

# OTC Drug Regulations- Overview of Global Practices & Way Forward for India

**Dr. Sonal Shidhore**  
**Director- Regulatory Affairs**  
**Johnson & Johnson Pvt. Ltd**

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# Overview of Selfcare & OTC Category

Well defined regulatory framework for OTC drugs in India is need of the hour, to cater responsible selfcare for minor ailments in Indian Population

# Key Factors addressing Healthcare

Accessibility

Availability

Affordability

Accountability

Information, Awareness and Education

# OTC: General Considerations



# Value of OTC medicines and Self-care

## Benefits to society are:

- Empowered patients with higher self-esteem
- improved wellness and longer life expectancy
- Reduced healthcare costs
- Access to medicines in spite of limited availability of healthcare professional/hospital

## Government and industry shared goal to improve public health:

- Indications are self-recognizable, relatively minor ailments
- Self-monitoring
- Self-management
- Symptomatic treatment of common health problems with medicines designed and labelled for use without medical supervision



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# Broader International Scenario on OTC

Independent  
Bodies: WHO,  
GSCF

Developed  
Markets

Developing  
Markets



# World Health Organization Definition of Self Care

- ... The ability of individuals, families and communities to:
  - Promote
  - maintain health
  - prevent disease
  - cope with illness
  - with or without the support of a healthcare provider.
- Promotion of self care is a means to empower individuals, families and communities for informed health decision-making.
- It has the potential to improve the efficiency of health systems and to contribute towards health equity.

# Regulatory Perspective of WHO on OTC Legislations

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## Qualifying criteria for reclassification

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The use of product should be sufficiently **extensive**, or it should be high in volume.

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**Duration** of a drug in market as a prescription category. It should not be there in the market for less than **five years**, before it's considered for a **switch**.

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Availability of **episodes of adverse events** and the **frequency** with which those pops up.

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**Investigational use** in **clinical trials** prior to marketing authorization.

# Global Self Care Federation

- From June 2019, **World Self-Medication Industry** (WSMI) is known as the **Global Self-Care Federation**. The change of name reflects a **fundamental shift** in WSMI's approach.
- **Re-positioning** to more outward-looking organization, with active role in **shaping the future of self-care**. Keeping in mind-
  - Growing **aging** global population with a greater need for **better chronic disease management**
  - Fast **evolving consumer**, changing ways of interactions with healthcare providers and the healthcare system
  - An **omnichannel world** where people want convenient, transparent and affordable options at their fingertips
  - **Demand** for holistic, personalized solutions in data driven world

# OTC Requirements Continuum

**Lower data requirements + same quality standards =**  
well-established active ingredients or are identical to existing OTC medicines

**High data requirements + same quality standards =**  
new drugs, new strengths and new indications require data similar to Rx

## **Monograph or exempted.**

E.g. Same or similar formulation, form, consistent indications.

**Reference product and BE study not required**

## **New Drug**

E.g. new API's; new combinations; new strengths, new claims

**Full safety and efficacy required**

**Consistent QUALITY; GMP; Post Market Surveillance standards**

# Risk Based -Well Known API Concept

Item	US Monograph System	EU Well Established Drug	Australian Monograph
<b>Scope</b>	<b>Generally Recognized as Safe &amp; Effective (GRASE)</b> <ul style="list-style-type: none"> <li>• General Provisions-Scope &amp; definition of conditions for active ingredients.</li> <li>• API- eg analgesics, cough/cold, allergy, heartburn, etc.</li> <li>• Labeling-Indications, Dosage form and strength, Directions, Warnings</li> <li>• Testing Procedures-Testing Part &amp; Method Reference</li> </ul>	<ul style="list-style-type: none"> <li>• Extensive and continued use over a period of at least 10 years in the Union.</li> <li>• Demonstration of a well-established medicinal use, with recognized efficacy and an acceptable level of safety.</li> </ul>	<ul style="list-style-type: none"> <li>• Introduction</li> <li>• Active substance</li> <li>• Dosage forms and strengths</li> <li>• Indications</li> <li>• Directions for use</li> <li>• Labelling</li> <li>• Quality requirements</li> </ul>
<b>Clinical Requirement</b>	Clinical studies, Reference product and BE <u>not required</u>	Clinical studies, Reference product and BE <u>not required</u>	Clinical studies, Reference product and BE <u>not required</u>
<b>Market Authorization</b>	No prior approval	Prior approval	Prior approval
<b>Governance Model</b>	Consistent QUALITY; GMP; Post Market Surveillance standards		



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# Present Regulation in India

OTC - Not defined

Prescription Drugs

Other than Prescription Drugs

Restriction on the Claims and  
Advertisements for prescription drugs

# General Understanding on OTC drug

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It is a non-prescription drug

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It can be used by patient directly for treating minor ailment with or without medical support

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Awareness of such drugs can be created through advertisement

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It can be sold at the Supermarkets / FMCG outlets/ Pharmacy Stores but without prescription



# Framing of OTC Regulation in India-Background

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**No** formal **Switch** process

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Very few switches from Rx to Non-Rx since last 45+ years-Examples-Aspirin (Aug 1972), APAP (Sept 1986), Chemical Contraceptives (Dec 1991), Nicotine 2 mg gum (July 2003)

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Omitted from Schedule H :Dextromethorphan Hydrobromide (Jul 2010), Chlorpheniramine Maleate (Aug 2013)- Sch G

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**Framing** of **OTC regulation** discussion taken up by **DCC** (Drug Consultative Committee)

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52<sup>nd</sup> DCC formulated **OTC- Sub Committee** to review earlier work and provide report

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In 57<sup>th</sup> DCC held in Aug.2019, OTC SubCommittee Submitted Preliminary Report

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**Sub Committee** for Review of **Advertisements Regulation** is also formed

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# Industry-Regulators Partnership for Policy Shaping

- **Industry- Regulators Dialogue ongoing through Industry Associations Forum :**
  - Industry having multiple meetings with OTC Sub-Committee members
  - Feedback provided on **Initial list** for OTC
  - **Companies** to take **responsibility** for providing **safety data**, justification for inclusion as OTC.



# Excerpts of Industry & DCC discussions

- Promote self-care without compromising **patient safety**
- Include the **definition for OTC drug** in the Drugs Law
- Classification of OTC drugs into OTC-1 and OTC-2
  - ❑ based on the extent of **evidence of safety**, therapeutic index
  - ❑ need for **accessibility to patients**, availability
  - ❑ **non-habit-forming** nature
  - ❑ **socioeconomic** conditions of the country
- Initial **list of OTC Drugs (API + FDC )**
- **Switch Process** for Rx to OTC
- Regulation of **New OTC Drug** Approval
- **Distribution & Sale and Advertising of OTC** Drugs

# Key Drivers for OTC Policy Implementation

## Identification of molecules/FDCs for OTC Switch

- where benefits outweigh risks
- Low potential misuse and abuse
- Acceptable margin of safety with previous use experience in India & other markets
- Molecule status as OTC in other markets
- Convenient for informed use with adequate information on label / package insert

## Patient Education through Labelling & Package Insert

## Patient Awareness through Advertisement

# Adequate labelling of OTC Drugs

Information on label in **simple, consumer friendly** language

Colour coding for **differentiation** between Rx , OTC-1 or OTC-2 drug (ease of identification)

Can use '**Drug Fact Box**' – Name of Drug, Actives, Use, Agewise dosing, Directions for Use, Warnings/ Do's & Don'ts, Duration for use, Customer Care Details

Additional Information on **PI** (package insert)

Use of 5-8 local languages apart from English for understanding of consumer/ patient across India

Use of **Pictorial** presentations for better understanding

**QR Code** can be displayed on pack and PI- scan code to get additional information in **text, pictorial** and **video** presentation format

Adequate information about the drug and **visual differentiation** from Rx drug will help the self medicating patient to use the drug **responsibly** with **informed decision**

# Role of Advertisement in Selfcare

- Currently, Drug **Advertisements** are controlled through a “**self-regulatory**” mechanism
- **ASCI** plays important role to ensure that the advertisements are not misleading directly or indirectly, no false claims or in any other way false or misleading in any aspect.
- Industry **recommendation** to **continue same process** for OTC drugs with publishing an additional **guidance documents** on ‘Do’s and Don’ts) of ethical advertisement
- Content of advertisements for which currently no advertisement can be made, examples: Ailments covered under Schedule J and DMR Act to be preapproved. For others, guidance document can be referred and ‘Self Regulatory ‘Mechanism to be followed

# Proposed Guidance Document

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Definition of Advertisement

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Advertisement of OTC to be allowed in all media

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claims to be consistent , non deceptive & simple to understand and to be supported with substantiation data

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Advertisement also to be used for awareness by urging consumers to read the label or patient information leaflet for more information

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advertisements must include mandatory warnings to seek a physician's opinion if symptoms persist for "X" no of days, depending on the ailment

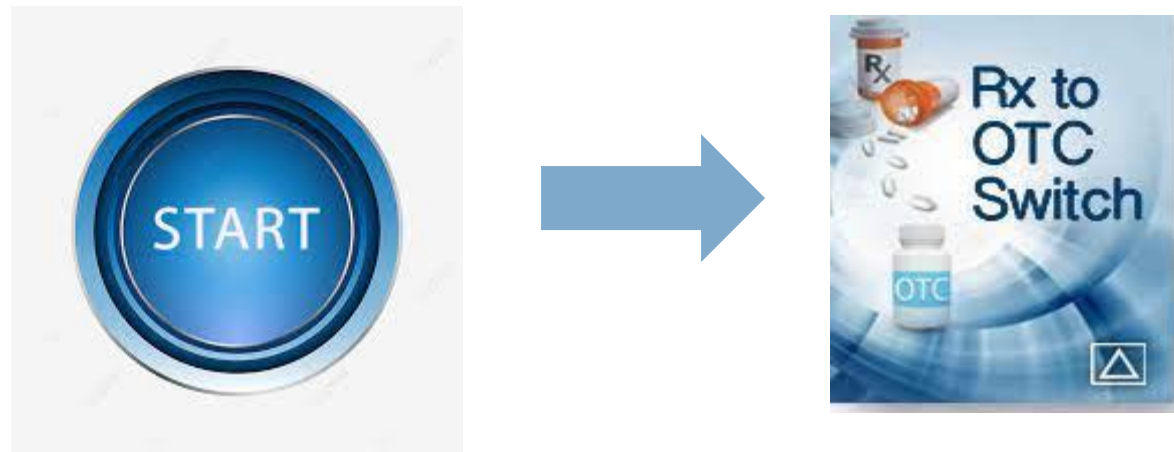
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Comparative -claims may be allowed without disparaging

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# Summary

- Well defined regulatory framework for OTC drugs in India is need of the hour.
- Strong advocacy campaign for creating general public awareness regarding responsible selfcare will be helpful to serve Public Interest
- In future, '**Rx to OTC switch process**' will be commonly used strategy for responsible selfcare to help achieve health goal of India







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**Thank You**