REPORT OF THE SUB-COMMITTEE OF DRUGS CONSULTATIVE COMMITTEE (DCC) ON OVER THE COUNTER(OTC) DRUGS

BY:

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PREFACE

As a Chairman of the Sub-Committee, I am happy to present in this report, the recommendations with respect to consideration of a definition for "**OTC Drugs**" for the first time under the Drugs and Cosmetics Act, 1940 and Rules, 1945 and the necessary modalities/regulatory pathways as to how certain drugs, presently being marketed or will be marketed can be considered for bringing them under the class of OTC drugs (over-the–counter). Before making certain conclusions, the sub-committee has examined the best practices globally in respect of drugs marketed as OTC vis-a-vis the various drugs that are being marketed in this country under various Schedules in an extensive manner. The sub-committee in this report has also recommended certain modalities/ amendments to be done in the licensing and labelling part so that the pharmacist can dispense the OTC drugs and the consumers can access them and responsibly indulge in self medicare in a hassle free manner. The committee also examined the issue of OTC drugs classification and regulations stipulated under various Schedules of Drugs and Cosmetics Act, 1940, so that it can be implemented in the country in an uniform manner. During this journey about four meetings were conducted and extensive brainstorming was done regarding OTC drugs with various stake holders, given within the ambit of the terms of references, the scope and its objective. Finally, we arrived with an unanimous model for the assigned task keeping in view the four cornerstones of healthcare i.e accessibility, availability, affordability and accountability of the stakes and stakeholders. In the next few pages a detailed report is furnished for the easy understanding and recommendations made by the sub-committee on the assigned tasks.

ACKNOWLEDGEMENTS

I am thankful to the Drugs Controller General (India), New Delhi for appointing me as Chairman of the sub-committee for making recommendations on OTC drugs to be marketed in the country. I also thank all the Sub-committee members for their valuable contributions made during the series of meetings. I thank every member of this sub-committee for sparing their valuable time for attending the various meetings at different stations conducted on my call in spite of their busy schedule.

I personally thank the Professors and HOD's of Government General Hospital and Guntur Medical College, Medical/Surgical speciality Experts from Dr.NTR Vaidya Seva Trust, Government of Andhra Pradesh and Sri M.B.R. Prasad, Director, DCA, Andhra Pradesh for their valuable suggestions in arriving at certain modalities for making recommendations on the assigned tasks for which the committee has been set-up.

I acknowledge and thank IDMA, AIOCD, IPA, IMA, Patient safety & Access India Foundation, OPPI, FICCI ,Heart care foundation of India trust,for their valuable Contributions.

I thank Mr. K. Raja Bhanu, Mr. K. Anil Kumar, Assistant Directors and Ms. Asha Shaik, Drugs Inspector, Drugs Control Administration, A.P who assisted me in drafting the entire sub-committee report and made it possible.

Dr. A. RAVI SHANKAR, I.P.S
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Report of the Sub-Committee of Drugs Consultative Committee (DCC) on Over The Counter (OTC) Drugs

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1.0 Introduction

1.1 Deliberations in the 52nd DCC meeting regarding regulation of OTC Drugs:

Drugs Consultative Committee (DCC) is a statutory body constituted under Section-7 of the Drugs and Cosmetics Act, 1940 (herein after referred as Act). The main objective of the committee is to secure uniformity throughout the Country in the administration of the Act. In the 50th and 52ndmeeting of the DCC, it has deliberated the matters related to feasibility of classification and regulation of the OTC products and recommended for creation of a separate category of OTC drugs to be sold on retail pharmacies and constituted a sub-committee.

In India, unlike the other developed nations, the healthcare access has four (4) key dimensions-

1. Physical accessibility of a requisite healthcare facility (OPD or IPD) within 5 Km from the place of residence or work.
2. Availability of the requisite healthcare resources for patient treatment (Doctors, Paramedics, Pharmacists etc., and other infrastructure)
3. Quality of the healthcare resources
4. Affordability of the treatment by the patient.

Even if one of the above key components is missing, a patient is unlikely to receive appropriate and efficient healthcare. This being an elusive thing even for the most advanced countries also, the patients for ages have become more and more self conscious about their health and self-care has become a lifelong habit and culture in this country with many systems of medicine available. It is the action that individuals take for themselves and for their families to stay healthy and take care of minor and long term conditions, based on their knowledge and the information available and working in collaboration with health and social care professionals where necessary.

Self-care involves:

- **Making healthy lifestyle choices** such as physical activity and healthy eating, which allow the maintenance of good health and the prevention of illness.
- **Making responsible use of all medicines** (prescription and non-prescription).

- **Self recognition of symptoms,** which involves assessing and addressing symptoms, if necessary in partnership with a healthcare professional (not necessarily a doctor).
- **Self-monitoring,** which involves checking signs and symptoms for deterioration or improvement?
- **Self-management,** which includes being able to manage the symptoms of disease, either alone or in partnership with healthcare professionals or other people with the same health condition.

A country which fully encourages self-care can expect to have a healthier population and redeploy scarce resources in priority areas. Self-care can play a crucial role in the prevention of the coming global epidemic of non-communicable chronic diseases such as cardiovascular diseases, cancer and diabetes.

The benefits of self-care to society are empowered patients with higher self-esteem, improved wellness and longer life expectancy and reduced use of healthcare services.

"Health systems in all world regions are under pressure and cannot cope if they continue to focus on diseases rather than patients; they require the involvement of individual patients who adhere to their treatments, make behavioural changes and self-manage"
-The International Alliance of Patients' Organizations. Declaration on patient-centered Healthcare. February 2006.

People should be given the information, education and tools they need to become more proactive in their healthcare and more confident to take good care of themselves. Health professionals, not least doctors and pharmacists, also have an important role in encouraging self-care.

"Every person has the right to health education that will assist him/her in making informed choices about personal health and about the available health services. The education should include information about healthy lifestyles and about methods of prevention and early detection of illnesses. The personal responsibility of everybody for his/her own health should be stressed. Physicians have an obligation to participate actively in educational efforts".World Medical Association.
-Declaration on the Rights of the Patient. 1981, revised 2005.

"Nowadays people are keen to accept more personal responsibility for their health status and to obtain as much sound information as possible from expert sources in order to help them make appropriate decisions in health care (…) Pharmacists have a key role to play in providing them with assistance, advice and information about medicines available for self-medication."

-***The International Federation of Pharmacists. Joint Statement by FIP & WSMI, 1999.***

Thus “Self-medication” is the treatment of common health problems with medicines especially designed and labelled for use without medical supervision and approved as safe and effective for such use.

Every day, everywhere, consumers reach for self-care products to help them through their common health problems. They do so because it may be easier for them, it may be more cost or time efficient, they may not feel their situation merits making an appointment with a healthcare professional, or they may have few or no other options.

Consumer interest is the health information explosion, made possible by technological advances that improve access to information that is more relevant and more useful to the end user. Consumers now have more tools to take an active role in their health care, and they are using them.

Aging populations, increased interest and emphasis on wellness and disease prevention, and consumer empowerment themes are all trends prevalent in many societies. Self-medication fits into these trends as well.

Society benefits from a citizenry that is better informed about healthcare and therefore more able to exercise self-reliance. Having the tools available to help consumers practice such self-reliance also allows scarce health resources to be directed toward illnesses or conditions that require treatment in the professional healthcare system. Having appropriate non-prescription medicines available can also reduce illegal use of prescription products without a prescription

World Health Organization has stated that responsible self-medication can:

- Help prevent and treat symptoms and ailments that do not require medical consultation;
- Reduce the increasing pressure on medical services for the relief of minor ailments, especially when financial and human resources are limited;
- Increase the availability of health care to populations living in rural or remote areas where access to medical advice may be difficult; and
- Enable patients to control their own chronic conditions.

As the most accessible form of health care, self-medication fills a series of valuable and sometimes crucial functions for individuals and healthcare systems. That healthcare systems as well as individuals benefit from self-medication emphasizes the need for clear policies by national governments.

Those policies should recognize the positive role played by products specifically intended for self-medication and should meet their citizens' desires to take an active role in their health.

The Self –medication which is being done through mostly non-prescriptions medicines/drugs, commonly known as OTC Medicines or drugs are a critical component in advancing consumer health because they allow people to treat or manage many health conditions conveniently and successfully. Because they enable people to self-treat, OTC medicines save health systems valuable resources and can save consumers time and money. OTC medicines have played a significant role in extended access to safe and effective treatments in developing regions of the world.

The drugs or medicines which are defined under the Drugs and Cosmetics Act, 1940 and Rules there under in this country has not explicitly defined the OTC Medicines or the Self-care medicines leaving for discretion and ambiguity among citizens, healthcare providers and other stake-holders.

In order to create extended access, empowerment and trust, the challenge and opportunity for government, healthcare professionals, and providers of self-medication products is to have a robust and responsible framework in place for self-medication products/OTC Medicines that will improve access and meet one of the WHO objectives of educating people about the risks of self-medication.

Thus it is incumbent upon the Government to propose the definition, necessary revisions in classification of drugs, labelling, advertising, distribution, pricing and the entire regulatory processes for enabling any existing prescription drugs to non-prescription drugs based on the safety, rational use, effectiveness and availability of drugs in comparison with the need and objective of expanding access to medicines to treat non-serious conditions.

Therefore the DCC after detailed deliberations felt that it is required to study the matters related to OTC and other best practices in the developed and developing countries and to evolve OTC regulations suitable for this country.

The DCC constituted a sub-committee consisting of the following members to examine the issue of OTC drugs on and matters arising out of the administration of the Drugs & Cosmetics Act-1940 & Rules made there under and for creation of separate category of OTC drugs for sale in India.

1. Dr. A. Ravi Shankar, IPS, Drugs Control Administration, Andhra Pradesh.
2. Drugs Controller, Chandigarh.
3. Drugs Controller, Uttarakhand.
4. Drugs Controller, Karnataka.
5. Joint Director, FDA, Mizoram.
6. R. Chandra shekhar, DDC(I) (Convener).

1.2 Terms of References of the Sub-committee:

1. The sub-committee shall examine comprehensively the drugs marketed in country vis-a-vis conditions for sale stipulated under various Schedules, namely Sch G, Sch H, Sch H1, Sch X and Sch K etc.
2. The sub-committee shall recommend the list of drugs which may be considered for marketing as OTC drugs.
3. The sub-committee shall recommend for the classification and regulation of the OTC drugs.
4. The sub-committee shall also recommend modalities / amendments needed in the conditions of sale licence so that Pharmacist, while dispensing the OTC drugs may supply any other generic preparations containing the same drug.
5. The committee shall furnish its report in three months.

The copy of the order constituting the Sub-committee is enclosed at Annexure-I.

1.3 Meetings & Consultations of the Sub-Committee:

The sub-committee constituted for evolving guidelines and regulations of OTC drugs has met and discussed during the following meetings

1. Meeting held on 22-12-2017 at RDTL, Chandigarh
2. Session on Emerging Landscape of Self-care and OTC in India on 23-12-2017 at 69th Indian Pharmaceutical Congress held at Chitkara University, Punjab.
3. Meeting held on 19-01-2018 at CDSCO, Mumbai
4. Meeting held on 12th& 13th March, 2018 at CDSCO, Hyderabad

Chairman of sub-committee has conducted extensive meetings with the following stake holders and Healthcare Experts for discussions and suggestions regarding introduction of a separate schedule for OTC drugs in the Act.

1. **Indian Medical Association- AP State Branch:** The office bearers & Medical Experts were consulted extensively several times for their opinions on present situation of OTC usage and preparation of the proposed list of OTC drugs
2. **ASHA: Association of Super speciality Hospitals of Andhra Pradesh:** The Association represents the majority of the healthcare providers in super speciality in the state. Extensive consolation

meetings were conducted with the representatives of the ASHA at Guntur, Ongole and Vijayawada and obtained expert opinions on burden on Healthcare providers and preparation of proposed OTC drugs.

3. **Professors of Guntur Medical College, Guntur:** The Chairman has conducted series of consultation meetings with the heads of the Departments of the various branches of medicine at Guntur Medical College (Teaching Hospital), Guntur, Andhra Pradesh for and preparation of the proposed list of OTC drugs based on the safety & efficacy profiles of the individual drugs.
4. **Experts of the Dr.NTR Vaidya Seva Trust:** The Dr.NTR Vaidya Seva Trust, Guntur is the Govt agency providing healthcare services to the BPL families in Andhra Pradesh. The speciality wise experts were consulted and discussed about the appropriateness of the present regulations on OTC drugs and their importance in the public healthcare.
5. **FICCI:** Federation of Indian Chamber of Commerce & Industry is non-government, not-for-profit organisation representing the various business & industry in India. Meetings were conducted with their representatives during 69th Indian Pharmaceutical Congress and submitted their views and recommendations subsequently.
6. **OPPI:** Organization of Pharmaceutical Producers of India represents the majority of companies' & research-based pharmaceutical companies in India along with the public sector units. Meetings were conducted with their representatives during 69th Indian Pharmaceutical Congress and submitted their views and recommendations subsequently
7. **IPA-AP State Branch:** The Indian Pharmaceutical Association represents the Pharmacists Community. Meetings were conducted to understand the role of possible extent of Pharmacist in the healthcare especially in Self-medication.
8. **SADDA (Seemandhra Drug Dealers Association):** The SADDA represents aprrox. 30,000 Dealers, chemists, druggists of the state of Andhra Pradesh. Several meetings were conducted with the representatives at Guntur and Vijayawada and received their opinions for understanding the behaviour of the consumer and ground level situations

Various aspects of the OTC drugs were deliberated during the above mentioned meetings and inputs were taken.

2.0. OTC - Current Regulatory framework In India:

Presently in India the import, manufacture and sale of drugs are regulated under Drugs & Cosmetics Act, 1940 and Rules made there under. The Drug is defined under Sec. 3(b) of the Act covering both the drugs & medical devices.

The drugs other than Homeopathic, Ayurvedic, Unani & Siddha are dealt under the Chapter-IV of the Act which are otherwise popularly known as Allopathic Drugs. The drugs falling under the purview Chapter-IV are further categorized into various schedules like Schedule-C, C1, G, H, H1&Xfor the purpose of better regulation with respect to manufacture, sale & distribution.

The labelling requirements for these scheduled drugs are prescribed in the Drugs & Cosmetics Rules, 1945. The Rule-65 mandates the manner of selling of these scheduled drugs as per the labelling directions mentioned in accordance with the rules and conditions of the licenses. Thus the drugs falling under Schedules H, H1 & X are the only category of drugs which are to be sold on the prescription of Registered Medical Practitioner. The drugs defined under Rule-122E and also the fixed dose combinations of the drugs in the above three (H, H1 & X) schedules with any other drugs will also fall under the category of schedule H, H1 & X. In the absence any specific classification or definition under the Act for OTC Medicines, all the allopathic drugs other than the Schedule H, H1 & X are technically deemed to be OTC drugs for sale, without the necessity of any prescription of registered medical practitioner.

Self Medication is the treatment of common and minor health problems with medicines especially designed and labelled for use without medical supervision and approved as safe and effective for such use. Self Medication is a critical component of a well functioning Health Care System as it is undoubtedly the primary resource for first line treatment in any health care system as espoused by the WHO. Non Prescription (OTC) medicines provide value through significantly expanded access to treatment for the most frequent and common illnesses, meets public health priorities through wellness and prevention, while also supporting the quality of life and productivity of a population.

World over, responsible self-medication is being acknowledged as a valuable tool to achieve public health goals such as improving access to medicine reducing health care costs and the burden on health infrastructure and positively influencing overall health seeking behaviour. The WHO recognises responsible self-medication as a part of self cure which, in turn, is acknowledged as integral to primary health.

Indians are already self medicating due to socioeconomic conditions, minimised access to health care professions especially to the population in rural areas, much higher rates of hospital consultations and diagnosis.

The rise in self medication during recent years is due to

- Globalization
- IT revolution (internet access, e-pharmacies& health apps)
- Emphasis on wellness
- Disease prevention
- Significant advertising of health care products through press and media

Apart from non prescription drugs, Indians are also self medicating with prescription drugs falling under the categories of Schedule H and H1 without prescription and were being treated by unqualified quacks without having much knowledge and safety information on hand which is not a healthy trend.

3.0. OTC – Global Scenario:

Developed countries across the globe designed and developed policies &regulations distinguishing between prescription and non prescription (OTC) drugs. There were clear laid down rules for manufacturing, distribution, labelling and advertising of OTC drugs in those countries. The OTC regulatory system is having an inbuilt dynamic process of Rx to OTC and OTC to Rx switching having to constantly evolving evidence of product safety and efficacy.

Key elements in regulation of OTC drugs in EU, Canada and US:

- It starts with the premise of non prescription status, with prescription status clearly defined
- Safety considerations weigh strongly- based on either side-effects, because the ingredient may be habit forming, or because of the dosage form a prescription is needed for safe use.
- The frame works do not subdivide non prescription products into categories where the products are sold such as pharmacist or pharmacy- only, general sale etc. while some EU member states subdivide non prescription medicines where the EU legislation does not.

3.1. Pillars of OTC regulations:

Permitted products and switch process: These are the products that can be sold without a doctor's prescription. The list of permitted products is guided by a system of classifying molecules/brands as OTC or changing their classification from Rx-to-OTC using the switch process which is a clear regulatory pathway specified by law.

Distribution: This covers the types of outlets through which an OTC product may be sold e.g. pharmacies and general sales outlets.

Advertising and promotion: This covers what the marketer communicates about the product to the consumer and the media on which it can do so.

Labelling: This covers the information that a label/package insert/product information leaflet should contain on the drug's use, side-effects, contraindications, dosing, etc. in language that is unambiguous and easy to understand.

Pricing: This decides the pricing treatment of OTC drugs e.g. whether they are controlled by the government or not, the manner of control, and also whether prices are covered by a payer such as the government or an insurer.

Monitoring & Pharmacovigilance: This refers to post-market surveillance reports, pharmacovigilance data and other documentary evidence that is required to alter the classification of a drug and to monitor safety of the drug post-approval.

3.2. OTC regulation in some other countries:

3.2.1. United States America:

- To deal with the vast number of OTC drugs that were already there in the market the FDA created the **OTC monograph** system to review classes of drugs and to categorize them as GRAS/E after review by expert panels.
- Certain classes of OTC drugs would not be required to obtain an NDA and could remain on the market if they conformed to the monograph guidelines for doses, labelling, and warnings finalized in the Code of Federal Regulations.
- Thus, an OTC drug product is allowed to be marketed either
  (1) Pursuant to an FDA monograph or
  (2) Pursuant to an NDA for products that do not fit within a specific monograph**.**
- FDA requires that all "new drugs" obtain a New Drug Application (NDA) before entering interstate commerce, but the act exempts any drugs generally recognized as safe and effective (GRAS/E).

OTC product labelling:

- The FDA requires OTC products to be labelled with an approved "Drug Facts" label to educate consumers about their medications. The labels comply with a standard format and are intended to be easy for typical consumers to understand.
- Drug Facts labels include information on the product's active ingredient(s), indications and purpose, safety warnings, directions for use, and inactive ingredients.
- Labelling should be understood by the ordinary individual, including individuals of low comprehension.

Advertising: The advertising of OTCs and dietary supplements is regulated by Federal Trade Commission (FTC), and follows regulatory standards:

- Advertising claims must be sustainable, advertisements may not be deceptive and advertisements may not be unfair
- Advertising of OTCs and dietary supplements is allowed in all media. However, in 2013 FTC became very aggressive against unsubstantiated dietary supplement benefit claims.

Distribution: OTCs and dietary supplements may be sold in any and all outlets in the U.S. – pharmacies, mass merchandisers, food stores, or others.

Price controls: Non-prescription medicines and dietary supplements are not subject to price controls in USA

Rx to OTC Switch: An Rx-to-OTC switch follows the same New Drug Application (NDA) as an Rx drug application. By the time a switch is considered, the molecule's safety and efficacy are well proven. New efficacy and safety data from controlled clinical trials are included in the switch application if the OTC indications or strength differ from those for the prescription drug product. A comprehensive review of safety also forms part of the switch application.

- In other words, the switch NDA builds on information from previous regulatory filling and the experience with use of the Rx product. The switch NDA contains both efficacy and safety data demonstrating that the drug product is sage to use in the OTC environment. That is, that the benefits of OTC use outweigh potential risks.
- A key benefit for marketers is a three-year exclusivity period to the switched molecule if significant new research supports the NDA uniquely for OTC distribution. Often Rx to OTC switch is a strategy to extend patent protection for drugs nearing the end of their Rx patents.
- New products with the same ingredients can be approved with an ANDA (abbreviated new drug application), citing the original data. OTCs with non-switch OTC ingredients already marketed and considered safe and effective are included in the OTC monograph for therapeutic categories and can be launched without an NDA.

3.2.2. United Kingdom:

Medication is governed by the Human Medicines Regulations 2012.

The description conveniently distinguishes medicines that can be bought from those that must be prescribed. The term 'over the counter medicines' is informal and is not used in the UK medicines regulations.

The legal classification of a pack of medicine determines the level of control over its supply. In part, classification rests on how much health professional input is needed to diagnose and treat the conditions for which the medicine might be used. Currently, there are three categories that a medicine can be classified within:

- **Prescription-Only Medicine (POM)** - has to be prescribed by a doctor or other authorised health professional and it has to be dispensed from a pharmacy or from another specifically licensed place;

  A rectangular box enclosing the letters POM appears on the packs of prescription-only medicines.

  In general, prescription-only medicines are used for conditions that are best diagnosed and managed by health professionals. Examples of prescription-

only medicines include virtually all antibiotics and medicines for treating high blood pressure.

- **Pharmacy (P)** - an intermediate level of control, can be bought only from pharmacies and under a pharmacist's supervision;

  Pharmacy medicine packs are generally for short term treatment of medical conditions that can be identified readily

  There may be a limit on how much pharmacy medicine a person can buy

  Examples of pharmacy medicines include tablets for emergency contraception, paracetamol and medicines containing codeine for treating pain that is not relieved by aspirin, ibuprofen or paracetamol alone.

- **General Sales List (GSL)** - may be bought from retail stores, such as a newsagent, a supermarket or a vending machine in a shop.

  People can buy general sale medicine packs from retail outlets such as corner shops and supermarkets. The medicines—also called 'general sales list (GSL) medicines'—are also available for self-selection in pharmacies. General sale medicines are taken for common, easily recognised ailments which usually last around 2–3 days. These medicines cause few troublesome side effects in normal use.

  Examples of general sale medicines include small packs of painkillers and of antihistamines for hayfever and other allergies.

The underlying principle for classifying medicines is to maximise timely access to effective medicines while minimising the risk of harm from inappropriate use.

- **OTC product labelling:** OTCs must include the full name of the product on at least three faces of the pack. Critical information must also be clearly presented.
- **Advertising:** P and GSL OTCs – Including those available for reimbursement can be freely advertised in all media.
- **Distribution :**an extensive mass market in the UK sees the majority of OTC sales come from outside the pharmacy channel; GSL medicines are sold in a wide number of retail outlets, including the thriving discount store channel, and online.
- At the same time, the role of the pharmacist- via the well – established pharmacy – only channel – is likely to increase as the Government aims to ease pressure on doctors

- With an estimated 13,000 pharmacies in the UK, pharmacy chains and supermarkets (via in -store pharmacies) account for around 61 per cent of the total, for outnumbering independent pharmacies
- **Reimbursement:** Many OTCs are available for reimbursement by the NHS, mostly generics but also brands. The same ingredients / products can be both reimbursable on the NHS and available pure PTC. Prescription are charged at $8.05 in England (as of April 2014), but are free in Scotland, Wales and N Ireland.
- **Price Controls :**Reimbursed OTCs are sold at the prescription price; non-reimbursed OTCs are freely priced
- Significant pressure is put on OTC pricing due to strong consumers support for store brands and Private Labels (PLs) as well as a well – developed mass market; chain pharmacies, drugstores and supermarkets are engaged in ongoing price war

Rx-to-OTC Switch:

- In 2012 the MHRA introduced a new procedure for Rx-to-OTC switch aimed at streamlining and speeding up the process
- Reclassifications normally follows a request from the Marketing Authorisation holder, although these can be made by any interested party
- A proposal to change a medicine's classification need to be supported by good evidence (e.g clinical studies, extensive clinical use indicating acceptable side effects) that focuses on the risk on the public on changing the classification
- Three types of reclassification applications are available:
    - Major (in a new therapeutic category or a new target population for existing products)
    - Standard (if it doesn't need to be referred to an expert advisory committee)
    - Simple (based on an analogous product which has already been reclassified)
- Applications are evaluated by the MHRA, which will make the request public for consultation. Only the product subject to the application will be reclassified following a positive review.

3.2.3. Canada:

In Canada, there are four drug schedules

1. **Schedule-1:** Requires a prescription for sale and are provided to the public by a licensed pharmacist.

2. **Schedule-2:** Does not require a prescription but requires an assessment by a pharmacist prior to sale. These drugs are kept in an area of the pharmacy where there is no public access and may also be referred to as **"behind-the-counter**" drugs.
3. **Schedule-3:** Does not require a prescription but must be kept in an area under the supervision of a pharmacist. These drugs are kept in an area of the retail outlet where **self-selection is possible**, but a pharmacist must be available to assist in the self-selection of medication if required.
4. **Unscheduled: Does not require a prescription and may be sold in any retail outlet**.

- All medications **other than Schedule-1 may be considered an OTC drug**, as they do not require prescriptions for sale.
- While the National Association of Pharmacy Regulatory Authorities provides recommendations on the scheduling of drugs for sale in Canada, each province may determine its own scheduling. The drugs found in each schedule may vary from province to province.

3.2.4 Australia:

Over-the-counter medicines (OTC) are medicines that are not prescription medicines and are not complementary medicines. OTC medicines can be supplied as:

- Pharmacy medicines (included in Schedule 2 to the Poisons Standard); or
- Pharmacist-only medicines (included in Schedule 3 to the Poisons Standard); or
- General sales medicines that are not included in any of the Schedules to the Poisons Standard.

Medicines are grouped into schedules according to the appropriate level of regulatory control over their availability to consumers.

How the TGA regulates over-the-counter medicines:
The Act requires that all medical products to be imported into, supplied in, or exported from Australia (other than those that are exempt) must be included in the Australian Register of Therapeutic Goods (ARTG).

In order for a medicine to be included in the Australian Register of Therapeutic Goods, a sponsoring company is required to lodge an application to the TGA. The TGA has developed the Australian Regulatory Guidelines for OTC Medicines (ARGOM) to assist sponsors of OTC medicines to meet their legislative obligations.

OTC medicines can be registered or listed on the Australian Register of Therapeutic Goods, depending on the level of risk associated with making the product available and accessible to consumers.

Registered OTC medicines are considered to be of lower risk than prescription medicines, but they still require an appropriate level of scrutiny.

Registering an OTC medicine in the ARTG:

An application to register an OTC medicine is submitted online through the TGA Business Services facility. The online application needs to be accompanied by:

- An application dossier in CTD format that contains the required information, including:
    - Data that support the safety, quality and efficacy of the product
    - Copies of all labelling
    - Copies of Product Information and Consumer Medicine Information documents, where relevant
    - Administrative information

The ARGOM contains detailed information to assist sponsors to prepare applications and describes the information to be supplied with applications for registration of new OTC medicines for human use in Australia, or to vary existing medicine registrations.

Applications to change conditions of registration:

Once a product has been registered, the sponsor can make further applications to change the conditions of registration. Some examples of changes that might be sought include:

- Label changes
- Shelf life changes
- Formulation changes
- Quality control changes
- Changes to indications
- Changes to directions for use

A 'Change Table' is included in the guidance Changing an OTC medicine: using the Changes Tables that provides details of changes that can be made and the information required to support a particular type of change.

Listing an OTC medicine in the ARTG:

The process involved in listing an OTC medicine is different to that associated with registering a medicine.

Further information on requirements relating to listing of OTC medicines on the ARTG can be found in the Australian Regulatory Guidelines for Complementary Medicines. Information on listing and registration of sunscreens on the ARTG can be found in the Australian Regulatory Guidelines for Sunscreens.

Monitoring the safety of OTC products:

The TGA has a multi-faceted program for monitoring therapeutic products that are on the market.

- The TGA has a problem reporting system for reporting:
  - Medicine deficiency or defect
  - Adverse reaction to a medicine
- Controls for the advertising of therapeutic goods
- Once a problem has been identified possible regulatory actions vary from continued monitoring to withdrawing the product from the market. Actions the TGA can take include:
  - Informing health care professionals and consumers about the risks of using the product
  - Re-assessing the benefit-risk profile
  - Requiring product labelling changes
  - Requiring design or manufacturing change
  - Recalling products
  - Removal of the product from the ARTG.

OTC product labelling: A number of therapeutic goods orders specify standards relating to the labelling and packaging of therapeutic goods. The standard for the uniform scheduling of Drugs and poisons (the poisons standard), the required advisory statements for medicine Labels (RASML) document and the labelling Order.

Advertising: Unscheduled medicines, S2 & S3 listed in Appendix-H of poisons Standard can be advertised in all media

Australia: switch climate

Switch environment is generally liberal, although some industry sources suggest that the regulatory environment is not conducive to encouraging switch because of the Government's conservative approach in granting consumer advertising

Australian Self Medication Industry (ASMI) is calling for a switch agenda to enable a more favourable regulatory environment to switch

In determining the classification of a substance, the TGA requires the following matters to be taken into account:

- The risks and benefits of the use of a substance

- The purposes for which substances is to be used and the extent of use
- The dosage, formulation, labelling, packaging and presentation of a substance
- Any other matters that the secretary considers necessary to protect public health
- The TGA's Advisory Committee on Medicines Scheduling gives recommendations on switch proposals
- Applications for change are filed three months in advance of the next quarterly meeting of the Advisory Committee on Medicines Scheduling (ACMS). Once the change has been approved, the decision can take up to seven months to incorporate into their legalisation.
- Reclassifications are specific to brand/products for specified ingredient, dosage, pack size and intended indication/application (some ingredients remain Rx for specific indications)
- PPIs Pantoprazole (2008), Rabeprazole (2009), Lansoprazole, Omeprazole (2010) and Esomeprazole (2014) all gained S3(pharmacist-only) status; all subsequently approved for S2 (pharmacy-only) status over 2015-16

3.2.5 Netherlands:

In the Netherlands, there are four categories of Drugs:

1. UR (Uitsluitend Recept): Prescription only
2. UA (Uitsluitend Apotheek): Pharmacist only
3. UAD (Uitsluitend Apotheek of Drogist): Pharmacist or drugstore only
4. AV (Algemene Verkoop): Can be sold in general stores

- A drug that is **UA can be sold OTC but only by pharmacists**. The drug can be on the shelves like any other product.
  Examples are Domperidone, 400 mg ibuprofen up to 50 tablets and Dextromethorphan.
- A drug that is UAD can also be sold at drugstores, stores where no prescription can be filed and there is only a relatively small selection of popular drugs like painkillers and cough medicine. The drugs in this category have limited risk and addiction potential.
  Examples are Naproxen and Diclofenac in small amounts, Cinnarizine, 400 mg Ibuprofen up to 20 tablets and also 500 mg Paracetamol up to 50 tablets.
- Drugs in the AV category can be sold at supermarkets, gas stations etc. and include only drugs with minimal risk to the public, like Paracetamol up to 20 tablets, 200 mg Ibuprofen up to 10 tablets, Cetirizine and Loperamide

3.2.6. China:

- Product classification:
    - Narcotics & Psychotic drugs,
    - Prescription drugs (Rx),
    - Class A OTCs (may only be sold by licensed pharmacists, red label),
    - Class B OTCs (mass market, green label)
    - Health foods (low-risk supplements, blue label)
- Some medicines hold “dual status” so may be Rx or OTC depending on indication
- The regular China Food and Drug Administration (CFDA) is in charge of enacting of the Classification administration measurements of prescription drugs and non-prescription drugs, administers the list of non- prescription drugs and carries out the appraisal of bidirectional conversion between prescription drugs and non-prescription drugs (i.e. change of legal status or prescription to non-prescription “switch”) since 2004

OTC product labelling:

- Class A OTC- must show red OTC logo on packaging
- Class B OTC -must show green OTC logo on packaging
- Health food- must show “blue hat “logo on packaging
- The size of the brand name must be half that of the ingredient name on packaging
- It is also vital labelling is easy for consumers to understand
- The recommended retail price must be printed on the products packaging

Advertising: All non-prescription medicine, including switched can be advertised in all media. Comparative advertisement is NOT allowed and all OTC ads subject to CFDA inspection.

- Art 61 of Drug Administration Law states: “The content of the medicine advertisement shall be truthful and lawful, and consistent with the leaflet approved by the drug regulatory department under the state council. Any false content shall not be permitted.”
- Drug advertising shall be in compliance with the following laws, regulations and related provisions:
    - Advertisement Law
    - Drug administration Law
    - Regulations for Implementation of Drug Administration Law
    - Criteria for Examining and Publishing Drug Advertisement
    - Other provisions of the state on advertisement regulation

Distribution: OTCs may be sold online, in pharmacies and in no-margin clinics, with certain brands and SKUs available in the mass market

- China is promoting a hierarchical medical system as part of its healthcare reforms, which will encourage more outpatients to shift their attendance from

hospital to lower level medical centres such as community clinics and retail pharmacies

- The Government is keen for the Top 20 health care distributors to increase their presence to encourage deeper market coverage to improve healthcare provisions in under-developed and remote areas
- Ordinary chain supermarkets can distribute class B non-prescription medicines. However, only the headquarters of the chain is allowed to stock and deliver the medicines, with branch outlets not being allowed to stock medicines independently.

Price controls: The majority of OTCs are free government-enforced price caps; for medicines reimbursed under Basic Medical Insurance (including some OTCs) BMI agencies are establishing payment standards with relevant departments to form reasonable market price, subject to regular inspection

China switch climate:

- China's switch environment is dynamic;
- Switch is by brand, not molecule.
- Marketer submits switch application, which is subject to a technical review by the CFDA's Centre for Drugs Re-evaluation. A public comment period is open for one month before the final decision is announced. When applying for an Rx-to-OTC switch, records of a drug's safety must be provided, as well as information on its suitability for self- selection and treatment.

3.2.7. Brazil:

Products classification:

- Without prescription,
- Prescription-only
- Prescription-only to be retained in the pharmacy for sanitary surveillance control

Herbal and homeopathic products- are considered as medicines and should be registered as medicines

Vitamins /minerals can be classified as

- Food supplements (for dosages 25-100 percent RDA)
- Non-prescription medicines (dosages above RVA and up to maximum allowed daily limit)
- Prescription-only medicines (dosages above the maximum allowed daily limit)

Regulatory body and market authorization*:* Market authorization procedure differs for each product classification and it is overlooked by the Brazilian Health Surveillance Agency (ANVISA), a regulatory body responsible for regulation and registration of pharmaceutical drugs, which publishes various regulatory Resolutions. Market authorization process is regulated by the Resolution 138/03(approved in May 2003).

- The registration process of OTCs takes approx. 18-24months, unless they are considered priority by ANVISA. Priority includes new generics, treatment for conditions where there is no or limited/restricted/ ineffective treatment e.g. hepatitis C, for conditions for which free treatment is provided.
- A “medicament novo “(new medicine) – one that has a synthetic or semi – synthetic active ingredient previously not marketed in the country – cannot come to market straight away as an OTC in Brazil. It must first be approved as a Rx medicine and then five years later, upon product registration renewal, the marketer can apply for OTC status.
- In 2015, new herbal regulations came into force with ANVISA’s decision to create a new category. The new ‘Traditional Herbal Products’ category follows similar European legislation, and a simplified registration process for marketers of plant- based medicines proven safe and effective for at least 30 years through international documentation and scientific references was introduced.
- A new classification for artificial tears and eye lubricants was introduced- medicaments specifics (specific medicines). Previously, such products were registered as products for health which encompasses materials or equipment for healthcare use, rather than being classified as a medicine, which must have a therapeutic action and can be used in palliative care. The category encompasses pharmaceutical products, which do not fall under one of the following: new, generic, similar, biological, herbal or notified medicine. For products already on the market, a 24- month transition period applies.
- Rx medicines in categories that are already approved for OTC use in the existing system including anti-diarrheal, topical analgesics, allergy remedies, systemic cold & flu products, colic treatments and wound healers- can be reclassified as OTC
- A product registered as OTC under the current system will remain so unless the lab requests
- A reverse switch; the new regulation also permits ANVISA to a solicit further information on existing OTCs and impose reverse-switch in the case of a regulation breach
- ANVISA permits the same registration to classify both Rx and OTC presentations if differentiated by dosage/concentration/format, and a pack insert (detailing the specific requirements for Rx or OTC usage) is included

- OTC products labelling: is regulated by Resolution N 71/09(an update of the Resolution N 333/03, published in December 2009). On- prescription medicines have to have indications and contraindications on the packaging.
- All non-Rx drugs should have detailed leaflets inside
- New labelling requirements applicable for food products, including food supplements
  and nutraceuticals registered as foods, new label requirements introduced and came into effect July 2016 in Brazil. The compulsory requirements include: the presence of any allergens in the product any main ingredients that are known to cause allergies must be declared in labelling.

Advertising: OTC advertising is possible in all media (Resolution N 96. Published in December 2008)

- Direct to consumer advertising of OTCS is allowed across all media; R_X advertising is strictly prohibited. Claims in consumer A+P must be scientifically proven; testimonials are not allowed (except for authorized professionals).
- Advertising is supervised by a non-governmental self-regulatory organization CONAR (the national council of advertising self-regulation) in its actions, CONAR follows the Brazilian advertising self-regulation code.
- Moreover, this code is complimented by a "The code of ethics and self-regulation for advertising of OTC drugs", developed by ASSOCIACAO BRASILEIRA DA INDUSTRIA OTC products.

Price controls: The governmental body CMED (the Camara de Regulacoa do Mercado de Medicamentos) oversees medications price control and annually publishes the Price Adjustment list

Switch climate

- Regulatory agency ANVISA announced updated rules and regulations governing OTC in August 2016, which offer a new Rx-to-OTC switch mechanism and could result in up to 30 new OTC categories(replaces RDC 138/2003) outlines set of criteria on Rx medicines that are eligible for switch:

    - Time on the market: Minimum 10 years Rx (with at least 5 years in Brazil), or 5 years OTC in another market
    - Proven safety record: toxicity, adverse reactions and interactions considered
    - Recommended treatment time: used for a short period of time, or fixed period for prevention
    - Easily managed by the consumer: or caregiver, under guidance of pharmacist
    - Low risk potential: even if misused, taken in higher dosages or for longer time than recommended

- No dependence potential: even if misused (as above)
- Not applicable for parenteral administered drugs (e.g. IV/IM injections), medicines that are not indicated for approved OTC therapeutic categories

3.2.8 Indonesia:

Products classification: Drugs and foods, including those with claims, require pre-registration prior to sales in Indonesia

- Drug: Drugs are classified into four categories:
  - Narcotic (O)
  - Prescription drugs (G)
  - Limited Free Medicine (W)
  - Free Medicine (B).

OTC drugs are classified to W and B classes, although OTC sales for G drugs are common

- Logos used to differentiate classes of medicine. W is noted with blue-dot, while B green-dot.
- W is permitted for sales in pharmacy (only), but are usually available in mass market as well
- The MoH Decree 1010/2008 on “Registration of Drugs” requires drugs to be manufactured in Indonesia, in Indonesia, in order to receive a marketing authorization; therefore, all pharmaceutical products must be produced locally in order to be marketed in Indonesia

OTC products labelling:

- The OTC Facts labelling follows a standardised format according to the proposed labelling requirements for ASEAN Harmonisation. These information includes Product name, Active Ingredient, Purpose or Indications, Uses, Warning, Directions, Other information and Inactive ingredients.
- Generic or chemical name of the products must be stated along with their brand name on the packaging
- Halal conformity is a must for Food registration; products without Halal labelling may be prevented from receiving a distribution licence, unless the Muslim clerical body declares otherwise

Advertising:

- BPOM regulates all drug advertising. There are no restrictions on advertising, DTC advertising allowed for Food, VMS, Jamu and OTC products.

- Pharmacy-only (category W) medicines need to provide warning labels on packaging and advertising; Advertising of category G (Rx) medicines is not permitted
- Direct-to-Consumers A+P (especially ATL) is crucial to the promotion of self-medication in Indonesia owing to low health literacy. Brands, instead of APIs, are the driver of purchase of a certain product. However, the government has also required the generic name of the product be printed along with the brand name so that the consumers may have the options to purchase the equivalent generics.

Price controls:

- No OTC price controls, but fixed-price (and locally-produced) generics are a kay sector, encouraged by the Government in order to promote self-medication among low-income consumers

Distribution: OTCs and supplements (including Jamu remedies) may be sold via pharmacies and the mass market channels such as convenience store, teleshopping, and online

- Pharmacies remain the dominant channel especially for VMS and direct selling companies are gaining market share in marketing health supplement
- Convenience stories, small grocers, warungs (road-side kiosks, about 200,000 of them throughout Indonesia) typically sell smaller packs of VMS and OTC drugs e.g., pack of 4 or 10; not a month's supply
- Pharmacist plays an important role as consumers are not very confident in buying products in self-selection mode, they prefer to buy from specialists/pharmacists, who are capable of giving product advice. Therefore, they will normally choose products and then ask the cashier/sales assistant to confirm if their choice is appropriate.
- Many OTC products are promoted via doctor's recommendations. Some of these are also prescribed and dispensed by doctors.

Indonesia: Switch climate

- No formal Rx-to-OTC switch process. There is no systematic official government document policy regarding OTC Switch; registrations and regulatory are based on a case-by-case basis.
- Switches are decided by the MOH under the recommendation of BPOM

OTC criteria include:

- Medicine must have proven safety and efficacy
- Not contra-indicated for pregnant women, children over 2 years and the elderly (above 65 years)
- Easy to self administer (not requiring special devices)

- For conditions of high prevalence which are amenable to self diagnosis with little supervision

3.2.9. Mexico:

- Comision Federal para la Proteccion contra Riesgos Sanitarios: Federal Commission for Protection against Sanitary Risks (COFEPRIS) has made huge advances recently in streamlining and evolving into an internationally-recognised and respected institution; and the agency continues to head towards international harmonisation and working more closely with foreign counterparts to expedite registrations
- COFEPRIS is set to update registration renewal processes for medicines as well as medical devices; and a review of new herbal regulations may well be possible in the near future

Product classification: Article 226 of the General Health Law classifies medicine as either prescription or non-prescription medicines

- Prescription drugs are grouped in four classes (I– IV), the first three are narcotic or psychotropic medicines that require a special prescription form or a common one that is retained at the pharmacy while class IV includes most of the prescription medicines that have no narcotic or psychotropic effect
- Non-prescription medicines are grouped in two classes, class V and class VI

OTC product labelling: Outer packaging of OTCs must include information on therapeutic indications, dosage, side-effects, advice on use during pregnancy/nursing, paediatric use, interactions with other medicines and overdose. It must also include the legend, “if symptoms persist, consult your physician.”

Advertising: Non-prescription medicines can be advertised in all media and comparative advertisement is allowed as long as it is well supported and does not diminish or denigrate competing products

- OTC products cannot be advertised as a definitive solution for the prevention or rehabilitation of an illness, be indicated in any symptomatic areas other than those approved, promote overconsumption, use anatomical images, unless they are needed to explain a product’s use or treatment, or use testimonials
- The Ministry of Health and the Institute of Industrial Property control the use of trademarks
- Applications for marketing authorisation of non-prescription medicines, vitamins/minerals
  Considered as medicines, homeopathic medicines products and herbal medicinal products

Should include technical and scientific information that demonstrate the identity and
Purity of their components in accordance to National, Homeopathic or International Pharmacopoeias or scientific international information sources, respectively

- This submission request should also include stability tests and information on safety and efficacy along with a draft of the product label
- No specific restrictions that prevent umbrella branding across various active ingredients if
  They are in the same therapeutic category, although in practice, same brand name for OTCs
  With different formulations not allowed.

Distribution:

- Non-prescription medicines classified in Class VI along with herbal medicines and remedies, homeopathic medicinal products and vitamins/minerals classified as non-prescription products can be sold both in pharmacies and in any other authorised outlet
- Non-prescription medicines classified in Class V can only be sold in pharmacies. Online

Price controls: The Ministry of Health & Economy is responsible for establishing the maximum Medicines retail prices in Mexico. The Government and individual manufacturer negotiate wholesale and retail margins. Patented OTC brands are subjects to price controls but off-patent and generic OTCs are freely prices.

Mexco: Switch climate

- No official switching rules or guidelines are incorporated in the General Health Law or its bylaws. Manufactures have to apply separately for switch or for non-prescription status

4.0 Stake holders Perspective:

Abstracts of the representations received from the Stakeholders furnished here.

4.1. FICCI (Federation of Indian Chambers of Commerce & Industry):

Non prescription (OTC) medicines provide value through significantly expanded access to treatment for the most frequent and common illnesses, meets public health priority through wellness and prevention, while also supporting the quality of life and productivity of a population.

OTC medicines currently have no legal recognition in the Drugs and Cosmetics Act and Rules of India. Instead all drugs that are not included in the list of prescription drugs are currently considered as non prescription drugs (OTC drugs). There is no clear process as set of criteria by which to determine if a drug is considered non prescription, thus leaving the current classification process opaque and subjective. Therefore in order to remove the ambiguity and to empower the consumer as well as the pharmacist to assist in making the choice the correct medication, there is an urgent and strong need to give OTC drugs a legal status that clearly defines the processes of OTC drugs approval, marketing and sales & distribution and the Drugs and Cosmetics Act and Rules of India.

FICCI recommendations for proposed India OTC framework and Rx to OTC switch

- A formal over the counter drug definition.
- Regulations (Principles and Practices) for import manufacture distribution and sale of OTC products as a separate schedule (OTC schedule) in Drugs and Cosmetics Act.
- An approved “Positive List of OTC active ingredients to be schedule in the Drugs and Cosmetics Act in line with the qualification criteria for inclusion in the positive list of OTC schedule.
- Directive with respect to Fixed Dose Combinations (FDCs) containing the active ingredients included in the positive list of OTC schedule.
- Schedule positive list of OTC active ingredients and FDCs monographed in the Indian Pharmacopoeia and in National Formulary of India (NFI).
- Well defined labelling requirements of OTC molecules to be included in Rule 96 of Drugs and Cosmetics Act.
- Well defined regulatory pathway, guiding principles and associated timelines to convert a prescription drug (Rx) into an OTC product.
- Well defined regulatory pathway, guiding principles and associated timelines for New OTC Drug Applications.

An enabling regulatory regime for OTC drugs in India would facilitate the introduction and access to new and innovative medicines that will serve not only consumers and patients but also address the broader needs of public health care system in the country.

OTC medicines primarily

- Empower consumers to take responsibility for their (and their families) health and wellness.
- Benefit public health by providing accessible treatment options that can improve quality of life and lead to better outcomes.
- Provide affordable and efficient treatment options that can result in significant cost savings to health care system.

OTC medicines are helping to educate consumers to the practice of healthy living habits. People are becoming that they have a role to play in their own healthcare and they believe that modern health care system and should offer increasing opportunities to access OTC medicines.

Importance of Self Medication for India:

With alarming increase in chronic and lifestyle diseases (e.g., respiratory or cardiovascular conditions, gastrointestinal conditions, diabetes etc.) in the country, that are practically preventable and manageable by the patient's own intervention and contribution towards his / her own wellbeing, the importance of Self-Care and Self-Medication is crucial to be realized in the country for improved healthcare and well being of the consumers. Hence, "well informed" use of Non-Prescription / Over-the-Counter products can make a significant contribution in not only the diagnosis, treatment or mitigation of such conditions, diseases and disorders rather they can be prevented from occurrence.

India needs Self Medication for the following reasons:

1. *Improved access to effective drugs & Enhanced Quality-of-Life*

   Because of barriers to obtain a prescription and to access to prescribed drug like unavailability of a doctor, time constraints in visiting doctor, cost of prescription, access to Chemist / Pharmacy the patient may chose to leave with and tolerate the symptoms assuming them to be self limiting over a due course of time which will significantly interfere with their performance and day-to-day living and work. Thus access to readily available OTC drugs will minimise the barriers and hence improve the overall quality of life.

2. *Prevention of unregulated, Off-the-Label use of medicines*

   Availability of OTC drugs for common ailments will reduce the chances of use of less effective home remedies, selection of less safe alternatives like use of unregulated products (allopathic, ayurvedic, herbal variants) from unlicensed magic remedy and cure claimants or self prescribed dosage strengths or irrational API combinations.

3. *Improved public health*
   OTC medicines provide an effective instrument for patients to practice self care thus moving from treatment to prevention health care mindset thus leading to improved public health standards in the country.

4. *Enhanced involvement by consumers in their health care*
   Provision of adequate consumer information regarding OTC drugs by making them aware of their product choices by means of informative labels, leaflets and consumer advertising will improve health awareness and adoption of healthy life styles among public.

5. *Economic benefits of Over-the-Counter accessibility*
   OTC drugs enable economic benefit to patient and also to industry thus encouraging industrial development within India.

6. *Promote Innovations in drugs*

4.2. OPPI (The Organisation of Pharmaceutical Producers of India):

The Story of healthcare in India has evolved. Patients are becoming more involved in their healthcare decisions. Digital intervention through social network, health apps and several digital solutions have helped in making healthcare convenient and cost-effective. While these are working well in the real world, another reality that stares at us is the over-burdened Indian healthcare system plagued by shifting disease patterns; shortage of doctors; uneven spread of healthcare services (32% of the total times rural population travels more than 5 km to seek OPD treatment as compared to 8% in urban), and a 62% of out of pocket healthcare expense[1]. Added to this, most parts of India lack access to health services.

OTC medicines are a critical component in advancing consumer health because they allow people to treat or manage many health conditions conveniently and successfully. Because they enable people to self-treat, OTC medicines save health systems valuable resources and can save consumers

time and money. OTC medicines have played a significant role in expended access to safe and effective treatments in developing regions of the world.

However, among countries with a sizeable population that self-medicates, India is counted among those that do not have the legal and policy framework to either support or regulate the distribution, marketing, promotion and consumption of over-the-counter (OTC) drugs. This is one reason why Indians are not just buying drugs generally accepted as OTC in other parts of the world- and in the country – without a doctor's prescription, but also drugs that absolutely require one. Insufficient regulatory rigour in the supervision of trade channels through which Rx drugs are sold, is another.

This is a dangerous trend. Unchecked self-medication poses a danger to patient safety and can negatively impact health outcome. For instance, the easy availability of antibiotics without a valid prescription has contributed to rising antimicrobial resistance in the country. It is vital that any attempt to put more power into the hands of the patient be stewarded and regulated by appropriate policy and laws.

MORE Rx THAN OTC: INDIAN LEGISLATION FOR PRESCRIPTION AND NON-PRESCRIPTION PRODUCTS

a) Lack of classification of drugs as non-prescription (OTC) drugs
b) Lack of defined procedure for Rx-to-OTC switches
c) Labelling/patient information
d) Similar advertising laws for Rx and OTCs
e) Restricted access for OTC medicines as per the current distribution laws
f) Price control for OTC drugs the same as for Rx drugs

Restrictive, outdated legislation such as the one India continues to abide by severely limits not only the number of products that are legally available without a doctor's prescription, but also curbs access to useful information that the patient needs for self-medicating judiciously. This is a disservice to the patient.

The right to healthcare is a fundamental right and the right to provide basic public health facilities is the fundamental duty of the Government. Combining this sentiment with a robust OTC guideline could be the success formula to expand access to medicines in the country.

4.3. Indian Pharmaceutical Association (IPA):

Extent of the Problem: Many / Most of the times prescription drugs are sold in most of the pharmacies without a valid prescription and reason for the problem is that the regulations not implemented / enforced properly because of insufficient regulatory officers to carry out routine inspections.

4.4. SADDA:Seemandhra Drug Dealers Association:

SADDA welcomed the concept of OTC drugs but only a registered pharmacy on employing the services of pharmacist should be permitted to sell the said drugs under OTC without prescription. No retail without a pharmacy licenses in Form 20 & 21 should be permitted to sell OTC drugs. Proper awareness to public for use of OTC medicines and stringent guidelines to registered pharmacist are required to avoid misuse of OTC drugs.

4.5. Doctors / Health Professionals:

Doctors of Dr. NTR Vaidya Seva Trust, Govt. of AP dealing with Below Poverty Line population of the State of Andhra Pradesh have given their recommendations regarding OTC drugs in suggested certain drugs to include in the proposed list of OTC drugs.

5.0 Discussion:

In India, non-prescription drugs are easily available for sale over the counter and are used for the treatment of minor illness. A wide range of common ailments such as cough, cold, fever, pain and sprains, heartburn and diarrhoea are treated by Indian consumers following self- medication. When suffering from an ailment, 45% of the patients visit the pharmacist. Countries across the globe have a formal process of transferring prescription (Rx) status to over-the-counter status and yet the term "over-the-counter drugs (OTC drugs)" is legally undefined in India. As there are no specific guidelines on the OTC medications it is imperative to create a list of OTC category medicines.

Increasing trend of practising responsible self medication in India due to rise in awareness due to mass media and internet about medicines and the right usage.

It is time that Indians are empowered with clear and useful information to choose the right medicine for the right ailment at the right time which will curb the misuse and in turn enhance the health outcomes. Self medication trend has almost doubled in the last ten years from 23 % to 41 %. In India we have a doctor population ratio of 0.62: 1000 (WHO standard: 1 : 1000) which is very low and this coupled with the fact that 74% of India's doctors cater to a third of urban population depriving rural areas of healthcare needs. All these results in high OOP expenses at the rate of 62% which can be brought down by bringing in a robust OTC Policy thereby the responsible self-care by the patients. In the developed countries the statistics reveal that each dollar spent on OTC saves 6-7 dollars on the public healthcare system.

Self-medication and the safe use of OTC medicines should be regulated and guided in this self-care and regional context. Based on the needs of the populace and feasibility of the process, switching prescriptions to OTC drugs should be considered. Developing a new framework by including the clinical insights would help determine the medicines that should be made available for self-care from medical professionals' perspectives. To promote self-care with OTC drugs, medicines with proven efficacy, safety, and quality should be used as instructed and reclassified substances are no exception. When reclassifying from prescription medicines to non-prescription drugs, safety, delays in seeking treatment for serious conditions, and the emergence of drug resistance are to be considered. Strategies for avoiding adverse drug reactions and pharmacovigilance are essential for non-prescription medicines, and they might require information unique to self-use. Although the concept of prescription drug Direct to Consumer Advertising (DTCA) may take a few years to be accepted in the Indian market, people in the country are already exposed to scaled down versions of DTCA like television and print ads for inhalers, contraceptive pills, insulin for diabetes mellitus and other over-the-counter (OTC) drugs.

As these OTC drugs are consumed by patients without physicians consent, it is very important that the patients have the access to clear and broad information to make an informed choice. A study revealed that the required information provided on OTC medicine labels in India is usually quite insufficient for the patient to make a “responsible” decision for self-medication as it even not have the therapeutic category details and the dose that has to be taken. OTC medicines are supposed to be relatively safe, readily available. However, all relevant issues surrounding co-morbidities and poly-pharmacy cannot be neglected. Studies suggest that the inadequacy of labelling is confounded by the functional illiteracy rate as population is intellectually and/or attitudinally unprepared to make objective and informed diagnostic and therapeutic decisions for themselves or those in their care. To foster the safe, appropriate, and effective use of non-prescription drugs the pharmacist-assisted self-care model can be adopted besides effective implementation of the Drug & Magic Remedies (Objectionable Advertisement) Act.

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A study conducted in Kolar district, India noticed that most of among pharmacists (96.5%) asked the consumer's complaints before dispensing the drug, but only few (51%) counselled them regarding the instructions to administer medication. A study in Bangalore observed that while dispensing the OTC drugs the pharmacists did not ask about drug allergy and the existing co-morbid conditions and did not dispense the drugs according to the appropriate dosage regimen. Appropriate instructions were not given to all patients and adverse effects of the drugs were not explained. As per Antibiotic Policy (MHFW 2011) H1 schedule restricts the OTC sale of antibiotics India. Under schedule H1, all third-generation and newer antibiotics are listed, for these antibiotics' prescription is mandatory and pharmacists are supposed to keep a record of the sale. In spite of federal regulation of schedule H1, a recent study (2016) has reported high sales of OTC antibiotics (including carbapenems) by pharmacists eliciting the importance of strategies to check the OTC sales.

Strategically positioned to serve as gatekeepers (portal-of-entry) into the health care system for self-medicating patients, Pharmacists with adequate knowledge and training in clinical pharmacology can help in improving the confidence of the patients in the community. The National Curriculum Survey on the Status of Instruction in Non-prescription Drug Therapy conducted in2002 and 2005 showed that even the American school of pharmacy curricula underemphasised the pharmacist-assisted self-care and non-prescription drug therapy. The survey recommended that core practice-relevant, patient-centred competencies need to be assured in the first- through third-professional years and built upon in the fourth-professional year. The curricular content should be relevant to the contemporary practice of pharmacy, addresses disease processes and systems that are highly prevalent in our society. An academic “sniff test” should be applied to the entire curriculum that recognizes that the focus needs to be on imparting knowledge that

has a high probability of being utilized (applied) by the pharmacist in serving the public health interest.

5.1. Challenges with OTC drugs in India:

- **Literacy of general population**
- Constraints with respect to labelling/ information (Language & Space)
- Drug Interactions (Drug- drug, Drug- Food Interactions and interactions with other system of medicine)
- Managing Adverse drug reactions/ Side effects with drugs on their own
- Issues with Chronic usage / long term usage
- Paediatric Vs Geriatric (Dose & Formulation)
- Patients with some existing disease conditions (Compromised liver, kidney and cardiac functioning)
- Issues with Similar sounding brands with different compositions (look alike and sound alike drugs)

6.0 RECOMMENDATIONS:

The Committee opinions that there is an urgent need for defining the OTC drugs and to laid down the specified regulations for OTC Drugs in the country.

1. The definition for OTC drug must be laid down in the Drugs & Cosmetics Rules-1945 by introducing a separate Part-XC (Definition and Specifications for OTC Drugs). The following definition may be considered for “OTC Drug”:

<u>OTC Drug</u>: Drugs defined under Sec. 3(b) of the Act meant for sale to consumer/patient without need for prescription of a Registered Medical Practitioner (Specified rule-2(ee)) and included in the Schedule-K1 & K2.

Alternatively the following definition may be considered

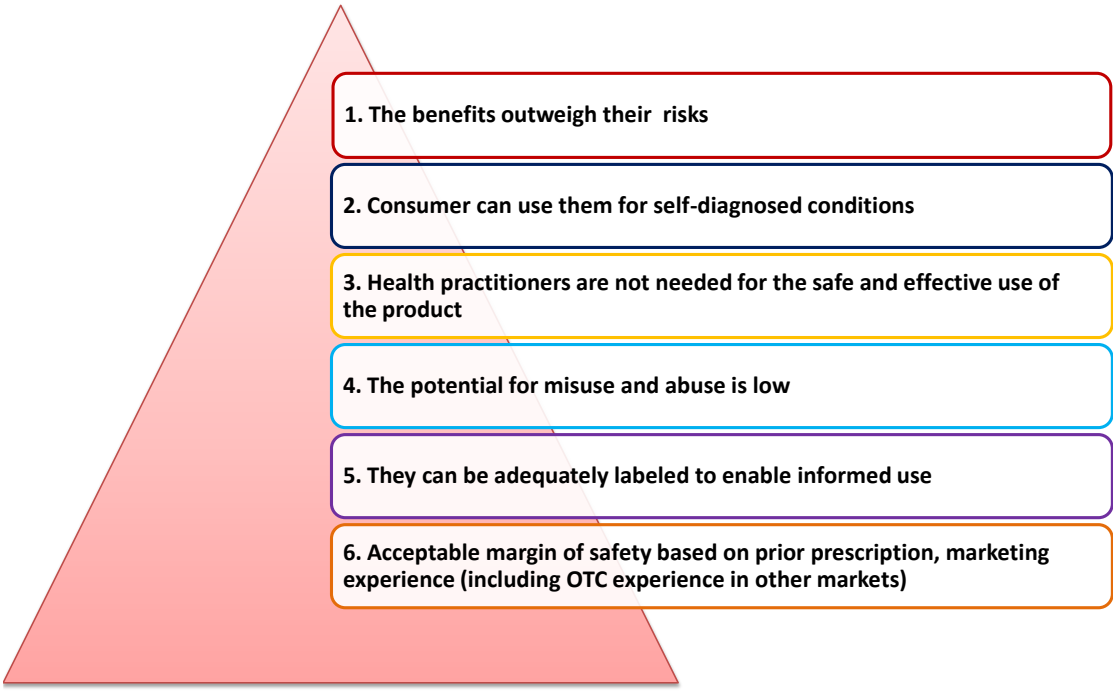
Drugs defined under Sec. 3(b) of the Act meant for sale to consumer/patient without need for prescription of a Registered Medical Practitioner (Specified rule-2(ee)) and permitted by the Central Licensing Authority in a specified forms OTC-I or OTC-II.

Note: Both Allopathic Drugs and Medical Devices (MDR-2017) will be covered under this definition.

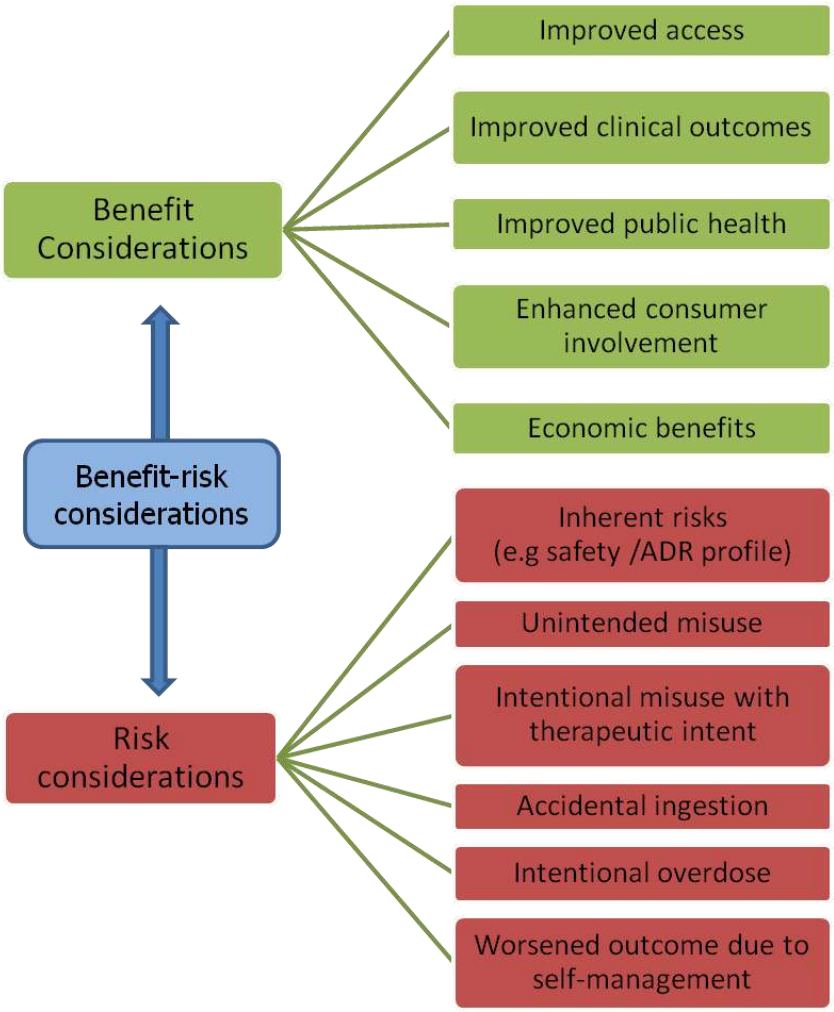
2. Basic Characteristics of OTC Drugs: A drug must possess the following characters for classifying as an OTC Drug

    - Safe (acceptable safety margin) and efficacious
    - Low misuse and habit forming potential
    - Condition to be treated is self-diagnosable
    - Does not require a Physician for safe and appropriate use
    - Adequate labelling so that consumers can
        – Self-diagnose
        – Self-select
        – Self-administer
        – Know when to stop using

QUALIFICATION CRITERIA FOR INCLUSION IN OTC SCHEDULE



A useful tool for conducting the benefit-risk analysis has been developed by Brass and is shown below



3. The OTC drugs can be classified in to 2 categories based on the **extent of evidence of Safety, Therapeutic Index, need for accessibility to patients, availability, non-habit forming nature, present supply chain mechanism, socio-economic conditions** of the country.

   a. ***Pharmacy only OTC drugs (Schedule-K1 or approved in OTC-I)****: These OTC drugs can be sold without prescription of RMP but shall be dispensed/ sold under the supervision of a Pharmacist only. The pharmacist will assist the patient in choosing right formulation, dose and helps in understanding about the proper usage of the drug.*
   Ex: Fluconazole 150 mg Tab, Domperidone 400 mg Cap,
   Explanation: These drugs are used for treatment of minor ailments which are self-diagnosable but require a suggestion of a healthcare professional like pharmacist to suggest the required dosage, duration of treatment, proper storage of drugs and patient counselling.

   Expected key counselling reminders from a Pharmacist to Patient using a ***Pharmacist Assisted OTC drug***:
   - The proper use of the selected drug including dosage, dosage intervals, route of administration and recommended duration of therapy, proper storage of drug as per the Approve Label of the drug.
   - Remind the patient not to exceed the recommended dose
   - Emphasis on reading the label
   - Recommend the patients consult a physician if symptoms do not improve or worsen
   - Remind patients to use OTC medications that treat specific symptoms
   - Remind parents of paediatric patients to use calibrated measuring devices and to give only those products formulated for paediatric patients

   b. ***OTC drugs for General Sale (Schedule-K2 or Schedule-K1 or approved in OTC-II)****: These OTC drugs can be sold without prescription of RMP and in any general retail outlet registered with State Drugs Controller (License is not mandatory and self registration is sufficient)*
   Ex: Paracetamol Tablets, Bandages,
   Explanation: This category include only drugs with minimal risk to the public and widely used like Paracetamol (OSD), Bandages and other household remedies which are presently exempted in Schedule-K at S. No: 2A, 9, 13, 14, 14A, 15, 26, 27, 33.

4. **Preparation of Initial list of OTC Drugs:**

i. Due to the constraints of lack of data, infrastructure & resources the committee at this point of time is unable to suggest the complete list of drugs to be considered as OTC drugs and their categorization. However as per the recommendations of the various expert bodies and Healthcare professionals and various stakeholders, duly considering the available data of safety, Therapeutic Index, a limited list of drugs declared as OTC by other Regulatory agencies which may be considered as OTC drugs in India is enclosed as Annexure.

ii. As per the Draft rules vide G.S.R. 629(E) dated: 11/07/2018, the Govt. of India brought in proposal for mandating uploading of the Manufacturing Licenses Data (products). Once the data of products in the country is populated in the Sugam Portal, the drugs other than Schedule-H, H1 & X has to be declared as OTC drugs. **The list must be explicit with the specific formulation, strength of the Drugs.**

iii. Then an expert committee shall be formed consisting of experts, health activists, Industry represents and this committee shall examine within 90 days and complete the process of classifying the OTC drugs and include them under Schedule-K1 or K2 or approved in informs OTC-I or OTC-II based on their safety and efficacy and therapeutic profiles and final approval OTC classification and individual OTC Monographs by DTAB. The OTC monographs **(conditions for each therapeutic category covering acceptable ingredients, uses, doses, formulations, labelling)** shall be published by the CDSCO to enable the subsequent manufactures to manufacture the OTC drugs as per the requirements and the State Drugs Controller for licensing & enforcement.

5. **Regulation of Rx Drug to OTC Drug Switch Process:**The request for switch from Rx to OTC shall be accepted from

I. The Industry (Manufacturers)

II. Consumers / Healthcare professionals/ Regulator Initiation

I. The Industry (Manufacturers): Switch Application form and requirements of safety & efficacy evidence and dossier must be specified by the Regulator in due course. The dossier must contain data of “OTC Consumer Studies”, the design & study requirements must be specified by the regulator. The switch application received from the manufacturer shall be processed by CDSCO on the existing lines for new drug approval and having regard to given approval for the switch the drugs has to be included in Schedule-K1 or approved in OTC-I for a period of 4 period and post marketing surveillance has to be made mandatory. After the period of 4 years the safety / pharmacovigilance data has to be evaluated and consider for inclusion in Schedule-K2 or approved in OTC-II.

II. A public comment period of one month should kept open before the final switch decision is implemented.
III. Consumers / Healthcare professionals/ Regulator Initiation: The requests from the Consumers or Healthcare professionals or any Govt. body must be considered for Rx to OTC switch with the existing **Safety data in Indian Population** from the PvPI or any other source. This process has to be done by CDSCO on the existing lines for new drug approval and having regard to given approval for the switch the drugs has to be included in Schedule-K1 or approval in OTC-I form for a period of 4 period and post marketing surveillance has to be made mandatory. After the period of 4 years the safety / pharmacovigilance data has to be evaluated and consider for inclusion in Schedule-K2 or approved in OTC-II or for withdrawal of the OTC status.
IV. Separate OTC forms as per the requirement may be included in the Schedule –A of the D & C Rules-1945.
V. The final approval of the OTC Switch shall include the following:
    a. Indications
    b. Pack Size
    c. Patient information leaflet
    d. Safety warnings and contraindications
    e. Treatment in case of overdose
    f. Labelling mandates
    g. Others

A permanent vertical must be established in CDSCO & State Regulators to continuously monitor the market complaints, safety issues and to consider the reverse switch of OTC to Rx.

6. <u>Regulation of New OTC Drug Approval:</u>

The approval of new drug either prescription drug or OTC as per Rule-122E shall be as per the existing rules for approval of new drug. This process shall not be considered as Rx to OTC switch. If it is regarded for OTC drug the conditions there of under Form-46 with respect prescribing and claims shall be modified and approved and the approval must specify the inclusion in Schedule-K1 or K2. Alternatively market authorization forms OTC-I or OTC-II may be considered. The Licensing authority at the time approval must also issue an OTC monograph to enable the consumer to self-diagnose, self-treat, and self-manage the condition being treated. The approved monograph must made available in official websites of the Regulators and they shall be made part of the conditions of the Licenses issued for such purposes.

7. <u>Manufacturing and Labelling of OTC Drugs:</u>

1. Manufacturing: The same existing regulations & licensing norms and procedure followed by State Licensing authority for issue of licenses for

manufacturing for sale under Drugs & Cosmetics Rules-1945 (Part-VII) & Medical devices Rules-2017 are applicable to OTC drugs also including the GMP & GLP norms.

2. Standards: Sec.16 of the Act r/w Schedule-II will apply to OTC drugs.
3. Labelling: Labelling with detailed guidance to the consumer & pharmacist is essential for empowering the consumer towards judicious self- medication and it is the basic tenate for the effective regulation of OTC Drugs. The existing Rule-96 & 97 shall be amended to mandate the manufacturers to abide by the OTC Monographs for individual OTC drugs approved by the Licensing Authority which is available with the official websites and they are part of the conditions of the license issued.

   -A straight line of Yellow colour of 2mm thickness on the label can be considered for ease of recognition of OTC Drugs. A Yellow line will be helpful in recognising the OTC Drugs from Prescription drugs.

The Committee also recommends the following labelling requirements for OTC drugs in supersession of the existing provisions:

i) Generic name of the drug
ii) Brand name of the formulation
iii) Composition
iv) No. of doses in the saleable pack
v) Manufacturing license number
vi) B.no/Mfg.date/Exp.date
vii) Form-OTC2 no. issued by the Licensing Authority under Rule 21
viii) Name and address of the manufacturer
ix) Logo (as prescribed) signifying OTC drug and OTC drug to be sold under the counselling of a Registered Pharmacist
x) Toll free phone no. to receive consumer complaints & email ID
xi) Patient information leaflet in English and Hindi. Information in local information may be made optional
xii) The information in regional languages may be obtained from the manufacturer's website through QR code
xiii) All the above information may also be embedded in the aforesaid QR code

Well-defined Labeling requirement of OTC molecules

In addition to labeling requirements given in Rule 96, the Labels of OTC drugs shall bear following mandatory information in national/ regional language to educate consumer on usage, dosage & contraindications.

- **when to use (Indication)**
- **How to Use (Dosage/Duration of Use/Maximum does in a day)**
- **How long to continue using it (including information on the timeline for the onset of relief):**
- **When not to use (warning/ Precautions/contraindications)**
- **Interactions with other drugs;**
- **When to consult a doctor;**
- **Possible side effects.**
- **Both actives and excipients of the product.**
- **To have appropriate information on the label to enable the consumer to reach out to the Marketer/Manufacturer for any queries and /or complaints**

The above information should be available with product packs in a simple and patient friendly language.

The manufacture to conduct "Label comprehension Studies" to ensure the consumer understanding and comprehension of Information, Key Messages and Drug Facts mentioned on the labels of OTC drugs to ensure self selection and safe usage. The manufacturer should take the onus for the conducts of these studies by a self-regulating mechanism/ procedure.

The updated labels for the products containing Rx-to-OTC switch molecules and new also Direct –to –OTC molecules must be included in the respective application (s) to the authority. Also the updated labels of the products containing Active ingredients included in the "Positive List" of proposed OTC Schedule must be "Notified: to the regulatory authority .

8. Distribution & Sale of OTC Drugs:

OTC can be sold online, in pharmacies and general sale outlets.

The provisions governing the sale of drugs by way of Wholesale (from manufacturer to retailer) will remain unchanged. The sale of OTC Drugs falling under K1 or OTC-I are governed by the provisions of retails sale (forms-20, 21).

Over the period of time licenses issued in forms-20A & 21A which are otherwise known as restricted licenses to the dealers or persons in respect the House hold remedies which does not required the services of qualified persons has drastically come down with the increase in the number of retail of Pharmacies in the country at village/ hamlets and also increased Govt. Supply. In view of the categorization of OTC medicines the issue of licenses for the above category of drugs can be abolished and Rule-62B can be amended to remove the application & license forms for 20A & 21A restricted licenses.

In place licenses in forms-20A & 21A a more liberalized and **simplified Registration** only (no license) system can be implemented for the sale of OTC drugs under Schedule-K2 for empowering the Consumer towards responsible self medication and to make OTC drugs more accessible, available & affordable to the public. The concepts of EoDB like online

registration & nominal fee payment and perpetual validity of registration shall be adopted. The registration application forms shall be included in the schedule-A as OTC forms.

Offences for violations related to stocking & sale of Schedule-K2 or OTC-II Drugs at retail level (without registration) can be made compoundable by framing rules under Sec.32B of the Act. A fine of Rs. 5000/- may be considered for stocking & selling Schedule-K2 or OTC-II Drugs without registration.

The above recommended provisions shall be brought in as Rules & Schedules, Forms etc by amendments and subsequently the procedures for preparation of the first OTC Drugs and Rx to OTC switch.

9. **Advertisement of OTC Drugs:** The provisions of the Schedule-J & DMR(O)A with respect to the provisions of prohibition of advertisement for certain ailments like fever, ulcers of GIT etc., need to be removed or modified to enable the manufacturers/ dealers to advertise the claims approved by the Licensing Authority at the time of approving OTC Monograph. Proposed list of ailments which can be removed immediately are Annexed. Requirement for getting clearance from the Advertisements Standards Council of India by the manufacturers before advertising may be considered to curtail to unethical practices in this area.
10. **Pricing:** OTC medicines need not be kept under price control. The competitive market forces will determine the price imposed by the manufacturer.

11. Miscellaneous:
    a. Exemptions at Sl. No: 2A, 9, 13, 14, 14A, 15, 26, 27, 33 of Schedule-K related to House hold remedies & other to be considered as OTC need to be revisited.
    b. Schedule-G must be repealed and Drugs listed in Schedule-G (which does not required prescription as per the present regulations) may be brought under Schedule K1 or K2 or authorized under forms OTC –I or OTC-II based on their individual pharmacological nature safety margin and rule-96 & 97 may be amended accordingly with respect to the labelling requirements for Rule-96
    c. The drugs (or specific formulations of drugs) listed in Schedule C & C1 need to be revisited for inclusion of suitable drugs in Schedule K1 or authorized under form OTC –I based on their individual pharmacological nature safety margin.
    d. A national Drug Information Center (24/7) run by the Govt must be established to give product information to the users of OTC drugs. This data collected must be integrated to PvPI for periodical review. The

contact number of the Patient Support centre must be printed on the Label of the OTC drugs. This Patient Support centre is essential for building trust in minds of the consumer and to enable responsible self-care medication.

In view of the undersigned Sub-committee members examined all the issues in a comprehensive manner after deliberate discussions and prepared this recommendations report in detail which is submitted herewith for further necessary action.

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Annexure-I
Order Constituting the Sub-Committee

File No. X.19013/2/2017-DC (Part 1)
Directorate General of Health Services
Central Drugs Standard Control Organisation
O/o Drugs Controller General (I)

Date 27 SEP 2017

OFFICE MEMORANDUM

Subject: Constitution of a Sub-committee for creation of separate provision for OTC drugs to be sold in retail pharmacies etc. - reg.

The 52[nd] meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 18th September 2017 and the deliberated the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and Rules made there under in the country. DCC recommended for creation of a separate category of OTC drugs to be sold on retail pharmacies and constituted a sub-committee

Composition of sub-committee

1. Dr. Ravi Shankar IPS, Drugs Controller, Andhra Pradesh
2. Drugs controller, Chandigarh
3. Drugs controller, Uttarakhand
4. Drugs controller, Karnataka
5. Joint Director, FDA, Mizoram
6. DDC(I), R. Chandrashekhar (Convener)

Terms of Reference:

1. The sub-committee shall examine comprehensively the drugs marketed in country vis-à-vis conditions for sale stipulated under various Schedules, namely Sch. G, Sch. H, Sch. H1, Sch. X and Sch. K etc.
2. The sub-committee shall recommend the list of drugs which may be considered for marketing as OTC drugs.
3. The sub-committee shall recommend for the classification and regulation of the OTC drugs
4. The sub-committee shall also recommend modalities/ amendments needed in the conditions of sale licence so that Pharmacist, while dispensing the OTC drugs may supply any other generic preparations containing the same drug.
5. The committee shall furnish its report in three months.

(Dr. G. N. Singh)
Drugs Controller General (India)

To,
The Members of Committee

Annexure-II

Proposed List of OTC Drugs	
Category	Proposed Drugs
Gastrointestinal System	Ranitidine, Omeprazole, Esomeprazole, Pantoprazole, Famotidine, Nizatidine, antacids like Magnesium Hydroxide, Aluminium Hydroxide, Magnesium aluminium silicate hydrate, calcium carbonate, magaldrate, sodium bicarbonate, Milk of magnesia, enzyme preparations, Sodium Docusate, Bisacodyl, Lactulose, Liquid paraffin, Loperamide, Zinc sulphate, Domperidone, Promethazine, Prochlorperazine, Hyoscine butylbromide, Scopolamine, Dicyclomine, Drotaverene, Ondonsetron, Bismuth subnitrate, Aspergillus oryza enzymes (except lactase enzyme derived from Aspergillus oryzae), Homatropine methylbromide, Digestive enzymes, Gripe water, Epsum salt, Dimenhydrinate, glycerine
Cough, Cold, Allergy	Pseudoephedrine, Chlorpheniramine, Diphenhydramine, phenylephrine, Bromhexaine , Ambroxol, Ammonium Chloride, Dextromethorphan, Guaiphenesin, Noscapine, Amylmetacresol, Dichlorbenzyl alcohol, Triprolidine, Triamcelone, Pheniramine maleate, Doxylamine Succinate, Diphenylaminepyraline, Loratidine, Azelastine, Fexofenadine, Levocetrizine, Cetirizine, Nasal saline, Xylometazoline, Oxymetazoline, Fluticasone, Hexylresorcinol (Lozenges), Ipratropium, Meclizine
Dermatology	Bacitracin, Benzolkonium chloride, Chlorpyridinium, Mupirocin, Tincture iodine, triclosan, Medicated dressings, cetrimide, Miconazole, Econazole, Terbinafine, Ketoconazole, Clotrimazole, Tolnaftate, Benzyl peroxide, Salicylic acid, glycolic acid, zync

	pyrithione, Minoxidil, white & yellow petroleum jelly, lanolin, boric acid, calamine, ointment of heparinoid and hyaluronidase 9.0% borotanic complex, Lindane
Analgesics& Antipyretics	Aspirin, Pracetamol, Ibuprofen, Diclofenac sodium, Aceclofenc, Ketoprofen, Naproxen, Mefenamic acid, Benzocaine, chondroitin, Propyphenazone, Glucosamine, Dicyclomine, Capsaicin, Glucosamine hydrochloride, Eugenol, Antipyrine
Respiratory	Salbutamol, Budenosine, caffiene, Theophylline, Etofyline
Disinfectants, Antimicrobial & Anti-viral	Acyclovir, Povidone-Iodine, Chlorhexidine, Benzoyl peroxide, Permanganates, Nitromersol, co-trimoxazole, all liquid disinfectants & anti-septic solutions (topical), Tincture iodine, povidone iodine, Tincture benzoin, Mercurochrome,
Vitamins & Supplements	Calcium, Vitamin-D3, B-Complex, Ascorbic Acid, Vitamin-E, Vitamin-A supplement, Folic acid, Ferrous Sulphate, others as per Schedule –V.
Anorectal	Boric acid, Boroglycerin, Cholecalciferol, Cod liver oil, Diperodon, Menthol (1.25 to 16 percent), Phenacaine hydrochloride, Precipitated sulfur, Resorcinol, Shark liver oil, Sodium salicylic acid phenolate, Tannic acid, Turpentine oil (rectified) (6 to 50 percent)
Antifungal	Butoconazole, Nystatin, 10.0% buclosamide, 5.0% diamthazole, 1.0% econazole, 0.4% hydrargaphen, terbinafine, griseofulvin 1%, nystatin, Fluconazole, Miconazole, 1.0% fenticlor, 10.0% polynoxylin, 70.0% pyrogallol, 0.1% thiomersal
Anticaries drug products	Calcium sucrose phosphate, Dicalcium phosphate dihydrate, Disodium hydrogen phosphate, Hydrogen fluoride, Phosphoric acid, Sodium carbonate, Sodium dihydrogen phosphate, Sodium dihydrogen

	phosphate monohydrate, Sodium monofluorophosphate (6 percent rinse), Sodium phosphate,
Nasal Decongestants	Methoxamine, Naphazoline, Phenylephrine, Tetrahydrozoline, Tramazoline, Tymazoline, Xylometazoline
Anti-Malarial	Quinine, Chloroquine, Iodochlorohydroxyquinoline,
Ophthalmic	Tetracycline, lubricant eye drops,
Miscellaneous	N,N -Diethyl benzamide, Permethrin, Chlorhexidine gluconate, nicotine, Levo-Norgestrol, Minoxidil, strontium chloride (toothpaste), Mechanical contraceptives, Vaginal contraceptives, all approved chemical contraceptives, Medicated dressings& bandages, bandages, ORS, first aid kits, Salicylic acid corn caps,

Note: 1. The proposed list is based on the recommendations of the medical experts, stake holders and scrutiny by the committee.

2. The above drugs shall go through the proposed regulatory pathway for OTC drugs.

ANNEXURE – III

List of Representations and suggestions received

S.NO	REPRESENTATION / SUGGESTIONS GIVEN BY
1.	Seema Andhra Drug Dealers Association, AP dt 21.12.2017
2.	Proposed list of drugs under OTC in General Surgery by Dr M. Govinda Naik
3.	Proposed list of drugs under OTC inENT by Dr K. Susrutha
4.	Proposed list of drugs under OTC in Dental Surgery by Dr J.Renuka Devi
5.	Proposed list of drugs under OTC in Nephrology by Dr B.Srinivasa Rao
6.	Proposed list of drugs under OTC in Dermatology by Dr Srinivasa rao
7.	Proposed list of drugs under OTC in oncology by Dr AY.Rao
8.	Proposed list of drugs under OTC in Dermatology by Dr Srinivasa rao
9.	Proposed list of drugs under OTC in Cardiology by Dr Mohan
10.	Proposed list of drugs under OTC in Ophthalmology by Dr A.v.Pitchireddy
11.	Proposed list of drugs under OTC in orthopaedic surgery by Dr G.Ravi Shankar Reddy
12.	Proposed list of drugs under OTC in Paediatric surgery by Dr G.Hasanthi
13.	Proposed list of drugs under OTC in oncology by Dr AY.Rao
14.	Note and Suggestions given by th Federation of Indian Chambers of Commerce & Industry, New Delhi
15.	Note and Suggestions given by the Indian Pharmaceutical Association, Mumbai
16	Note and Suggestions given by the Organisation of Pharmaceutical Producers of India, Mumbai