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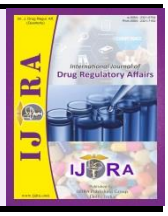

**Review Article**

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# Scenario of Over the Counter Medicines Worldwide

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## Abstract

Over the counter (OTC) drugs are medicines sold directly to consumer without any prescription. The OTC drug market in India is expected to grow by $6.6 billion by 2016 with Pharmaceutical companies and chemists increasing their presence in rural market. The market share of hospitals is expected to increase from 1.3% in 2009 to 26% in 2020. Also the Health Ministry has banned 344 fixed drugs combinations through a gazette notification issued over the weekend March, 2016. These include several cough syrup solutions, analgesics and antibiotic combinations and in which many of are sold over the counter. There is list of banned drugs which include Nimesulide which had been a cause for long for health experts for includes for its continued use in India despite being banned in most of the developed nations. Some of banned drug combinations are: a) Nimesulide + Diclofenac B) Diclofenac + Tramadol + Paracetamol C) Heparin + Diclofenac D) Azithromycin + Cefixime E) Telmisartan + Metformin and many more. Also India's OTC drug market stood at $3 billion in 2011 and a rise to $6.6 billion is forecast by 2016 according to sectoral document for pharmaceuticals industry. And in future India is known and expected to rank amongst top three pharmaceutical markets in terms of incremental growth by 2020.

**Keywords:** Amendments, banned drugs, OTC catalog, health ministry, adverse effects, FDA.

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## 1. Introduction

Over the counter (OTC) drugs are those which are sold without any prescription in comparison to medicine. OTC drugs are those which can be taken by any individual without the help of any healthcare professional. OTC drugs are selected by regulatory agencies to be made in such a way to ensure that the ingredients used in are safe and effective when used without the help of any physician. Around 100,000 OTC drugs are marketed, 800 significant active ingredients and 80 therapeutic categories are there. OTC drugs basically create competition and make the price down in comparison to other drugs other than OTC. As per CHPA (Consumer Healthcare Products Association) 73% Americans would like to treat themselves at home than to see a doctor. In America, more than 5 Billion OTC drug products are bought every year according to the survey done in 2012. India was being ranked on 11$^{th}$ spot in global OTC market size in 2011. Typical OTC products used include digestives, antacids, cold rubs, analgesics, throat lozenges, cough liquids, Ayurvedic medicines and preparations etc. As for the normal drugs, OTC drugs also have label specification which is regulated by FDA (Food and Drug Administration) and advertising is regulated by FTC (Federal Trade Commission).OTC drugs registered as 'Ayurvedic Medicines' are also regulated by DCA (Drug and Cosmetic Act) and DCR (Drug and Cosmetic Rules. Ayurvedic drugs or medicines are manufactured under manufacturing license issued by State Licensing Authorities. Also they don't require a drug sale license and therefore can be sold freely by non-chemists. Some of the largest OTC brands in India are registered as 'Ayurvedic Medicines' are Vicks VapoRub, Itch Guard Cream, Zandu Pain Balm, Iodex Pain Balm, Moov Pain Cream, Vicks Cough Drop, Calcium Sandoz etc. (1, 2)

**Table 1** Examples of OTC drugs and its uses are (3, 4)

| BRAND NAME | GENERIC NAME | INDICATION OR USES |
|---|---|---|
| **ASPILET** | Aspirin | Prophylactic treatment of thromboembolic disorders, transient ischemic attacks (TIA) and strok. |
| **BETADINE** | Providone –Iodine | Disinfection of wounds, lacerations and burns. Prophylaxis against infection in hospital and surgery. |
| **BIOGESIC** | Paracetamol | Relief of fever, minor aches and pain. |
| **CALTRATE** | Calcium carbonate | Supply of vitamin D and calcium. |
| **ENEVRON** | Multivitamins | Helps ensure optimum energy and increase body resistance against infections and other stress conditions. |
| **ADVIL** | Ibuprofen | • Migraine and tension headaches.<br>Contraindications<br>• Hypersensitivity to NSAIDS |

**2. Adverse effects associated with OTC Drugs**

What are adverse effects?

It is an undesired harmful effect resulting from a medication or other intervention such as surgery. It is also termed as side effect. It results from an unsuitable or incorrect dosage or procedure called a medical error.

Basically OTC drugs have low extent of adverse effects. But to some people they can pose a greater risk including very young children, older adults and people having more than one type of medicine. People also at higher risk who are suffering from asthma, bleeding disorders, diabetes, heart disease, kidney's problem, liver problem, thyroid problem and more.

OTC drugs are safe and deliver immediate relief but it can be dangerous if given in combination with other medicine or misused. Also like Aspirin can cause adverse effects or cause harm if one doesn't follow recommended doses, directions and warnings. OTC medicines are used to treat short term illness but ingesting them for long time can cause various side effects or adverse effects and also can lead the disease to a worst condition. Patient's needs to understand what they are putting in their body. OTC drugs can interact with patient's prescription. Aspirin, for example, can adversely interact with many of the drugs like blood thinner's, antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs) etc. (5).

FDA (FOOD and DRUG ADMINISTRATION) give some tips about using OTC drugs: (6)

FDA or USFDA is a federal agency of United States Department of Health and Human Services. It is one of the United States federal executive departments. The FDA is responsible for promoting public health through control and supervision of the food safety, tobacco products, dietary supplements, prescription and over the counter pharmaceutical drugs, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods and feed and veterinary products. The FDA is empowered by United States Congress to enforce Federal Food, Drug and Cosmetic Act.

1. Keep records of all medications you take, whether prescription or OTC as well as vitamins and supplements. Make sure your doctor and pharmacist are aware so that they can spot potential drug interaction.
2. Don't forget that many personal care items contain drug based ingredients such as fluoride and antibiotics. Read label carefully and look for warnings on thing like mouthwash and toothpaste. FDA classifies anti-perspirants as OTC drugs because they usually contain aluminum.
3. When taking cough-syrups and or other liquid medications, use the measuring tool that comes with the drug to make sure you are getting the right dose.
4. Don't crush or split up tablets unless directed by a doctor. This could affect how your body absorbs them and impact their effectiveness.
5. In 2014, FDA also asked doctor's to stop prescribing combination drugs that exceed 325mg of acetaminophen per dose. Also FDA issued a warning in January about sodium phosphate laxatives, saying there had been 54 reports of serious side effects and 13 deaths among people who overdosed or had coexisting health conditions.
6. In July 2015, FDA even called for drug makers to strengthen their warning labels on non-aspirin NSAIDs. The FDA stated the labels must now carry language warning of increased risk of heart attack or stroke, including "the risk of heart attack or stroke can occur as early as first week of using NSAIDs". Risks may increase with the longer use of NSAIDs and may appear at higher dose (5-8).

***In March 2014, Health Ministry bans 344 drugs including Nimesulide***

The Health (9) Ministry has banned 344 FDC (fixed drug combinations). This includes various cough syrups solution, analgesics and antibiotic combination, many of which are sold OTC. These are banned because they affect body's important part such as liver, lungs and kidney. The bam which comes in effect follows recommendations of expert committee formed to examine the efficacy of these

drug combinations. The list of banned drugs also include Nimesulide which had been a cause of concern for long for health experts for its continued in India despite being banned in most of the developed nations. The Health Ministry also launched a drive to crack down upon irrational use of antibiotic and also notified a special schedule of drugs which chemists will not only need to check the prescription before selling them but also maintain records with themselves or face government actions.

**Table 2** List of some drug combinations banned by Health Ministry (10, 11)

| Sr.no. | Drug combinations |
|---|---|
| 1 | FDC Aceclofenac+ Paracetamol+ Rabeprazole |
| 2 | FDC Nimesulide+ Diclofenac |
| 3 | FDC Nimesulide+ Cetirizine+ Caffeine |
| 4 | FDC Paracetamol+ Cetirizine+ Caffeine |
| 5 | FDC Diclofenac+ Tramadol+ Paracetamol |
| 6 | FDC Naproxen+ Paracetamol |
| 7 | FDC Tamsulosin+ Diclofenac |
| 8 | FDC Paracetamol+ Phenylephrin+ Chlorpheniramine+ Dextromethorphan+ Caffeine |
| 9 | FDC Heparin+ Diclofenac |
| 10 | FDC Paracetamol+ Tapentadol |
| 11 | FDC Aceclofenac+ Paracetamol+ Famotidine |
| 12 | FDC Azithromycin+ Cefixime |
| 13 | FDC Nimorazole+ Ofloxacin |
| 14 | FDC Cefuroxime+ Linezolid |
| 15 | FDC Metronidazole+ Tetracycline |
| 16 | FDC Metformin+ Atorvastatin |

And many more are there.

**3. Latest amendments**

A. In August 2015, OTC Pediatric Oral Liquid Products Containing Acetaminophen (12):

In August 2015, FDA gives the guideline on OTC Pediatric Oral Liquid Products Containing Acetaminophen. This is made to help the drug manufacturers, packagers, and labelers to minimize the risk to the consumers of Acetaminophen- related liver damage associated with the non- prescription drugs or OTC drugs. OTC pediatric oral liquid drug products containing Acetaminophen have been associated with the overdoses due to medication errors that result in serious adverse events, including severe liver-damage and death. By watching all these events in June 2009, three FDA committees,

a) The Drug Safety and Risk Management Advisory Committee;
b) The Non-Prescription Drugs Advisory Committee and
c) The Anesthetic and Life Support Advisory Committee met jointly to fix a dose or range of risk reduction measures.

Also in May 2011, a joint meeting was being conducted by FDA of Non- Prescription Drugs Advisory Committee and Pediatric Advisory Committee to discuss the use of Acetaminophen in children. Shortly after this meeting another meeting was also conducted by Consumer Healthcare Products Association (CHPA) proposed to voluntarily phase out all of the existing single ingredient concentrated drop formulation OTC Pediatric Oral Liquid Drug Products and market only the 160 mg/5ml formulation.

FDA published a Drug Safety Communication on December 22, 2011, to inform the public of the 160mg/5ml concentration now marketed for children ages 2 to 3 years and to recommend that end users of the product read the drug facts label to identify the concentration of oral liquid Acetaminophen dosage and direction of uses. Also in 2011 FDA issued guidance for Industry on Dosage Delivery Devices (9):

a) Dosage delivery device not being packaged with the medication and
b) Poorly designed delivery devices (e.g. devices difficult to read markings or device designs that make it difficult to dispense a precise- dose).

B. In Nov. 2016, Non- Prescription Sunscreen Drug Products- Safety Effectiveness Data:

In Nov. 2016, FDA gives guideline on safety and effectiveness data needed to determine whether a non-prescription sunscreen active ingredient, evaluated under the Sunscreen Innovation Act (SIA) is generally recognized as safe and effective (GRASE) and not misbranded when used under specific conditions. The recommendation in this guidance are designed to ensure the FDAs GRASE determination for OTC sunscreen active ingredients under SIA are consistent, up to date and appropriately reflect current scientific knowledge and patterns of non-prescription sunscreen use by consumers.

Also sunscreen products are formulated with two or more active ingredients and in some cases

additional data and testing beyond what is recommended in guidance may be needed to support a positive GRASE determination and to establish the conditions for that particular ingredient. The following are examples in which additional data may require:

a) Data suggest that there may be safety or efficacy concern with a particular combination of active ingredients or active and inactive ingredients;
b) Information indicates that an active ingredient is unstable when exposed to sunlight and suggests that active ingredients may need to be combined with a photo stabilizer to be safe and effective.

FDA's OTC drug regulation identify both types of safety information that sponsor should submit as evidence that an OTC drug is GRASE for use and standard by which such safety information is to be judged. FDA also make sure that broad spectrum sunscreens must have a sun protection factor (SPF) value of 15 or higher can make to decrease the risk of skin cancer and early skin aging caused by the sun if used as directed with other sun protection measures. FDA has to balance the potential benefits of sunscreen products used by consumers against their potential risks.

C. In Nov. 2016, Nonprescription Sunscreen drug products- Format and Content of data submission (13):

In Nov. 2016, this guidance being prepared and given by the Division of Nonprescription Drug Products and the Office of Regulatory Policy in the Center for Drug Evaluation and Research (CDER) at the FDA. This guideline address the current thought of FDA on format and content of information provided to support a request submitted under section 586A of the Federal Food, Drug and Cosmetic Act (FD&C Act), as amended by the SIA (enacted November 26, 2014) or in support of the pending request as defined in section 586(6) of FD&C Act.

This whole guidance is issued in accordance with SIA followed by FDA which calls FDA to publish a draft and guidance on format and content of information submitted by a sponsor in support of a 586A request or pending request. All sunscreens are regulated as drugs in United States under one of two processes:

a) The new drug approval process described in part 314 (21 CFR part 314)
b) The OTC drug monograph process (also known as OTC drug review) described in part 330 (21 CFR part 330), as supplemented by SIA (13).

D. In April 29,2016, A Bill to allow women greater access to safe and effective contraception:

In April 29, 2016 a Bill was enacted by the Senate and House of Representatives of the United States of America in which there is "Allowance to women greater access to safe and effective use of contraceptives". This act may be cited as "Over-The-Counter Contraceptives Act 2016".

1. The priority of this application is to give priority to any supplemental application submit under section 505(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(b)) for a contraceptive drug and is given by The Secretary of Health and Human Services(Secretary) and it provide:-
   a) The supplemental application is with respect to a drug intended for routine use;
   b) If the supplemental application is approved, with respect to individuals aged 18 and older, such drug would not be subjected to section 503(b) (1) of the Federal, Food, Drug and Cosmetic Act.
2. The secretary shall waive the fee under section 736(a)(1) of the Federal, Food, Drug and Cosmetic Act (21 U.S.C. 379h(a)(1)) with respect to a supplemental application that receives priority review under subsection A.
3. Eligibility of drug to those who are of age 18 or older and all is done under the provision of law under section 503(b) (1) of Federal, Food, Drug and Cosmetic Act (21 U.S.C. 353(b) (1)) (12).

E. In January 1, 2016, Proposed Listing Changes for OTC items:

Under the Pharmaceutical Benefits Scheme (PBS) a list was proposed which contain "Proposed Listing Changes for OTC items" and proposed in 1 January, 2016. This list was prepared in December 2015 but propose in January 2016.

In some cases, sponsor has elected to de-list their brands from PBS and furthermore some brand deletions will result in the whole item being deleted from the PBS:

a) Aluminum hydroxide with magnesium trisilicate and magnesium hydroxide
b) Chloramphenicol
c) Ferrous fumarate
d) Ferrous fumarate with folic acid (11).

**4. Initiative by Companies (13)**

Some companies have taken up the initiative and they launch a catalog for the OTC products, which include all the OTC medicines and products. These companies make OTC products available online and which people can buy easily. They made it easy for people to buy it online that is place order online or place order on phone and they deliver it on their doorsteps. They have created a catalog in which they have mentioned the name of the drug, generic name of the drug, quantity, amount, brand name, ID etc. which help people a lot and easy.

Catalogs available are:

1. 2013 Over the counter(OTC) Benefit catalog by Care 1st Health Plan
2. 2015 OTC product catalog by Dr. Reddy's
3. 2017 Over the counter catalog by Gateway Health Medicare Assured
4. 2017 Over the counter(OTC) catalog, Medicare advantage plans by Well Care Health Plans

5. Over the counter (OTC) catalog 2017 by Ameri group Real Solutions in Healthcare (13).

**Table 3** Categories which came under the catalogues and their examples are (14, 15)

| S.No. | Category | Drug name | Work | Brand name |
|---|---|---|---|---|
| 1. | Acne | 1. Acne gel 10% Benzoyl peroxide<br>2. Clean and clear advantage acne spot treatment | Acne gel<br>Acne spot | Clean and clear |
| 2. | Allergy | 1. Citrizine hydrochloride tablets<br>2. Nasoflow allergy relief | Allergy relief<br>Allergy relief | Zyrtec<br>Flonase |
| 3. | Analgesic/ antipyretic | 1. Acetaminophen 325mg tab<br>2. Aspirin 81mg chewable | Acetaminophen tablets<br>Aspirin chewable tab | Tylenol<br><br>Bayer |
| 4. | Antacids and acid reducers | 1. Acid reducer (Famotidine) 10mg tab<br>2. Acid reducer (Omeprazole) | Acid reducer Famotidine<br>Acid reducer Omeprazole | Pepcid<br><br>Nexium |
| 5. | Anticandidal | 1. Miconazole vaginal cream<br>2. Clotrimazole vaginal cream | Miconazole cream<br>Clotrimazole cream | Monistat |
| 6. | Antidiarrheal and laxatives | 1. Adult glycerine suppositories<br>2. Stomach relief flavored tab | Suppositories<br>Stomach relief tab | Fleet<br>Pepto-bismol |
| 7. | Anti-inflammatory | 1. Ibuprofen 200mg liquid gel caps<br>2. Naproxen sodium 220mg tab | Ibuprofen gel caps<br>Naproxen sodium tab | Advil<br>Aleve |
| 8. | Arthritis | 1. Arthritis pain relief caplets<br>2. Hot/cold patches | Arthritis pain relief caplets<br>Patches | Tylenol<br><br>Icy hot patches |
| 9. | Bladder control items | 1. Adult protective briefs S/M<br>2. Disposable bed underpads | Protective briefs<br><br>Underpads | Adult protective briefs<br>Disposable bed underpads |
| 10. | Cold/cough/flu remedies | 1. Cough/throat drops<br><br>2. Mucus relief Dm tablets<br>3. Nasal decongestion PE tab | Cough and throat drops<br>Mucus relief tab<br>Nasal decongestion tab | Halls<br><br>Mucinex<br>Sudafed |
| 11. | Dental and denture care | 1. Denture adhesive cream<br>2. Sensitive teeth toothpaste | Denture cream<br>Toothpaste | Fixodent<br>sensodyne |
| 12. | Ear care | Ear wax drops | Ear drops | Debrox |
| 13. | Eye care | Red eye relief drops | Eye drops | Visine |
| 14. | Fiber supplements | Fibertab tab | Fiber tab | Fibercon caplets |
| 15. | First aid and medical supplies | 1. Alcohol pads<br>2. Athletic bandage<br>3. Cotton swabs | Alcohol pads<br>Bandage<br>Swabs | Alcohol pads<br>Athletic bandage<br>Q-tips |
| 16. | Motion sickness | Motion sickness tab | Motion sickness | Dramamine |
| 17. | Sleeping aids | Sleep aid tab | Sleep aid tab (doxylamine) | Unisom |
| 18. | Topical ointment and cream | 1. Anti-itch cream<br>2. Petroleum jelly | Anti-itch cream<br>Jelly | Benadryl cream<br>Vaseline |
| 19. | Topical ointment and cream | 1. SPF50 sunblock<br>2. Cold sore treatment | Sunscreen lotion<br>Cold sore | Coppertone<br>Abreva cream |
| 20. | Vitamins and minerals | 1. Calcium chewable tab<br>2. Vitamin C gummy | Chewable tab<br>Vitamin C gummy | Windmill<br>Vitamin C gummy |
| 21. | Diagnostic equipments | Advocate non-contact infrared thermometer speaks English/ Spanish | Thermometer | Advocate |
| 22. | Support ankle and elbow | 1. Procare elastic ankle support<br>2. Procare elastic elbow support | Ankle support<br>Elbow support | Procare<br>Procare |
| 23. | Condoms | Trojan ultra-thin lubricated condoms 3 CT | Lubricated condom | Trojan |
| 24. | Diaper rash cream | Balmex clear protection ointment | Ointment | Balmex |

| | | | | |
|---|---|---|---|---|
| 25. | Feminine hygiene | Stayfree ultra-thin overnight with wings | Safety pads | Stayfree |
| 26. | Gastrointestinals | 1. Alka-saltizer tab<br>2. Fleet glycerine suppositry | Gastric<br>Suppositrty | Alka-saltizer<br>Fleet |
| 27. | Pain relievers | 1. Advil liquid-gel CT<br>2. Bayer child chew aspirin low dose | Tab<br>Chewable tab | Advil<br>Bayer |

## 5. Conclusion

Over the counter (OTC) drugs are medicines sold directly to consumer without any prescription. OTC drugs are safe and deliver immediate relief but it can be dangerous if given in combination with other medicine or misused. OTC medicines are used to treat short term illness but ingesting them for long time can cause various side effects or adverse effects and also can lead the disease to a worst condition. Patient's needs to understand what they are putting in their body. In future India is known and expected to rank amongst top three pharmaceutical markets in terms of incremental growth by 2020.

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## Conflict of interest

The authors declare that there is no conflict of interest.

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