Decisions of the Technical Committee for Drug Control at its session on 04/01/2024

* - Approval to receive new reference preparations containing Doxophylline, and these preparations are followed up by Pharmacovigilance Department in accordance with the rules, and the decision is implemented from 01/02/2024.

Decisions of the Technical Committee for Drug Control at its session on 11/01/2024

*- Not approving the reception of new preparations and not approving to complete the registration procedures for preparations under registration that contain the Cefpirome in the form of injection & deleting them from the boxes, and cancelling them from the Egyptian Drug Authority database, with applying the rules.

Decisions of the Technical Committee for Drug Control at its session on 13/02/2024

*- Approval to receive the reference formulation containing (Sodium Szulene Sulfonate Hydrate + Cetylpyridinium Chloride) in the form of Buccal spray from the beginning of March 2024 in accordance with the rules, based on the decision of the Combined Specialized Scientific Committee for Ear, Nose and Throat Diseases at its session on 17/01/2024.

Note: -

The preparation was presented to the Combined Specialized Scientific Committee for Ear, Nose and Throat Diseases at its session on 17/01/2024, which recommended:

Approval of the preparation as it is used as soothing agent in cases of mucositis in cancer patients as a result of complications after radiation sessions, in addition to the lack of alternatives. The formula is also popular in the reference country, Japan.

Decisions of the Technical Committee for Drug Control at its session on 22/02/2024

* - The use of all preparations containing Oxytocin that are circulated locally is limited to hospitals only, with applying the rules, and the preparations are given only 3 months from the committee date to implement the decision based on the decision of the Combined Specialized Scientific Committee for Gynecology and Obstetrics at its session on 22/01/2024.

Note: -

It was presented to the Combined Specialized Scientific Committee for Obstetrics and Gynecology at its session on 22/01/2024, which recommended:

Not to approve the company's request and to limit the use of Oxytocin to hospitals only because it requires medical supervision while taking the drug because it has side effects and may affect the fetal heartbeat, according to the scientific reference BNF 85 & MHRA.

Decisions of the Technical Committee for Drug Control at its session on 07/03/2024

*- Reference concentrations must be adhered to when receiving requests for registration of new preparations containing Nordazepam based on the decision of the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 26/02/2024.

- Note: -

- A preparation containing Nordazepam 15 mg in the form of tablets was presented to the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 26/02/2024, which recommended:

Not to approve the preparation from a scientific standpoint, as the concentration presented is the highest concentration of the active substance permitted in the day, according to what was stated in the leaflet of the Brand Product in France, which may lead to an increase in the side effects of the group of Benzodiazepines to which the preparation belongs, which are Respiratory depression, Seizures, Confusion in the morning, Personality changes, and the usual concentration used in cases of Anxiety is 5 mg or 10 mg , in addition the reasons for withdrawing the Brand Product from France are unknown.

Decisions of the Technical Committee for Drug Control at its session on 28/03/2024

*- Approval to receive new reference preparations containing Clobetasol Propionate 0.05% in the form of Ophthalmic Preparations & The decision application will be implemented starting from 01/04/2024.

Decisions of the Technical Committee for Drug Control at its session on 04/04/2024

*- Not approving the reception of new preparations and not approving completing the registration procedures for the preparations under registration that contain the composition (Clarithromycin 250 mg + Omeprazole 20 mg + Tinidazole 500 mg) in the oral dosage form and deleting them from the boxes and cancelling them from the Egyptian Drug Authority database with Appling the rules , based on the decisions of the Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its two sessions on 14/09/2023 and 25/03/2024 and the decision of the Pharmacovigilance Committee at its session on 09/11/2023.

- Note: -

1- It was presented to the Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 14/09/2023, which recommended:

Not approving the preparation from a scientific standpoint for the following reasons:

a. The concentration of Clarithromycin provided falls below the therapeutic range in treating H. pylori and the therapeutic concentration is 500mg twice a day, which leads to antibiotic resistance.

b. The dose provided by the company is used for 10 days, and the therapeutic dose must not be less than 14 days.

2- The Request submitted was presented to the Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 25/03/2024, which recommended:

After reviewing the studies submitted by the company, the committee decided not to approve the Request submitted by the company for the following reasons:

1. According to international guidelines for the treatment of Helicobacter pylori

- World Gastroenterology Organization Global Guidelines 2021

- ESPGHAN/NASPGHAN Guidelines for the Management of Helicobacter pylori in Children and Adolescents

The effective concentration of Clarithromycin in treating H. pylori is 500 mg, and therefore using a concentration of 250 mg will cause an increase in the resistance to antibiotics in treating H. Pylori in Egypt. In addition, the concentration of Clarithromycin 250 mg is effective in children whose weight ranges from 15 kg to 24 kg.

2. The presented pharmaceutical form, enteric coated tablet, is not suitable for children of this weight. In addition, the dose of tinidazole 500 mg is not suitable for use in children, as the maximum daily dose of this substance for children is 480mg (20mg/kg/day).

3. The studies submitted by the company regarding the effectiveness of 250 mg concentration for treating H. pylori are not recent. In addition, the studies presented do not relate to the effectiveness of clarithromycin 250 mg with the same formulation provided.

-It was presented to the Pharmacovigilance Committee at its session on 09/11/2023, which decided:

First: *Regarding the combination Clarithromycin + Omeprazole + Tinidazole, although it is not a reference, it is listed in scientific references and is present in the Egyptian market, and there is no information that negatively affects the balance of benefits and risks.*

Second: *The effective concentration of Clarithromycin in treating Hpylori is 500 mg according to the Guidelines.*

World Gastroenterology Organization Global Guidelines Therefore, using a concentration of 250 mg will cause an increase in the resistance to antibiotics, with emphasis on the warnings in the leaflet.

Decisions of the Technical Committee for Drug Control at its session on 09/05/2024

*- Not approving to complete the registration of under-registration Products that contain Tofogliflozin at non-reference concentrations & deleting them from the boxes, and cancelling them from the Egyptian Drug Authority database with the applying of the rules, and Not approving the reception of new preparations containing Tofogliflozin at non-reference concentrations, based on the decision of the Combined Specialized Scientific Committee for Endocrine and Metabolism Diseases at its session on 29/04/2024.

- Note: -

It was presented to the Combined Specialized Scientific Committee for Endocrine and Metabolism Diseases at its session on 29/04/2024, which recommended: Not approving the product for the following reasons:

1- There is no reference for the provided dose ,10 mg.

2- The company did not provide accredited scientific studies published in international journals indicating the effectiveness of the concentration provided.

Decisions of the Technical Committee for Drug Control at its session on 23/05/2024

*- Not approving the reception of new preparations and cancelling the preparations under registration containing the combination (Sodium phenylbutyrate + Ursodoxicoltaurine) and deleting them from the boxes and the Egyptian Drug Authority database with applying the rules based on the decision of the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 26/02/2024 and the Pharmacovigilance Committee at its session on 02/05/2024.

- Note: -

- It was presented to the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 26/02/2024, which decided that ALS is a rare disease, and despite its registration in the FDA and Canada, the presented formula has not proven its effectiveness in treating this disease so far in the countries of the European Union, according to the reports received from the EMA Health Authority on 23/06/2023 and 13/10/2023, which did not favor the product as follows:

"After re-examining its initial opinion, the European Medicines Agency has confirmed its recommendation to refuse marketing authorization for the medicine Albrioza. The medicine was intended for the treatment of amyotrophic lateral sclerosis"

And there are no alternatives to this combination in treating this disease in the Egyptian market.

- It was presented to the Pharmacovigilance Committee at its session on 02/05/2024, and the committee recommended rejecting the preparation for the following reasons:

1- The product was rejected by the European Agency EMA website.

2- The product was withdrawn by the company in Canada and America, as the results of studies and clinical trials were not in favor of the product, according to what was published on the company's official website.

Decisions of the Technical Committee for Drug Control at its session on 10/06/2024

*- Approval to receive new preparations containing Clobetasol, provided that they are in reference pharmaceutical concentrations and dosage forms. The decision will be implemented starting from 01/07/2024, based on the decision of the Combined Specialized Scientific Committee for Dermatology and Venereology at its session on 20/05/2024.

- Note: -

It was presented to the Combined Specialized Scientific Committee for Dermatology and Venereology at its session on 20/05/2024, which decided that, due to the lack of many alternatives and the need of the Egyptian market, the committee recommends cancelling its previous decision on 30/08/2009 and approving the registration of Clobetasol in reference pharmaceutical concentrations and dosage forms.

- As clobetasol belongs to the group of very Potent Corticosteroids, which is used in cases of severe skin infections that are resistant to the rest of the group of Corticosteroids (Less Potent), according to the scientific reference BNF 85.

Short-term treatment only of severe resistant inflammatory skin disorders such as recalcitrant eczemas un responsive to less potent corticosteroids │ Psoriasis

Decisions of the Technical Committee for Drug Control at its session on 27/06/2024

*- Not approving the reception of new preparations with the combination (Pramipexole 0.6 mg (as Dihydrochloride monohydrate) & Rasagiline 0.75 mg (as Mesylate)) based on the decision of the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 20/05/2024.

- Note: -

- It was presented to the combined specialized scientific committee for psychiatric and neurological diseases at its session on 20/05/2024, which recommended: not to approve the preparation from a scientific standpoint, as the presented formulation is still under clinical studies and that the Pharmacodynamics & Pharmacokinetics of the formulation combined together is unknown.

- Approval of the recommendation submitted by the Combined Specialized Scientific Committee for Chest Diseases at its session on 20/05/2024 to limit the circulation of registered preparations containing Aminophylline in form of injection to hospitals only.

Decisions of the Technical Committee for Drug Control at its session on 04/07/2024

*- Not approving the reception of new preparations containing the formula Loteprednol etabonate + Moxifloxacin in the pharmaceutical form of Eye Drops. The under-registration preparations will be canceled and deleted from the boxes and the database of the Egyptian drug Authority in accordance with the rules, based on the decision of the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 09/06 /2024.

- Note: -

- It was presented to the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 09/06/2024, which recommended: rejecting the preparation from a scientific standpoint because the company did not submit approved scientific studies published in scientific journals with a high impact factor in the field of eyes that indicate the effectiveness and safety of the presented formulation.

*- Not approving the reception of new preparations containing the formula Azithromycin dihydrate + Loteprednol etabonate in the pharmaceutical form Ophthalmic Suspension, under registration preparations are cancelled and deleted from the boxes and the database of the Egyptian drug Authority in accordance with the rules, based on the decision of the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 09/06 /2024.

- Note: -

- It was presented to the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 09/06/2024, which recommended: Refusing to register the preparation from a scientific standpoint because the company did not submit approved scientific studies published in

scientific journals with a high impact factor in the field of eyes proving the safety and effectiveness of the presented formulation.

*- Not approving the reception of new preparations containing Flibanserin 50 mg in pharmaceutical dosage form Film coated tablets. The under-registration preparations are cancelled and deleted from the boxes and the Egyptian drug Authority database in accordance with the rules, based on the decision of the Combined Specialized Scientific Committee for Obstetrics and Gynecology at its session on 29/05/2024.

- Note: -

It was presented to the Combined Specialized Scientific Committee for Gynecology and Obstetrics at its session on 29/05/2024, which recommended: rejecting the preparation from a scientific standpoint because the company did not submit recent scientific studies approved by international bodies indicating the effectiveness of the 50 mg concentration in accordance with the committee's request at its session on 22/01/ 2024.

*- Not approving the reception of new preparations containing Tadalafil in the pharmaceutical form of Nasal spray, and the under-registration preparations are canceled and deleted from the boxes and the database of the Egyptian drug Authority in accordance with the rules, based on the decision of the Combined specialized scientific committee for kidney and urinary tract diseases at its session on 06/06/2024.

- Note: -

It was presented to the Combined Specialized Scientific Committee for Kidney and Urinary Tract Diseases at its session on 06/06/2024, which recommended: Refusing to register the product from a scientific standpoint because the company did not meet the requirements of the committee at its session on 14/03/2024 by not submitting recent scientific studies conducted on a large number of patients and published in accredited scientific journals proving

the safety and effectiveness of Tadalafil in the pharmaceutical dosage form Nasal spray for treating:
-Benign prostatic hyperplasia
-Erectile Dysfunction

*- Not approving the reception of new preparations containing Tiadenol in the pharmaceutical dosage form of tablet, and the under-registration preparations are canceled and deleted from the boxes and the database of the Egyptian drug Authority in accordance with the rules, based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 02/06/2024.

- Note: -

It was presented to the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 02/06/2024, which recommended: Rejecting the preparation because the company did not submit recent, approved scientific studies indicating the effectiveness and safety of the active substance for the therapeutic purpose provided by the company.

*- Approval to receive new reference preparations containing the following Combo Pack formula:
Sulbactam 1gm Powder for Solution for I.V Infusion
Durlobactam 0.5gm Powder for Solution for I.V Infusion
Durlobactam 0.5gm Powder for Solution for I.V Infusion
This is based on the decision of the Combined Specialized Scientific Committee for Chest Diseases at its session on 20/05/2024, and reception will take place from the beginning of the month of 08/2024.

- Note: -

It was presented to the Combined Specialized Scientific Committee for Chest Diseases at its session on 20/05/2024, which recommended the following:

Approval of the preparation from a scientific standpoint due to the need for it, as it is used in cases of:
hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia

*- Approval to receive new reference preparations containing Mifepristone based on the decision of the Combined Specialized Scientific Committee for Gynecology and Obstetrics at its session on 29/05/2024, while adhering to the requirements stated in the Scientific Committee's decision, and the reception will take place from the beginning of the month of 08/2024.

- Note: -

- It was presented to the Combined Specialized Scientific Committee for Obstetrics and Gynecology at its session on 29/05/2024, which recommended the following: Approval of the preparation from a scientific standpoint, as Mifepristone is used as an anti-progesterone, which has a different mechanism of action than the alternatives registered in the Egyptian market, which are effective in cases of developing intra-uterine pregnancy that require an abortion when there is a risk to the mother's life that the completion of the pregnancy may be, provided that it is used for this therapeutic purpose only.

It is worth noting that this substance is used with Misoprostol, which works as an induction of labor, in accordance with the treatment protocols approved by international health authorities.

Accordingly, the committee recommends that the use of preparations containing Mifepristone be limited to medical supervision in hospitals only based on a medical report signed by 3 doctors in the hospital stating that the patient needs to terminate the pregnancy for a medical reason in order to prevent misuse.

Decisions of the Technical Committee for Drug Control in its session on 22/08/2024

- Not approving the reception of new preparations containing the combination Mosapride citrate 10 mg (as dihydrate) + Simethicone 125 mg in the pharmaceutical form Tablets, and the under registration preparations will be cancelled and deleted from the boxes and the database of the Egyptian Drug Authority according to the rules, and the registered preparations will be cancelled and deleted from the boxes and the database of the Egyptian Drug Authority with the application of the rules, based on the decision of the Combined specialized Scientific Committee for Digestive System and Liver Diseases in its session on 22/07/2024.

- Note: -

It was presented to the Combined specialized scientific committee for digestive system and liver diseases in its session on 22/07/2024, which recommended the following: Not to approve the preparation, as the provided concentration of Mosapride at 10 mg does not provide any therapeutic advantage over the reference concentrations of 2.5 mg & 5 mg, and it may increase the occurrence of side effects of Mosapride, in addition to the fact that the studies provided by the company at a concentration of 10 mg are old and insufficient to prove the safety of the preparation.

Decisions of the Technical Committee for Drug Control at its session on 29/08/2024

*- Not approving the reception of new preparations containing Sofosbuvir 100 mg in the pharmaceutical dosage form of Film Coated Tablets. The under-registration preparations will be cancelled and deleted from the boxes and the Egyptian drug Authority database in accordance with the rules, based on the decision of the Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 22/07/2024.

- Note: -

It was presented to the Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 22/07/2024, which recommended the following: Not approving the preparation, as the concentration provided at 100 mg falls below the therapeutic range in the treatment of HCV, as the first therapeutic dose is 150 mg, according to scientific references. In addition, the company did not submit files proving the effectiveness and efficiency of this concentration.

*- Not approving the reception of new preparations containing the following composition:

(Benzoic acid 0.1% +Cellulase 0.3% + Disodium Hydrogen Phosphate 0.1% + Glucose Oxidase 0.1% +Glycerin 55% +Lactoferrin 0.1 % + Lactoperoxidase 0.1% +Lysozyme Hydrochloride 0.1% (as dihydrate) + Polyacrylic Acid 1% +Sorbic Acid 0.1 % + Sorbitol 40%)

in the pharmaceutical dosage form of Buccal and Gingival Gel. The under-registration preparations are cancelled and deleted from the boxes and the database of the Egyptian Drug Authority in accordance with the rules, based on the decision of the Combined Specialized Scientific Committee for Dental Diseases and Surgery at its session in 19/08/2024.

- Note: -

It was presented to the Combined Specialized Scientific Committee for Dental Diseases and Surgery at its session on 19/08/2024, which recommended the following: rejecting the preparation from a scientific standpoint because the company did not provide scientific support for the use of the submitted concentrations of active materials for the therapeutic purpose presented and the role of these materials in the submitted formulation in accordance with the committee's decision. At its session on 17/04/2024.

*Not approving the reception of new preparations containing Glycopyrrolate 0.85 mg in Oral dosage form, and the under-registration preparations are cancelled and deleted from the boxes and the Egyptian Drug Authority database in accordance with the rules, based on the decision of the Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 22/07/2024.

- Note: -

It was presented to the Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 22/07/2024, which recommended: Not approving the preparation due to the lack of need for the emergence of modern alternatives that are more effective and have fewer side effects than Glycopyrrolate, and its effectiveness has been proven in the Egyptian market, such as PPI and H2. receptor antagonist.

*- Due to the request of the reference authority in France from companies holding marketing licenses for preparations containing the active ingredient Minoxidil in the Topical dosage form to put Child Resistant Cap, the following is done:

- Registered preparations that do not adhere to the child resistant cap and that contain the active ingredient Minoxidil in the topical dosage form are obligated to write the following in a clear and prominent manner on the external packaging

of the preparations: “Keep away from children” and to place a picture indicating this within six months from the date of Committee.

Registered preparations containing the active ingredient Minoxidil in the topical dosage form are given a period of two years from the date of the committee to comply with the requirement of putting Child Resistant Cap; if they do not comply with this, in accordance with the rules.

Decisions of the Technical Committee for Drug Control at its session on 05/09/2024

*- Not approving the reception of new preparations containing Lomefloxacin in oral dosage forms, under registered preparations shall be canceled and removed from the boxes and the Egyptian Drug Authority database in accordance with the rules. Registered preparations shall also be canceled and removed from the boxes and the Egyptian Drug Authority database in accordance with the rules, based on the decision Combined Specialized Scientific Committee for Kidney and Urinary Tract Diseases at its session on 29/07/2024.

Note:

It was presented to the Combined Specialized Scientific Committee for Kidney and Urinary Tract Diseases at its session on 29/07/2024, which recommended: Refusing the preparation from a scientific standpoint based on the company's statement that there are no recent scientific studies confirming the safety of Lomefloxacin, as it has been withdrawn from reference countries.

Decisions of the Technical Committee for Drug Control at its session on 19/09/2024

*- Not approving the reception of new preparations containing Josamycin (as Propionate) at a concentration of 125 mg/5 ml in oral dosage forms. under registration preparations shall be cancelled and removed from the boxes and the Egyptian Drug Authority database in accordance with the rules based on the decision of Combined Specialized Scientific Committee for Pediatric Diseases at its session on 03/09/2024.

Note:

It was presented to the Combined Specialized Scientific Committee for Pediatric Diseases at its session on 03/09/2024, which recommended: Refusing the preparation from a scientific standpoint that the dosage form is not suitable for use in the age group of newborn infants and those with low birth weight (weighing between 2–3 kg), and is not appropriate for the presented uses submitted by the company, as injectable forms are used in this age group to treat severe infections.

*- Not approving the reception of new preparations containing the Ezogabine (Retigabine). under registration preparations shall be cancelled and removed from the boxes and of the Egyptian Drug Authority database in accordance with the rules. Registered products shall also be canceled and removed from the boxes and the Egyptian Drug Authority database, in accordance with the rules, based on the decision of the Combined Specialized Scientific Committee for Psychiatric and Neurological Disorders at its session on 21/08/2024.

-Note: -

- It was presented to the Combined Specialized Scientific Committee for Psychiatric and Neurological Disorders at its session on 21/08/2024, which recommended disapproval of preparation from a scientific standpoint due to the serious side effects of this substance, according to reports from international health authorities (FDA & EMA), such as:

- Risk of retinal abnormalities, potential vision loss, and skin discoloration with this anti-seizure drug.
- Additionally, it has been withdrawn from the FDA and EMA regulatory bodies.

Decisions of the Technical Committee for Drug Control at its session on 10/10/2024

Updating the decision of the Technical Committee at its session on 03/02/2022 to be: Approval to register all preparations containing Vitamin D (Cholecalciferol, Ergocalciferol) in Oral dosage form individually at a concentration higher than 4000 IU/Day as human pharmaceutical preparations, based on what was stated in the reference "Health Canada".

Note: -

- The Technical Committee decided at its session on 03/02/2022: to approve the registration of all preparations containing Vitamin D (Cholecalciferol, Ergocalciferol) in Oral dosage form individually at a concentration higher than 2500 IU, as well as all preparations containing Vitamin D (Cholecalciferol, Ergocalciferol) in Oral dosage form, which is used for children, in addition to all preparations containing Vitamin D in the form of injections as human pharmaceutical preparations, provided that preparations containing Vitamin D (Cholecalciferol, Ergocalciferol) in Oral dosage form individually at a concentration of up to 2500 IU are considered a nutritional supplement in pharmaceutical dosage form.

Decisions of the Technical Committee for Drug Control at its session on 17/10/2024

*- Not approving the reception of new preparations containing Pirfenidone in the Topical dosage form, canceling the preparations under registration and deleting them from the boxes and the Egyptian Drug Authority database in accordance with the rules, based on the decision of the Combined Specialized Scientific Committee for General Surgery at its session on 26/08/2024.

Note: -

- The Combined Specialized Scientific Committee for General Surgery, at its session on 26/08/2024, recommended:

To reject the preparation from a scientific standpoint:

- The company did not provide new, approved scientific studies for this pharmaceutical form and the indications for use provided by the company.
- There are alternatives in the Egyptian market that are used for the same therapeutic purpose provided by the company.

*- Not approving the reception of new preparations containing any combination containing these two substances together (Bempedoic Acid) + (Statins), and the preparations under registration are cancelled and deleted from the boxes and the database of the Egyptian Drug Authority in accordance with the rules, based on the decision of the combined Specialized Scientific Committee for Cardiovascular Diseases at its session in 07/10/2024.

- Note: -

The Combined Specialized Scientific Committee for Cardiovascular Diseases, at its session on 07/10/2024, recommended:

Rejecting the preparation from a scientific standpoint because the company did not provide new scientific studies (Pharmacokinetics & Pharmacodynamics) for these materials combined at the concentrations provided when used together in one tablet for the therapeutic purpose provided by the company.

The committee believes that it is difficult to combine the two substances: Atorvastatin & Bempedoic acid in one tablet, because the dose must be adjusted for each patient's condition, as it is mentioned in the MHRA.

-Bempedoic acid increases plasma concentrations of statins

-Potential risk of myopathy Bempedoic acid with concomitant use of statins.

-All patients receiving Bempedoic acid in addition to a statin should be advised of the potential increased risk of myopathy and told to report promptly any unexplained muscle pain, tenderness, or weakness. If such symptoms occur while a patient is receiving treatment with Bempedoic acid and a statin, a lower maximum dose of the same statin or an alternative statin, or discontinuation of Bempedoic acid and initiation of an alternative lipid-lowering therapy should be considered under close monitoring of lipid levels and adverse reactions.

*- Not approving the reception of new preparations containing the substance Prednisolone (as Sodium Metasulfobenzoate) in the form of Oral solution, and the preparations under registration are cancelled and deleted from the boxes and

the database of the Egyptian Drug Authority in accordance with the rules, based on the decision of the Specialized Combined Scientific Committee for Pediatric Diseases at its session on 03/09/ 2024.

- Note: -

The Combined Specialized Scientific Committee for Pediatric Diseases, at its session on 03/09/ 2024:

To reject the preparation from a scientific standpoint for the following reasons:

A- The company did not submit recent approved scientific studies indicating the stability of Prednisolone (as Sodium Metasulfobenzoate) in Oral Solution pharmaceutical dosage form based on the request of the Scientific Committee at its session on 16/07/2024, as the only study submitted by the company is a patent study and not a recent published study. In 2011, before the date of its suspension in France on 28/06/2021.

B- Based on the decision of the Quality module evaluation Committee regarding Prednisolone (as Sodium Metasulfobenzoate) in Oral Solution pharmaceutical dosage form at its session on 20/04/2022, which states: The use of the active ingredient Prednisolone in its salt form, sodium Metasulfobenzoate, in Oral Solution pharmaceutical dosage form is not appropriate, as It is susceptible to hydrolysis, which may lead to instability of the final product and a high percentage of impurities in it.

*- Not approving the registration of any veterinary preparations containing Pregabalin based on the decision of the Specialized Scientific Committee for Veterinary Medicines and Feed Additives at its session on 30/09/2024.

Note: -

- The Specialized Scientific Committee for Veterinary Medicines and Feed Additives, at its session on 30/09/2024, decided not to approve the registration of this preparation because it contains pregabalin. The Committee recommends not registering any preparations containing this substance to avoid its illegal circulation and misuse for non-medical purposes for animals and its use in humans unsafely, which threatens his mental and physical health.

Decisions of the Technical Committee for Drug Control in its session on 24/10/2024

*- Not approving the reception of new preparations containing the formula:

-Amlodipine + Azilsartan + Chlorthalidone

And the preparations under registration will be cancelled and deleted from the boxes and the database of the Egyptian Drug Authority according to the rules, based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases in its session on 07/10/2024.

- Note: -

- The Combined Specialized Combined Scientific Committee for Cardiovascular Diseases in its session on 07/10/2024 recommended:

Rejecting the preparation from a scientific point of view:

1-The company did not submit the studies required by the Specialized Scientific Committee for the Heart in its session on 02/06/2024 (Pharmacokinetics & Pharmacodynamics) for these substances combined at the concentrations provided when used together in one tablet for the therapeutic purpose provided by the company.

2- According to the reference preparations, the concentration of Azilsartan with Amlodipine differs from its concentration with Chlorthalidone as follows:

Azilsartan 20 mg + Amlodipine 2.5 mg tablets

Azilsartan 20 mg + Amlodipine 5 mg tablets

Azilsartan Medoxomil 40 mg + Chlorthalidone 12.5 mg tablets

Azilsartan Medoxomil 40 mg + Chlorthalidone 25 mg tablets

The dose in both formulations is one tablet per day, and therefore the dose cannot be adjusted for the three substances provided together in one tablet.

Decisions of the Technical Committee for Drug Control in its session on 07/11/2024

*- Not approving the reception of new products, the products under registration containing Glycopyrrolate 1.7 mg in the form of oral dosage forms are cancelled and removed from the boxes and the Egyptian Drug Authority database according to the regulations. Not approving the reception of new products containing Glycopyrrolate in non-reference pharmaceutical dosage forms and concentrations, which were rejected by the Specialized Scientific Committees, based on the decisions of the Specialized Scientific Committees for Gastrointestinal and Liver Diseases in their sessions on 22/07/2024 and 28/10/2024.

- Note: -

- The Specialized Scientific Committee for Gastrointestinal and Liver Diseases, in its session on 22/07/2024, recommended: Not approving the product due to the lack of need, given the availability of newer alternatives that are more effective and have fewer side effects than Glycopyrrolate, which has proven its effectiveness in the Egyptian market, such as PPI and H2 receptor antagonists.

- The specialized scientific committee for Gastrointestinal and Liver Diseases, in its session on 28/10/2024, recommended: Not approving the preparation due to the lack of need, given the availability of newer alternatives that are more

effective and have fewer side effects than Glycopyrrolate, which has proven its effectiveness in the Egyptian market, such as PPI and H2 receptor antagonists.

*- Not approving the reception of new products containing the formulation:
Tilbroquinol 200 mg + Tiliquinol 50 mg + Tiliquinol Lauryl Sulphate 50 mg
In the form of oral dosage forms, the registered products are cancelled and removed from the boxes and the Egyptian Drug Authority database in accordance with the regulations, based on the decision of the Specialized Scientific Committee for Gastrointestinal and Liver Diseases in its session on 28/10/2024 and the reply from the Egyptian Pharmaceutical Vigilance Center dated 12/09/2024.

- Note: -

- The specialized scientific committee for gastrointestinal and liver diseases, in its session on 28/10/2024, recommended:

Not to approve the preparation for the following reasons:

1. The serious side effects of Tilbroquinol according to scientific references DrugBank.com, Martindale & France

According to DrugBank.com : Tilbroquinol was approved in France, Morocco, and Saudi Arabia but it has been withdrawn in France and Saudi Arabia markets mainly due to its hepatotoxicity risk outweighing the drug benefit.

According to Martindale : Tilbroquinol: A report of neurotoxicity, considered to be subacute myelo-optic neuropathy, in a patient who had taken tilbroqirinol with tiliquinol for 4 years. Hepatotoxicity has also been reported with this combination.

According to Vidal : This medicine has long been used to treat mild acute diarrhea, but the discovery of a risk of hepatitis or nerve damage due to this medicine has led the Medicines Agency to reserve its use for the sole treatment of amoebiasis.

2. The company has not submitted scientific files proving the efficacy and safety of the formulation.
3. There are other alternatives with fewer side effects and greater safety available in the Egyptian market for treating amoebiasis, such as Metronidazoles.
4. This formulation has not been traded in the Egyptian market for a long time.

The Egyptian Pharmacovigilance Center reported via email on 12/09/2024 the following:

- The General Administration of Pharmaceutical Vigilance conducted research and study on the subject, and based on the results of the research and study, it is not possible to determine the safety of the inquired formulation at this concentration and pharmaceutical dosage form as it is not registered in any of the reference countries.

Decisions of the Technical Committee for Drug Control in its session on 21/11/2024

*- Not approving the reception of new products, canceling the products under registration containing the composition Levofloxacin + Loteprednol Etabonate in the dosageform of Eye Drops & removing them from the boxes and the Egyptian Drug Authority database according to the rules, based on the decision of the Specialized Scientific Committee for ophthalmology and retina diseases and surgery in its session on 30/10/2024.

- Note: -

- The specialized scientific committee for ophthalmology and retinal diseases and surgery, in its session on 30/10/2024, recommended:

Rejection the preparation scientifically because:

- Due to the company's failure to provide approved studies published in scientific journals with a high impact factor that demonstrate the pharmacokinetics, dynamics, efficacy and safety of the presented formulation.
- The existence of alternatives in the Egyptian market that serve the same therapeutic purpose.

*- Confirmation of the Technical Committee's decision in its session on 20/09/2012 regarding products containing Cyproheptadine, with the non-approval of receiving new products containing Cyproheptadine as an appetite

stimulant in any pharmaceutical dosage forms. The products under registration will be canceled and removed from the boxes and the Egyptian Drug Authority database according to the regulations, as the benefit-risk balance is not in favor of the product for the indications presented as an appetite stimulant, based on the Pharmacovigilance Committee's decision in its session on 06/11/2024.

- Note: -

The Pharmacovigilance Committee decided in its session on 06/11/2024 the following: The substance Cyproheptadine is registered and circulated in several reference countries for use as an antihistamine. As for its use as an appetite stimulant, the committee sees the following:

1- It has been found that Cyproheptadine is registered as an appetite stimulant in formulations with amino acids, including Arginine, only in Spain, and products containing this substance have been withdrawn from Australia, New Zealand, and Portugal since 1994 for this use, with the reasons for the withdrawal being unknown.

2- The use of the substance as an appetite stimulant (off-label use) in the American market (FDA) was warned against in an article dated 28/04/2023 due to its adverse effects.

3- The preparation has many side effects on the nervous system such as sedation and drowsiness, in addition to other side effects according to the reference product leaflet registered as an appetite stimulant.

Leukopenia, neutropenia, agranulocytosis, thrombocytopenia, hemolytic

anemia, palpitation, tachycardia, extrasystoles, Alteration of liver function (increased transaminases), Liver failure, Jaundice, cholestatic and/or cytolytic hepatitis….

And Overdose of some antihistamines in children can cause hallucinations, CNS depression, seizures, respiratory and cardiac arrest, and even death.

And it was mentioned in the leaflet (do not use for more than 8 weeks), and therefore, when used as an appetite stimulant, the duration of use will be longer than when used as an antihistamine, and thus the aforementioned side effects will be more severe.

4- The company did not conduct any clinical studies to prove the efficacy of the preparation for the purpose of use as an appetite stimulant, but relied solely on already published studies, which are insufficient to prove the efficacy and safety of the preparation for this use. Among the results was that weight returns to the pre-use level after discontinuation of the preparation.

Decisions of the Technical Committee for Drug Control in its session on 05/12/2024

*- Not approving the reception of new preparations and not approving the completion of registration procedures for the preparations under registration that contain Obeticholic acid, canceling and deleting them from the boxes and the Egyptian Drug Authority database with the application of the rules, based on the decisions of the Pharmacovigilance Committee in its session on 10/07/2024, and the decision of the Specialized Scientific Committee for Gastrointestinal and Liver Diseases in its session on 28/10/2024.

- Note: -

- The Pharmacovigilance Committee decided in its session on 10/07/2024 the following: The committee recommends following the EMA's decision to revoke the marketing authorization for products containing the active ingredient Obeticholic Acid because the benefit-risk balance is not in favor of the product.

- The product was presented to the specialized scientific committee for gastrointestinal and liver diseases in its session on 28/10/2024, which recommended: Despite the reference of Obeticholic Acid in many global health authorities and reference countries such as the FDA Canada and TGA, according to the reports published by the EMA health authority, the marketing license for products containing Obeticholic Acid has been withdrawn because the benefit-risk balance is not in favor of the product, as studies have not confirmed the therapeutic benefit of the reference product in treating Primary Biliary Cholangitis.

The committee believes that the products containing Obeticholic Acid may be misused in the treatment of nonalcoholic steatohepatitis, and this use is not globally authorized.

In addition to the serious side effects of Obeticholic acid as stated in the reference product insert by the FDA, which include the following:

Hepatic decompensation and failure in PBC patients with cirrhosis

- Hepatic failure, sometimes fatal or resulting in liver transplant, has been reported with OCALIVA treatment in primary biliary cholangitis (PBC) patients with decompensated cirrhosis

Accordingly, the committee recommends supporting the decision of the Pharmacovigilance Committee in its session on 10/07/2024 to follow the EMA's decision to revoke the marketing authorization for products containing the active substance Obeticholic Acid, as the benefit-risk balance is not in favor of the product.

Decisions of the Technical Committee for Drug Control in its session on 19/12/2024

* - Not approving the reception of new preparations, and the preparations under registration containing the substance Zucapsaicin are canceled and removed from the boxes & the Egyptian Drug Authority database according to the regulations. The registered preparations are also cancelled and removed from the boxes and database of the Egyptian Drug Authority with the application of the regulations, based on the decision of the Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedic Surgery in its session on 12/06/2024.

- Note: -

- The Specialized Scientific Committee for Rheumatology, Rehabilitation, and Orthopedic Surgery, in its session on 12/06/2024, recommended: rejecting the preparation for the following reasons:

1- The lack of sufficient studies proving the efficacy of the submitted formulation.

2- The lack of reference for the substance Zucapsaicin.

3- In addition to the existence of alternatives in the Egyptian market that serve the same therapeutic purpose and have proven their effectiveness.

4- Side effects mentioned for the product, such as cough and headache, according to the scientific file submitted by the company.

* - Not approving the reception of new preparations, and cancelling the products under registration containing the formulations containing:

1-Dapagliflozin 10 mg (as propanediol monohydrate) + Metformin Hydrochloride 1000 mg + Sitagliptin 50 mg (as phosphate monohydrate)

2- Dapagliflozin 5 mg (as propanediol monohydrate) + Metformin Hydrochloride 1000 mg + Sitagliptin 50 mg (as phosphate monohydrate)

3- Dapagliflozin 5 mg (as propanediol monohydrate) + Metformin Hydrochloride 1000 mg + Sitagliptin 100 mg (as phosphate monohydrate)

And removing them from the boxes and the Egyptian Drug Authority database in accordance with the regulations, based on the decision of the specialized scientific committee for endocrine and metabolism diseases in its session on 04/12/2024.

- Note :-

The specialized scientific committee for endocrinology and metabolism, in its session on 04/12/2024, recommended: The difference in concentrations of the submitted formulations from the reference formulation (Dapagliflozin 10 mg + Sitagliptin 100 mg) may cause incorrect practices if used in sub-therapeutic doses, as the effective daily dose of Dapagliflozin is 10 mg and the effective daily dose of Sitagliptin is 100 mg.

100 mg, and therefore the presence of doses lower than these effective therapeutic doses may cause confusion among doctors and lead to misuse and incorrect dosing. Accordingly, the committee recommends rejecting the proposed formulation Dapagliflozin + Metformin + Sitagliptin at concentrations

of 10/1000/50 mg, 5/1000/50 mg, and 5/1000/100 mg.

* - Approval to receive new preparations containing Imeglimin and the cancellation of the Technical Committee for Drug Control decision in its session on 28/02/2019, with the decision to be implemented from 01/01/2025.

* - Approval of the submitted recommendation regarding the unification of decisions related to the sources of active raw materials for products manufactured locally under the license of a foreign company, with the recommendation being as follows: (Under-license)

1- Commitment to the sources of the active raw material for the product in the country of origin.

2- In the event of a difference in the sources of the active raw material used in the local manufacturing of the product compared to the sources of the active raw material in the country of origin, the company is obligated to submit the quality file of the product (S&P Part) for evaluation and approval within a period of eighteen months from the date of the Technical Committee for Drug Control meeting on 19/12/2024.