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ETHIOPIAN FOOD & DRUG AUTHORITY

Ethiopian Food and Drug Authority

Over - the - Counter Medicines List for Ethiopia

Third Edition

የኢትዮጵያ ገቢዎች ሚኒስቴር
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Ethiopian Ministry of Revenues
Records & Documentation No.1

July 2022

Addis Ababa, Ethiopia

Contents

Foreword iii
Acknowledgements iv
1. Introduction 1
2. Guidance on Over-the-Counter Medicines use 3
3. Therapeutic classifications of OTC medicines 6
3.1. Gastrointestinal Drugs 6
3.1.1. Antacids and Other Acid Reducers 6
3.1.2. Antispasmodics / Spasmolytic Analgesics 8
3.1.3. Antiemetics 8
3.1.4. Cathartics and Laxatives 9
3.1.5. Medicines Used for Diarrhea 10
3.1.6. Anti-flatulent 10
3.1.7. Antihaemorrhoidal Agents 10
3.2. Respiratory Drugs 11
3.2.1. Antitussives/Expectorants/Mucolytics 11
3.2.2. Antiasthmatics 12
3.3. Analgesics /Antipyretics 12
3.4. Antimigraine medicines 13
3.5. Antirheumatics/Medicines for musculoskeletal disorders 13
3.6. Anthelmintics 14
3.7. Vitamins and/or Minerals 14
3.8. Ear, Nose and Throat Preparation 15
3.9. Antihistamines and Antiallergics 16
3.10. Topical Anti-infectives 16
3.11. Keratolytics /Caustics agents 17
3.12. Topical agent for psoriasis and eczema 17
3.13. Antiprurities 18
3.14. Antiseptics (skin disinfecting agents) 18
3.15. Dermatological and Others 18
3.16. Contraceptives 19
3.17. Miscellaneous 20
Annex I: Zero Draft Revision Participants List 21
Annex II: Consultative Workshop Participant List 22
Annex III: Validation Workshop Participant List 24

Ethiopian Ministry of Revenues Records & Documentation No.1

Index 26

Foreword

Pharmacotherapy has always been an essential part of the healthcare system and will remain so in the future. It ensures the safe, appropriate, and economical use of medications. This relies on the availability of safe, effective, quality-assured, and affordable medicines. Moreover, the rational prescribing, dispensing, and use of medicines has a paramount influence on the proper use of medicines. The Ethiopian drug policy highlights those medicines used in the health system have to be identified and classified based on the nature of the products and the standards of health institutions. One of the main classifications of medicines is Over-the-Counter (OTC) medicines. The Authority shall determine a list of over-the-counter medicines to be sold in medicine retail outlets, according to Proclamation No. 1112/2019, article 36 (4).

Over-the-Counter medicines are medicines that are legally allowed to be dispensed to end users under the supervision of pharmacy professionals without the need for a prescription. Medicines for self-medication are those which do not require a prescription and which are sold primarily with the intention that they will be used by consumers on their own initiative and responsibility for minor ailments and self-limiting conditions. The reclassification of medicines from prescription only to nonprescription is of great interest. However, they can still carry a risk, due to the possibility of side effects, interactions, or harm due to excessive doses. There might also be misuse of these medicines.

The development and periodic revision of OTC medicines by law and monitoring of their potential benefits and risks will help to optimize their use. Therefore, it gives me great pleasure to introduce the third edition of the OTC medicines to all beneficiaries, and I urge health professionals to comply with it.

Finally, I would like to express my gratitude to all those who have directly or indirectly participated in the revision of the list. I also call upon health professionals and other stakeholders to continue their usual support by forwarding comments and suggestions to the Ethiopian Food and Drug Authority (EFDA) for updating the list.

Heran Gerba
Director General, EFDA

Ethiopian Ministry of Revenues Records & Documentation No.1

Acknowledgements

The Authority would like to give appreciation to the members of the core team for their commitment and contribution in revising the OTC medicine list. The Authority would also thank those who were involved in the review workshops, including participants from the Ministry of Health, associations, universities, drug retail outlets, and development partners for their commitment and valuable contribution towards enriching the OTC Medicines List for Ethiopia.

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6.	Selamawit Dagne	EFDA	Clinical Pharmacist
7.	Shemsu Umer (Dr.)	EFDA	Pharmacologist
8.	Wondie Alemu	EFDA/GHSC-PSM	Pharmacist
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11.	Yodit Assefa	UNICEF	Pharmacist

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1. Introduction

The provision of a complete healthcare service necessitates the availability of safe, quality, efficacious, and affordable medicines. The Ethiopian drug policy ensures that medicines that are required for prevention, diagnosis, treatment, mitigation, and rehabilitation of diseases affecting the majority of the Ethiopian people have to be identified and classified into respective levels of healthcare.

The Food and Medicine Administration Proclamation No. 1112/2019, Article 36 (4), stated that the Authority shall determine a list of over-the-counter medicines to be sold in medicine retail outlets. Furthermore, according to article 37 (1) of Proclamation No. 1112/2019, the classification of any medicine is determined by the Authority based on the nature of the product and the standard of the health institution. As per article 37 (2a), one of the classifications is medicine that will be available on the advice of a pharmacy professional, without a prescription from an authorized prescriber, and available only in authorized medicine retail outlets.

Evidence-based medicine classification is important to increase access to these medicines as well as for the public to take a more active role in their own healthcare. OTC medicines are medicines that may be sold directly to consumers without a prescription from medicine retail outlets. OTC medicines are not risk free due to side effects, contraindications, and interactions with other medicines, supplements, foods or drinks. Others may cause health problems for people with certain medical conditions or allergic reactions to active ingredients or excipients. Therefore, OTC medicines have to be dispensed with sufficient counseling by qualified pharmacy professionals.

Over - the - Counter Medicines are generally used to treat minor symptoms and self-limiting diseases that do not necessitate direct supervision by a physician, and they have proven to be relatively safe and well accepted.

For the last two decades, the EFDA has been defining the list of OTC medicines for Ethiopia. The second edition has been in use for the last ten years. Due to different changes, it is time to revise the list in light of the latest developments in the fields of medicine and pharmacy.

During the revision process, national and global experiences were considered. Medicines were carefully and systematically selected using an evidence-based approach with due consideration

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of public health relevance, efficacy and safety, comparative cost-benefit, and availability of medicines in the country. In the process of revising OTC medicines list, at least the following scientific criteria for addition or deletion were created and used.

- Safety profile of the medicine
- Potential for misuse and abuse
- Suitability for use in self-medication
- Drug resistance issues
- Diseases characteristics
- Experiences from other countries
- Registration status of the medicine in Ethiopia
- Availability of the medicine in the latest Medicine Retail Outlet Lists

Accordingly, additions, deletions, or changes/modifications were made to the previous edition of the OTC medicine lists. The OTC medicine list contains 128 medicines, as compared to the previous edition, which contains 92 medicines. Medicines are listed in their International Non-proprietary Names (INN) or generic names in alphabetical order.

This medicine list should be of benefit to the public. Hence, it will be updated regularly and be widely accessible in both electronic and printed copies. Consequently, all users of this list are invited to send their comments and suggestions to the Ethiopian Food and Drug Authority, Addis Ababa, Ethiopia, P.O. Box 5681, Tel. +251-11-552-41-22, www.efda.gov.et



2. Guidance on Over-the-Counter Medicines use

What are over the counter (OTC) medicines?

OTC medicines are legally classified as non-prescription medicines used to treat minor symptoms and self-limiting conditions. These medicines do not need a prescription from an authorized physician but are dispensed under the supervision of pharmacy professionals from medicine retail outlets.

What should users do when buying OTC medicines?

Any medicine is a chemical that can harm the health of an individual or a community. Anyone who takes over-the-counter medicine should consider the following advice.

1. Consult pharmacy professional when you are considering buying OTC medicines. Get as much information as possible about the medicine. Ask the following questions:
    - What is the name of the medicine?
    - What is the purpose of taking the medicine?
    - What is its registration status?
    - How to take the medicine?
    - When to take the medicine?
    - How much to take?
    - How many times should it be taken in a day?
    - How long should it be used?
    - What are the side effects of the medicine?
    - Does it interact with any other medicine, food, or disease?
    - How should it be kept or stored?
2. Always read and follow the instructions on the medicines labels. Over-the-counter medicines labels provide the information you need in order to take your medicines correctly, such as :
    - Active ingredients and excipients
    - The use of medicine
    - The maximum allowable dose
    - The right method to take the medicine and the right time to take or not to take the medicine
    - Possible interactions or side effects

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- Other precautions
- Handling and storage conditions

3. Select appropriate OTC medicine for your complaints.
   It is better that you use medicine that is only used to treat the conditions or symptoms that you are having. Seek advice from your pharmacy professional. If you are taking more than one medicine, please take note of the active ingredients to avoid taking medicines with the same active ingredients.
4. Check the packaging and expiry date.
   Do not buy medicines that have damaged packaging or have expired. The expiry date will indicate that the medicine will no longer be effective after the date.
5. Inform your healthcare provider if you are taking OTC medicines frequently. OTC medicines are only used for a short period of time.
6. Stop taking the medicine if you experience any intolerable effects or if you notice any unusual reactions. Report it to the pharmacist or any other healthcare provider.

Are OTC medicines safe to use?

OTC medications can still carry a risk, even though they do not require a prescription. There is the possibility of side effects, interactions, or harm due to excessive doses. Consumers should read the leaflet that is found on all OTC products. All patients should consult with their doctor, pharmacist, or other healthcare provider if they have additional questions concerning OTC medicine use.

Pregnant and lactating women should speak with their physician before taking any medication, vitamin, or herbal supplement, even if it is an OTC product.

Notes for Pharmacy personnel

As per article 36 (1) of the proclamation no. 1112/2019, medicines shall only be dispensed by a pharmacy professional acting within his scope of practice. Besides, Article 11 (12) of the Rational Medicines Use Directive No. 40/2019 says: Any pharmacy professional shall be liable for damages caused by noncompliance with the Good Dispensing Practices.

In this connection, dispensers should be knowledgeable about OTC medications in order to provide appropriate advice to users. While dispensing an OTC medicine, every pharmacy professional shall ensure that the patient or client is informed about the identity, use, instructions

Ethiopian Ministry of Revenues Records & Documentation No.1

for use, precautions, side effects, and other relevant information about the dispensed medicine. In this third edition, short notes are included for most of the medicines included in the list as a quick reference, but it has to be noted that this is not complete and the pharmacy personnel should be competent enough to have detailed knowledge of each and every medicine under their custody. Special attention is required for vulnerable groups such as children, pregnant women, geriatrics, and other immunocompromised people. In addition, you are also advised to refer to the quick notes stated in this list.

If a molecule is on the OTC medicine list but not all formulation types are, only those formulations that are listed are deemed OTC. POM will be applied to other formulations of the same chemical. Salbutamol aerosol and syrup, for example, are OTC, whereas salbutamol tab is not. Furthermore, as there are molecules with the same formulation but different strengths, it is to be noted that the strengths indicated in this list are OTC. For instance, because of the difference in therapeutic indication, Acetyl Salicylic Acid 300mg and higher strengths are OTC, whereas lower strengths are prescription only medicines. On the other hand, there are a few specific areas stating, "Any therapeutically effective combinations approved/authorized by EFDA can be considered as OTC," to provide options for other similar combinations not specified in the list.



3. Therapeutic classifications of OTC medicines

3.1. Gastrointestinal Drugs				
3.1.1. Antacids and Other Acid Reducers				
S.N.	**Name**	**Strength**	**Dosage form**	**Maximum quantity allowed to be dispensed at one time**
1.	Aluminum Hydroxide + Magnesium Hydroxide ♣	(220mg+ 195mg)/5ml	Suspension	2 bottles
		400mg+400mg; 405mg +100mg	Tablet (Chewable)	30 tablets
		• Ask your doctor or pharmacist if this medicine is safe to use if you have: o Cardiac disease o Kidney disease; or o If you are on a low-magnesium diet. • Aluminum-containing antacids should be used with caution in infants and young children with renal failure.		
2.	Aluminum Hydroxide	320mg/5ml; 360mg/5ml	Mixture/Gel Suspension	1 bottle
		500mg	Tablet (Chewable)	20 tablets
		• Ask your doctor or pharmacist if it is safe for you to take this medicine if you have: o kidney disease, a history of kidney stones; o severe constipation; o if you are dehydrated; or o If you drink alcohol frequently. • Avoid taking other medications within 2 hours before or 2 hours after you take aluminum hydroxide.		
3.	Aluminium Hydroxide + Magnesium Hydroxide + Simethicone ♣	(225mg + 200mg + 25mg)/5ml, (200mg + 200mg + 20 mg)/5ml, (400mg + 400mg + 40 mg)/5ml	Suspension	2 bottles
		200mg + 200mg + 25mg	Chewable tablet	30 tablets
		• Ask your doctor or pharmacist if this medicine is safe to use if you have: o Kidney disease; or		

Ethiopian Ministry of Revenues Records & Documentation No.1

		○ If you are on a low-magnesium diet. • Aluminum-containing antacids should be used with caution in infants and young children with renal failure.		
4.	Aluminum Hydroxide + Magnesium Trisilicate♣	(310 mg + 620 mg)/5ml	Suspension	2 bottles
		120mg + 250mg; 250 mg + 500mg	Tablet (Chewable)	30 tablets
		• Ask your doctor or pharmacist if this medicine is safe to use if you have: ○ Kidney disease; or ○ If you are on a low-magnesium diet. • Aluminum-containing antacids should be used with caution in infants and young children with renal failure.		
5.	Calcium carbonate	100mg, 350mg, 500mg, 700mg	Chewable Tablets	10 tablets
		• This medicine should not be given to children under 12 and individuals with renal problems. • It shouldn't be used for more than 2 weeks for stomach symptoms without speaking to your healthcare provider.		
6.	Calcium Carbonate + Magnesium Carbonate	680mg + 80mg,	Chewable tablet	10 tablets
		• Avoid taking drugs whose absorption is affected by antacids within 1 hr. of administration. • Do not use the maximum dosage for >2 weeks; if symptoms persist, discontinue and contact a health care provide.		
7.	Aluminum Hydroxide + Magnesium Hydroxide + Sodium Alginate + Simethicone	(125mg + 250mg + 100mg + 50mg)/5ml	Suspension	2 bottle
		200mg + 400mg + 100mg + 50mg	Tablet	20 Tablets
8.	Magnesium Hydroxide	375mg/5ml, 125mg/5mg	Suspension	1 bottle
		300mg; 311mg	Tablet (Chewable)	20 tablets
		• Magnesium salts may cause central nervous depression in the presence of renal insufficiency and should be used with caution in patients with advanced renal disease.		
9.	Magnesium Trisilicate	500 mg	Tablet (Chewable)	20 tablets
		• Magnesium salts may cause central nervous depression in the presence of renal insufficiency and should be used with caution in		

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		patients with advanced renal disease		
10.	Sodium carbonate Anhydrous + Sodium Bicarbonate + Citric acid anhydrous	450mg + 2059.2mg + 1941.3mg	Powder	5 sachets
♣ Any therapeutically effective combinations approved/authorized by EFDA can be considered as OTC.				
3.1.2. Antispasmodics / Spasmolytic Analgesics				
S.N.	**Name**	**Strength**	**Dosage form**	**Maximum quantity allowed to be dispensed at one time**
1.	Alverin citrate + simethicone	60mg+ 30mg	Capsule	10 capsules
		• Not recommended for children under 12.		
2.	Hyoscine (Scopolamine) Butyl bromide	5mg/5ml	oral drops	1 bottle
		10mg	Tablet	10 tablets
		7.5mg, 10mg	Suppository	10 suppositories
		• This medicine should not be taken on daily basis or for extended period of time without investigating the cause of abdominal pain. • It may cause drowsiness.		
3.1.3. Antiemetics				
S.N.	**Name**	**Strength**	**Dosage form**	**Maximum quantity allowed to be dispensed at one time**
1.	Dimenhydrinate	50mg	Tablet	10 tablets
		• Should not be used in children under the age of two. • It causes significant drowsiness. • May impair ability to drive or operate heavy machinery • May mask early signs of ototoxicity if given concomitantly with ototoxic drugs (e.g., Aminoglycosides)		
2.	Hyoscine (Scopolamine) Hydrobromide	0.6mg	Tablet	10 tablets
		◦ Should not be used in children aged less than 4 years ◦ Do not take more than 3 doses in 24 hours. ◦ May cause depression; caution when operating heavy machinery or tasks which require mental alertness.		

Ethiopian Ministry of Revenues Records & Documentation No.1

3.1.4. Cathartics and Laxatives				
S.N.	**Name**	**Strength**	**Dosage form**	**Maximum quantity allowed to be dispensed at one time**
1.	Bisacodyl	5mg, 10mg	Suppository	10suppository
		5mg,10mg	Tablet	10 tablets
		• Not recommended in children under 4 years. • Use of this drug continually over one week indicates the individual should seek medical advice. • Not recommended in patients with acute inflammatory bowel diseases		
2.	Docusate sodium	50mg, 100mg, 250mg	Capsule	10 capsules
		50mg, 100mg	Tablet	10 tablets
		4mg/ml	Oral liquid	500ml
		• Prior to OTC use, patients should contact a healthcare professional if stomach pain, nausea, vomiting, or bleeding are present, or if a sudden change in bowel habits occurs and persists over 14 days.		
3.	Glycerin	0.7g, 0.9g, 1g, 1.36g, 2g, 2.76g	Suppository	10 suppositories
		• Do not use when abdominal pain, nausea, or vomiting present (unless directed by physician). • Do not use for longer than 1 week • If constipation continues after one week of use, contact your physician		
4.	Magnesium sulphate	30g/sachet	Oral powder	1 sachet
5.	Polyethylene glycol 3350	10g/sachet, 17g/sachet	sachet	**5 sachets**
		• Shouldn't be used for more than 7 consecutive days and in children below 6 months.		
6.	Psyllium	400mg	capsule	10 capsules
7.	Sennosides (Senna and its preparations)	7.5mg	Tablet	10 tablets
		• Not recommended: o For children under 18 years. o During pregnancy/ breastfeeding.		
8.	Sorbitol	70%	Oral Solution	1 bottle

Ethiopian Ministry of Revenues Records & Documentation No.1

3.1.5. Medicines Used for Diarrhea				
S.N.	**Name**	**Strength**	**Dosage form**	**Maximum quantity allowed to be dispensed at one time**
1.	Oral Rehydration Salt (ORS)*	Sachet	Powder	4 sachets
2.	Zinc sulfate	10, 20mg	Tablet	20 tablets
***ORS-Zinc co-pack is considered as OTC.**				

3.1.6. Anti-flatulent				
S.N.	**Name**	**Strength**	**Dosage form**	**Maximum quantity allowed to be dispensed at one time**
1.	Activated charcoal	125mg, 250mg	Tablet	
		15g	Suspension	
		5g, 25g, 30g	Powder for reconstitution	
2.	Simethicone	60mg, 80mg, 95mg	Tablet (chewable)	10 tablets
		95 mg, 125 mg	Capsule	10 capsules
		40mg/ml, 66.6mg/ml	Oral drops	1 bottle

3.1.7. Antihaemorrhoidal Agents				
S.N.	**Name**	**Strength**	**Dosage form**	**Maximum quantity allowed to be dispensed at one time**
1.	Bismuth Subgallate Compound*(Bismuth Subgallate + Bismuth Oxide + Peru Balsam+ Zinc Oxide)	2.25% + 0.875% + 1.875% + 10.75%	Ointment	1 tube
		59mg + 24mg + 49mg + 296mg	Suppository	10 suppositories
		• Bismuth containing drugs may cause black stools.		
2.	Lidocaine HCl + Tribenoside	(2.12gm + 5gm)/100gm 40mg + 400mg	Cream Suppositories	1 tube 10suppositories
***And any other antihaemorrhoidal preparation proven to be therapeutically effective can be used**				

Ethiopian Ministry of Revenues Records & Documentation No.1

3.2. Respiratory Drugs				
3.2.1. Antitussives/Expectorants/Mucolytics				
S.N.	**Name**	**Strength**	**Dosage form**	**Maximum quantity allowed to be dispensed at one time**
1.	Chlorpheniramine maleate + Ammonium chloride + Sodium Citrate	(4mg + 200mg + 88mg)/10ml	Syrup	1 bottle
2.	Dexchlorpheniramine + Guaifenesin + Pseudoephedrine	(2mg + 100mg + 10mg)/5ml	Syrup	1 bottle
		• Pseudoephedrine containing drugs are not recommended in • Children under 12 years • Pregnancy, breastfeeding • Severe hypertension or severe coronary artery disease • Severe renal impairment		
3.	Dextromethorphan HBr	5mg/5ml, 7.5mg/5ml	Syrup	1bottle
		• It should not be taken by individuals who are taking CNS depressive drugs, opiates, and other psychoactive drugs, or children under 4 years of age. • Do not take dextromethorphan for persistent or chronic cough associated with smoking, asthma, or emphysema.		
4.	Dextromethorphan Hydrobromide + Guaicol Sulphonate	(0.3gm + 7.6gm)/100ml	Syrup	1 bottle
5.	Diphenhydramine + Sodium citrate + Ammonium chloride	(12.5mg + 60mg + 130mg)/5ml	Syrup	1 bottle
6.	Dextromethorphan + Guaifenesin + Pseudoephedrine	(10mg + 100mg + 30mg)/5ml	Oral solution	1 bottle
		• Do not take dextromethorphan for persistent or chronic cough associated with smoking, asthma, or emphysema		
7.	Guaifenesin	100mg, 200mg, 400mg	Tablet	10 Tablets
		200mg	Capsule	10 tablets
		100mg/5ml	Syrup	1 bottle
		• Not recommended for children below 2 years. • Adequate hydration will augment the effect of guaifenesin.		

Ethiopian Ministry of Revenues Records & Documentation No.1

8.	Ibuprofen + Pseudoephedrine HCl + Chlorpheniramine maleate	200mg + 30mg + 2mg	Tablet	12 tablets
9.	Paracetamol + Chlorpheniramine + Pseudoephedrine	(160mg + 1mg + 15mg)/5ml	Syrup	1bottle
		500mg + 1.25mg + 30 mg	Tablet	10 tables
		• Chlorpheniramine may cause significant sedation; not for administration to < 2 years of age. • Paracetamol is found in many other dosage forms and products, check label carefully to avoid overdose.		
10.	Paracetamol+ Pseudoephedrine+ Diphenhydramine	500mg + 30mg+ 12.5mg	Tablet/capsule	10 tablets
		• Paracetamol is found in many other dosage forms and products, check label carefully to avoid overdose. • Risk of hepatotoxicity is higher in alcoholics or with use of more than one acetaminophen-containing product		

3.2.2. Antiasthmatics

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Salbutamol (Albuterol)	0.1mg/dose	Inhalation (aerosol)	1 canister
		2mg/5ml	Syrup	1 Bottle

3.3. Analgesics /Antipyretics

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Acetylsalicylic acid	300mg, 500mg	Tablet	20 tablets
		• May cause Reye's syndrome in infants and children, which can lead to fatal brain swelling. Therefore, children younger than 14 years of age should not take Aspirin. • Aspirin can cause irritation of the stomach and may lead to ulcers and bleeding. Individuals with a history of ulcers or other stomach problems should not take aspirin, and those who take blood thinners should use caution when taking aspirin at the same time.		
2.	Diclofenac diethylamine	1%, 1.16%, 2.32%	Gel	1 tube
3.	Diclofenac diethylamine +	1% + 3%, 1.16% +10%	Gel	1tube

Ethiopian Ministry of Revenues Records & Documentation No.1

	Methyl salicylate			
4.	Ibuprofen	200mg, 300mg, 400mg	Tablet/capsule	20 tablets
		75mg, 150mg	Suppository	10 suppositories
		100mg/5ml	Suspension	1 bottle
		5%, 10%	Gel	1 tube
		• Patients at greatest risk include the elderly, those with impaired renal function, hypovolemia, heart failure, liver dysfunction, or salt depletion, and those taking diuretics, angiotensin-converting enzyme (ACE) inhibitors, or angiotensin receptor blockers.		
5.	Paracetamol	100mg/5ml	Drops	1 bottle
		125mg, 250mg	Suppository	10 suppositories
		120mg/5ml, 250mg/5ml	Syrup	1 bottle
		100mg, 500mg	Tablet	20 Tablets
		• Adequately labeling mentioning hepatitis warning. • Maximum dose 1g; maximum daily dose 4g for adults.		
6.	Paracetamol + Caffeine	500mg + 30mg, 500mg + 50mg, 500mg + 65mg	Tablet	20 Tablets
7.	Paracetamol + Caffeine + Chlorpheniramine	500mg + 30mg + 2mg	Tablet	20 Tablets

3.4. Antimigraine medicines

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Acetylsalicylic acid	300mg, 500mg	Tablet	20 Tablets
2.	Acetylsalicylic acid + Paracetamol + Caffeine	250mg + 250mg + 65mg ; 250mg + 400mg + 65mg	Tablet	20 Tablets
3.	Ibuprofen	200mg, 400mg	Tablet	20 Tablets
4.	Paracetamol + Caffeine	500mg+30mg ; 500mg+50mg ; 500mg + 65mg	Tablet	20 Tablets

3.5. Antirheumatics/Medicines for musculoskeletal disorders

S.N	Name	Strength	Dosage form	Maximum quantity allowed

Ethiopian Ministry of Revenues Records & Documentation No.1

				to be dispensed at one time
1.	Acetylsalicylic acid	300mg, 500mg	Tablet	20 Tablets
2.	Acetylsalicylic acid + Paracetamol + Caffeine	250mg + 250mg + 65mg ; 250mg+400mg+65mg	Tablet	20 Tablets
3.	Diclofenac diethylamine + Methyl salicylate + Menthol	1.16% + 10% +5%	Gel	1tube
4.	Ibuprofen	200mg, 400mg	Tablet/capsule	20 Tablets
		100mg/5ml	Syrup	1 Bottle
5.	Indomethacin	100mg	Suppository	10 Suppositories
6.	Methyl salicylate	6%, 25%	Ointment/cream	1 Tube

3.6. Anthelmintics

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Albendazole	100mg/5ml	Suspension	1 bottle
		200mg, 400mg	Tablet	6tablets (200mg); 3tablets (400mg)
2.	Levamisole	40mg	Tablet	3 Tablets
3.	Mebendazole	100mg/5ml	Suspension	1bottle
		100mg 500 mg	Tablet Tablet	12 Tablets 1 Tablet
4.	Piperazine	500mg/5ml, 622.5mg/5ml, 700mg/5ml, 750mg/5ml, 937.5mg/5ml, 1000mg/5ml	Elixir	1 bottle
5.	Pyrantel pamoate	250mg/5ml	Suspension	1bottle
		125mg, 250mg	Tablet	8 Tablets
		• Maximum daily dose should not exceed a total of 1 gram.		

3.7. Vitamins and/or Minerals

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Ascorbic acid (Vitamin C)	100mg, 250mg, 500mg, 1000mg	Tablet	30 Tablets
		100mg/ml, 200mg/ml	Oral solution	3 bottles
		1000mg	Sachet	5 Sachets

Ethiopian Ministry of Revenues Records & Documentation

2.	Calcium + Vitamin D	315mg + 250IU, 500mg + 200IU, 500mg + 600IU	Tablet	30 Tablets
3.	Folic acid + Vitamin B6	400mcg+25mg	Tablet	30 Tablets
4.	Folic acid	5mg	Tablet	30 Tablets
5.	Multivitamin Preparations*		Drops	
			Syrup	
			Tablet	
6.	Multivitamin with minerals and/or extracts*		Drops	
			Syrup	
			Tablet	
7.	Vitamin B Complex Preparations* (B_1+B_6+B_{12})	100mg+200mg+ 1000µg	Tablet	30 bottles
8.	Vitamin B6 (pyridoxine)	25mg, 40mg, 50mg,100mg, 300mg, 500mg	Tablet	30 Tablets
***Any combinations proven to be therapeutically effective can be acceptable**				

3.8. Ear, Nose and Throat Preparation

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Amylmetacresol + 2, 4-Dichlorobenzyl alcohol	0.6mg + 1.2mg	Lozenges	12 lozenges
2.	Amylmetacresol + 2,4-Dichlorobenzyl alcohol + Vitamin C	0.6+1.2+100mg	Lozenges	12 lozenges
3.	Chlorhexidine gluconate	0.12%, 0.2%	Oral solution	100ml
4.	Dequalinium chloride	0.25mg	Lozenges	12 lozenges
5.	Dequalinium chloride + Lidocaine hydrochloride	0.25mg +1mg	Lozenges	12 lozenges
6.	Hexetidine *	0.1%	Solution	1000ml
7.	Hydrogen peroxide	1.5%, 3%	Solution	120ml
8.	Menthol + Eucalyptus oil	2% +10%	Inhalation	1 bottle
9.	Povidone-iodine	0.1%	Solution	1 bottle
10.	Saline solution	0.9%	Nasal Spray Solution	1 Canister
		0.65 %	Nasal Spray Solution	1 Canister
11.	Triclosan + sodium fluoride	0.03%+0.05 %	Solution	1 bottle
12.	Xylometazoline	0.05%, 0.1%	Nasal drop/spray	

Ethiopian Ministry of Revenues Records & Documentation No.1

		• Treatment duration should not exceed 3 days; frequent or prolonged use may cause nasal congestion to recur or worsen. • Used for adults and children over 12 years of age. • Maximum strength 0.05% & 0.025%.		
***Any preparation proven to be therapeutically effective can be acceptable**				
3.9. Antihistamines and Antiallergics				
S.N.	**Name**	**Strength**	**Dosage form**	**Maximum quantity allowed to be dispensed at one time**
1.	Chlorpheniramine maleate	2mg/5ml	Syrup	1 bottle
		2mg, 4mg	Tablet	10 tablets
		• Use in children less than 2 years is not recommended/prohibited. • Use in children less than 6 years without medical supervision is not recommended. • May cause drowsiness; caution when driving a motor vehicle or operating machinery.		
2.	Dexchlorpheniramine maleate	2mg, 4mg	Tablet	10 tablets
		2mg/5ml	Syrup	1 bottle
		• It may cause drowsiness. Use caution when driving or using machine.		
3.	Loratadine	5mg/5mL	Syrup	1bottle
		10mg	Tablet	10 tablets
4.	Loratadine+ Pseudoephedrine	5mg + 120mg 10mg + 240mg	Tablets	10 tablets
		• See health-care provider if symptoms do not improve within 7 days or are accompanied by fever.		
5.	Pheniramine aminosalicylate	25mg, 50mg, 75mg	Tablet	10 tablets
		• Antihistamines may cause drowsiness. Use caution when driving or using machine.		
3.10. Topical Anti-infectives				
S.N.	**Name**	**Strength**	**Dosage form**	**Maximum quantity allowed to be dispensed at one time**
1.	Benzoic acid+ Salicylic acid	6% +3%, 12% +6%	Ointment	1 tube
2.	Benzyl benzoate (BBL)	25%	Lotion	1 bottle
3.	Beta-sitosterol	0.25%	Ointment	1 tube

Ethiopian Ministry of Revenues Records & Documentation No.1

		• Recommended for moist exposed burn.		
4.	Gentian violet (GV)	0.5%, 1%	Solution	1 bottle
5.	Ivermectin	1%	Cream	1tube
		0.5%	Lotion	1 Bottle
6.	Ketoconazole	1%, 2%	Shampoo	1 bottle
7.	Nitrofurazone	0.2%	Ointment	1 tube
8.	Selenium sulfide	2.5%	Shampoo/Topical Suspension	1 bottle
9.	Sulphur	5%, 10%	Ointment	1 tube
10.	Zinc undecenoate + Undecanoic acid	20% +5%	Ointment	1 tube
		20% +2%	Powder	1 bottle

3.11. Keratolytics /Caustics agents

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Benzoyl peroxide	2.5%, 4%, 5%, 8%, 10%	Gel	1tube
		2.5%, 5%, 10%	Solution	1Bottle
		2.5%, 3.5%, 7%	Lotion	1 Tube
		2.5%, 5.5%,6%,10%	Cream	1 Tube
2.	Camphor	3.1%	Cream	1 tube
		10%, 11%	Ointment	1 Tube
		10%	Topical liquid	1 Bottle
3.	Coal tar	2%, 5%	Ointment	1tube
		0.5%, 2.9%	Gel	1 Tube
		25%	Lotion	1 Tube
4.	Coal Tar + Salicylic acid + Sulphur	12% + 2% + 4 %	Ointment	1 Tube
5.	Salicylic acid	2%, 5%, 10%	Ointment	1tube
6.	Salicylic acid + Lactic acid + Polidocanol	(2g+0.5g +0.2g)/10g	Tincture	1bottle

3.12. Topical agent for psoriasis and eczema

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Ichthammol	10%, 20%	Ointment	1 tube
2.	Sun screen	with SPF 30+ (UVA + UVB block)	Cream	1 tube

Ethiopian Ministry of Revenues Records & Documentation No.1

3.	Zinc oxide	15% 15%, 20%	Ointment/cream/ Lotion/ paste	1tube

3.13. Antiprurities

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Calamine	5%	Lotion	1 bottle
2.	Calamine + Zinc oxide	4%+3%	Cream	1 tube
		15%+ 5%	Lotion	1 bottle

3.14. Antiseptics (skin disinfecting agents)

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Chlorhexidine gluconate + Cetrimide	1.5%+15%, 0.3%+3%	Solution	1000ml
2.	Ethyl alcohol	70%	Solution	1000ml
3.	Ethyl alcohol + Glycerol + Hydrogen Peroxide	80% + 1.45% + 0.125%	Solution	1000ml
4.	Iodine Tincture	2%	Solution	1000ml
5.	Isopropyl alcohol + Glycerol + Hydrogen peroxide	80% + 1.45% + 0.125%	Solution or jell	1000ml
6.	Hydrogen Peroxide	3%, 6%	Solution	120ml
7.	Povidone-iodine	0.1%, 4%, 7.5%, 10%	Solution	1 bottle

3.15. Dermatological and Others

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Crotamiton	10 %	Cream	1 tube
		10%	Lotion	1 tube
		◦ Effective for the relief of itching and skin irritation ◦ For children under three years of age, usage should only be used under medical supervision and it should not be applied more than once a day.		

Ethiopian Ministry of Revenues Records & Documentation No.1

2.	Dexpanthenol	5%w/w	Ointment /Cream	1 tube
		◦ It is used as a moisturizer to treat or prevent dry, rough, scaly, itchy skin and minor skin irritations (e.g., diaper rash, skin burns from radiation therapy). ◦ If you are using this product to help treat diaper rash, clean the diaper area well before use and allow the area to dry before applying the product.		
3.	Methyl salicylate	61.1mg/g	Ointment	1 tube
4.	Minoxidil	2%; 5%	Solution	1 bottle
		2%	Gel	1 Tube
		◦ Rist of contact dermatitis/eczema with topiacl sypmtoms of itching and scaling		
5.	Permethrin	5%	Cream	1 tube
		1%, 5%	Lotion	1 Tube
		1%	Shampoo	1 bottle
		• Leave on hair for 10 minutes (but no longer), use for a single application but may repeat 7 days after first treatment if lice still present.		
6.	Talc dusting powder		Powder	1 bottle

3.16. Contraceptives

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Drospirenone + Ethinyl estradiol	3mg+0.02mg,3mg +0.03mg	Tablet	
2.	Levonorgestrel (D-norgestrel)	0.03mg (minipil)	Tablet	
		0.75mg	Tablet	2 tablets
		1.5mg	Tablet	1tables
3.	Levonorgestrel (D-Norgestrel) + Ethinyl estradiol with/without Iron*	(0.15mg + 0.03mg)**	Tablets	3 cycles
4.	Norethindrone (Norethisterone) + Ehinylestradiol	0.5mg +0.035mg, 1mg+ 0.03mg	Tablet	3 cycles

Ethiopian Ministry of Revenues Records & Documentation No.1

5.	Norethindrone (Norethisterone) + Mestranol and Iron*	1mg + 0.05mg	Tablet	3 cycles
*** Each iron tablet contains: Ferrous Fumarate-75mg** **** Any combination of strengths effective for use is OTC**				

3.17. Miscellaneous

S.N.	Name	Strength	Dosage form	Maximum quantity allowed to be dispensed at one time
1.	Aluminium chloride	20 %	Solution	
		• Shouldn't be applied to broken or infected skin • External use only		
2.	Artificial Tear		Eye drop	



Annex I: Zero Draft Revision Participants List

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Ethiopian Ministry of Revenues Records & Documentation No.1

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Ethiopian Ministry of Revenues Records & Documentation No.1

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Ethiopian Ministry of Revenues Records & Documentation No.1

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Ethiopian Ministry of Revenues Records & Documentation No.1

Index

A

Acetylsalicylic Acid....14
Acetylsalicylic Acid + Paracetamol+ Caffeine....13
Acetylsalicylic Acid+ Paracetamol + Caffeine....14
Activated Charcoal....10
Albendazole....14
Aluminium Hydroxide+....6
Aluminum Hydroxide....6, 7
Amyl-Meta-Cresol + Dichlorobenzyl Alcohol....15
Ascorbic Acid (Vitamin C)....14

B

Benzoic Acid+ Salicylic Acid....16
Benzoyl peroxide....17
Benzyl Benzoate....16
Bismuth Subgallate +Bismuth Oxide + Peru Balsam+ Zinc Oxide....10
Bismuth Subgallate Compound*....10

C

Calamine....18
Calamine+Zinc Oxide....18
Chlorhexidine Gluconate....15
Chlorhexidine Gluconate+ Cetrimide....18
Chlorpheniramine Maleate....16

D

Dequalinium Chloride....15
DexchlorpheniramineMaleate....16
Dextromethorphan Hydrobromide + Guaicol Sulphonate 11
Diclofenac diethylamine....12
Diphenhydramine+....11
Drospirenone +Ethinyl Estradiol....19

E

Ethinylestradiol with/without Iron....19
Ethyl Alcohol....18

G

Gentian Violet....17
Guaifenesin....11

H

Hexetidine *....15
Hydrogen Peroxide....15, 18

I

Ibuprofen....13, 14
Ichthammol....17
Indomethacin....14
Iodine....18

L

Levamisole....14
Levonorgestrel (D-Norgestrel)....19
Lidocaine HCl + Tribenoside....10
Loratadine....16
Loratadine + pseudoephedrine....16

M

Magnesium Hydroxide....6, 7
Magnesium Hydroxide♣....6
Magnesium Sulphate....9
Magnesium Trisilicate....7
Mebendazole....14
Menthol + Eucalyptus Oil + Light Magnesium Carbonate 15
Methyl salicylate....14
Methylsalicylate ♣....19
Multivitamin Preparations....15
Multivitamin with Minerals and/or Extracts....15

N

Nitrofuranzone....17
Norethindrone (Norethisterone) + Ehinylestradiol....19
Norethindrone (Norethisterone) + Mestranol and Iron*....20

O

Oral Rehydration Salt....10

P

Paracetamol....13
Paracetamol + Caffeine....13
Pheniramine Aminosalicylate....16
Piperazine....14
Pyrantel Pamoate....14

S

Salbutamol (Albuterol)....12
Salicylic Acid....17
Simethicone....6, 10
Sorbitol....9
Sulphur....17

T

Talc Dusting Powder....19

V

Vitamin B Complex Preparations*....15

Z

Zinc oxide....18
Zinc tablet....10
Zinc Undecenoate+ Undecenoin Acid....17

Ethiopian Ministry of Revenues Archives & Documentation No.1