Decisions of the Technical Committee for Drug Control at its session on 21/1/2021

*- For preparations containing Diclofenac in the form of suppositories at a concentration higher than 50 mg:

The warning must be written either “Not for use by children” or “For adults” on the outer packaging and leaflet.

Decisions of the Technical Committee for Drug Control at its session on 04/02/2021

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Vancomycin in the form of gel based on the decision of the Specialized Scientific Committee for Dental Diseases and Surgery at its session on 29/7/2020 and the decision of the Pharmacology Committee at its session on 22/10/2020.

Note: -

1-**The Pharmacology Committee decided at its session on 22/10/2020**: not to approve the registration of the preparation because the pharmaceutical form is not suitable for the use provided by the company and for fear of its being misused topically.

2- The Specialized Scientific Committee for Dental Diseases and Surgery recommended in its session on 29/07/2020: not to approve the preparation as it is not registered in any reference country and it is mentioned in the FDA that it is used by injection and that its absorption is weak orally, and the file submitted by the company contains a small group of research, its results should not be taken in absolute terms.

*- Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Candesartan + Nifedipine) based on the decision of the Specialized Scientific Committee for Cardiology at its session on 04/11/2020 and the decision of the Pharmacology Committee at its session on 21/07/2016.

Note: -

1- **The Specialized Scientific Committee for Cardiology decided, in its session on 04/11/2020**: not to approve the preparations due to the lack of completion of clinical studies, and Short acting Nifedipine is not first line treatment in hypertension.

2-The Pharmacology Committee, at its session on 21/07/2016, recommended rejecting the formulation for the following reasons:

1- Published clinical studies on the (Nifedipine + candesartan) formulation did not exceed eight weeks, and therefore the results of long-term use of this formulation are not yet known.

2- Nifedipine contained in the preparation I.R. It is prohibited to use this pharmaceutical form to treat Essential Hypertension.

*- Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Ramipril + Amlodipine) in the form of Sustained Release based on the decision of the Specialized Scientific Committee for Cardiovascular Diseases at its session on 9/9/2020 and the decision of the Non-Reference Medicines Committee at its session on 05/11/ 2020.

Note: -

1-The Specialized Scientific Committee for Cardiovascular Diseases recommended, at its session on 9/9/2020, not to approve the preparation due to the lack of submission of studies proving Plasma Concentration for each active substance separately, such as Sustained Release.

2- The Non-Reference Medicines Committee decided at its session on 05/11/2020: not to approve the registration of the preparation because there is no scientific basis for using the same concentrations found in the immediate release pharmaceutical form in sustained release pharmaceutical form.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Molsidomine At a concentration of 2mg in the form of Prolonged Release, based on the decision of the Specialized Scientific Committee for Cardiology at its session on 04/11/2020 and the decision of the Pharmacology Committee at its session on 22/11/2018.

Note: -

1- The Specialized Scientific Committee for Cardiology decided at its session on 04/11/2020: not to approve the preparation because the company did not submit studies indicating the safety and efficacy of the active substance in this concentration and pharmaceutical form.

2- The Pharmacology Committee, at its session on 22/11/ 2018, recommended refusing to register the product due to the lack of reference to the concentration in the pharmaceutical form provided by the company.

*- Amending the decision of the Technical Committee at its session on 31/12/2020 to be: "Cancelling the preparations under registration and not approving the reception of new preparations containing Cefmenoxime in the form of injection, based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 26/02/2019 and the decision of the Pharmacology Committee at its session." On 01/10/2020."

Note: -

1- The Technical Committee decided at its session on 31/12/2020: to cancel the preparations under registration and not to approve the reception of new preparations containing Cefmenoxime, based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on

26/02/2019 and the decision of the Pharmacology Committee at its session on 01/10/2020

*- Approval to receive new preparations containing the combination (Amlodipine + Hydrochlorothiazide + Irbesartan) based on the decision of the Specialized Scientific Committee for Cardiology at its session on 04/11/2020 and the decision of the Pharmacology Committee on 17/12/2020, provided that the decision is implemented starting from the month following its issuance.

Decisions of the Technical Committee for Drug Control at its session on 18/02/2021

*- Approval to receive new preparations containing the formulation (Bupivacaine + Meloxicam) in the form of Prolonged release wound solution, provided that adhering to reference format (a prolonged-release formulation of bupivacaine and meloxicam using a polymer-based drug delivery system. Following single- dose application, bupivacaine and meloxicam are released simultaneously from the polymer for approximately 3 days) and the decision is implemented starting from the month following its issuance, as an exception to the decision of the Technical Committee at its session on 01/04/2010 regarding NSAIDS, which states: “Not to receive any preparations.” NSAID's, starting from the date of the committee, and the boxes will not be applied to these drug groups. In case of submitting a preparation that contains a new substance or a new pharmaceutical form, an application will be submitted for presentation to the technical committee.

*Excluded from this decision are:

- Registration is for export only
- Preparations for topical use.
- Salicylic acid preparations at a dose of 150 mg or less.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition:

Matricaria recutita (Chamomile) Dil. D3 2.2 mcg
+ Echinacea Dil. D2 0.55 mcg
+ Hepar Sulfuris dil. D6 aquos. 2.2 mcg
+ Hamamelis virginiana Dil. D1 0.22 mcg
+ Arnica Montana Dil. D2 2.2 mcg
+ Aconitum napellus dil. D2 1.32 mcg
+ Atropa belladonna dil. D2 2.2 mcg
+ Mercurius Solubilis Hahnemanni Dil. D6 aquos. 1.1 mcg
+ Hypericum perforatum Dil. D2 0.66 mcg
+ Symphytum officinale Dil. D6 2.2 mcg
+ Calendula officinalis Dil. D2 2.2 mcg
+ Achillea millefolium dil. D3 2.2 mcg
+ Echinacea purpurea Dil. D2 0.55 mcg
+ Bellis perennis Dil. D2 1.1 mcg

Decisions of the Technical Committee for Drug Control at its session on 04/03/2021

*- Approval of the following proposal submitted by the Department of Registration of Food Supplements and Herbal Medicines regarding preparations previously registered as food supplements that may fall under the classification of herbal medicines and which had previously obtained approval to proceed with re-registration procedures, and the approval to proceed had expired without obtaining re-registration license:

Companies are given a period of one year from the date of the technical committee to apply for re-registration of these preparations and evaluation as herbal medicines.

Decisions of the Technical Committee for Drug Control at its session on 11/03/2021

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Ciprofloxacin 250mg + Metronidazole 250 mg) at these concentrations based on the decision of the Pharmacology Committee on 20/06/2019 and the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 24/11/2020.

Note:

1-The Pharmacology Committee, at its session on 20/06/2019, recommended refusing to register the product for the same reasons mentioned in the Pharmacology Committee's decision dated 22/09/2016, which states:

*Both substances included in the formula are available in the Egyptian market in abundance in individual preparations that allow them to be used together when needed, in the required doses of each substance, with greater flexibility to adjust the doses according to the disease condition.

*Both substances included in the formula are commonly used in Egyptian society, and combining them may lead to significant misuse of this F.D.C.

-In addition to the warnings issued by the EMA regarding the legalization of the use of substances belonging to the fluoroquinolones group due to their side effects (disabling).

2-The Specialized Scientific Committee for Internal Medicine Diseases at its session on 24/11/2020: which recommended not approving the preparation as the company did not submit to the committee's requests at its session on 25/06/2019 to clarify the scientific basis for the formulation.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the combination (Dapagliflozin + Metformin + Saxagliptin) based on the decision of the Specialized Scientific Committee for Endocrinology and Metabolism on 20/01/2021 and the decision of the Non-Reference Medicines Committee at its session on 03/02/2021.

Note:

1- At its session on 20/01/2021, the Specialized Scientific Committee for Endocrinology and Metabolism recommended rejecting the preparation for the following reasons:

1. Withdrawing the original product from scientific references (FDA, EMA)
2. There is no need for it because there are preparations in the Egyptian market that contain this presented formula not combined in one tablet.

2-The Non-Reference Medicines Committee decided at its session on 03/02/2021: to reject the preparation for the following reasons:

1-Withdrawal of the product from the FDA.

2- Not providing sufficient studies on the presented formulation proving its efficacy in one tablet.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Samidorphan + Olanzapine) based on the decision of the Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 23/12/2020 and the decision of the Non-Reference Medicines Committee at its session on 03/02/2021.

Note:

1-The Specialized Scientific Committee for Psychiatric and Neurological Diseases recommended at its session on 23/12/2020: not approving the formulation due to the lack of completion of clinical studies proving the safety and efficacy of the formulation in the presence of Samidorphan.

2-The Non-Reference Medicines Committee decided at its session on 3/02/2021:

The preparation was rejected due to the lack of completion of clinical studies proving the safety and efficacy of the formulation.

*- Cancellation of preparations under registration and not approving the reception of new preparations with the formulation (Omeprazole + Rifabutin) based on the decision of the Specialized Scientific Committee for Liver Diseases at its session on 30/11/2020 and the decision of the Non-Reference Medicines Committee at its session on 03/02/2021.

Note:

1-The Specialized Scientific Committee for Liver Diseases recommended at its session on 30/11/2020: By not approving the preparation, as tuberculosis is endemic in Egypt and Rifabutin is an essential drug for treating it, and the frequent use of Rifabutin leads to the emergence of resistance strains of tuberculosis that do not respond to Rifabutin.

2-The Non-Reference Medicines Committee decided at its session on 03/02/2021:

Not approving the preparation in order to avoid resistance to Rifabutin, which is an essential drug for treating patients with tuberculosis, which is an endemic disease in Egypt.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Rolapitant in the form of injection based on the decision of the Specialized Scientific Committee for Cancer and Radioisotopes at its session on 12/01/2021 and the decision of the Non-Reference Medicines Committee at its session on 03/02/2021.

Note:

1-The Specialized Scientific Committee on Cancer and Radioisotopes recommended at its session on 12/01/2021: refusing the preparation due to stop Circulation of the product at the FDA and not submitting studies proving the efficacy and safety of the formulation of the product.

*It is worth noting that the product was transferred from the Egyptian Pharmaceutical Vigilance Center, as the product has lost its reference.

2-The Non-Reference Medicines Committee decided at its session on 03/02/2021:

The preparation was rejected for the following reasons:

1-Withdrawal from the FDA

2- Not providing sufficient studies on the preparation to prove the efficacy and safety of the preparation.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Sildenafil in the form of Sustained Release based on the decision of the Specialized Scientific Committee for Dermatology, Venereology and Andrology at its session on 30/07/2018 and the decision of the Non-Reference Medicines Committee at its session on 03/02/2021.

Note:

1-The Specialized Scientific Committee for Dermatology, Venereology and Andrology decided at its session on 30/07/2018: Not approving the registration of the preparation because there is no scientific reference for this pharmaceutical form.

2-The Non-Reference Medicines Committee decided at its session on 03/02/2021:

Rejection of the preparation due to lack of sufficient studies indicating the safety and efficacy of the preparation.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Nifedipine at a concentration of 2%, based on the decision of the Specialized Scientific Committee for General Surgery at its session on 27/06/2018 and the decision of the Pharmacology Committee at its session on 21/01/2021.

Note:

1-The Specialized Scientific Committee for General Surgery recommended at its session on 27/06/2018: rejecting the preparation for not providing sufficient studies indicating the efficiency, safety and efficacy of the preparation.

2-The Pharmacology Committee decided at its session on 21/01/2021: Not approving the registration of the product at its current concentration.

Decisions of the Technical Committee for Drug Control at its session on 25/03/2021

*- Cancelling the preparations under registration and not approving the reception of new preparations containing the combination (Dequalinium + Benzocaine + Trypsin) based on the decision of the Specialized Scientific Committee for Ear, Nose and Throat Diseases at its session on 30/09/2020 and the Non-Reference Medicines Committee on 05/11/2020.

Note:

1- The Specialized Scientific Committee for Ear, Nose and Throat Diseases at its session on 30/09/2020: recommended not approving the preparation because the company did not provide reasons for not marketing the preparation in Portugal and because information was not obtained regarding the safety of the formulation, according to the report of the Pharmacovigilance Center on 06/08/2020.

2-The Non-Reference Medicines Committee decided on 05/11/2020: Not approving the registration of the preparation due to failure to submit sufficient documents supporting and confirming the formulation of the preparation for the aforementioned therapeutic purpose.

*- Cancelling the preparations under registration, not approving the re-registration of the preparations, and not approving the reception of new preparations that contain the combination (Amylocaine + Papain + Pepsin + Diastase) based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 15/10/2019 and the decision of the Non-Reference Medicines Committee At its session on 31/10/2019 and the decision of the Pharmacology Committee at its session on 21/01/2021.

Note:

1-The Specialized Scientific Committee for Internal Medicine Diseases decided at its session on 15/10/2019:

The preparation was rejected due to the lack of scientific evidence for the use of Amylocaine in the mentioned uses of the drug.

2-The Non-Reference Medicines Committee decided at its session on 31/10/2019:

Not approving the re-registration of the product based on the rejection of the Specialized Scientific Committee for Internal Medicine Diseases on 15/10/2019.

3-The Pharmacology Committee recommended at its session on 21/01/2021:

refusing to re-register the product due to the lack of scientific support for the presence of Amylocaine in the formulation, and in support of the internal Medicine Diseases committee's decision on 15/10/2019.

*- Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Chloropheniramine Maleate + Hydrocodone) based on the decision of the Specialized Scientific Committee for Chest Diseases at its session on 19/01/2021 and the Pharmacology Committee at its session on 25/02/2021.

Note:

1-The Specialized Scientific Committee for Chest Diseases decided at its session on 19/01/2021 The product was not approved for the following reasons:

1-Stopping the product by the FDA

2- Serious side effects of Hydrocodone, according to the FDA leaflet, are: Addiction, Abuse, And Misuse; Life-Threatening Respiratory Depression; Accidental Ingestion; Medication Errors; Cytochrome P450 3a4 Interaction; Concomitant Use with Benzodiazepines or Other CNS Depressants; Interaction with Alcohol; Neonatal Opioid Withdrawal Syndrome

2-The Pharmacology Committee recommended at its session on 25/02/2021:

By refusing to register the product in support of the decision of the Chest Committee on 19/01/2021 and because of the danger of its misuse.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Clioquinol 10 mg/gm + Hydrocortisone 10 mg/gm) in these concentrations in the form of Topical Preparations based on the decision of the Specialized Scientific Committee for Dermatology at its session on 24/06/2019 and the Pharmacology Committee At its session on 18/02/2021.

Note:

1-The following was presented to the Specialized Scientific Committee for Dermatology at its session on 24/06/2019.

The committee recommends rejecting the formulation due to the lack of sufficient scientific studies on the concentration of Clioquinol 10mg\gm

2-The following was presented to the Pharmacology Committee at its session on 18/02/2021. The committee recommends refusing to register the preparation as the concentration of Clioquinol is less than the therapeutic concentration and the company has not provided sufficient studies indicating the efficacy of this concentration.

*- Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Azelastine + Fluticasone + Oxymetazoline) based on the decision of the Specialized Scientific Committee for Ear, Nose and Throat Diseases at its session on 24/02/2021.

Note:

The Specialized Scientific Committee for Ear, Nose and Throat Diseases at its session on 24/02/2021:

The committee recommends not approving the preparation for the following reasons:

The difficulty of combining Oxymetazoline and Azelastine + Fluticasone in one combination, as Oxymetazoline is used in acute and not chronic cases (short treatment) for a maximum period of 7 days, otherwise side effects will appear such as Damage mucosa, rebound congestion & Tolerance. As for the two substances Azelastine + Fluticasone is used in severe chronic cases for a period of many months that may reach 3 months.

*- Cancelling the preparations under registration and not approving the reception of new preparations containing the combination (Ciprofloxacin + Ornidazole) based on the decision of the Combined Specialized Scientific Committee for Internal Medicine Diseases at its session on 16/02/2021.

Note:

The combined specialized scientific committee for internal Medicine Diseases recommended at its session on 16/02/2021: Not approving the product for the following reasons:

1- There is no scientific advantage from using the two substances together in one formulation.

2- Side effects of the formula on the nervous system, such as Tendinitis, Tendon rupture, Peripheral neuropathy, Central nervous System (CNS) effects and Exacerbation of Myasthenia Gravis.

3- Both substances included in the formula are available in the Egyptian market in abundance in individual preparations that allow them to be used together when needed and in the required doses of each substance with greater flexibility to adjust the doses according to the disease condition.

4- Both substances included in the formula are commonly used in Egyptian society, and combining them may lead to significant misuse of this F.D.C.

5- Ciprofloxacin belongs to the Fluoroquinolone group, and warnings were received from the EMA on 15/11/2018 specifically for this group, including the following:

The CHMP confirmed that the use of the remaining fluoroquinolone antibiotics should be restricted.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the combination (Levofloxacin + Metronidazole) based on the decision of the Specialized Combined Scientific Committee for Internal Medicine Diseases at its session on 16/02/2021.

Note:

The combined specialized scientific committee for internal Medicine Diseases held its session on 16/02/2021, which decided the following: The committee still stands by its previous decision on 24/11/2020, where it recommended not to approve the preparation for the following reasons:

1- There is no scientific advantage from using the two substances together in one formulation.

2- Side effects of the formula on the nervous system, such as Tendinitis, Tendon rupture, Peripheral neuropathy, Central Nervous System (CNS) effects and Exacerbation of myasthenia gravis

3- Both substances included in the formula are available in the Egyptian market in abundance in individual preparations that allow them to be used together when needed and in the required doses of each substance with greater flexibility to adjust the doses according to the disease condition.

4- Both substances included in the formula are commonly used in Egyptian society, and combining them may lead to significant misuse of this F.D.C.

5- The warnings received from the EMA regarding the group of quinolone and fluoroquinolone antibiotics on 15/11/2018, which state:

The CHMP confirmed that the use of the remaining fluoroquinolone antibiotics should be restricted

6- There is no scientific rationale for combining Metronidazole & Levofloxacin, as Levofloxacin is effective in treating respiratory or urinary system conditions and not in treating digestive system conditions.

7- The dose of Levofloxacin is once daily, while the dose of Metronidazole is every 8-12 hours, according to the scientific reference BNF80.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Cimetropium based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 16/02/2021.

Note:

The Specialized Scientific Committee for Internal Medicine Diseases recommended at its session on 16/02/2021: Not approving the product for the following reasons:

1. Withdrawn from Italy.

2. Atropine has many side effects, such as increased eye pressure, rapid heartbeat in heart patients, and urinary retention in prostate patients.

3. There are many safer alternatives, such as Buscopan (Hyoscine butyl bromide).

*- Cancelling the preparations under registration and not approving the reception of new preparations containing the combination (Fexofenadine + Montelukast) based on the decision of the Specialized Combined Scientific Committee for Ear, Nose and Throat Diseases at its session on 24/02/2021.

Note:

The following was presented to the Specialized Combined Scientific Committee for Ear, Nose and Throat Diseases at its session on 24/02/2021:

The committee recommends not approving the composition for the following reasons:

1- There is no scientific basis for combining Fexofenadine + Montelukast together in treating cases of chest allergies and nasal allergies.

2- Montelukast has no role in treating allergic rhinitis, and it is only used in patients who suffer from allergic rhinitis with asthma, in accordance with approved international guidelines, and there is no need to have the two substances together in one tablet.

3- Serious side effects of Montelukast, according to the FDA Black warning box, which includes the following:

Postmarketing report:

- Serious Neuropsychiatric disorders: agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, nightmares, dysphemia (stuttering), hallucinations, insomnia, irritability, memory impairment, depression, obsessive-compulsive symptoms, restlessness, somnambulism, suicidal thinking and behavior

(including suicide), tic, and tremor.

There is no need to combine it with another active substance that may increase these side effects

4- The presence of preparations available in the Egyptian market that contain these active ingredients in a single form.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Omeprazole at a concentration of 25 mg based on the decision of the Combined Specialized Scientific Committee for Internal Medicine Diseases at its session on 16/02/2021.

Note:

1-The Combined Specialized Scientific Committee for Internal Medicine Diseases at its session on 16/02/2021: Which recommended not to approve the product for the following reasons:

1. Non-referenced concentration and pharmaceutical form.
2. Not submitting any studies indicating the efficacy of the concentration provided and the therapeutic advantage of the pharmaceutical form provided

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Ribavirin at a concentration of 100 mg/5ml in the form of Oral Solution based on the decision of the Specialized Combined Scientific Committee for Liver and Digestive System Diseases at its session on 25/02/2021.

Note:

The specialized combined scientific committee for diseases of the liver and digestive system recommended its session on 25/2/2021. rejecting the preparation for the following reasons:

1- The concentration provided is less than the required concentration (subtherapeutic) and is ineffective in the treatment protocol for chronic hepatitis C for children.

2- Since the therapeutic purpose provided by the company includes Ribavirin/Interferon or peginterferon combination therapy, this protocol has no use in treating chronic hepatitis C in children, in accordance with approved international guidelines.

3- The existence of safer and more effective therapeutic alternatives, such as Ledipasvir/Sofosbuvir.

Decisions of the Technical Committee for Drug Control at its session on 01/04/2021

*- Regarding human drug preparations for intramuscular injection that contain Lidocaine as a solvent:

Approval of the proposal submitted by the Human Drug Registration Department to allow companies to use a Lidocaine solvent with a different volume than the quantity to be reconstituted (provided that the solvent is registered as a separate preparation), with the requirement to state on the package and leaflet the quantity of solvent to be used for reconstitution, according to the approved package insert. This will be subject to inspection follow-up, and shall be valid for only one year from the date of the committee's decision, in order to reconcile the situation and ensure the availability of these preparations for Egyptian patients, especially given the coronavirus crisis and the need for antibiotics, while the Human Drug Registration Department is directed to implement the rules.

Decisions of the Technical Committee for Drug Control at its session on 08/04/2021

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Midecamycin based on the decision of the Pharmacovigilance Committee at its session on 07/10/2020, the Specialized Scientific Committee for Chest Diseases at its session on 19/10/2021, and the Specialized Scientific Committee for Internal Medicine Diseases at its session on 16/02/ 2021.

Note:

1- The preparation was presented to the Specialized Scientific Committee for Chest Diseases at its session on 19/01/2021, and the committee decided not to approve the preparation for the following reasons:

-There are alternatives to Macrolides in abundance in the Egyptian market that are more efficient and safer in terms of side effects.

-In addition to the many side effects resulting from this active substance that affect the skin and liver patients, according to the product leaflet in Spain and Italy.

It can cause skin rashes and hives.

In case of decompensated hepatic insufficiency, administration of Midecamycin is not recommended.

- Report of the Pharmacovigilance Committee at its session on 07/10/2020.

The committee's decision was as follows: Reservation on registering the substance Midecamycin, as the substance is not registered in most reference countries, and many adverse effects have been reported, most of which are specific to Gastrointestinal Disorders & Skin & Subcutaneous Tissue Disorders in the global adverse effects database Vigilyza.

2-The preparation was presented to the Specialized Scientific Committee for Internal Medicine Diseases at its session on 16/02/2021, where the committee recommended not approving the preparation for the following reasons:

-There are alternatives to Macrolides in abundance in the Egyptian market that are more efficient and safer in terms of side effects.

-The product was withdrawn from Italy and France.

-In addition to the many side effects resulting from this active substance that affect the skin and liver patients, according to the product leaflet in Spain and Italy:

It can cause skin rashes and hives.

In case of decompensated hepatic insufficiency, administration of Midecamycin is not recommended.

- Report of the Pharmacovigilance Committee at its session on 07/10/2020.

The committee's decision was as follows: Reservation on registering the substance Midecamycin, as the substance is not registered in most reference countries, and many adverse effects have been reported, most of which are specific to Gastrointestinal Disorders & Skin & Subcutaneous Tissue Disorders in the global adverse effects database Vigilyza .

Decisions of the Technical Committee for Drug Control at its session on 06/05/2021

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the formula (Etofenamate 100 mg +Benzyl nicotinate 10 mg/1 gm) at these concentrations in the form of Topical Dosage forms based on the decision of the Combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics at its session on 25/03/ 2021.

Note: -

It was presented to the combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics at its session on 25/03/2021.

Which decided to reject the preparation for the following reasons:

1- The suspension of the originator/reference product circulation from several reference countries (Portugal, Germany, and New Zealand) without knowing the reasons.

2- Due to the availability of many preparations in the Egyptian market that perform the same purpose, which is topical treatment, the Egyptian market does not need more than these available preparations.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Etofenamate at a concentration of 50mg/ml in the

form of Depot Injection based on the decision of the Combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics at its session on 25/03/2021.

Note: -

It was presented to the combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedic Surgery at its session on 25/03/2021: which decided not to approve the preparation because the concentration submitted by the company is less than the therapeutic concentration of the active ingredient(subtherapeutic), according to the reference preparations leaflet.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Ibuprofen in the form of Vaginal Dosage forms based on the decision of the Combined Specialized Scientific Committee for Gynecology and Obstetrics at its session on 29/03/2021.

Note:

The following was presented to the Specialized Scientific Committee for Gynecology and Obstetrics at its session on 29/03/2021: The committee decided to stick with its previous decision not to approve the preparation for the following reasons:

1. Due to the failure to provide sufficient accredited scientific studies indicating the efficacy and safety of the preparation, and the ineffectiveness of the preparation for the therapeutic purpose submitted by the company, as the symptoms of genital tract infection are due to the presence of mixed fungi or bacteria, and that Ibuprofen has no role in treating them.

2- Ibuprofen in the pharmaceutical form of the vaginal preparation may cause systemic absorption, leading to the appearance of side effects.

*- Canceling the preparations under registration and not approving the reception of new preparations with the combination (Belladonna + Ergotamine + Phenobarbital) based on the decision of the Specialized Scientific Committee for Gynecology and Obstetrics at its session on 28/10/2020 and the Combined Specialized Scientific Committee for Obstetrics and Gynecology at its session on 29/03/2021.

Note: -

1- It was presented to: The Specialized Scientific Committee for Obstetrics and Gynecology at its session on 28/10/2020: Which decided not to approve the registration of the preparation due to the lack of sufficient studies indicating the safety of this formulation as Extended-Release Tablet.

2-The Combined Specialized Scientific Committee for Obstetrics and Gynecology at its session on 29/03/2021:

It decided not to approve the registration of the product for the following reasons:

1- There is no role for Ergotamine or Belladonna in treating Functional menopause symptoms, as it is through hormonal and non-hormonal treatment in accordance with international guidelines.

2- The presence of side effects to Phenobarbital and Ergotamine according to the reference leaflet in Canada.

Psychologic and Physiologic Dependence Prolonged use of phenobarbital and ergotamine may result in psychologic and physiologic dependence. Withdrawal symptoms may occur following abrupt termination causing nightmares or insomnia, sweating, irritability, tremor, weight loss, anorexia or after chronic use of large doses, resulting in delirium, seizures, or death. Withdrawal should be cautious and gradual.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Reproxalap in the form of Ophthalmic Preparations based on the decision of the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 22/03/2021.

Note: -

It was presented to the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 22/03/2021, which decided not to approve the preparation due to the lack of completion of clinical studies proving the safety and effectiveness of the preparation.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the combination (Piroxicam + Idrocilamide) in the form of Topical Dosage forms based on the decision of the Combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics at its session on 25/03/2021.

Note: -

The preparation was presented to the Combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics at its session on 25/03/2021, which decided: not to approve the preparation for the following reasons:

1- There are no scientific studies indicating the efficacy and safety of the formula.

2- Side effects may occur when combining the two substances.

3- The Combination has no reference.

Decisions of the Technical Committee for Drug Control at its session on 20/05/2021

*- Approval to open a new box for Ferric pyrophosphate Citrate, based on the decisions of the Pharmacology Committee on 21/07/2020 and 04/02/2021, and implementation will take place starting from 01/07/2021.

*- Amending the decision of the Technical Committee at its session on 08/04/2021 to be "cancellation of preparations under registration, cancellation of registered preparations, and not approving the reception of new preparations containing Midecamycin based on the decision of the Pharmacovigilance Committee at its session on 07/10/2020 and the Specialized Scientific Committee for Chest Diseases at its session in 19/01/2021 and the Specialized Scientific Committee for Internal Medicine Diseases at its session on 16/02/2021" and is submitted to the Chairman of the Egyptian Drug Authority for approval.

Note: -

1- The preparation was presented to the Specialized Scientific Committee for Chest Diseases at its session on 19/01/2021, and the committee decided not to approve the preparation for the following reasons:

-There are alternatives to Macrolides in abundance in the Egyptian market that are more efficient and safer in terms of side effects.

-In addition to the many side effects resulting from this active substance that affect the skin and liver patients, according to the product leaflet in Spain and Italy:

It can cause skin rashes and hives.

In case of decompensated hepatic insufficiency, administration of Midecamycin is not recommended.

- Report of the Pharmacovigilance Committee at its session on 07/10/2020.

The committee's decision was as follows: Reservation on registering the substance Midecamycin, as the substance is not registered in most reference countries, and many adverse effects have been reported, most of which are specific to Gastrointestinal Disorders & Skin & Subcutaneous Tissue Disorders in the global adverse effects database. Vigilyza.

2-The preparation was presented to the Specialized Scientific Committee for Internal Medicine Diseases at its session on 16/02/2021, where the committee recommended not approving the preparation for the following reasons:

-There are alternatives to Macrolides in abundance in the Egyptian market that are more efficient and safer in terms of side effects.

-The product was withdrawn from Italy and France.

-In addition to the many side effects resulting from this active substance that affect the skin and liver patients, according to the product leaflet in Spain and Italy:

It can cause skin rashes and hives.

In case of decompensated hepatic insufficiency, administration of Midecamycin is not recommended.

- Report of the Pharmacovigilance Committee at its session on 07/10/2020.

The committee's decision was as follows: Reservation on registering the substance Midecamycin, as the substance is not registered in most reference countries, and many adverse effects have been reported, most of which are specific to Gastrointestinal Disorders & Skin & Subcutaneous Tissue Disorders in the global adverse effects database. Vigilyza.

Decisions of the Technical Committee for Drug Control at its session on 17/06/2021

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Cefatrizine based on the decision of the Combined Specialized Scientific Committee for Internal Medicine Diseases on 21/04/2021.

Note:

The preparation was presented to the Specialized Scientific Committee for Internal Medicine Diseases at its session on 21/04/2021:

The committee recommends not approving the preparation for the following reasons:

- For not providing reasons for suspending the product Circulation in Italy, France and Spain.

-There is no need in the Egyptian market for such a material.

There are many alternatives available in the Egyptian market that belong to the group of Second generation Cephalosporins that have been proven to be safe and effective.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Dolasetron mesylate in the form of injection based

on the decision of the Specialized Scientific Committee for Internal Medicine Diseases on 21/04/2021.

Note:

The following was presented to the Combined Specialized Scientific Committee for Internal Medicine Diseases at its session on 21/04/2021:

Which recommended not approving the product for the following reasons:

1. Serious side effects of Dolasetron Mesylate, according to the FDA Drug Safety Communication, are:

1. Abnormal heart rhythms associated with use of Dolasetron Mesylate.

2.The presence of alternatives available in the Egyptian market, such as Ondansetron and Granisetron.

3. The active ingredient was withdrawn from several reference countries, such as: FDA, Orange book, Germany, Ireland, France, Sweden, Canada, New Zealand & Italy

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Eluxadoline at a concentration of 25 mg based on the decision of the Combined Specialized Scientific Committee for Internal Medicine Diseases on 21/04/2021.

Note:

The presentation was made to the combined Specialized Scientific Committee for Internal Medicine Diseases on Wednesday, 21/04/2021.

The committee recommends not approving the registration of the preparation because the concentration of 25mg is subtherapeutic dose, as the therapeutic dose is 75mg & 100mg according to the scientific reference FDA, and in order to achieve the required therapeutic dose, this requires giving the patient 3 to 4 tablets, and this is not compatible with Patient Compliance.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Carbazochrome at concentrations of 10 mg/2ml or 25 mg/5ml in the form of injection based on the decision of the combined Specialized Scientific Committee assembled for General Surgery on 29/04/2021.

Note:

The Combined Specialized Scientific Committee for General Surgery decided at its session on 29/04/2021:

Disapproval of the concentrations submitted due to the lack of sufficient studies indicating the efficacy and safety of this concentration.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Dequalinium Chloride + 2,6-di-Tert-Butylnaphthalene-1-Sulfonicacid-3,7-Di-Tert-Butylnaphthalene-2-Sulfonic acid Na salt) Based on the decision of the Specialized Scientific Committee for Ear, Nose and Throat Diseases on 30/09/2020 and the Non-Reference Medicines Committee on 06/05/2021.

Note:

1-The preparation was re-presented to the Specialized Scientific Committee for Ear, Nose and Throat Diseases at its session on 30/09/2020:

It recommended not approving the registration of the preparation due to the lack of information regarding the reasons for not marketing the preparation in Germany and the failure to provide studies proving the safety and efficacy of the preparation.

2-The preparation was presented to the Non-Referenced Medicines Committee at its session on 06/05/2021:

Not approving the registration of the preparation due to the failure to submit studies proving the safety and efficacy of the preparation for the therapeutic purpose provided

*- Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Lidocaine + Hydrocortisone Hemisuccinate + Allantoin + 9-Aminoacridine) in the form of Rectal Dosage Forms based on the decision of the Specialized Scientific Committee for General Surgery at its session on 29/04/2021.

Note:

The preparation was presented to the Specialized Scientific Committee for General Surgery at its session on 29/04/2021:

The formulation was not approved due to the failure to provide reasons for discontinuing the product in Spain and the presence of Allantoin as a keratolytic agent, which is not suitable for the therapeutic purpose in cases of hemorrhoids.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Tyloxapol at a concentration of 1% in the form of inhalation based on the decision of the Combined Specialized Scientific Committee for Chest Diseases on 27/04/2021.

Note:

The following was presented to the combined Specialized Scientific Committee for Chest Diseases at its session on 27/04/2021:

Which recommended not approving the preparation for the following reasons:

1. Because the formula has no reference with the concentration provided.

2. The concentration registered in Japan is much lower than the submitted concentration.

3. For not clarifying the method of use of the preparation, how to inhale, the solution used for inhalation, the size of the inhaled particles, and how to convert them from a liquid to a drug for inhalation.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Vaniprevir based on the decision of the Specialized Scientific Committee for Liver and Digestive Diseases on 29/03/2018 and the Pharmacology Committee on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Liver and Digestive System Diseases, at its session on 29/03/2018, recommended rejecting the preparation for the following reasons:

-Since there are not sufficient scientific studies on the preparation.

-Because there are safer and more effective alternatives in the Egyptian market.

-Because it is still under clinical studies, Phase 2, according to ClinicalTrials.gov

2-The concentration of 300 mg was presented to the Pharmacology Committee at its session on 01/10/2020. Which recommended not approving registration due to the lack of submission of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Menatetrenone based on the decision of the Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics on 24/02/2019 and the Pharmacology Committee on 05/11/2020.

Note:

1-The following was presented to the Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics at its session on 24/02/2019:

Which recommended rejecting the substance due to the lack of sufficient accredited scientific studies from international bodies proving the therapeutic purpose presented.

2-It was presented to the Pharmacology Committee at its session on 05/11/2020, and the committee's decision was as follows: The committee believes that the clinical studies presented did not prove the effectiveness of the two preparations in treating Osteoporosis and preventing bone fractures.

*- Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Cyanocobalamin + Nicotinamide + Oligo (o-sulfo) Rutoside) in the form of injection based on the decision of the Combined Specialized Scientific Committee for Internal Medicine Diseases on 21/04/2021.

Note:

The preparation was presented to the Combined Specialized Scientific Committee for Internal Medicine Diseases at its session on 21/04/2021:

Which recommended not approving the registration of the product for the following reasons:

1. Not providing sufficient studies on the use of Rutoside as injection.
2. There is no scientific rationale to combine these materials together.

*- Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Hydrocodone Bitartrate + Pseudoephedrine Hydrochloride) based on the decision of the Specialized Scientific Committee for Chest Diseases on 19/01/2021 and the Non-Reference Medicines Committee on 08/04/2021.

Note:

1-The preparation was presented to the Specialized Scientific Committee for Chest Diseases at its session on 19/1/2021, where it recommended: The product was not approved for the following reasons:

1-Suspending the product by the FDA.

2-Serious side effects of Hydrocodone, according to the FDA leaflet, are:

Addiction, Abuse, and Misuse; Life-threatening Respiratory Depression; Accidental Ingestion; Medication Errors; Cytochrome P450 3a4 Interaction; Concomitant Use with Benzodiazepines or Other CNS Depressants; Interaction with Alcohol; Neonatal Opioid Withdrawal Syndrome.

2-The preparation was presented to the Non-Referenced Medicines Committee at its session on 08/04/2021, which recommended: The product was refused for registration due to the serious side effects of Hydrocodone, according to the FDA leaflet for the product, which are:

Addiction, Abuse, and Misuse; Life-threatening Respiratory Depression; Accidental Ingestion; Medication Errors; Cytochrome P450 3a4 Interaction; Concomitant Use with Benzodiazepines or Other CNS Depressants; Interaction with Alcohol; Neonatal Opioid Withdrawal Syndrome.

Decisions of the Technical Committee for Drug Control at its session on 24/06/2021

*- Approval of the proposal submitted by the Central Administration for Biological and Innovative Preparations and Clinical Studies to amend the decisions of the Technical Committee dated 21/05/2015 (for local preparations) and 18/08/2015 (for imported preparations) regarding re-analysis of biological preparations without the need for presentation to the Technical Committee to become as follows:

"Approval to re-analyze in laboratories specialized in assessment without the need to refer to the technical committee in the event of any of the following changes:

* Change in the description or composition of the product.

* Addition or replacement of manufacturing facility for drug product.

* Major change in the manufacturing process of drug product.

* Major change in the manufacturing process of drug substance directly or indirectly affecting the drug product.

* Change in primary container closure system for drug product.

* Replacement/Addition of supplier/manufacturer of diluent/ excipient.

* Change in supplier for the plasma-derived excipient.

Decisions of the Technical Committee for Drug Control at its session on 08/07/2021

*- Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Mometasone + Miconazole + Nadifloxacin) based on the decision of the Combined Specialized Scientific Committee for Dermatology, Venereology and Andrology at its session on 27/05/2021.

Note:

The preparation was presented to the Combined Specialized Scientific Committee for Dermatology, Venereal Diseases and Andrology at its session on 27/05/2021:

Disapproval of the preparation due to the failure to provide sufficient studies on the submitted formulation proving its safety and efficacy.

Decisions of the Technical Committee for Drug Control at its session on 15/07/2021

*- Amending the decision of the Technical Committee at its session on 24/06/2021, which states:

"Approval of the proposal submitted by the Central Administration for Biological and Innovative Preparations and Clinical Studies to amend the decisions of the Technical Committee dated 21/05/2015 (for local preparations) and 18/08/2015 (for imported preparations) regarding re-analysis of biological preparations without the need to present them to the Technical Committee to become as follows:

"Approval to re-analyze in laboratories specialized in assessment without the need to refer to the technical committee in the event of any of the following changes:

* Change in the description or composition of the product.
* Addition or replacement of manufacturing facility for drug product.
* Major change in the manufacturing process of drug product.
* Major change in the manufacturing process of drug substance directly or indirectly affecting the drug product.
* Change in primary container closure system for drug product.
* Replacement/Addition of supplier/manufacturer of diluent/ excipient.
* Change in supplier for the plasma-derived excipient."

This becomes:

""Approval to re-analyze in laboratories specialized in assessment without the need to refer to the technical committee in the event of any of the following changes:

* Change in the description or composition of the product.
* Addition or replacement of manufacturing facility for drug product and drug substance.
* Major change in the manufacturing process of drug product.
* Major change in the manufacturing process of drug substance directly or indirectly affecting the drug product.
* Change in primary container closure system for drug product.
* Replacement/Addition of supplier/manufacturer of diluent/ excipient.
* Change in supplier for the plasma-derived excipient."

Decisions of the Technical Committee for Drug Control at its session on 29/07/2021

* Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Atorvastatin + Metformin) based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 29/05/2021.

Note:

The preparation was presented to the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 29/05/2021, which recommended not approving the formulation for the following reasons:

1. There is no scientific basis for combining Atorvastatin & Metformin together in one tablet, as Atorvastatin is taken before bedtime, while Metformin is taken with meals, in accordance with the approved therapeutic protocols for treating patients with type 2 diabetes mellitus associated with dyslipidemia, and therefore they cannot be taken together in same time.
2. The presence of preparations available in the Egyptian market that contain these active ingredients in a single form.

* Not approving the re-registration of preparations, cancellation of preparations under registration, and not approving the reception of new preparations

containing Cefazolin at a concentration of 250 mg in the form of injection, based on the decision of the Combined Specialized Scientific Committee for Pediatric Diseases at its session on 06/07/2021.

Note:

The following was presented to the Combined Specialized Scientific Committee for Pediatric Diseases at its session on 06/07/2021:

Which recommended rejecting the preparation for the following reasons:

1- Since Cefazoline (first generation Cephalosporin) in the concentration provided in the form of injections is not for use in children.

2- The availability of more effective Third generation alternatives in the Egyptian market.

* Cancellation of preparations under registration and not approving the reception of new preparations containing the composition:

Sacubitril Valsartan Crystalline Complex (As Tri-Sodium Hemi pentahydrate) 400 mg

Sacubitril 194mg +Valsartan 206mg

In These concentrations, based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 29/05/2021.

Note:

The composition was presented to the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 29/05/2021, which decided not to approve the registration of the preparations due to the companies' lack of commitment to submit studies that show the effectiveness and safety of the mentioned concentrations of Sacubitril 194mg + Valsartan 206mg.

Decisions of the Technical Committee for Drug Control at its session on 26/08/2021

*- For registered preparations containing Heptaminol 150 mg in the form of Oral drops: The concentration of the active ingredient is adjusted to become the same as the reference concentration of 305 mg/ml, while the doses and indications for use are modified to become the same as the reference preparation, based on the decision of the Combined specialized scientific committee for cardiovascular diseases in 10/08/2021, provided that they are considered new preparations and their place in the box is kept q and the letter N is added to the name. A period of one year is given from the date of the committee to reconcile the situation and production by the old composition, canceling the preparations under registration and not approving the reception of new preparations containing the substance at a concentration of 150 mg in the form Oral drops.

Note:

The following was presented to the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 10/08/2021:

Which recommended approving the re-registration of the preparation after adjusting the concentration of the active ingredient to become the same as the reference concentration of 305 mg/ml and modifying the doses and indications for use like the reference preparation in France. There is no need to double the dose used as it will become 6 times a day and this will affect patient compliance.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the combination (Rosuvastatin + Bempedoic acid) based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases on 10/08/2021.

Note:

The following was presented to the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 10/08/2021:

Which recommended not approving the preparation for the following reasons:

1- There are no known and internationally approved scientific studies indicating the efficacy and safety of using the two substances together in one tablet.

2- The pharmacokinetics of the formulation is unknown.

3- The composition is not referenced.

*- Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Clonazoline + Fluocinolone Acetonide) based on the decision of the Combined Specialized Scientific Committee for Ear, Nose and Throat Diseases on 14/07/2021.

Note:

The preparation was presented to the Combined Specialized Scientific Committee for Ear, Nose and Throat Diseases at its session on 14/07/2021:

It recommended not approving the formulation for the following reasons:

1. The product has been discontinued in Italy.

2. The absence of this formula in any scientific reference or reference country.

3. The presence of intranasal steroids and intranasal decongestant in a single form in the Egyptian market.

4. Side effects of the formulation provided according to the original preparation leaflet in Italy, such as: -Burning Sensation, Itching, Irritation, Dryness of The Inner Lining of The Nose (Nasal Mucosa),

-Very Prolonged Treatment: Narrowing (Atrophy) Of the Inner Walls of The Nose (Nasal Mucous Membranes) May Occur.

- Blurred Vision May Occur.

5. The committee's fear of misuse of this formulation, as it contains the corticosteroid group, which is used for a long period up to 3 months, while the nasal decongestant group, which is used for a short period of 3 days or less. Therefore, the two substances cannot be combined together.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Mavacamten based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases on 10/08/2021.

Note:

The following was presented to the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 10/08/2021:

Which recommended not approving the preparation as it is still under clinical studies in approved and international bodies due to the lack of sufficient scientific studies indicating the efficacy and safety of the active substance.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the combination (Chlorpheniramine Maleate + Prednisolone) based on the decision of the Combined Specialized Scientific Committee for Pediatric Diseases on 06/07/2021.

Note:

The following was presented to the Combined Specialized Scientific Committee for Pediatric Diseases at its session on 06/07/2021:

Which decided to reject the preparation for the following reasons:

1-There is no scientific reason to combine the two substances together for use in children.

2-The concentration of prednisolone in the formula is subtherapeutic.

3- Availability of prednisolone individually in the Egyptian market.

*- Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Dexamethasone + Tramazoline) in the form of Ophthalmic Preparations based on the decision of the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery on 18/08/2021.

Note:

The preparation was re-presented to the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 18/08/2021:

The committee believes that the two substances can be used together in certain cases, such as episcleral inflammation, conjunctival allergy, and other immune-related ocular surface diseases, in accordance with international protocols, but the committee recommends not approving the registration of the preparation:

1- Not providing sufficient studies of the presence of the two substances together in one package, despite the possibility of using the two substances together in certain cases.

2- To withdraw the preparation from Germany

3- The presence of preparations in the Egyptian market that contain active ingredients for the same therapeutic group as the formula in a single form.

Decisions of the Technical Committee for Drug Control at its session on 16/09/2021

*- Approval of the proposal submitted by the Central Administration for Biological and Innovative Preparations and Clinical Studies to give companies a period of six months to implement the latest leaflet approved by the Variation Unit after making changes to the approved leaflet, in order to allow companies to import or produce with the current leaflet until this change is implemented without the need to present it to the Technical Committee for Drug Control.

Note: This proposal does not apply to leaflets in which Safety Update occurs, and companies must apply this leaflet as soon as it is approved by the Variation Unit.

*- Approval to receive new preparations containing Fosfomycin in the form of an infusion, and limiting its use in hospitals only, based on the decision of the Combined Specialized Scientific Committee for Kidney and Urinary Tract Diseases at its session on 23/08/2021, and the decision is implemented from the beginning of the month following the issuance of the decision.

Note:

The combined specialized scientific committee for kidney and urinary tract diseases at its session on 23/08/2021:

The committee recommends approving the preparation from a scientific standpoint and limiting its use in hospitals only, provided that it is written on the outer packaging that "it should only be used under the supervision of a doctor".

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Ciprofloxacin at a concentration of 1000mg in the form of Immediate Release based on the decision of the Combined Specialized Scientific Committee for Internal medicine Diseases at its session on 24/08/2021.

Note: -

The preparation was presented to the Combined Specialized Scientific Committee for Internal medicine Diseases at its session on 24/08/2021.

Which recommended not approving the product for the following reasons:

1. The reference pharmaceutical form for this concentration is extended-release, which has proven its effectiveness in the Egyptian market.
2. The plasma half-life of Ciprofloxacin is 8-12 hours, which may lead to an accumulation of the concentration of Ciprofloxacin at this time if taken in tablet form, which leads to an increase in the appearance of side effects from the group

of Quinolones to which Ciprofloxacin belongs, while the remaining 12 hours of the day the concentration of Ciprofloxacin may decrease.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Cefaclor at a concentration of 250mg and in the pharmaceutical form of Effervescent Tablets based on the decision of the Combined Specialized Scientific Committee for Pediatric Diseases at its session on 06/07/2021 and the Combined Specialized Scientific Committee for Internal medicine Diseases at its session on 24/08/2021.

Note:

1- The following was presented to the Combined Specialized Scientific Committee for Pediatric Diseases at its session on 06/07/2021:

Which decided to reject the preparation because it was not appropriate to use the pharmaceutical form provided for children, as the dose is calculated in mg/kg/day, and this cannot be applied to the provided pharmaceutical form.

2-The following was presented to the Combined Specialized Scientific Committee for Internal medicine Diseases at its session on 24/08/2021:

Which recommended rejecting the preparation for the following reasons:

1. The concentration of Cefaclor is not suitable for adults, as the concentration provided is subtherapeutic, which requires taking the dose up to 4 times a day, and this may affect the patient's compliance.
2. The product has been withdrawn from France and Germany.

Decisions of the Technical Committee for Drug Control at its session on 14/10/2021

*- Based on the latest information and what was published on the EMA website on 12/03/2020 regarding Ulipristal at a concentration of 5mg: Amending the decision of the Technical Committee on 03/09/2020 to be: "Approval to receive new preparations and to complete the procedures for registering registered and under Registration preparations containing Ulipristal at a concentration of 5mg, provided that the use of preparations containing it is limited to cases of uterine fibroids in premenopausal women for whom surgical procedures (including uterine fibroid embolisation) are not appropriate or have not worked According to what was published by the European Medicines Evaluation Agency (EMA), companies that own preparations containing this active substance are committed to follow the precautions taken by the EMA regarding educational materials, including distributing their DHPC and committing to conduct a liver function analysis before starting to take the drug and during Treatment and after the end of the treatment period with follow-up pharmacovigilance and writing on the outer packaging "It is not used except under the supervision of a doctor, based on the decision of the Pharmacovigilance Committee at its session on 29/07/2021 and the Combined Specialized Scientific Committee for Gynecology and Obstetrics at its session on 20/09/2021" and it will be applied starting from the month. following the issuance of the decision.

Note:

The Technical Committee for Drug Control decided at its session on 03/09/2020

Canceling the preparations under registration and registered preparations and not approving the reception of new preparations containing Ulipristal at a concentration of 5 mg, based on the decision of the Pharmacovigilance Committee on 26/03/2020, the Specialized Scientific Committee for Gynecology and Obstetrics at its session on 10/06/2020, and the Specialized Scientific Committee for Liver and Digestive System Diseases at its session on 10 /8/2020

*- Cancellation of the preparations under registration and not approving the reception of new preparations containing the combination (Mitiglinide + Metformin) based on the decision of the Combined Specialized Scientific Committee for Endocrinology and Metabolism at its session on 01/09/2021.

Note:

It was presented to the Combined Specialized Scientific Committee for Endocrine and Metabolism Diseases at its session on 01/09/2021: The committee recommends rejecting the preparation for the following reasons:

1- The company did not provide studies for the fixed dose combination proving the efficacy and safety of the preparation

2- Failure to fulfill the committee's previous requests at its session on 25/12/2017.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Telavancin based on the decision of the Pharmacovigilance Committee at its session on 18/03/2021, the Combined Specialized Scientific Committee for Dermatology and Andrology at its session on 27/09/2021, and the Combined Specialized Scientific Committee for Chest Diseases at its session on 28 /9/2021.

Note:

1-The preparations submitted for registration containing this substance were presented to the Pharmacovigilance Committee at its session on 18/03/2021, which decided the following:

Reservation on registering telavancin (as Hydrochloride) for the following reasons:

- Since the balance of benefits and risks is not in favor of the preparation, and since this preparation has no benefit that exceeds the therapeutic benefit of available alternatives such as vancomycin.

The marketing license for the product was withdrawn by the regulatory authority EMA, and the product was withdrawn from some other reference countries.

In addition, this substance has more serious adverse effects than vancomycin, the most important of which are:

-Prolongation of cardiac repolarization (QTc prolongation)

-Nephrotoxicity

-Ototoxicity

2- The substance was presented to the Combined Specialized Scientific Committee for Dermatology and Andrology at its session on 27/09/2021:

The committee recommends that Telavancin should rarely be used in the field of dermatology, in addition to the existence of safer alternatives with fewer side effects, such as Vancomycin.

3- The substance was presented to the Combined Specialized Scientific Committee for Chest Diseases at its session on 28/09/2021:

The committee recommends not approving the registration of the active substance for the following reasons:

1. The balance of benefits and risks is not in favor of the preparation, as this preparation has no benefit that exceeds the therapeutic benefit of available alternatives such as vancomycin.

2. The marketing license for the product was withdrawn by the regulatory authority EMA, and the product was withdrawn from some other reference countries.

3. In addition, this substance has more serious adverse effects than vancomycin, the most important of which are:

- Prolongation of cardiac repolarization (QTc prolongation)
- Nephrotoxicity
- Ototoxicity

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Brexanolone based on the decision of the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 29/09/2021.

Note:

The preparation was presented to the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 29/09/2021:

The committee recommends not approving the registration of this active substance due to its serious side effects, and the existence of antidepressants used in such cases that are safer and have fewer side effects, such as SSRI (Selective Serotonin reuptake Inhibitor).

SNRI (Selective Serotonin nor Epinephrine Inhibitors)

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Terguride based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 14/09/2021 and the Combined Specialized Scientific Committee for Gynecology and Obstetrics at its session on 20/09/2021.

Note:

1-The preparation was presented to the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 14/09/2021, which recommended not approving the registration of the preparation for the following reasons:

1. There is no use for this active substance in the treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, according to international guidelines.
2. There are no approved scientific studies indicating the efficacy and safety of the active ingredient.

2-The preparation was presented to the Combined Specialized Scientific Committee for Gynecology and Obstetrics at its session on 20/09/2021:

Which recommended not approving the product for the following reasons:

1. There are no approved scientific studies indicating the efficacy and safety of the active ingredient.
2. The availability of other safer preparations in the Egyptian market with no reports of side effects, such as Bromocriptine.
3. There is no scientific rationale for using the active ingredient for the indications for use mentioned by the company.

*- Cancellation of the preparations under registration, not approving the reception of new preparations, and not approving the re-registration of registered preparations containing the combination (Simvastatin + Niacin) based on the decision of the Pharmacology Committee at its session on 04/02/2021 and the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 10/ 8/2021 and the Pharmacovigilance Committee on 27/06/2019.

Note:

1-It was re-presented to the Pharmacology Committee at its session on 4/2/2021, and the committee's decision was as follows:

Which recommended refusing to register the preparations for the following reasons:

1- Based on the report of the Egyptian Pharmacovigilance Center, which states that the use of Niacin extended release with Statins has been withdrawn due to the lack of any additional benefits of Niacin, and the FDA has already withdrawn two preparations from the market "Statins + Niacin Combination" because Niacin does not add any additional benefit in reducing cardiovascular events resulting from the use of statins alone.

2- The recommendation of the Pharmacovigilance Committee on 27/06/2019 to refuse the preparations registration and to consider the situation of the registered/under-registration preparations for the same formulation.

3- The formula is not registered in any of the reference countries.

3- It was re-presented to the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 10/08/2021:

Which saw that there is no objection for using the drug of Niacin and Simvastatin together in cases that require it in accordance with the approved international protocols, but the committee rejects the combination due to what was published in (The daily journal of the United States government) Federal Register regarding the withdrawal of the original preparation. Simcor (Simvastatin +Niacin) from the FDA because it did not reduce the incidence of cardiovascular disease risk.

The formulation was previously presented to the Pharmacovigilance Committee on 27/06/2019, and its decision was as follows:

The committee recommends rejecting the formulation as it has no additional benefit versus its risks, according to what was published in the FDA as follows:

FDA has determined that the benefits of Niacin (Extended release) tablets & Fenofibric acid (Delayed release) capsules for coadministration with statins no longer outweigh the risks, & the approvals for this indication should be withdrawn

It also recommends considering the situation of registered and under-registered preparations with the same formulation.

Decisions of the Technical Committee for Drug Control at its session on 04/11/2021

*- Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Acetylcysteine + Acebrophylline) based on the decision of the Combined Specialized Scientific Committee for Chest Diseases dated 28/09/2021.

Note:

The preparation was presented to the Combined Specialized Scientific Committee for Chest Diseases on 28/09/2021, and the committee recommended the following:

The committee recommends not approving the registration of the preparation for the following reasons:

1. Acebrophylline is (Theophylline + Ambroxol). Accordingly, there is no scientific basis for combining two substances that have the same pharmacological effect, such as Mucolytic, in one formulation.
2. The indications for use provided by the company are not compatible with the mentioned formulation.
3. The formulation is not referenced.

*- Cancellation of the preparations under registration and not approving the reception of new preparations containing the composition (Bentonite +

Precipitated sulfur + Triclosan) based on the decision of the Combined Specialized Scientific Committee for Dermatology, Venereal Diseases and Andrology Diseases dated 27/09/2021.

Note:

The preparation was presented to the Combined Specialized Scientific Committee for Dermatology, Venereal Diseases and Andrology on 27/09/2021, and the committee recommended the following:

The committee recommends not approving the preparation for the following reasons:

1. Not providing sufficient scientific studies proving the effectiveness of the formula in treating acne.

2- The product has been discontinued from New Zealand.

*- Approval to complete the procedures for re-registering preparations containing Drotaverine and approval to receive new preparations containing it, based on the decision of the Non-Reference Medicines Committee at its session on 23/09/2021, and the decision will be implemented starting from the month following the issuance of the decision.

Decisions of the Technical Committee for Drug Control at its session on 25/11/2021

*- Cancellation of the preparations under registration and not approving the reception of new preparations containing the combination (Bilastine + Montelukast) based on the decision of the Combined Specialized Scientific Committee for Ear, Nose and Throat Diseases at its session on 03/11/2021.

Note:

The preparation was presented to the Combined Specialized Scientific Committee for Ear, Nose and Throat Diseases at its session on 03/11/2021:

It recommended not approving the formulation for the following reasons:

1- There is no scientific basis for combining Bilastine + Montelukast together in treating cases of chest allergies and nasal allergies.

2- Montelukast has no role in treating allergic rhinitis, and it is only used in patients who suffer from allergic rhinitis with asthma, in accordance with approved international guidelines, and there is no need for the two substances to be together in one tablet.

3- The presence of preparations available in the Egyptian market that contain these active ingredients in a single form.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Bulevirtide in the form of Oral Dosage forms

based on the decision of the Combined Specialized Scientific Committee for Liver and Digestive System Diseases at its session on 18/10/2021.

Note:

The following was presented to the Combined Specialized Scientific Committee for Liver and Digestive System Diseases at its session on 18/10/2021:

Which recommended not approving the registration of the preparation for the following reasons:

1. There is no reference for the concentration and pharmaceutical dosage form provided.
2. There are no approved scientific studies indicating the effectiveness and safety of the formula in this concentration and pharmaceutical dosage form.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Dextromethorphan + Ethyl-P-aminobenzoate + Potassium Guaiacolsulfonate + Sodium benzoate) based on the decision of the Combined Specialized Scientific Committee for Chest Diseases on 28/09/2021.

Note:

The preparation was presented to the Combined Specialized Scientific Committee for Chest Diseases on 28/09/2021, and the committee recommended the following:

The committee recommends not approving the preparation for the following reasons:

1. Discontinuation of the product in Spain.
2. There is no scientific basis for combining these active ingredients together.
3. There are no studies proving the effectiveness and safety of the formula.

*- Cancellation of preparations under registration, not approving the reception of new preparations, and not approving the re-registration of preparations containing the combination (Citiolone + L-Cysteine) or Citiolone, based on the decision of the Pharmacology Committee at its session on 13/02/2020 and the Non-Reference Medicines Committee at its session on 03 /09/2020 and the combined Specialized Scientific Committee for Liver and Digestive System Diseases at its session on 18/10/2021.

Note: The preparation was presented to the following committees:

1-The Pharmacology Committee at its session on 13/02/2020:

Which recommended rejecting the registration of the preparation as a human pharmaceutical preparation for the following reasons:

1- The substances included in the formula are used as auxiliary substances to improve liver functions and do not have a therapeutic effect

2- Citiolone is not marketed in any of the reference countries and was withdrawn from the only country where it was marketed, which is Italy.

3- The papers submitted by the company did not prove the effectiveness and safety of the formula or that it is marketed in any of the reference countries

2-The Non-Reference Medicines Committee, at its session on 03/09/ 2020, recommended refusing to re-register the preparation as a human pharmaceutical preparation due to the lack of sufficient documents proving the effectiveness of the preparation or the presence of any therapeutic effect.

3-The Combined Specialized Scientific Committee for Liver and Digestive System Diseases at its session on 18/10/2021:

Which recommended refusing to register the preparation for the following reasons:

1- Citiolone has no therapeutic benefit in liver diseases.

2- Citiolone is not marketed in any of the reference countries and was withdrawn from the only country where it was marketed, which is Italy.

3- The papers submitted by the company did not prove the effectiveness and safety of the formula or that it is marketed in any of the reference countries.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Dimetotiazine based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 25/12/2018 and the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 29/09/2021.

Note: The preparation was presented to the following committees:

1- The Specialized Scientific Committee for Internal Medicine Diseases at its session on 25/12/2018:

Which recommended not approving the registration of the preparation due to the lack of scientific rationale for its use in treating migraine.

2-The Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 29/09/2021:

Which recommended not approving the registration of the preparation for the following reasons:

1. The company did not submit the committee's requests at its session on 01/07/2020.
2. There are no scientific studies proving the effectiveness and safety of the preparation.
3. The mechanism of action of the preparation is unknown in the treatment of migraines.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition
(Econazole Nitrate + L-menthol + Salicylic Acid + Lidocaine) in the form of Topical Dosage forms based on the decision of the Combined Specialized Scientific Committee for Dermatology, Venereology and Andrology at its session on 27/09/2021.

Note:

The following was presented to the Combined Specialized Scientific Committee for Dermatology, Venereology and Andrology at its session on 27/09/2021:

Which recommended not approving the preparation for the following reasons:
1. There is no scientific basis for combining these active ingredients together in the mentioned use as Antifungal.
2. Lidocaine is not necessary in this formulation.

3. The lack of sufficient scientific studies indicating the effectiveness and safety of the formula.

*- Cancellation of the preparations under registration and not approving the reception of new preparations containing the combination (Methyclothiazide + Triamterene) based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 14/11/2021.

Note:

The following was presented to the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 14/11/2021: Which recommended not approving the registration of the preparation for the following reasons:

- Failure to control the potassium blood level, as Triamterene may cause an increase in the level of potassium in the blood ("hyperkalemia"), while Methyclothiazide may cause a decrease in the level of potassium in the blood ("Hypokalemia).
- The company did not submit any papers confirming the effectiveness and safety of this composition.
- The product was withdrawn from France.

There are products used as Diuretics, that have proven their effectiveness and safety in the Egyptian market.

Decisions of the Technical Committee for Drug Control at its session on 30/12/2021

*- Approval to receive new preparations containing Buprenorphine in implementation of the Minister of Health's decision No. 640 of 2020 regarding the treatment program with alternative drugs to opiates, in the pharmaceutical form of subcutaneous injection, while adhering to the Circulation requirements in accordance with the decision of the Minister of Health, and the application will be implemented beginning in January 2022, in accordance with the request of the General Secretariat of Mental Health. .

*- Prohibiting the use of Levocetirizine for children under two years old based on the decision of the Pharmacovigilance Committee on 02/12/2021

And for registered preparations, the leaflets, and if any labels are available, are amended in accordance with the decision of the Technical Committee, and companies are given a year for Circulation until their situation is reconciled, while committing them to distribute a dear dr letter warning of the ban on use for children under two years, with follow-up inspection.

Note:

The issue was presented to the Pharmacovigilance Committee at its session on 02-12-2021, and its decision was as follows:

- Levocetirizine is used in children starting from the age of two years.

*- Approval to give an additional period of 6 months for the production and Circulation of Paracetamol Solution for infusion preparations whose composition statement contains the inactive ingredient Sodium Metabisulphite.