The Next Generation of Rx-to-OTC switch

Focus on U.S, UK. and EU

IQVIA Consumer Health – June 2023

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Rx-to-OTC Switch Today

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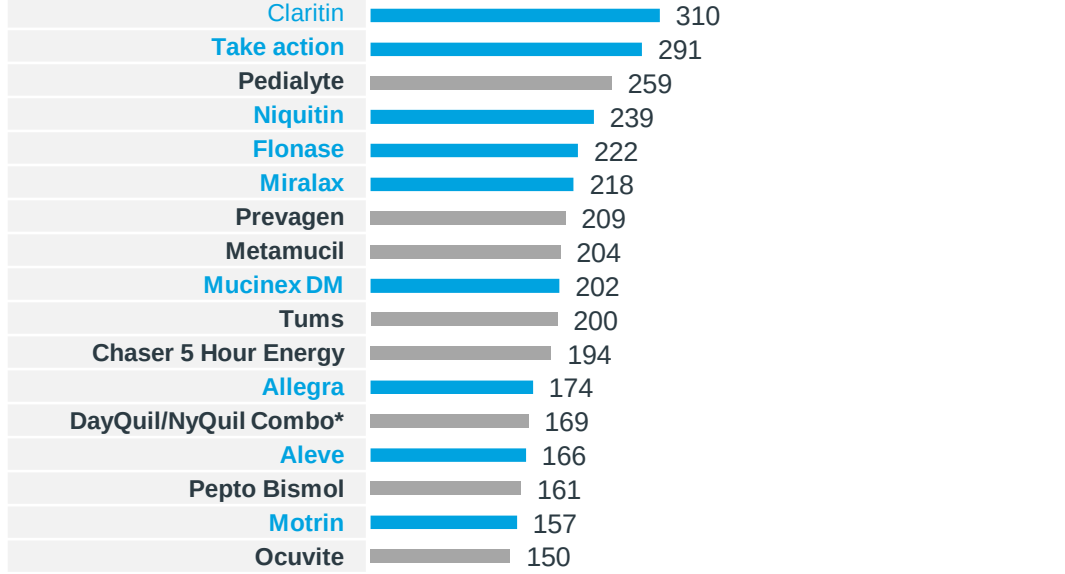
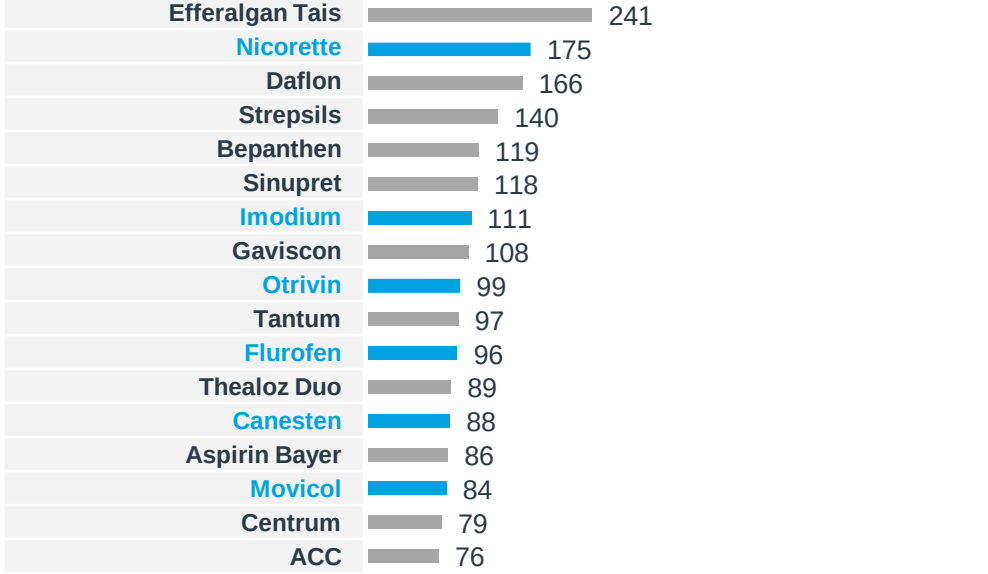
Switches are a key growth driver of OTC businesses

- **55% sales** and **10 out of top 20** brands in the USA are from switch heritage
- **€2.7bn** switch sales contribution

- **42% sales and 8 out of top 20 brands in Europe are from switch heritage**
- **€1.4bn switch sales contribution**





Switch heritage is a key sales driver accounting for €2.7bn in the USA and €1.4bn in Europe

Note: Brands total sales defined by IQVIA International Product name and may be known by different local names in countries. International Product name is a globally recognized name for a product
Source: IQVIA Customized Insights MAT Sep 22 1 Europe includes EU countries covered by IQVIA Database * Some SKUs contain doxylamine switch molecule
The Future of Rx-to-OTC switch – Consumer Health - June 2023 - IQVIA Consumer Health

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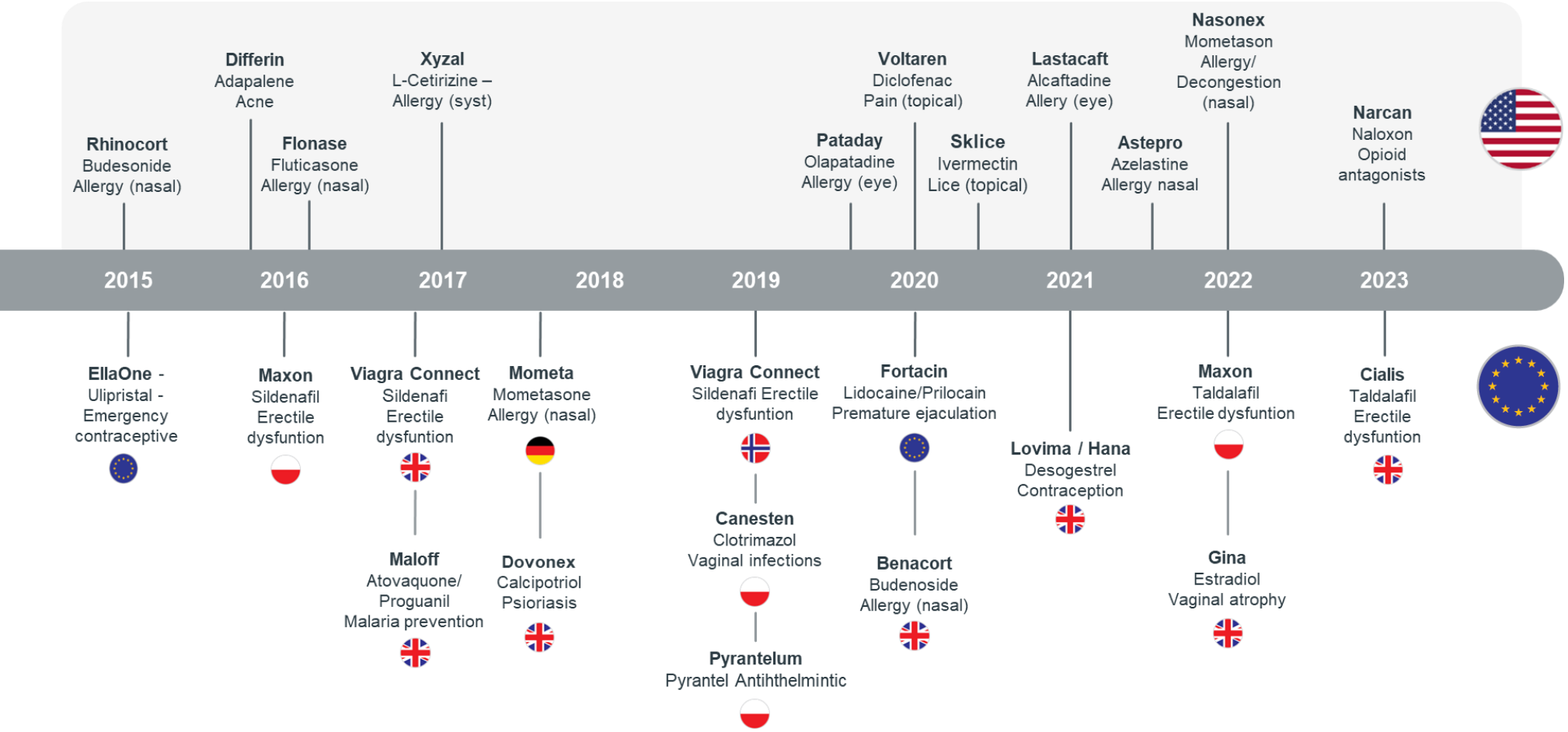
While established indications were dominant in US switches, new OTC indications have been explored in the EU/UK



General Sales

3 years of exclusivity possible

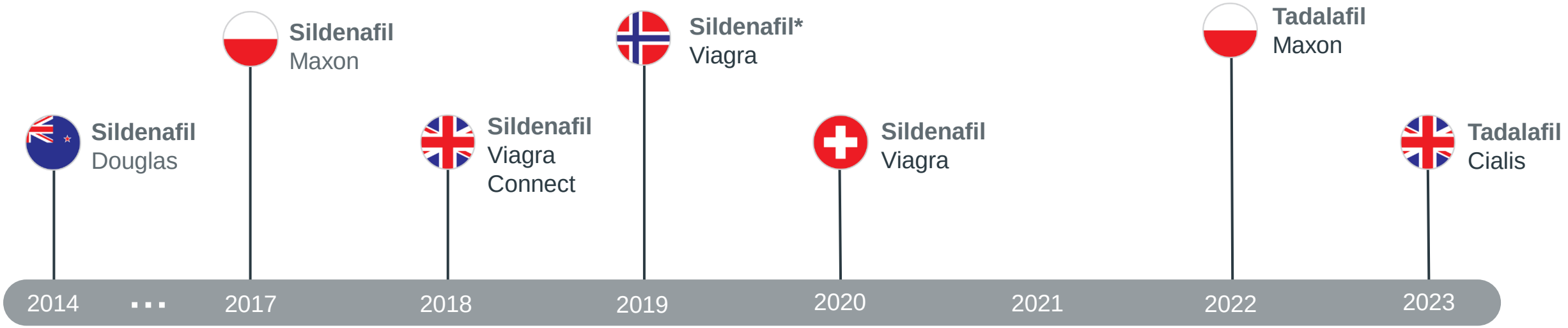
Pharmacy-only General Sales

1 year of exclusivity possible

More innovative switches are expected for the US market in the near future

Case study EU: Innovative Rx-to-OTC switches – Erectile dysfunction

Access restricted through interaction with a pharmacist (suitability check), dosage and pack size



***Norway changed its laws in 2018, to increase the number of OTC products on the market and created a third class called "non-prescription medicines with guidance".**

The absence of a pharmacy-only OTC status in the U.S. might have hindered more innovative switches, but new strategies are on the horizon

Switch from Rx to OTC involves a thorough evaluation process

Will future technologies impact how conditions are diagnosed & products are selected and used?

Safety profile

- Ensuring that the drug has a well-established safety record with minimal side effects, low potential for abuse, and low toxicity is crucial, as it reduces the risk of complications from unsupervised use

Effectiveness

- The drug should be effective for its intended use, providing clear benefits to consumers without the need for direct supervision by an HCP

Self-diagnosable / self-selection condition

- The condition should be easily diagnosable by the consumer, reducing the need for professional diagnosis and ensuring appropriate use

Self-treatable condition

- The condition should be manageable by the consumer without the need for medical supervision, minimizing risks associated with self-treatment

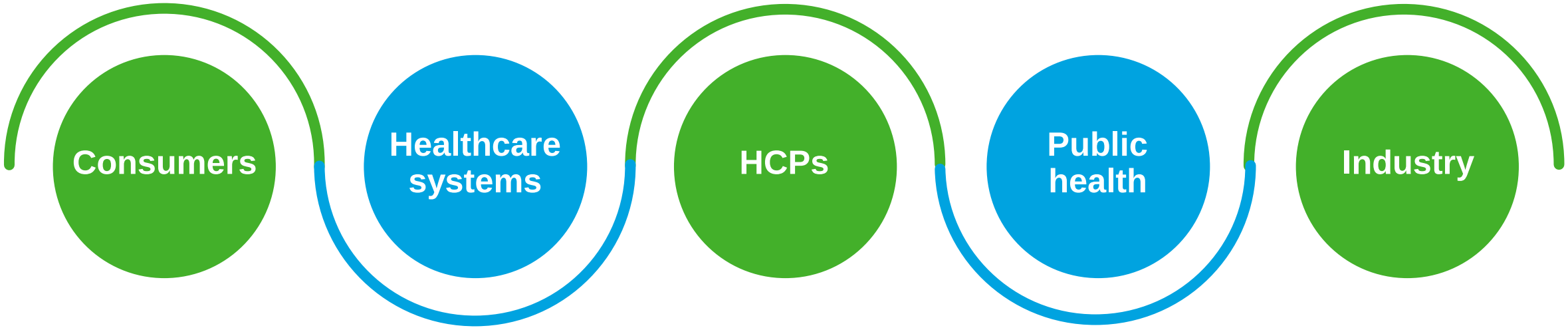
Clear instructions

- Providing consumers with clear instructions on dosage, usage, and potential side effects is vital for the safe and effective use of the drug

In the future, the requirements will likely remain the same, but fulfilling them may be influenced by new approaches and technologies

Rx-to-OTC switch is gaining importance and a win for all parties

Accelerated by the global rise in self-care practices



"We want self-care"

Demand for affordable and accessible medications

Increased health literacy

Digital health tools rising

Aging consumers need access to chronic treatments

Big relieve

Significant savings in money & time

More focus on pressing healthcare needs

Relieve & motivation

Reducing strain on healthcare providers

Motivation for pharmacists through new offerings

Better outcomes

Improved acute and long-term outcomes through fast and easy access

Growth

Patent cliff saver

Long-term innovation pipeline

The propensity for Rx-to-OTC switches in a country depends on many factors

Rx-to-OTC Switch in the U.S. Market

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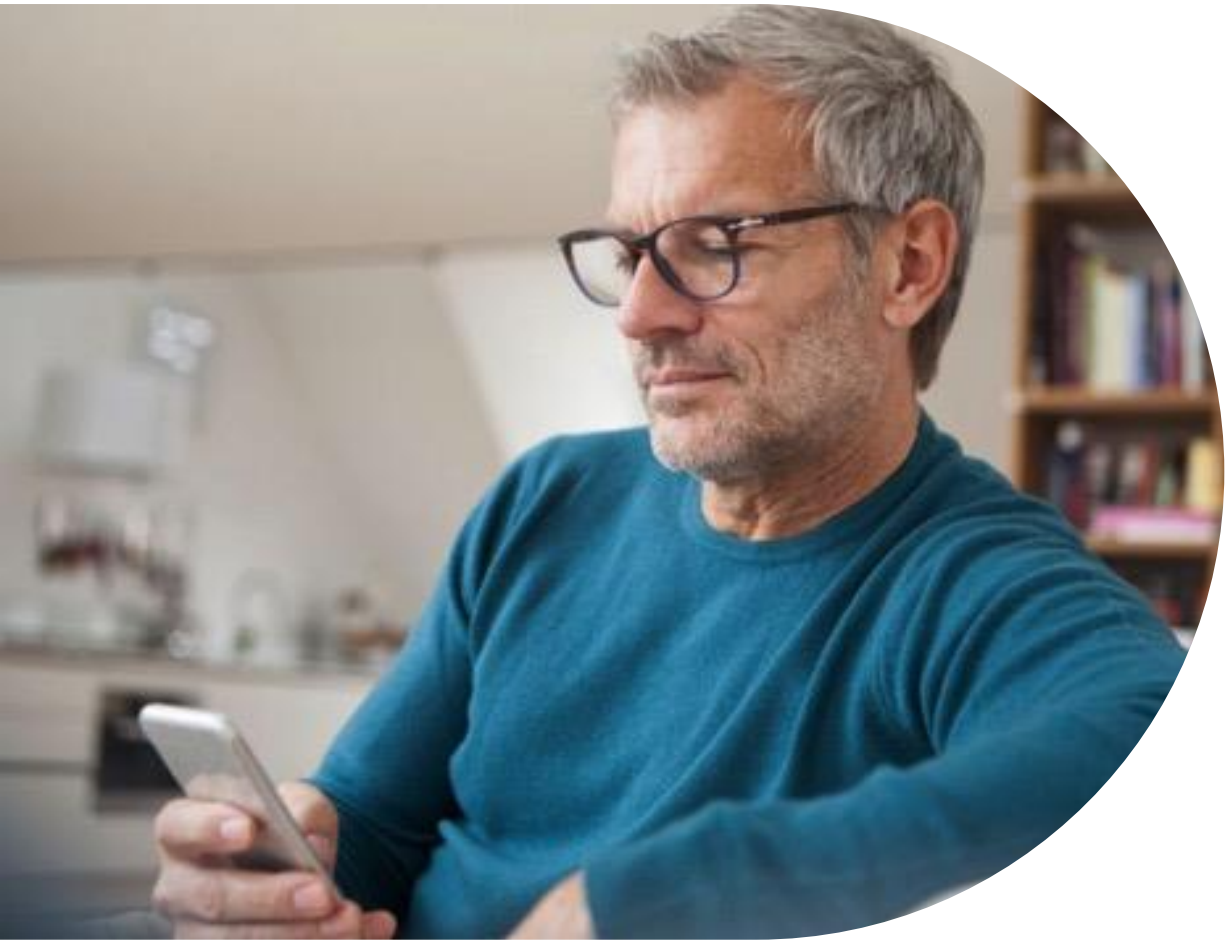
Self-Care is the future

Consumers worldwide desire more access and control over their healthcare

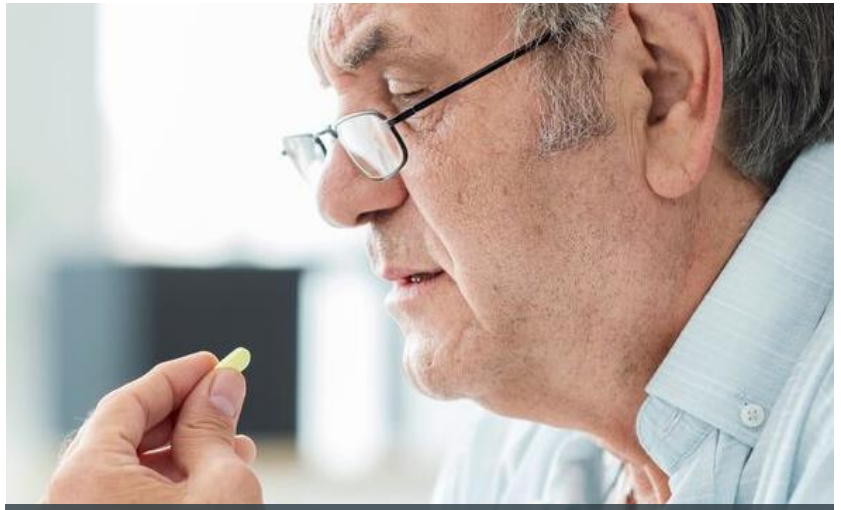


- Healthcare resources will continue to decentralize
- Care will become more self-directed
- Access to OTCs for chronic conditions will accelerate to improve public health
- Access to OTCs will increase access through e-commerce solutions
- Use of sensors, wearables and ability to get local diagnostics will increase
- Connections will be created with healthcare providers for questions
- Digital support will evolve to AI and ML models

There is a public health imperative to increase access

Rx-to-OTC Switch drugs are no longer limited to symptom relief of acute conditions

CHRONIC CONDITIONS CAN BE MANAGED



CONTINUOUS USE CAN BE MANAGED

PUBLIC HEALTH IMPACT WILL EXPAND SIGNIFICANTLY

Better Access and Support

- No longer limited to a physical retail setting
- Online ordering
- Use of technology, at home on smartphone
- Set-up of repeat ordering – to facilitate adherence
- Delivery to the doorstep

Rx-to-OTC switch is a strategic endeavor

Focus is benefit/risk and the unique aspects of the drug and the population

- **Considerations of population, drug [warnings], ability to self-manage [ease of use]**
- **Considerations of risk mitigations**
  - Labeling, technology, education, 'meeting the consumer where they are' considering the population and proper use
  - Assistance with self-selection – "ruling in and ruling out criteria"
  - Assistance with safety in use (right dose, right frequency, right 'stop use' for any adverse effects', effectiveness in unsupervised setting
- **Considerations for other sources of data**
  - Data to support Rx-to-OTC Switches expanded to RWE
  - Learnings from unsupervised use in Rx environment (at home, self-administered)
  - Learnings post-approval (continuous improvements and adjustments)
  - Real-world incidence of adverse events, DDIs, medication adjustments, comorbid conditions, changes in health over time

- Switch is currently a marathon, not a sprint
  - Iterative process
  - Requires repeated interaction with regulators
- Opportunities exist to accelerate Switch – we can do better.
  - Consider burden of proof vs. perfection

Key success factors

Innovate, educate, accelerate

Use of innovative approaches and digital tools will accelerate

Digital tools are now being incorporated into Rx-to-OTC switch programs

- Aid in self-selection (before use)
- Aid in proper use and adherence (during use)
- Aid in education
- Provide tracking and feedback
- Provide convenient re-ordering

Further innovations are forthcoming to facilitate self-care

- Notifications/communications to one's healthcare provider
- Identification of drug-drug interactions with current medications
- Incorporation of sensors and wearables for incorporation of diagnostics (e.g., blood pressure, glucose monitoring)
- Incorporation of local incidences of allergy, infectious diseases etc.

To date, we have been limited by data for Switch Support

We have opportunities to accelerate and innovate Rx-to-OTC Switch approaches

Current Challenges

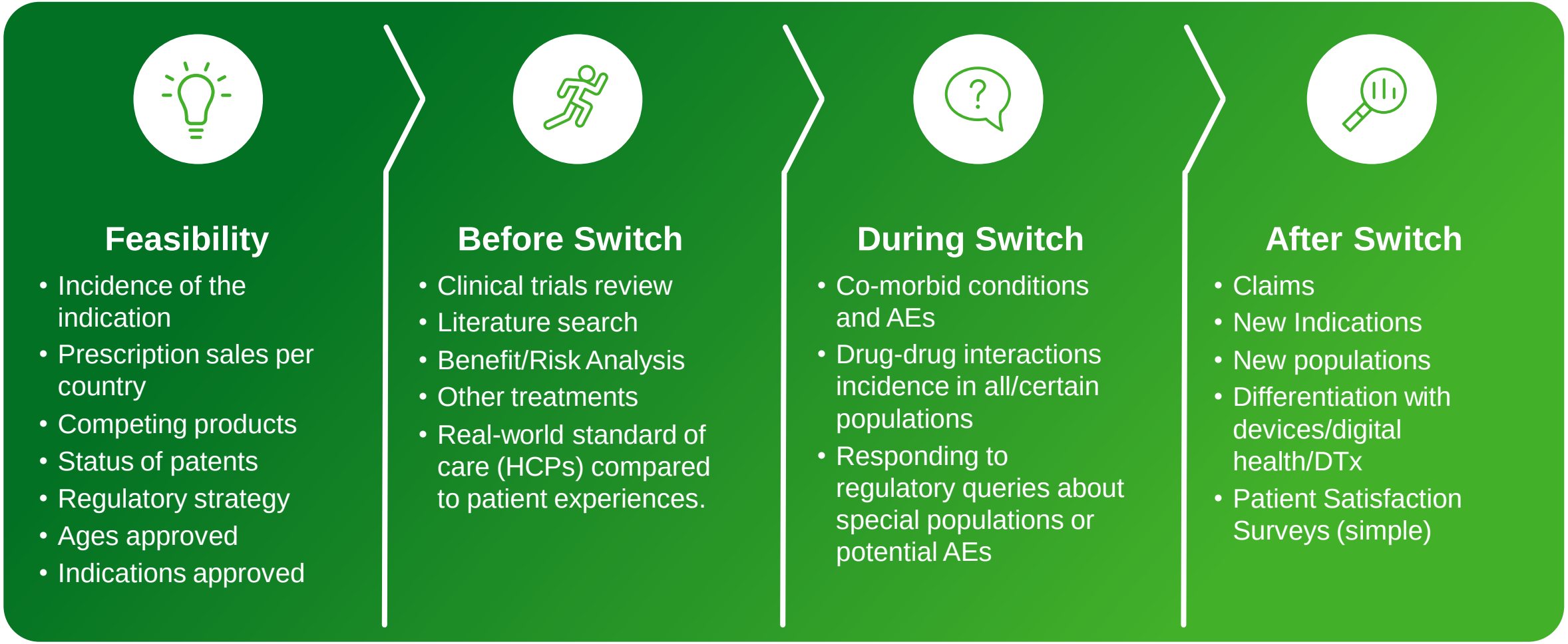
- **Label Comprehension**
  - Many rounds with evolving expectations from regulators about changes
  - Causes cycling in programs and delays
- **Self-selection**
  - Many special populations have been added to provide evidence that contraindicated populations do not select
- **Actual Use**
  - Expectations for a naturalistic, real-world approach but in the context of an uncontrolled clinical study

Future Opportunities

- **Accelerating by using new methods and approaches**
  - New methods for comprehension
  - Increased use of virtual methods
  - Aligning expectations with ROW for burden of proof
- **Use of real-world data**
  - Current use of the prescription drug
  - Adverse events
  - Meta-data based on large databases and literature
- **Use of global studies and experience**
  - Many Switches approved in other countries
- **Consideration for post-marketing data**
  - Not all questions can be answered in moderate-sized consumer studies

Leveraging RWE in Rx-to-OTC Switch

Real-world data can facilitate a Switch throughout the life cycle



RWD / RWE
in Rx-to-OTC switch

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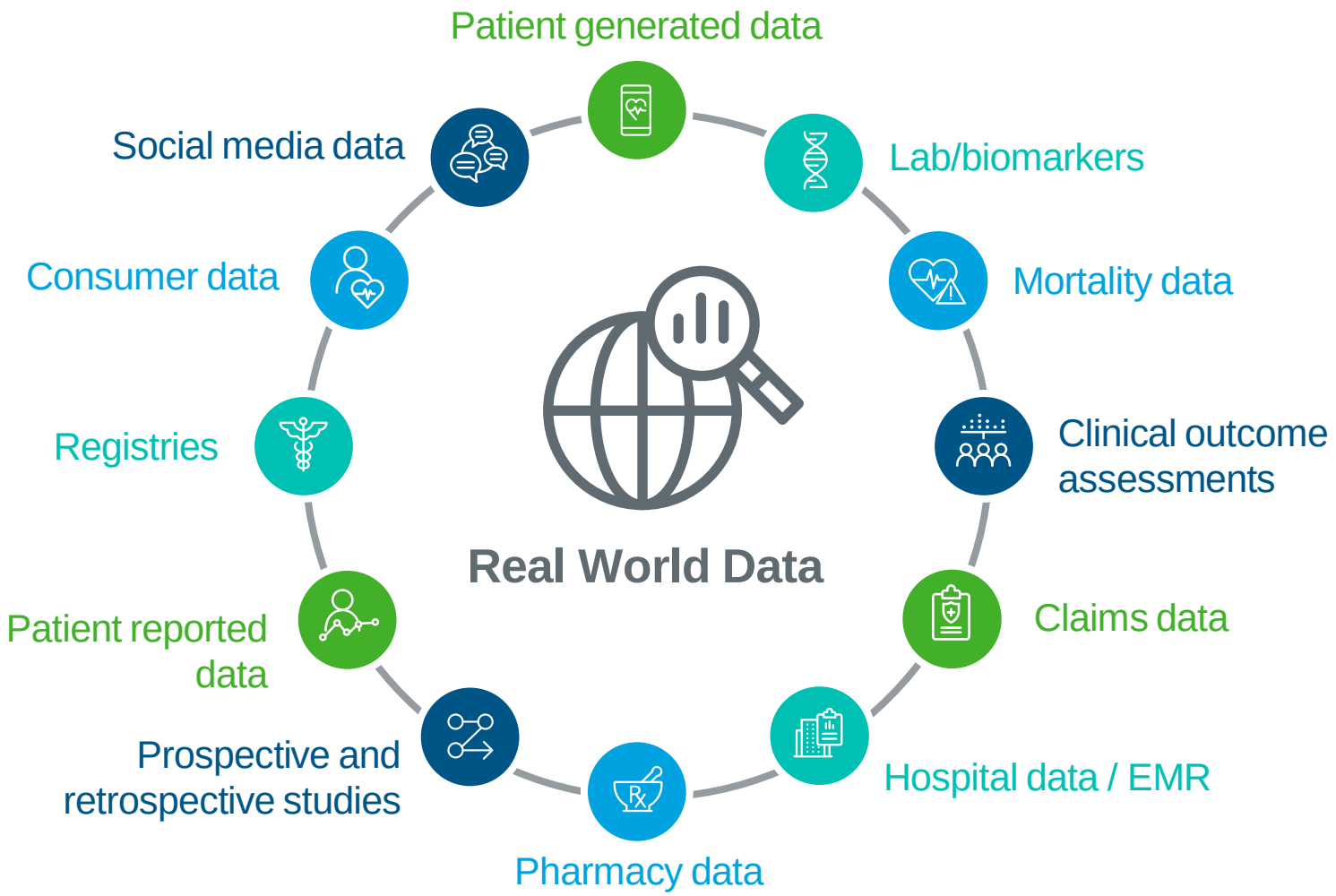
How do we define RWD and RWE?

Definitions vary around the world

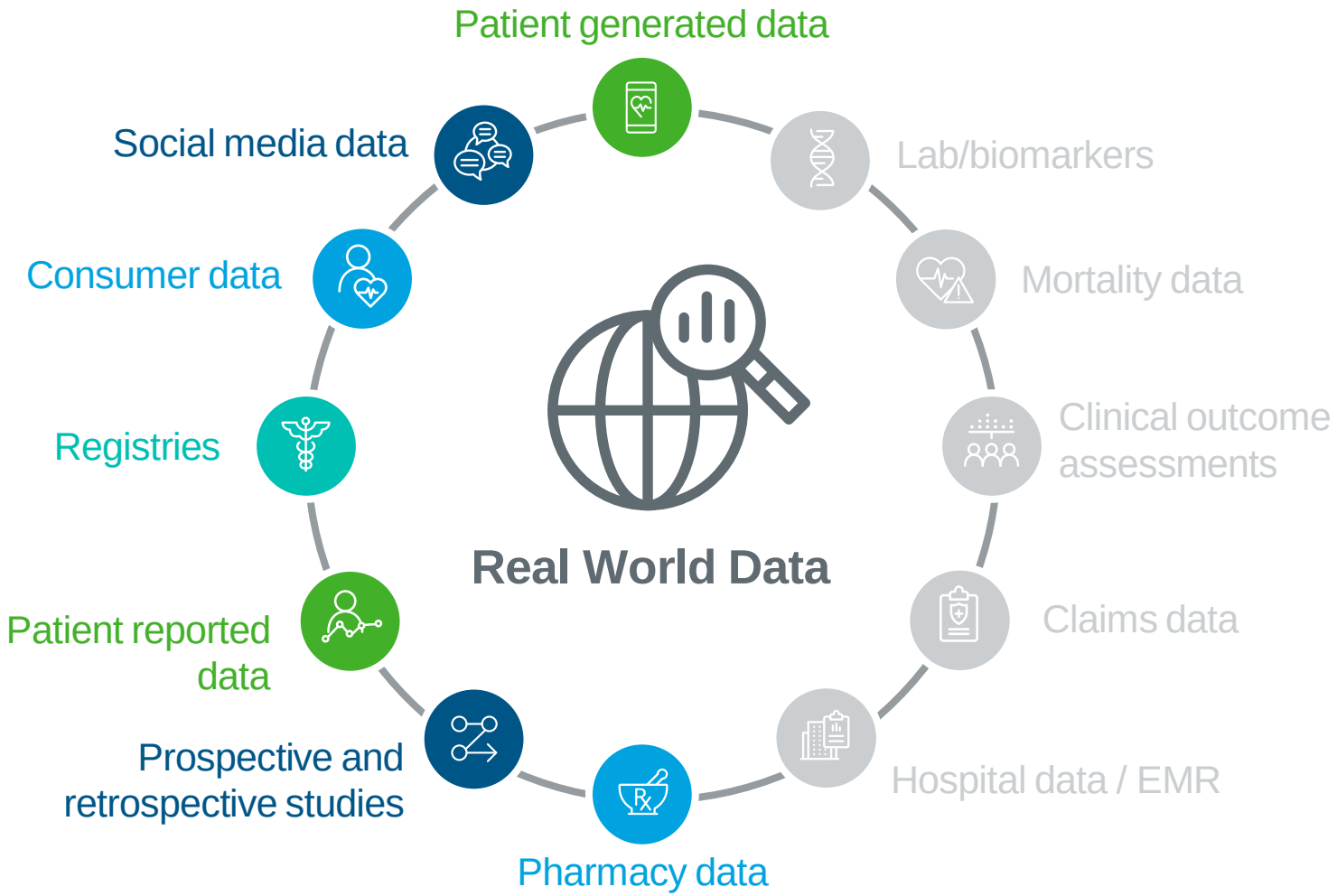
	Real-World Data (RWD)	Real-World Evidence (RWE)
	Data relating to patient health status and/or the delivery of health care **routinely collected** from a **variety of sources**.[1]	The **clinical evidence** regarding the usage and potential benefits or risks of a medical product derived from **analysis of RWD**.[1]
	Data usually collected **outside of the clinical trial** (for therapeutics) or **investigational testing** (for medical devices) setting.[2]	**Clinical evidence** regarding the use and potential benefits or risks of a medical product derived from **analysis of RWD**.[2]
	Data relating to patient health or experience or care delivery **collected outside the context of a highly controlled clinical trial**.[3]	**Evidence** generated from the **analysis of real-world data**.[3]

Sources: 1. Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices Guidance for Industry and Food and Drug Administration Staff Document issued on August 31, 2017. \ 2. Real world evidence and patient reported outcomes in the regulatory context. TGA Version 1.0, November 2021. 3. NICE real-world evidence framework Corporate document Published: 23 June 2022

RWD can come from a variety for data sources



RWD can come from a variety for data sources

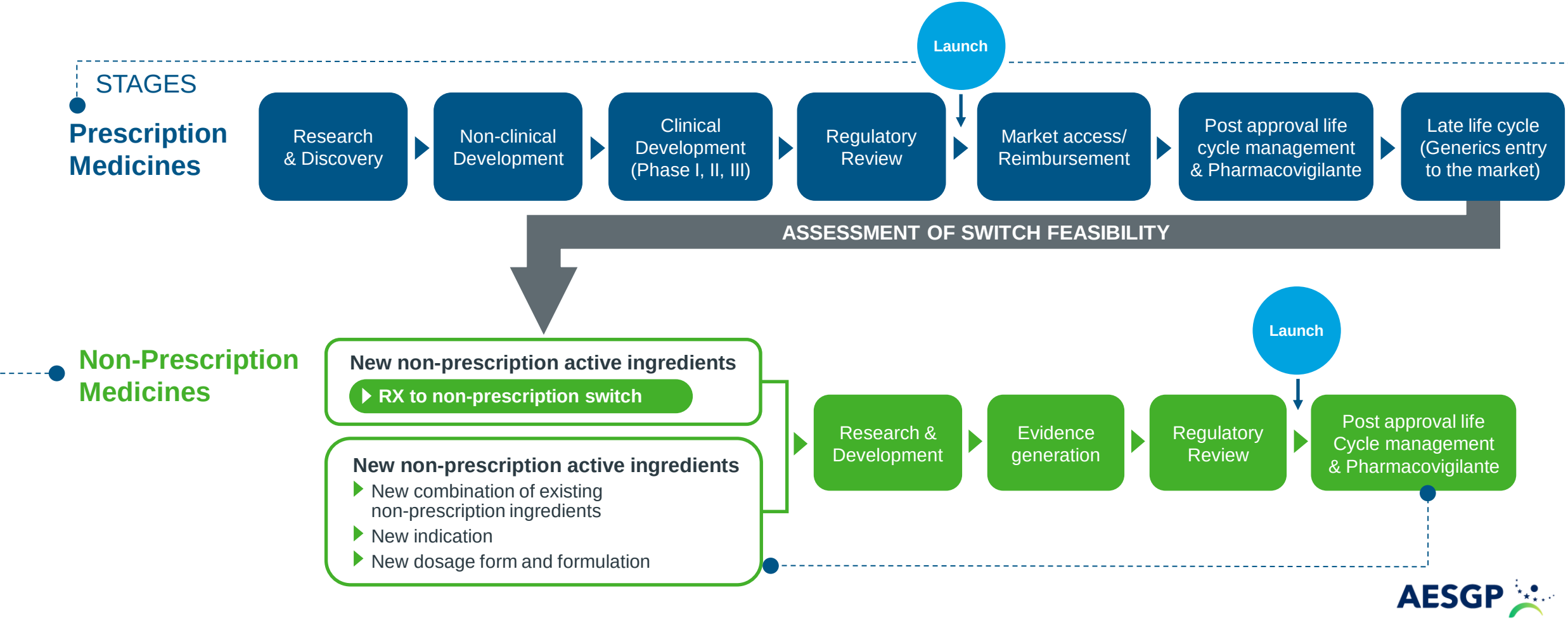


RWD for OTCs

There are fewer RWD sources that routinely collect data on OTCs because most non-Rx medicines are not prescribed or reimbursed.

Life cycle of prescription and nonprescription medicines

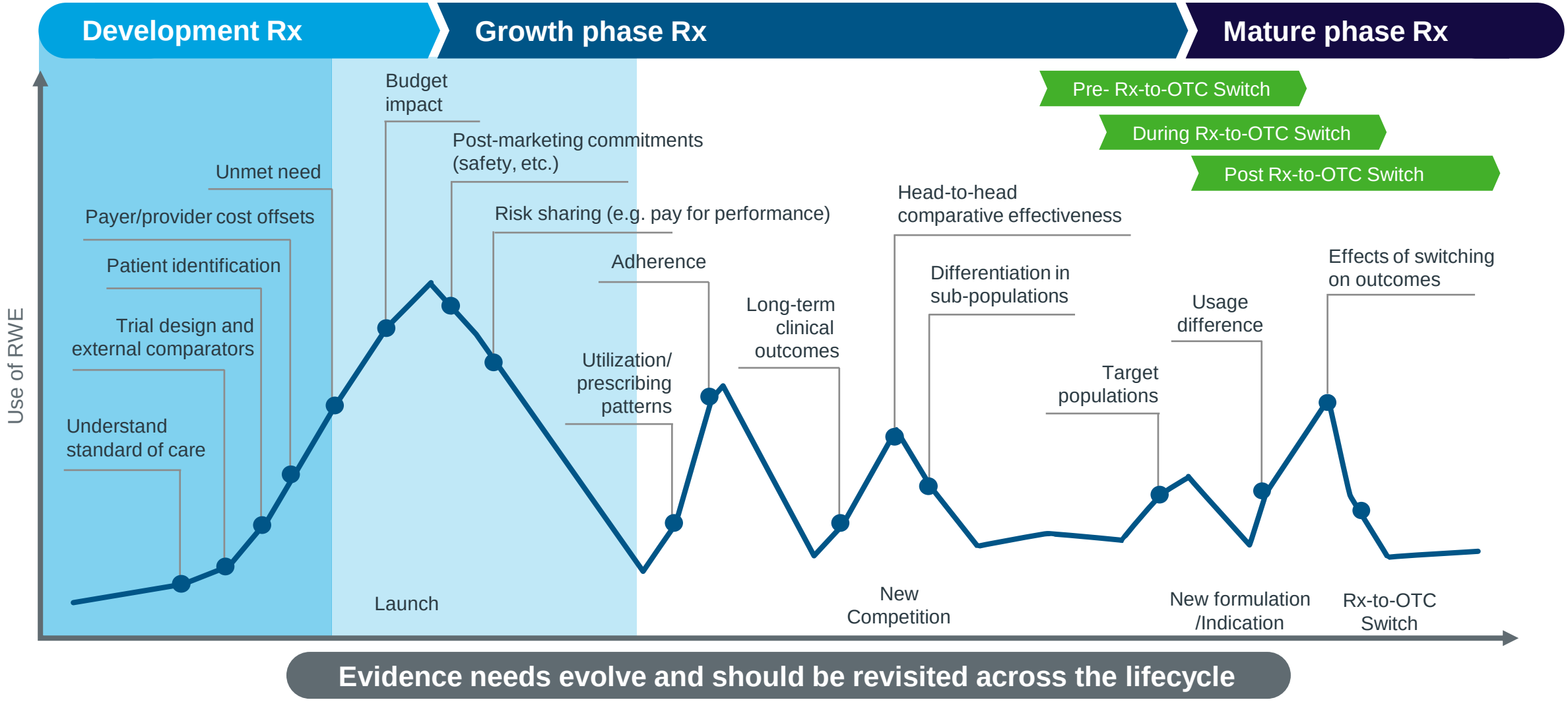
How can real-world evidence aid decision making during the life cycle of nonprescription medicines?



AESGP

Source: How can real-world evidence aid decision making during the life cycle of nonprescription medicines? Emese Csoke, Sabine Landes, Matthew J. Francis, Larry Ma, Denise Teotico Pohlhaus, Christelle Anquez-Traxler. Clinical Translational Sci, Volume: 15, Issue: 1, Pages: 43-54, First published: 18 August 2021, DOI: (10.1111/cts.13129) Fig 1

RWE is increasingly being used across the product life cycle



Evidence needs evolve and should be revisited across the lifecycle

RWE will increasingly be used to support switch from Rx-to-OTC

The power of RWE is being unleashed to increasingly support regulatory decision making

Increasing use and opportunity to use RWE for regulatory decision making

- Original new drug applications (NDA) will increasingly include RWE
- Digital health technologies are driving access to patient centric real world data sources such as patient generated health data (PGHD)
- New data sources also leading to innovative study designs e.g., RCTs with external comparators arms from RWD
- Increasing use of mobile devices, decentralized clinical trials and remote monitoring facilitates pathways to collect high quality, relevant and reliable RWD in the home setting
- Increasing guidance on best practices to generate fit for purpose RWE

What type of RWE will regulators accept for decision making

"FDA does not endorse one type of RWD over another. Sponsors should select appropriate RWD sources based on their suitability to address specific regulatory questions….

… In order to determine the suitability of RWD for regulatory decision-making, FDA will assess the **relevance and reliability of the source** and its specific elements…"

U.S. Food and Drug Administration
Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Device. Guidance for Industry and Food and Drug Administration Staff. *Issued on August 31, 2017*

"We're moving into an era where we want to facilitate the use of RWD and RWE,…

… exclusivity will be given if RWD/RWE can be shown to be **as robust as that generated by clinical trials**…"

EU DG for Health and Food Safety
Olga Solomon DG Sante unit, Medicines: Policy, Authorization and Monitoring, European Commission Rx to OTC exclusivity panel discussion, AESGP 59th Annual Meeting in Paris, France. *23 May 2023*

To maximise the success of Rx to OTC switch studies, high quality, reliable & relevant RWE will be required

Is today's required evidence really showing today's US consumer?

Vidhu Bansal-Dev, Vice President, Rx to OTC Switch and Digital Transformation, Haleon US

> ***Is the threshold of evidence FDA is requiring for Rx-to-OTC switch genuinely the best way to characterize consumer behavior and reflective of today's consumer?***

- Today's evidence requirements don't accurately represent how consumers behave
- RWE to support Rx-to-OTC switch should be more widely accepted in the U.S.
- Significant Disparity in FDA Approvals of Rx-to-OTC Switches for New OTC Indications Compared to UK/EU
- Benefit and risks should be considered for any Rx-to-OTC Switch NOT just the risks

Vidhu Bansal-Dev

Vice President, Rx to OTC Switch and Digital Transformation

Haleon US

Conclusion

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The future of Rx-to-OTC switches

Rx-to-OTC switches are a significant opportunity for all stakeholders

Tailwinds

The potential benefits of Rx-to-OTC switches are huge, from increased sales and market expansion to improved public health and relief for healthcare systems.

With supportive regulatory environments, advancing technology, and the potential to tap into new indications and markets, Rx-to-OTC switches represent a significant opportunity for the pharmaceutical industry.

Consumer demand

Convenience, accessibility, and often lower cost

Healthcare systems relief

Costs healthcare systems and time for HCPs

Untapped markets

Growth opportunities across the globe

New technologies

Facilitate more advanced switches ensuring proper self-selection, usage, and monitoring

Government support

Regulatory agencies and governments are supportive

RWD/RWE as new evidence

New insights to support switches

Potential for new indications

Plenty of new indications which could be OTC ready

Some drugs need fast access

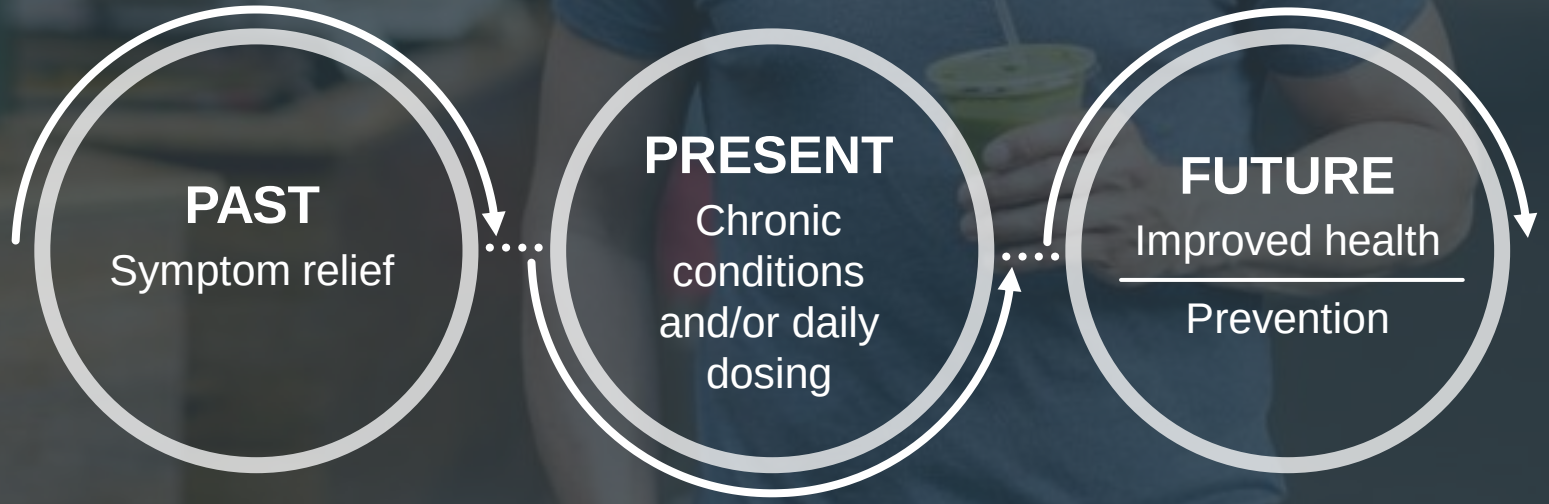
Better public health by providing OTC access (e.g., influence)

Public health benefits

Better access to medications, can improve public health,

The Future... Improved health and quality of life

Focus now is on improving health and quality of life for consumers



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