Decisions of the Technical Committee for Drug Control at its session on 02/01/2025

* - Not approving the reception of new products, cancelling the products under registration, and deleting them from the boxes and the Egyptian Drug Authority database according to the rules for products containing the following concentrations:

Dapagliflozin 5 mg (as propanediol monohydrate) + Sitagliptin 50 mg (as phosphate monohydrate)

Dapagliflozin 5 mg (as propanediol monohydrate) + Sitagliptin 100 mg (as phosphate monohydrate)

Dapagliflozin 10 mg (as propanediol monohydrate) + Sitagliptin 50 mg (as phosphate monohydrate)

This is based on the decision of the combined specialized scientific committee for endocrine diseases and metabolism at its session on 04/12/2024.

Note:

The combined specialized scientific committee for endocrine and metabolism diseases, at its session on 04/12/2024, recommended: regarding the formulation presented in concentrations of 5/100 mg, 10/50 mg, 5/50 mg: The difference in concentrations of the submitted formulations compared to the reference formulation (Dapagliflozin 10 mg + Sitagliptin 100 mg) may lead to 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. Therefore, the presence of lower doses than these effective therapeutic doses may cause confusion among doctors and lead to misuse and incorrect dosing. Accordingly, the committee recommends rejecting the submitted formulation with concentrations of 5/100 mg, 10/50 mg, and 5/50 mg.

Decisions of the Technical Committee for Drug Control at its session on 23/01/2025

* - Not Approving to complete the registration procedures for the products under registration that contain Chlorpheniramine maleate 2 mg/ml + Dexamethasone 0.5 mg/ml in syrup dosage form & deleting them from the boxes, and cancelling them from the Egyptian Drug Authority database according to the regulations, and not approving the reception of similar products, based on the decision of the combined specialized scientific committee for general internal medicine at its session on 24/12/2024.

Note:

- The combined specialized scientific committee for general internal medicine, at its session on 24/12/2024, recommended: Not approving the preparation scientifically for the following reasons:

1. The concentrations provided are 1ml, while the same concentrations in reference bodies are 5ml, which may lead to difficulties in administering the required dose for adults as recommended by the company. This may be particularly challenging to follow in Egypt, especially since these preparations may be used as OTC (over-the-counter) products, potentially leading to misuse and increasing the side effects of Dexamethasone and Chlorpheniramine.
2. The available alternatives in the Egyptian market contain the same formulation with reference concentrations of the active ingredients that have proven effective in the Egyptian market.
3. The concentrations of the active ingredients in the provided formulation are not referenced.

* - For registered products containing Obeticholic acid, companies are granted a one-time six-month grace period from the committee's date for production and trading. During this period, raw materials and all actual stocks of the products held by the companies must be exhausted according to the quantities mentioned in the Central Operations Administration's report. After this period, the registration of these products will be cancelled, and they will be cancelled from the boxes and the Egyptian Drug Authority's database, with applying the rules.

Decisions of the Technical Committee for Drug Control at its session on 13/02/2025

* - Not Approving to complete the registration procedures for the products under registration containing:
Amlodipine 10 mg (as Besylate)
Perindopril tert-butylamine 8 mg
Rosuvastatin 10 mg (as Calcium)
In the form of an oral dosage form, & deleting them from the boxes, and cancelling them from the Egyptian Drug Authority database according to the regulations, and Not Approving the reception of new products based on the decision of the specialized scientific committee for cardiovascular diseases in its sessions on 07/10/2024 and 22/01/2025.

Note:

- The combined specialized scientific committee for cardiovascular diseases, at its session on 07/10/2024, recommended:

The preparation is rejected scientifically due to the company's failure to provide approved scientific studies for these substances combined at the concentrations presented when used together in a single tablet for the therapeutic purpose offered by the company.

- The combined specialized scientific committee for cardiovascular diseases, at its session on 22/01/2025, recommended:

The company's Request is rejected, and the committee maintains its previous opinion on 7/10/2024, as follows:
1- Due to the company's failure to provide pharmacokinetics and dynamics studies for these substances combined at these concentrations.
2- There is no need for the presented preparation because there are alternatives registered in the Egyptian market, and each individual substance is present in the Egyptian market.

* - Non-approval of completing the registration procedures for products under registration containing Amlodipine + Carvedilol in the form of oral dosage form, and their cancellation and removal from the Egyptian Drug Authority's database and boxes according to the rules, and the non-approval of receiving new products, based on the decision of the combined specialized scientific committee for cardiovascular diseases at its session on 22/01/2025.

Note:

- The combined specialized scientific committee for cardiovascular diseases, at its session on 22/01/2025, recommended:

Rejecting the products scientifically due to the company's failure to provide:

1- Recent studies published in accredited scientific journals for this formulation at these concentrations.

2-Pharmacokinetics and pharmacodynamics for these combinations.

Decisions of the Technical Committee for Drug Control at its session on 13/03/2025

* - Non-approval of receiving new preparations containing Ataluren, and the preparations under registration are canceled and removed from the Egyptian Drug Authority's boxes and database according to the regulations, based on the decision of the Pharmacovigilance Committee at its session on 10/07/2024, and the decision of the combined specialized scientific committee for psychiatric and neurological diseases at its session on 19/02/2025.

Note:

- The Pharmacovigilance Committee, at its session on 10/07/2024, recommended the following: The committee recommends maintaining the presence of products containing the active ingredient Ataluren in the Egyptian market based on the publication on the European Medicines Agency (EMA) website, which recommends not renewing the marketing authorization for the product Translarna (Ataluren) because the benefit-risk balance is not in favor of the product.

The committee recommends contacting the specialized scientific committee to provide information on the extent of the Egyptian market's need for the product.

- The combined specialized scientific committee for psychiatric and neurological diseases, at its session on 19/02/2025, recommended:

1- support of the decision of the Pharmacovigilance Committee at its session on 10/07/2024, which recommended the following:

Withholding the continued presence of products containing the active ingredient Ataluren in the Egyptian market based on what was published on the European Medicines Agency (EMA) website. With the recommendation not to renew the marketing authorization for the Translarna (Ataluren) product because the benefit-risk balance is not in favor of the product.

- In addition, the results published in studies on global health organization

websites are insufficient and unconfirmed in treating genetic muscular atrophy in children.

* - Non-approval of receiving new preparations containing Vonoprazan at a concentration of 40 mg in oral dosage form, and the cancellation of preparations under registration and their removal from the Egyptian Drug Authority's boxes and database according to the rules based on the decision of the Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 12/02/2025.

Note:

- The Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases, at its session on 12/02/2025, recommended:

Not approving the formulation scientifically, as the presented concentration of 40 mg is still under clinical studies in global authorities, and there are not enough scientific studies to prove the safety and efficacy of the presented concentration.

* - Not approving the reception of new formulations containing Dexlansoprazole in the pharmaceutical form of Oral disintegrating film, and cancelling the formulations under registration and deleting them from the boxes and the Egyptian Drug Authority database according to the rules based on the decision of the combined specialized scientific committee for gastrointestinal and liver diseases at its session on 12/02/2025.

Note:

- The combined specialized scientific committee for gastrointestinal and liver diseases, at its session on 12/02/2025, recommended:

Not approving the formulation as the company did not meet the committee's requests during its session on 28/10/2024 to provide studies proving the efficacy and safety of Dexlansopazole in an Immediate release form, as this formulation

is available in scientific references and global health authorities in the form of a Delayed release dosage form.

Decisions of the Technical Committee for Drug Control at its session on 20/03/2025

* - Not approving the reception of new preparations containing Glycopyrronium 12.5 mcg (as Glycopyrrolate), not approving the completion of registration procedures for products under registration, & their cancellation and removal from the boxes & Egyptian Drug Authority database according to the rules, based on the decision of the Combined Specialized Scientific Committee for Respiratory Diseases at its session on 24/02/2025.

Note:

- The Combined Specialized Scientific Committee on Respiratory Diseases, at its session on 24/02/2025, recommended: Rejecting the product scientifically because:

- The concentration provided by the company Glycopyrronium 12.5 mcg falls within the therapeutic range and is not used in therapeutic protocols for the treatment of COPD.

Since the effective daily dose for treating COPD with Glycopyrronium is 50 mcg, which is the reference concentration to be taken once daily and not twice as provided by the company, misuse of the product at the provided concentration may occur, leading to the administration of an ineffective dose to the patient.

- The studies presented by the company are scientifically modest and outdated, and they are insufficient to prove the efficacy and feasibility of using this concentration for the treatment of COPD.

Availability of registered and marketed products in the Egyptian market containing Glycopyrronium at a concentration of 50 mcg.

Decisions of the Technical Committee for Drug Control at its session on 27/03/2025

* - Not approving the reception of new preparations and the cancellation of the preparations under registration containing Iron (III) Pyrophosphate Citrate complex in the form of Injection, which will be cancelled and removed from the boxes and the Egyptian Drug Authority database according to the regulations based on the decision of the Pharmacovigilance Committee at its session on 20/03/2025, and the decision of the combined specialized scientific committee for nephrology and urology at its session on 25/11/2024.

Note:

- The Pharmacovigilance Committee, at its session on 20/03/2025, recommended:

1- There are no comparative studies between Ferric Pyrophosphate and other iron salts to determine whether it provides an additional therapeutic advantage or not.

2- The marketing of the product in Egypt is very recent, and there is no clinical experience regarding its use in hospitals.

Therefore, there is a need for more time to circulate until sufficient information is available to assess the safety of the product.

- The Combined Specialized Scientific Committee for Nephrology and Urology, at its session on 25/11/2024, recommended : The committee still stands by its previous decision on 29/7/2024 to reject the product from a scientific standpoint, and this is because:

1- The product does not offer a therapeutic advantage over other products used as iron replacement products because:

* Its use is limited to the following therapeutic purpose: for the replacement of

iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease.
And it will not replace the use of IV Iron replacement products in cases of Iron Deficiency.
* It has not been proven that the product is safer and more effective than IV Iron replacement products
2- The lack of sufficient studies on the safety of Iron Pyrophosphate.

Decisions of the Technical Committee for Drug Control at its session on 23/04/2025

* - Not approving the completion of registration procedures for preparations under registration that contain the formulation (Paracetamol + Diclofenac + Caffeine) in the form of an Oral Dosage Form, which will be cancelled and removed from the boxes and the Egyptian Drug Authority database according to the regulations, and not approving the reception of new products, based on the decision of the Scientific Evaluation Committee for Medical Products for Rheumatology, Rehabilitation, and Orthopedic Surgery at its session on 19/03/2025.

- Note: -

- The Scientific Evaluation Committee for Medical Products for Rheumatology, Rehabilitation, and Orthopedic Surgery, at its session on 19/03/2025, recommended: Not approving the product scientifically for the following reasons:

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

2- Combining the three substances into one formulation may lead to increased side effects.

3- The presented formulation does not offer any therapeutic advantage over the alternatives available in the Egyptian market.

* - Not approving the completion of registration procedures for preparations under registration that contain Oestradiol Benzoate in the form of Injection dosage form individually, they will be cancelled and deleted from the boxes and the Egyptian Drug Authority database according to the rules, and not approving the reception of new preparations, based on the decision of the Combined Specialized Scientific Committee for Obstetrics and Gynecology at its session on 29/07/2024, and the decision of the Scientific Evaluation Committees for Medical Preparations for Obstetrics and Gynecology at its session on 19/03/2025, and the Combined Specialized Scientific Committee for Oncology and Surgery at its session on

12/09/2024, and the decision of the Scientific Evaluation Committees for Medical Preparations for Oncology and Surgery at its session on 10/03/2025, and the list of deficiencies will be amended to contain only the reference esters of estradiol (Estradiol Valerate, Estradiol Cypionate) in the form of Injection Dosage Form.

Note:

- The combined specialized scientific committee for obstetrics and gynecology, at its session on 29/07/2024, recommended: rejecting the preparation from a scientific standpoint, as the use of Estradiol in individually in the pharmaceutical form presented as Oily Depot Solution for Intramuscular Injection in cases of Hormonal Replacement Therapy in Post-Menopausal women would be prolonged, which may increase the side effects of Estradiol and potentially raise the incidence of cancerous diseases.

The committee believes that according to therapeutic protocols, Estradiol is used with Progesterone in cases of: Hormonal Replacement Therapy for Post-menopausal, which reduces side effects. Additionally, Estradiol can be used alone in tablet dosage form for symptoms of menopause (Climacteric) according to reference countries and therapeutic protocols.

- The Scientific Evaluation Committees For Medical Products In Obstetrics And Gynecology, In Their Session On 19/03/2025, Recommended: After reviewing the studies submitted by the company: The committee remains firm in its previous decision during its session on 29/07/2024 to reject the product scientifically, as the use of Estradiol individually in the presented Pharmaceutical Form, Oily Depot Solution for Intramuscular Injection, in cases of Hormonal Replacement Therapy in Post-Menopausal Women, will be for a long period, which will increase the side effects of Estradiol and may increase the rate of cancer and heart disease.

The committee believes that according to therapeutic protocols, Estradiol as an Injection is not used alone but rather with Progesterone, which reduces side effects. Additionally, Estradiol can be used alone in tablet dosage form for

symptoms of menopause (Climacteric) according to reference product leaflets and therapeutic protocols.
Therefore, its presence in the Egyptian market as a standalone injection will lead to its prolonged misuse, increasing the rate of cancer incidence.
- The combined specialized scientific committee for oncology diseases and surgery, at its session on 12/09/2024, recommended: not approving the re-registration of the product, as the long-term use of Estradiol may increase the risk of cancer and heart diseases according to the FDA leaflet. Additionally, this drug is very old and is no longer included in the global guidelines for the treatment of Prostate Cancer and Breast Cancer in men.
- The Scientific Evaluation Committees for Medical Products for Oncology and Surgery, at its session on 10/03/2025, recommended: Despite the reference of the Estradiol Injection usage in Carcinoma of the Prostate (For palliation only), the committee maintains its previous decision from its session on 12/09/2024, where it recommended not approving the re-registration of the product. This is because prolonged use of Estradiol may increase the risk of cancer and heart diseases, as stated in the FDA leaflet. Additionally, this drug is very old and is no longer included in global guidelines for the treatment of Prostate cancer & Breast Cancer in men.

* - Not approving the completion of registration procedures for the preparations under registration containing the formulation (Clarithromycin 500 mg + Omeprazole 20 mg + Tinidazole 500 mg) in an Oral Dosage Form, and to cancel and remove them from the boxes and the Egyptian Drug Authority database according to the regulations, and not approving the reception of new products, based on the decision of the Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 12/02/2025. The concentration of Omeprazole will be adjusted to 40 mg in the registered products upon re-registration.

- Note :-

- The Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases, at its session on 12/02/2025, recommended: According to the latest global guidelines for the treatment of H. Pylori, which include Omeprazole, when taken at a high concentration of 40 mg twice daily, helps increase the effectiveness of the triple therapy regimen in overcoming and eradicating the disease.

Based on practical practices in the Egyptian market for treating H. Pylori, it has been observed that there is a significant increase in resistance cases to this disease using a concentration of Omeprazole 20 mg twice daily, and it requires increasing the concentration to 40 mg twice daily to enhance the effectiveness of the treatment and overcome thedisease.

Accordingly, the committee recommends not approving the formulation from a scientific standpoint, as the 20 mg concentration of Omeprazole reduces the efficacy of the proposed formulation in treating Helicobacter pylori.

** The committee also recommends adjusting the concentration of Omeprazole to 40 mg in the registered generic formulations in the Egyptian market to comply with global guidelines for the treatment of Helicobacter pylori.

Decisions of the Technical Committee for Drug Control at its session on 08/05/2025

* - According to the decision of the Scientific Evaluation Committee for Medical Preparations for Oncology Diseases and Surgery ,and with the assistance of professors in pharmacology and toxicology at its session on 16/04/2025, and the decision of the Pharmacovigilance Committee at its session on 06/02/2025, there is no objection to the continued use of Titanium Dioxide, with a ban on its use in the form of Nanoparticles in all Preparations, even if they are for topical use on the skin. In case the company requests to remove or replace Titanium Dioxide for export purposes, the company is obliged to take the same action for the local Preparation and is granted a one-year grace period from the date the Technical Committee for Drug Control approves the company's request for export purposes to comply with the regulations.

- Note :-

- The Scientific Evaluation Committee for Medical Preparations for Oncology Diseases and Surgery, and with the assistance of professors of pharmacology and toxicology at its session on 16/04/2025, recommended:

After reviewing the subject and the stance on Titanium dioxide in global bodies, the committee found the following:

1- The use of titanium dioxide (TiO2) in food is banned and is not considered safe by the European Union and the European Food Safety Authority (EFSA), primarily due to concerns related to its potential to cause genetic mutations (Genotoxicity).

In contrast, other global bodies such as the FDA (USA), FSANZ (Australia/NZ), JECFA (WHO), and Health Canada still consider it safe, especially when it is not in the form of nanoparticles.

2- Based on what has been reported by some global organizations, there is insufficient scientific evidence to support the safety of titanium dioxide in the

form of nanoparticles when inhaled during food manufacturing processes and when consumed as a food additive.
3- There is insufficient scientific evidence and clinical studies to indicate that this substance causes genotoxicity in pharmaceutical preparations.

Based on the above, the committee recommends the following:

1- That there is no objection to the use of Titanium dioxide in pharmaceutical preparations, with the necessity of regularly monitoring pharmacovigilance for the EMA's stance on the use of this substance.
2- Endorsement of the Pharmacovigilance Committee's decision at its session on 06-02-2025, which was as follows: The committee recommends that it still stands by its previous decision regarding Titanium Dioxide in its session held on 28-12-2023, which is that there is insufficient scientific evidence to prohibit the use of Titanium Dioxide in pharmaceutical preparations because it:
• It is still registered as an active ingredient in pharmaceutical dosage forms such as Ointment (5 gm, 50 mg, 5 gm, 20% w/w), Paste (30 mg), cream (2 gm), suppository (200 mg) in some reference authorities like MHRA, France, Sweden, Portugal, Austria & Norway, in addition to FDA, Canada, Ireland.
• It is also still registered as an excipient without mentioning the concentration in some reference authorities such as New Zealand, Italy, and the Netherlands, in addition to Japan, Germany, Switzerland, Spain, Sweden, Belgium, Austria, Finland, Iceland, and Portugal.
*With the emphasis on the necessity of continuing to monitor the matter until the final decision from the EMA regarding the evaluation of the impact of the removal of titanium dioxide from the list of authorized food additives on medicinal products is announced.

* - Non-approval of completing the registration procedures for under registered preparations that contain the formulation (Adapalene 0.1 % w/w + Dapsone 5 % w/w) and their cancellation and removal from the boxes and the Egyptian Drug Authority database according to the regulations, and the non-approval of

receiving new preparations, based on the decision of the Scientific Evaluation Committee for Dermatological, Venereal, and Andrological Medical preparations at its session on 30/04/2025.

Note: -

- The Scientific Evaluation Committee for Dermatological, Venereal, and Andrological Medical preparations, at its session on 30/04/2025, recommended: non-approval of the preparation from a scientific standpoint for the following reasons:

1. The studies submitted by the company are insufficient to prove the efficacy and safety of the formulation.
2. There is no scientific basis for combining the two substances in the formulation, as Dapsone is used twice a day and Adapalene is used once at night.

Decisions of the Technical Committee for Drug Control at its session on 15/05/2025

* -Non-approval of completing the registration procedures for under registered preparations, and non-approval of the reception of new preparations containing the formulation (Diphenhydramine HCl 12.5mg + Phenylephrine HCl 5 mg) in the pharmaceutical dosageform of Oral dissolvable strip, and to cancel and remove them from the boxes and the Egyptian Drug Authority database according to the regulations, based on the decision of the Scientific Evaluation Committee for Ear, Nose, Throat Medical preparations at its session on 29/04/2025.

- Note :-

- The Scientific Evaluation Committee for Ear, Nose, Throat Medical preparations, at its session on 29/04/2025, recommended: not approving the preparation for the following reasons:

1. The company did not submit approved scientific documents proving the efficacy and safety of the formulation in the presented pharmaceutical dosage form, Oral dissolvable strip, and did not meet the committee's requests on 19/11/2024.
2. The submitted pharmaceutical form, Oral dissolvable strip, may lead to increased side effects of the formulation, such as high blood pressure and irregular heartbeat.
3. The original preparation has been withdrawn from Canada.

* - Adding the following sentence to the previous definition of Line extension: "Adding the same concentration and pharmaceutical dosage form using a new treatment use that differs in dosage, provided that this addition is based on an approved scientific reference in one of the reference countries."

Decisions of the Technical Committee for Drug Control at its session on 22/05/2025

* - The decision of the Technical Committee at its session on 23/04/2025 is amended to: Not approving the reception of new preparations containing the composition (Clarithromycin 500 mg + Omeprazole 20 mg + Tinidazole 500 mg) in oral dosage form. As for the products under registration: The concentration of Omeprazole must be adjusted to 40 mg while retaining the studies and applying the established rules in this regard based on the decision of the combined specialized scientific committee for gastrointestinal and liver diseases at its session on 12/02/2025. As for the registered preparations: The concentration of Omeprazole must be adjusted to 40 mg in the registered products upon re-registration.

* - The use of all preparations containing Carbetocin, which are locally marketed, is restricted to hospitals only with the application of regulations. The preparations are granted a period of 3 months from the committee's date to comply with the conditions, based on the decision of the Scientific Evaluation Committee for Obstetrics and Gynecology Medical Pharmaceuticals on 19/03/2025.

- Note :-

- The Scientific Evaluation Committee for Obstetrics and Gynecology Pharmaceuticals, at its session on 19/03/2025, recommended: limiting the distribution of preparations containing Carbetocin to hospitals only, as it is used post-delivery in cases of Postpartum Hemorrhage, which requires treatment by specialists in hospitals under medical supervision.

Decisions of the Technical Committee for Drug Control at its session on 19/06/2025

* - The registration of Suzetrigine in its reference pharmaceutical dosage forms and concentrations is to be adhered to, based on the decision of the Scientific Evaluation Committee for Medical Products for Pain and Anesthesia Diseases at its session on 22/05/2025.

Note: -

- The Scientific Evaluation Committee for Medical Products for Pain and Anesthesia Diseases, at its session on 22/05/2025, recommended that: after reviewing the subject, the committee found the following:

1- The substance Suzetrigine has been recently registered with the U.S. Food and Drug Administration (FDA) on 30/01/2025 in the pharmaceutical dosage form (Tablet).

2- This substance is not yet available in the Egyptian market.

3- The absence of any scientific studies regarding the substance Suzetrigine in the presented pharmaceutical dosage form of Oro-dispersible tablet.

Accordingly, the committee recommends rejecting the preparation from a scientific perspective and also recommends registering Suzetrigine only in its reference pharmaceutical dosage forms and concentrations.

* - Approval of the following proposal:

Not accepting any registration requests for human medicinal preparations that contain Proton Pump Inhibitors or Potassium-Competitive Acid Blocker In a non-sterile dosage form, Individually, and in the case of submitting a preparation containing a new substance or a new pharmaceutical form, a request is submitted for presentation to the Technical Committee for Drug Control.

*And this decision does not apply to:

1. Registration for export and tenders.
2. The preparation submitted for registration as a Line Extension.

And this is after the approval of Head of the Egyptian Drug Authority, in accordance with the rules and the organizing ministerial decisions.

- Note: -

- Approved by Head of the Egyptian Drug Authority on 07/07/2025

Decisions of the Technical Committee for Drug Control at its session on 02/07/2025

*- Companies owning products containing the substance Red Dye 3 (127 E) or its following names: C.I.NO.45430, erythrosine, F.D., C.No.Red3, CI Food Red 14, Acid Red 51, E127, & Red Dye 3 in their composition statement are granted grace period For 3 years From The date of the technical committee or upon re-registration, whichever is later, to delete or replace Red Dye 3 (E127) or any of its previously mentioned names from the formulation, and the General Administration of Drug Vigilance will re-present the matter & The Issue will be Represented to the Technical Committee for Drug Control in case any new signals related to this substance appear from any of the following Global Health Authorities: EMA, Canada, Swiss medic, PMDA.based on The decision of the vigilance committee at its session on 06/03/2025.

- Note :-

- The vigilance committee, at its session on 06/03/2025, decided the following: The committee recommends referring the Issue to the technical committee.

To consider the possibility of stopping the use of RED Dye as a coloring agent in oral medications & The cessation should be gradual over several years. Based on the results of the studies conducted in.FDA on rats and reported the potential carcinogenic effect of this substance when used in large doses, so it is necessary to Starting to look for natural alternatives to this substance.

Decisions of the Technical Committee for Drug Control at its session on 17/07/2025

*- Not approving the reception of new products containing Diclofenac Potassium 2ml/mg in the form of Oral Suspension, and the cancellation of preparations under registration and their removal from the Egyptian Drug Authority's boxes and database according to the rules, based on the decision of The Scientific Evaluation Committee for Pediatric Medical Products at its session on 13/05/2025.

- Note: -

- The Scientific Evaluation Committee for Pediatric Medical Products, at its session on 13/05/2025, decided the following:

The committee recommends not approving from a scientific standpoint the products that contain Diclofenac Potassium for children for the following reasons:

1 - Diclofenac Potassium in the Egyptian market is widely misused as an antipyretic. For children, without adhering to the indications and age group mentioned in scientific references, which leads to an increased The chances of occurring side effects, including

- Stomach ulcers and bleeding
- Hepatotoxicity risk
- Renal impairment risk

2- The use of the mentioned material for children in the reference 2023-2022 Children for BNF is as follows:

-Pain and inflammation in rheumatic disease and other musculoskeletal disorders. Child 14–17 years: 75–100 mg daily in 2–3 divided doses.

-Post-operative pain Child 9–13 years (body-weight 35 kg and above): Up to 2 mg/kg daily in 3 divided doses; maximum 100 mg per day.

-Fever in Ear, nose and throat infection Child 9–17 years (body-weight 35 kg and above): Up to 2 mg/kg daily in 3 divided doses; maximum 100 mg per day.

3- The existence of effective, safer alternatives permitted for use in children from the age of 3 months according to the scientific reference.
MHRA, such as Ibuprofen

Decisions of the Technical Committee for Drug Control at its session on 31/07/2025

*-Regarding the expiration of the deadline granted to companies for using the Lidocaine solvent in a quantity different from the specified amount which will be resolved on 18/07/2025 -: approval to extend the deadline for another six months for all similar cases, provided that companies submit a detailed plan of what has been accomplished and a detailed plan of the remaining steps. To complete them within the six months that will be granted to the company on the link of the Human Products Monitoring Unit.
They are evaluated and reviewed by the General Administration for the Registration of Human Products before granting the company what indicates Approval to extend the deadline for another six months

*- Update of the Technical Committee's decision on 31/01/2017 and approval to receive new reference preparations containing Mecobalamin in the form of injection, Based on the decision of the combined specialized scientific committee for General Internal Medicine Committee at its session on 25/02/2025, and the report from the General Directorate of Drug Vigilance

- Note: -

- **The decision of the technical committee on 31/01/2017:** Not approving the continuation of the registration procedures for the product
And the cancelation of the products under registration containing Mecobalamin in the form of Injection and non-approval of receiving Similar new preparations Based On The decision of the specialized scientific committee for internal medicine at its session on 31/05/20216

- The specialized scientific committee for general internal medicine, at its session on 25/02/2025, which Recommended: Approval of the preparation from a scientific perspective, as the formulation is registered in the reference country, Japan, and falls within the therapeutic range for the uses mentioned by the company. Within the therapeutic scope of the uses mentioned by the company, in addition to the fact that the method of administration can be controlled.
Through the injection method IV & IM

Decisions of the Technical Committee for Drug Control at its session on 07/08/2025

*- Update of the Technical Committee's decision at its session on 05/01/2023 to become "Approval for receiving new formulations Contains the formulation (Tamsulosin + Tadalafil) provided that ,it is the same reference Concentration included the immediate release dosage form for Tadalafil & extended release dosage for Tamsulosin Based On the scientific evaluation committees of Urology and Nephrology Surgery decision on their session On 20/07/2025 and the decision will be implemented from the beginning of Next September.

Note: -

- The Decision of the technical committee at its session on 05/01/2023: not approving the reception of new products and not Approval to complete the registration procedures for the products under registration that contain the formulation (Tamsulosin + Tadalafil) due to lack of reference.

- The Decision of the scientific evaluation committees of Urology and Nephrology Surgery decision on their session on 20/07/2025, which recommended the following:

1 - The presence of Tamsulosin and Tadalafil in a single formulation makes it an effective therapeutic choice. For patients suffering from prostate hyperplasia accompanied by erectile dysfunction, based on the latest approved global protocols for using these two substances in the aforementioned medical conditions.

2 - The provided formulation helps enhance patient compliance with the treatment.

3-The Submitted Dosage Form is Capsule That Include immediate release dosage form Of Tadalafil and the extended release dosage form of Tamsulosin ensure that there is no effect. On the drug's kinetics or the presence of drug interactions between the two substances in a single FDC preparation compared to taking each substance separately.at the same dosage of mg 5mg/0.4mg, based on the studies conducted on the original formulation.

*- The decision of the technical committee at its session on 23/10/2014 regarding the formulation (Proton + NSAID Inhibitor Pump) is being updated. to include the decision "not to approve the reception of new reference or non-reference products. Contains the formulation (potassium -competitive acid blocker- + NSAID) and the non-completion of the registration procedures of the under-registration product that contains this formulation, and that the NSAID include Acetylsalicylic acid in all its uses.

Note: -

- The decision of the technical committee at its session on 23/10/2014 -: Not to accept Receiving new products containing the formulation (Inhibitor Pump Proton + NSAID) and not completing the registration procedures for the products under registration that contain this formulation Based on the decision of the specialized scientific committee for internal diseases at its session on 02/10/2013.

Decisions of the Technical Committee for Drug Control at its session on 02/10/2025

*-Approval for receiving a new reference product containing Tolperisone for Reference use " Symptomatic treatment of post-stroke spasticity in adults" & To Be Applied From 01/11/2025 Based on the Scientific Evaluation Committee for Medical Products for Mental and Neurological Disorders on 17/09/2025.

Note: -

- The Scientific Evaluation Committee for Medical Products for Mental and Neurological Disorders recommended at its session on September 17, 2025, as follows: Approval of Tolperisone from a scientific perspective for the following reasons:

1 - Tolperisone is an effective muscle relaxant and has references in many accredited global organizations. as the Netherlands, Germany, Switzerland, and EMA, which have proven its effectiveness in the following therapeutic purpose according to European Medicines Agency (EMA) report.

Symptomatic treatment of post-stroke spasticity in adults.

The report also included that there are not enough studies to use this substance in other therapeutic indications.

2- The mechanism of action of Tolperisone is different from other muscle relaxants available in the Egyptian market., and it has the therapeutic advantage of not causing drowsiness (Non-Sedative Effect).

*-Not accepting any registration requests for human medicines that Contains a non-sterile dosage form of Amoxicillin/Clavulanic acid & that Contains non-sterile dosage form of Metronidazole in Separate Form & In the case of Submitting a preparation that contains a new pharmaceutical form requires a request to be presented to the technical committee.
*And the following are exempt from this decision:
1. Registration for export and tenders.
2. The products submitted for registration as Extension Line.

And this is after the approval of his excellency. Head of the Egyptian Drug Authority according to the regulatory rules.

Note:

Approved by the esteemed Professor Dr. Head of the Egyptian Drug Authority on November 18, 2025.

Decisions of the Technical Committee for Drug Control at its session on 16/10/2025

*- Not approving the reception of new preparations containing Pipazethate in all forms. And non-approval of completing the registration procedures for the products under registration, and the cancellation of preparations under registration and their removal from the Egyptian Drug Authority's boxes and database according to the rules, and Cancelling registered products With the pharmaceutical forms of oral drops and suppositories are canceled according to the regulations and their removal from the Egyptian Drug Authority's boxes and database with adherence to the regulations & update Internal Leaflets for Registered Products with Dosage Form Tablets & Syrups and reviewing the prescribed doses by the Pharmacology Committee at the Central Administration For pharmaceutical care, and adding warnings related to overdose in the leaflet, with the following warning written on the outer packaging and the leaflet "not to be used for children under four years old," and the Pharmacovigilance Unit conducts close monitoring For registered products, they are presented to the technical committee if necessary, and re-registration of registered products in the forms of Tablets & Syrups is not approved.

Re-registration of registered pharmaceutical forms Tablets & Syrups and their cancelation upon re-registration, and thus Based on the decision of the Pharmacology Committee at its session on the date 30/06/2025, and the Pharmacovigilance Committee at its session on 21/08/2025, and the General Administration of Pharmacy Vigilance By addressing the various central departments at the Egyptian Drug Authority to implement the decision, each in its respective area according to the rules.

- Note: -

- The Issue was presented to the Pharmacology Committee to provide their opinion regarding the preparation and the proposed amendments to the internal leaflet at its session on (30/06/2025) and re-presentation to The Pharmacovigilance Committee at its session on (21/08/2025) and the final recommendation was as follows:

Based on the warning issued by the FDA on 11/07/2024, which stated the following:

"Over-the-counter (OTC) medicines are available to treat cough and cold symptoms. The FDA doesn't recommend OTC medicines for cough and cold symptoms in children younger than 2 because they could cause serious and potentially life-threatening side effects. Manufacturers voluntarily label these cough and cold products to state: "Do not use in children under 4 years of age."

The committee recommends the following:

• Do not use the preparation for children under 4 years in any pharmaceutical form (Dosage Form).

• The preparation in the form of "Drops Oral" is canceled due to the difficulty in adjusting the dose, which increases the risk of the."Overdose risk of seizure".

Opinion

• Review of the prescribed doses by the Scientific Evaluation Committee for Pediatric Medical Products.

• Adding warnings about overdose in the product leaflet.

Decision of the Technical Committee for Drug Control at its session on 30/10/2025

*- Amendment The decision of the Technical Committee for Drug Control at its session on 16/10/2025 regarding products containing Pipazethate to include:

*- For registered products in the syrup form, companies are committed to provide a measuring cup with each package to ensure dose accuracy.

*- For registered products in the syrup and tablets forms, Companies are granted a three-month grace period ending on 16/01/2026 to implement the decision. After the grace period expires, the Central Administration of Inspection on Pharmaceutical Institution will take necessary actions against any Batches that have not complied with the decisions of the Technical Committee for Drug Control.

Decisions of the Technical Committee for Drug Control at its session on 13/11/2025

*-The decision of the Technical Committee for Drug Control at its session on 02/03/2017 regarding products containing Trimetazidine is updated to include: "Approval of accepting new products with a concentration of 80 mg, provided that the decision is applied starting from December 2025 according to the rules," based on the decision of the Scientific Evaluation Committee for Medical Products for Cardiovascular Diseases at its session on 27/07/2025.

-Note:

- The Technical Committee at its session on 02/03/2017 decided: Approval of completing the registration procedures for products containing Trimetazidine at a concentration of 35 mg in the Pharmaceutical Form of Modified release film coated tablets only, and disapproval of accepting or completing registration procedures for products at a concentration of 80 mg.

- Regarding the 20 mg concentration, registered products are to be re-evaluated upon Re-registration, based on the decision of the Specialized Scientific Committee for Heart Diseases at its session on 01/08/2016.

- The Scientific Evaluation Committee for Medical Products for Cardiovascular Diseases at its session on 27/07/2025 recommended: approval of the product from a scientific perspective due to the need for this concentration in the Egyptian market, as the submitted concentration increases Patient compliance for the intended therapeutic purpose, since it is used once daily.

*- The previous decision of the Technical Committee at its session on 05/02/2015 regarding products containing Metoclopramide is updated to be: The Patient Information Leaflets of all products containing Metoclopramide in all its Pharmaceutical Forms and for all uses are to be updated to state that:

- The duration of use shall not exceed five days under any circumstances, and that it should not be used in children under ten years of age.

- Regarding Safety information, it shall be included according to the leaflets of reference products in approved reference countries to follow Reliance rules.

-The General Administration of Pharmaceutical References and Leaflets shall communicate with companies to implement the decision of the Technical Committee and update the leaflets according to the mentioned uses, with commitment to applying the rules.

-This is due to the availability of safer therapeutic alternatives in the Egyptian market with fewer side effects, used for the same therapeutic purpose and not affecting the central nervous system, unlike Metoclopramide, which may lead to serious neurological disorders such as Tardive Dyskinesia with long-term use. This is based on the decision of the Scientific Evaluation Committee for Medical Products for Liver and Gastrointestinal Diseases at its session on 13/10/2025, and the decision of the Scientific Evaluation Committee for Medical Products for Internal Medicine at its session on 21/10/2025.

- Note:

The Scientific Evaluation Committee for Medical Products for Liver and Gastrointestinal Diseases at its session on 13/10/2025 recommended the following:

-After reviewing the leaflets of reference products, scientific references, and international health authorities, the committee finds that many international authorities have permitted the use of Metoclopramide for a maximum of 5 days

only, such as EMA, Compendium, Rote List, Vidal, MHRA, Switzerland, Sweden, Denmark, Finland, Ireland, Italy, Ansm, Spain, Netherlands, Iceland, Germany, Belgium, Portugal & Austria.

- Regarding the possibility of allowing the use of Metoclopramide for a period ranging from 4-12 weeks for the therapeutic purpose of Gastroesophageal reflux according to the FDA, the committee finds that there are therapeutic alternatives available in the Egyptian market that are safer and have fewer side effects, used for the same therapeutic purpose and not affecting the central nervous system, such as Domperidone and Itopride, unlike Metoclopramide, which may lead to serious neurological disorders such as Tardive Dyskinesia with long-term use.

-Based on this, the committee recommends not allowing the duration of use of Metoclopramide to exceed 5 days only, maximum.

- The Scientific Evaluation Committee for Medical Products for Internal Medicine at its session on 21/10/2025 recommended: endorsing the decision of the Scientific Evaluation Committee for Medical Products for Liver and Gastrointestinal Diseases.

Decisions of the Technical Committee for Drug Control at its session on 11/12/2025

*-Regarding preparations containing Metoclopramide: The decision of the Technical Committee at its session on 13/11/2025 is amended to include the following: "Companies are granted a six-month grace period ending on 13/05/2026 to implement the decision."

Note:

-The Technical Committee decided at its session on 13/11/2025:

-The previous decision of the Technical Committee at its session on 05/02/2015 regarding preparations containing Metoclopramide is to be updated as follows:

- The Patient Information Leaflets of all preparations containing Metoclopramide in all pharmaceutical forms and for all uses must be updated to state that the duration of use shall not exceed five days under any circumstances, and that it should not be used in children under ten years of age. Regarding safety information, it is to be included in accordance with the Patient Information Leaflets of reference products in reference countries approved for following the Reliance rules.

-The General Administration of Pharmaceutical References and Leaflets shall communicate with companies to implement the Technical Committee's decision and update the leaflets according to the mentioned uses, while adhering to the application of the rules. This is because there are safer therapeutic alternatives available in the Egyptian market with fewer side effects, used for the same therapeutic purpose, and which do not affect the central nervous system, unlike Metoclopramide, which may lead to serious neurological disorders such as Tardive Dyskinesia when used for long periods. This is based on the decision of the Scientific Evaluation Committee of Medical Products for Liver and Gastrointestinal Diseases at its session on 13/10/2025, and the decision of the

Scientific Evaluation Committee of Medical Products for Internal Medicine at its session on 21/10/2025.

-The Scientific Evaluation Committee for Medical Products for Liver and Gastrointestinal Diseases at its session on 13/10/2025 recommended the following:

-After reviewing the leaflets of reference products, scientific references, and international health authorities, the committee finds that many international authorities have permitted the use of Metoclopramide for a maximum of 5 days only, such as EMA, Compendium, Rote List, Vidal, MHRA, Switzerland, Sweden, Denmark, Finland, Ireland, Italy, Ansm, Spain, Netherlands, Iceland, Germany, Belgium, Portugal & Austria.

- Regarding the possibility of allowing the use of Metoclopramide for a period ranging from 4-12 weeks for the therapeutic purpose of Gastroesophageal reflux according to the FDA, the committee finds that there are therapeutic alternatives available in the Egyptian market that are safer and have fewer side effects, used for the same therapeutic purpose and not affecting the central nervous system, such as Domperidone and Itopride, unlike Metoclopramide, which may lead to serious neurological disorders such as Tardive Dyskinesia with long-term use.

-Based on this, the committee recommends not allowing the duration of use of Metoclopramide to exceed 5 days only, maximum.

- The Scientific Evaluation Committee for Medical Products for Internal Medicine at its session on 21/10/2025 recommended endorsing the decision of the Scientific Evaluation Committee for Medical Products for Liver and Gastrointestinal Diseases.

Decisions of the Technical Committee for Drug Control at its session on 25/12/2025

*- Regarding products containing Sulbactam + Cefoperazone, commitment to use by intravenous injection only, similar to the product circulating in Korea and the reference products in Japan which contain the same composition but at different concentrations. Use is to be restricted to hospitals only.

- Registered products are granted a grace period of six months from the date of the committee meeting to rectify their situation. This is based on the decision of the Scientific Evaluation Committee for Medical Products for Chest Diseases at its session on 08/12/2025 and the decision of the Scientific Evaluation Committee for Medical Products for Kidney and Urinary Tract Diseases and Surgery at its session on 10/12/2025.

Note:

- The Scientific Evaluation Committee for Medical Products for Chest Diseases at its session on 08/12/2025 recommended: To approve the Registration of the product from a scientific perspective for the following reasons:

1. The composition at the submitted concentrations falls within the therapeutic range for treating respiratory tract infections, as Cefoperazone is a broad-spectrum antibiotic.

2. There are similar products circulating in the Egyptian market a while ago, and no reports of serious Adverse Events have been received.

With emphasis on:

1. The product should be used by intravenous injection only, similar to the product circulating in Korea and the reference products in Japan which contain the same composition but at different concentrations.

2. Its use should be restricted to hospitals only, and this applies to similar cases.

- The Scientific Evaluation Committee for Medical Products for Kidney and Urinary Tract Diseases and Surgery at its session on 10/12/2025 recommended to approve the registration of product from a scientific perspective for the following reasons:

1. The composition at the submitted concentrations falls within the therapeutic range for treating urinary tract infections, as Cefoperazone is a broad-spectrum antibiotic.

2. There are similar products circulating in the Egyptian market a while ago, and no reports of serious Adverse Events have been received.

With emphasis on:

1. The product should be used by intravenous injection only, similar to the product circulating in Korea and the reference products in Japan which contain the same composition but at different concentrations.

2. Its use should be restricted to hospitals only, and this applies to similar cases.