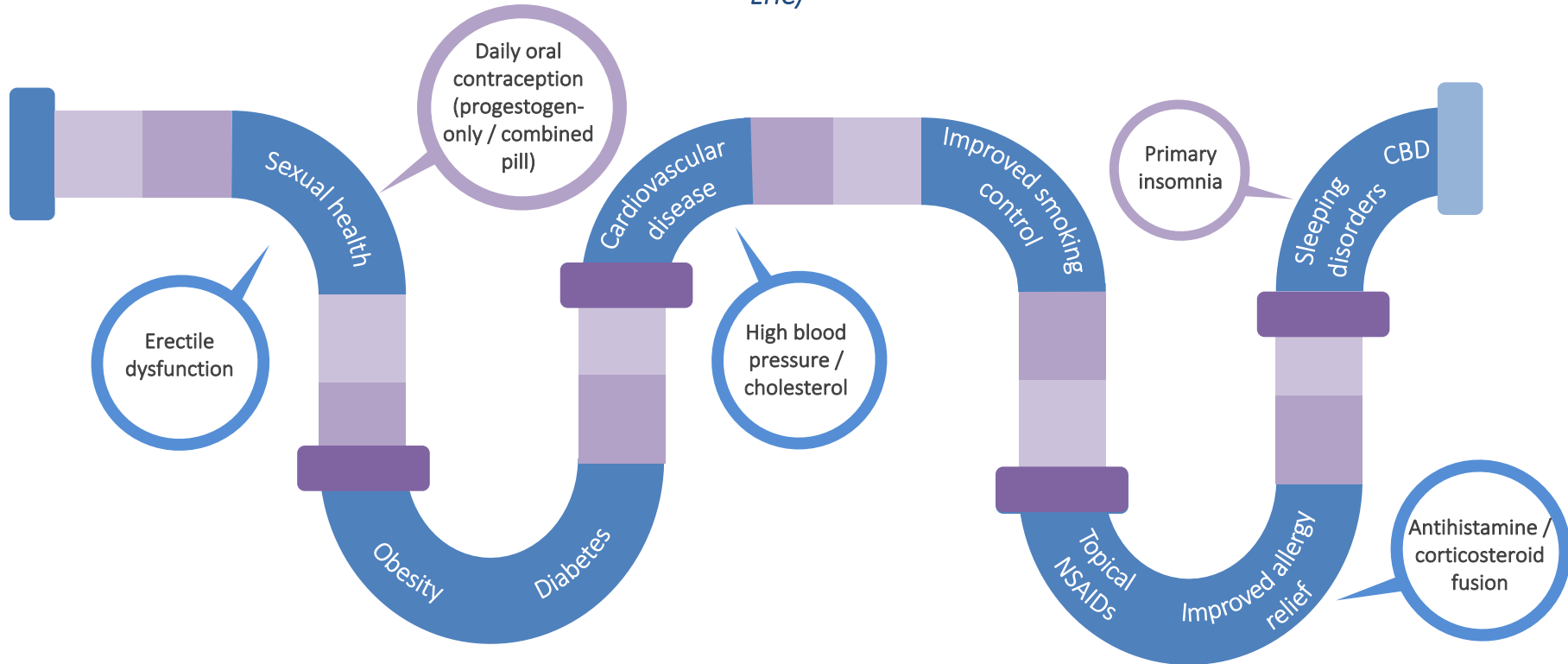


*Undertreatment is caught in a self-perpetuating cycle, ageing populations only set to increase pressure – **solutions are both wanted and needed**, and increasing access to self-care is one route that can help break the cycle*

Switch pipeline overview

Future of switch to enable OTC access to treat and / or prevent chronic conditions

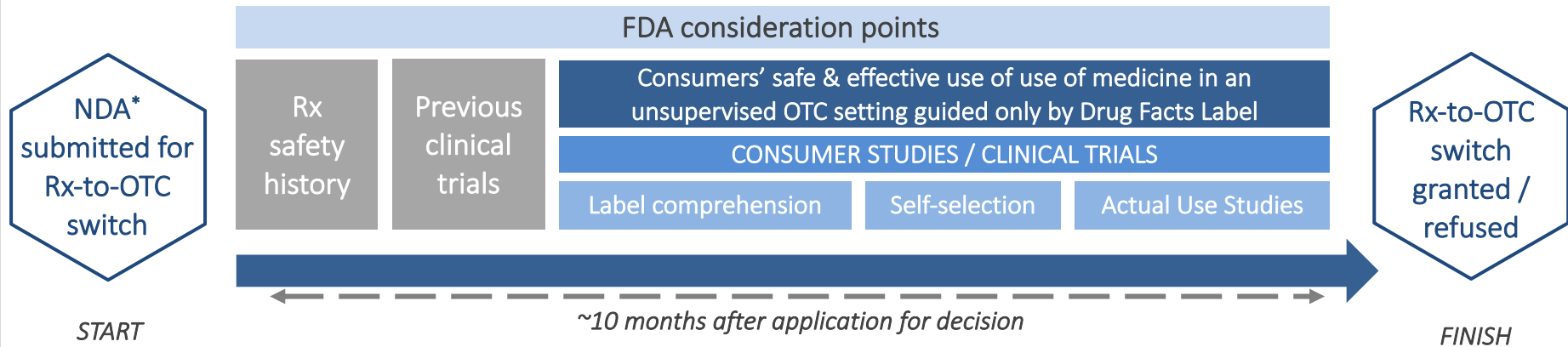
Future switch activity will centre around reversing undertreatment of chronic disease. It will also see markets like US and Japan (where local legislation has Rx-bound widely-switched molecules) play catch-up with the global environment (e.g. switch of topical NSAIDs and EHC)



USA switch mechanism

No formal process; safety essential in face of Rx-to-mass market switch

- No formal switch criteria, but significant historical precedent – FDA assesses and offers significant guidance on case-by-case basis
- New categories usually require an Advisory Committee
- FDA open to new conditions of OTC safe use



NDA switch has potential for 3 years marketing exclusivity if FDA determines clinical studies required

Clinical studies (consumer studies) most likely required for a "first-in-class" switch

*New Drug Application

Digital test and treat in action

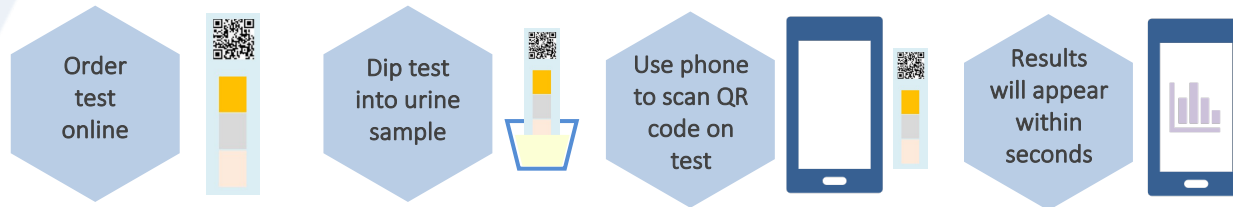
Antibiotic to treat UTIs can be dispensed after test by pharmacy

Superdrug launches digital UTI test & treatment kit in the UK (March 2021)

- Health & beauty retailer Superdrug now offers consumers an at-home UTI test & treat service
- The kit, from TestCard (£9.99 / US\$13.89), **combines with a mobile app that allows a smartphone camera to scan a urine sample to provide straightforward results**
 - “negative”, “possible UTI” or “high possibility of UTI”
- Service is conducted via the Superdrug Online Doctor service; consumers with a positive result would continue with the service and can obtain a treatment (at an additional cost to the test)
- Michael Henry, Superdrug healthcare director commented: *“When the NHS is as stretched as it is, we’re delighted to be able to support our customers and offer this new at-home UTI test and treat service which is **easy, accessible and convenient** and will also **help to reduce the pressure on GP services**”*



Step-by-Step Process Overview



If result is positive, can then discuss with doctors an appropriate treatment; nitrofurantoin (MacroBid) offered by Superdrug Online Doctor

Australia – #11 CHC market globally

~2% of global CHC market share; switches S3 / S2 first

Key information



Population: 25.8mn



OTC sales per capita: \$111.57



Regulatory Body: Therapeutic Goods Administration (TGA)



Consumer association: Australian Self-Medication Industry (ASMI)



Ingredient / product led switch: Product



OTC pricing: Most OTCs not price controlled, but OTCs covered by *PBS may have controls (incl. some S2 & S3)

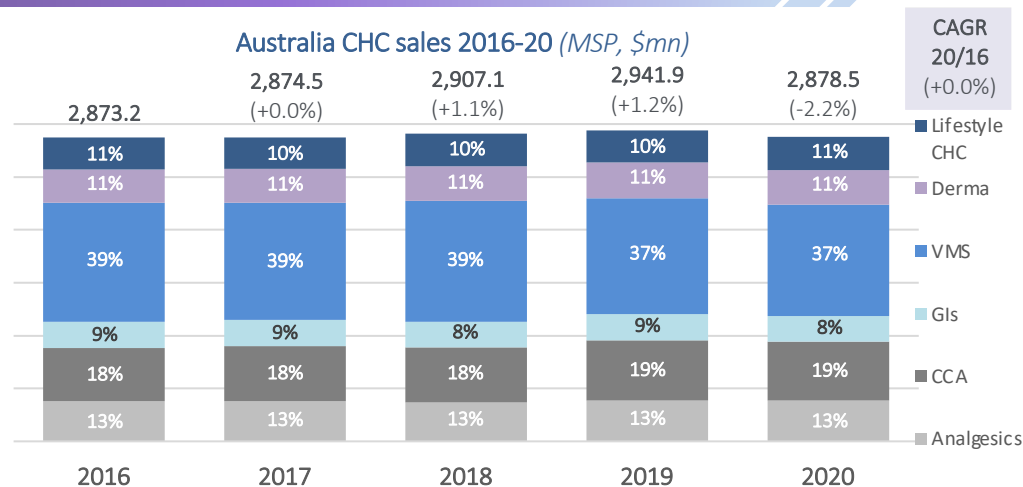


Shared Rx / OTC branding: Assessed case-by-case

Drug classes

- Rx / Schedule 4 (S4) – Prescription sale only
- Schedule 3 (S3) – Pharmacist-only medicine; pharmacy-only sale; kept BTC and dispensed at pharmacists' discretion; may only be advertised if included in Appendix H
- Schedule 2 (S2) – Pharmacy Medicine; pharmacy-only sale; self-selection
- Unscheduled – Free for general sale in mass market; self-selection

Australia CHC sales 2016-20 (MSP, \$mn)



*Pharmaceutical Benefits Scheme

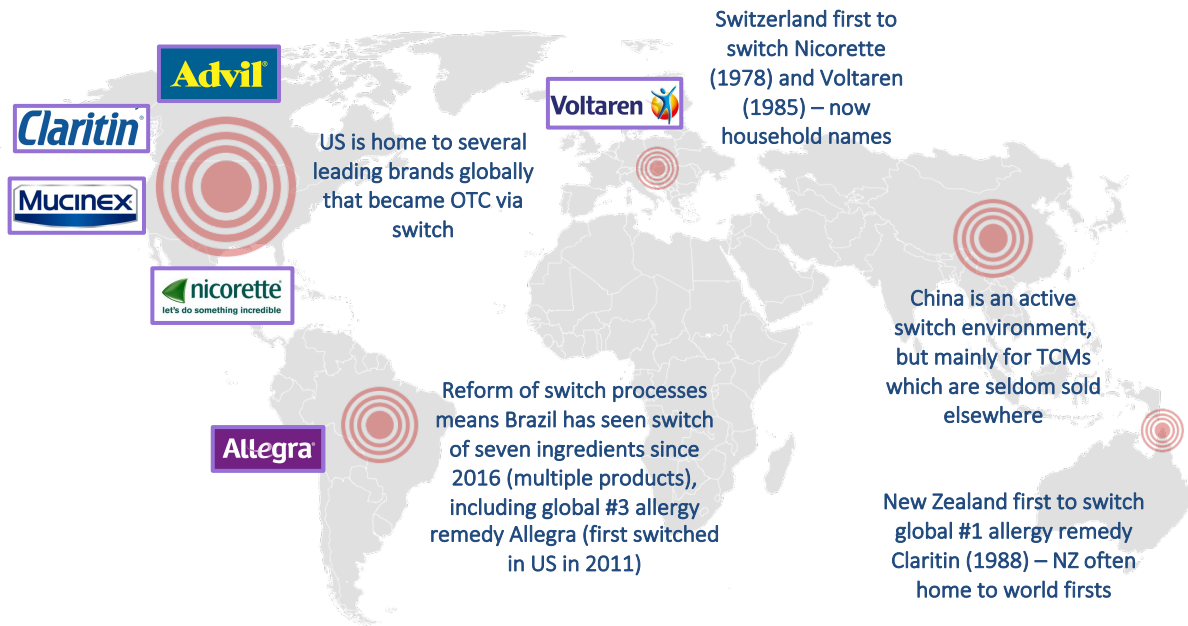
Top brands (by revenue) that switched in past 10 years

Brand (Marketer)	2020 (\$mn)	2020/19 (%)	CAGR (20/16) (%)	Year of switch	Ingredient (s)
Nexium 24 HR (GSK)	12.3	16.1%	19.4%	2014	Esomeprazole
Maxigesic (AFT Pharma)	5.3	5.5%	40.4%	2014	Paracetamol, ibuprofen

Leading global switches

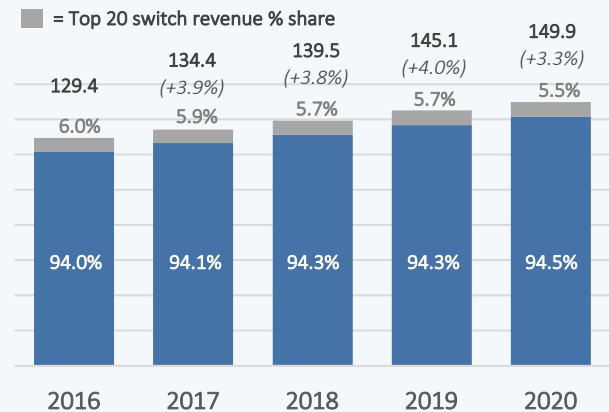
Majority of leading switched brands by revenue are Analgesics and Cough, Cold & Allergy products

Revenue from the Top 20 switches (by sales) combined accounts for ~5.5% of global CHC sales in 2020



Top 3 historical global switches by sales took place over 30 years ago while majority of Top 20 occurred over 10 years ago, and have long been subject to generic competition – however, many remain leading global brands in the CHC market

Global CHC sales with % of Top 20 switch sales (MSP, \$bn)



Top 20 switches sales by major category 2020 (%)

