Decisions of the Technical Committee for Drug Control at its session on 13/01/2022

*-Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Ertugliflozin 10 mg + Sitagliptin 100 mg) at the concentrations provided as it is non-referenced and based on the decision of the Specialized Scientific Committee for Endocrinology and Metabolism at its session on 17/12/2018 and the Pharmacology Committee on 02/09/2021.

Note:

1- **The Specialized Scientific Committee for Endocrinology and Metabolism decided at its session on 17/12/2018:** Not approving the preparations as the concentration of Ertugliflozin present in the formulation has no scientific reference.

2 - **The Pharmacology Committee decided on 02/09/2021:**

Which decided not to approve the registration of the preparation because the company did not submit sufficient studies indicating the effectiveness of the preparation at this dose.

*- Not approving the reception of new preparations containing Glucosamine in the form of injection based on the decision of the Combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics at its session on 15/12/2021.

Note:

The preparation was presented to the Combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics at its session on 15/12/2021, and the committee recommended: Not approving the registration of the preparation as a human medicine for the following reasons:

1- The lack of sufficient scientific studies indicating the effectiveness and safety of Glucosamine in the form of injection as an adjuvant treatment in cases of Osteoarthritis.

2- The warnings that may occur when using this preparation, according to what was stated in the leaflet of the original preparation in Portugal, are as follows:

- The Injectable form, because of its lidocaine content, should be used with caution in patients with cardiac conduction disorders or decompensated heart failure.
- As Glucosamine is obtained from shellfish, persons who are allergic to shellfish should use caution when taking this medication.

Decisions of the Technical Committee for Drug Control at its session on 03/02/2022

*-Regarding preparations containing Xylometazoline in the form of Nasal spray or Nasal drops: Approval to add the phrase "Patients are advised not to use decongestant nasal drops or sprays for more than seven consecutive days, as continuous and intense use causes dependence and harm, and it is necessary to review the internal leaflet of the preparation before use." In The Advertisements in clear font, as well as adding the phrase "Patients are advised not to use decongestant nasal drops or sprays for more than seven consecutive days, as continuous and intense use causes dependence and harm" in the internal leaflet for these preparations.

*- Approval to register all preparations containing Vitamin D (Cholecalciferol, Ergocalciferol) in Oral dosage form individually at a concentration higher than 2500 IU, as well as all preparations containing Vitamin D (Cholecalciferol, Ergocalciferol) in Oral dosage form that are used for children, in addition to All preparations containing Vitamin D are in the form of injections as human pharmaceutical preparations, provided that preparations containing Vitamin D (Cholecalciferol, Ergocalciferol) in Oral dosage form individually at a concentration up to 2500 IU are considered as Dietary supplement
in pharmaceutical form.

Decisions of the Technical Committee for Drug Control at its session on 24/02/2022

*- For preparations containing Minocycline in the form of Periodontal Gel:
Approval to receive new preparations containing Minocycline in the pharmaceutical form of Periodontal Gel.

Decisions of the Technical Committee for Drug Control at its session on 03/03/2022

*- Not approving to complete registration procedures for preparations containing (Ipratropium Bromide + Oxymetazoline HCl) in the form of Nasal Preparations in any concentrations and not approving the reception of new preparations containing it, 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 Combined Specialized Scientific Committee for Ear, Nose and Throat Diseases at its session on 03/11/2021**: which recommended not approving the registration of the Preparation for the following reasons:

1. There is no scientific basis for combining the two substances together, as Ipratropium is used in the treatment of Rhinorrhea, which used as a long term, that may reach 3 weeks, while Oxymetazoline belongs to the sympathomimetic group and is used as a nasal decongestant, which used as a short term of 3- 7 days Only. Therefore, the two substances cannot be combined as this combination may be misused.

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

*- Not approving to complete registration procedures for preparations containing (Ectoin 2% + Sodium Hyaluronate 0.05%) in the form of Eye Drops, Solution at the same concentrations and not approving the reception of new preparations containing it, based on the decision of the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 22/12/2021.

Note: -

- The Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery, at its session on 22/12/2021, recommended refusing to register the preparation, as the studies submitted did not prove the safety, benefit, and effectiveness of Ectoin in eye diseases, and this substance does not qualify for registration as a medicine.

*- Not approving to complete registration procedures for preparations containing (Hypromellose + Povidone + Glycerol) In the form of Eye Drops in any concentration and not approving the reception of new preparations containing them, based on the decision of the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 22/12/2021.

Note: -

- The Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery, at its session on 22/12/2021, recommended refusing to register the preparation because the company did not submit studies indicating the safety and effectiveness of the formula despite Addressing the company more than once.

*- Not approving to complete registration procedures for preparations containing (Echinacea + Sodium hyaluronate + N-hydroxymethyl glycinate) in the form of Ophthalmic solution in any concentrations and not approving the reception of new preparations containing it, based on the decision of the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 22/12/2021.

Note: -

- The Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 22/12/2021: recommended to reject the preparation for the following reasons:

1- Not providing sufficient studies indicating the effectiveness and safety of Echinacea as an anti-inflammatory in eye drops, according to the scientific file submitted by the company.

2- N-hydroxymethyl glycinate has no therapeutic role and is used as a preservative according to what was provided by the company.

Decisions of the Technical Committee for Drug Control at its session on 10/03/2022

*- For preparations containing Carbetocin 100 mcg/ml in the form of Injection for Local Registration (Circulation in general pharmacies): It will be transferred for submission at Pharmacology Department To make a leaflet in Arabic in addition to the English leaflet for these preparations.

Decisions of the Technical Committee for Drug Control at its session on 17/03/2022

*- For preparations containing Mephenesin:

Not approving the reception of new preparations, canceling the preparations under registration, and recommending the cancellation of registered preparations with applying the rules based on the decision of the Combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics at its session on 09/03/2022 and the decision of the Pharmacovigilance Committee at its session on 03/02/2022.

Decisions of the Technical Committee for Drug Control at its session on 31/03/2022

*- Approval to register the composition, Each (100 grams) contains: Hexamine 10 g + Khellin 35 mg + Piperazine 3g, an analogue of the Coli urinal preparation, in the form of Effervescent granules, based on the decision of the Non-Referenced Medicines Committee at its session on 05/11/2020.

Note: -

-**The study was presented to the Non-Reference Medicines Committee at its session on 05/11/2020**:

After evaluating the presented results, the committee decided the following: Approving the results received and approving the post-marketing study submitted for the coli urinal eff. granules preparation and approving to re-register the preparation with the same formulation and without removal piperazine, with referring the matter to the Technical Committee for Drug Control for taking the necessary action and changing its decision issued on 05/12/2017

*- Approval for the registration of veterinary preparations containing Enrofloxacin submitted for registration for export only, with the conformity of the scientific data of the preparation with the scientific data of the reference preparation, and commitment to implement the mechanism proposed by the Central administration of Operations Department to ensure the export of fully manufactured preparations without leaking any part of them to the local market, provided that the companies pledge not to convert the registration of the preparation from export only to local registration

Decisions of the Technical Committee for Drug Control at its session on 07/04/2022

*- Approval to register the formulation (Diloxanide Furoate 250 mg + Metronidazole 200 mg) in the form of tablets and to register the formulation (Diloxanide Furoate 2 gm + Metronidazole Benzoyl Ester 6.4 gm eq. to Metronidazole 4 gm)/100 ml in the form of Suspension based on the decisions of the Non-Referenced Medicines Committee in its two sessions in 31/12/2015, and 24/03/2022.

Note: -

-**It was presented to the Non-Reference Medicines Committee on 31/12/2015 and decided**:

After studying the results of the study conducted on the preparation, the following points became clear to the committee:

• The presence of cysts and vegetable form together occurs in many cases. Therefore, using the combination from the beginning has a scientific and clinical basis, and this is what the study has proven.

• Major Adverse Events did not occur in either side of the study

• Using the combination is more positive in terms of the patient's adherence to the treatment program.

Based on these results, the committee believes that there is no objection to re-registering the preparation.

-**The Modifications were presented to the Non-Reference Medicines Committee at its session on 24/03/2022**:

Which decided after reviewing the post marketing studies provided by the company, the following has been shown:

1- The requirements of the Non-Referenced Medicines Committee were fulfilled at its session on 23/09/2021, and the study was conducted based on the protocol

that was approved by the Non-Referenced Medicines Committee at its session on 14/08/2014.

2- The results of the study showed that major adverse events did not occur in either side of the study.

Based on the above, the submitted study was approved.

*-Not approving the registration of Tulobuterol in the form of Transdermal Patch based on the decision of the Combined Specialized Scientific Committee for Chest Diseases at its session in 23/02/2022

Note: -

It was presented to the Combined Specialized Scientific Committee for Chest Diseases at its session on 23/02/2022, where it recommended the following: The committee believes that there is no need to register this pharmaceutical form, as:

* It does not offer a therapeutic advantage over Inhalers.
* In addition, its side effects mentioned in the Japanese scientific reference exceed the side effects of inhalers, as the pharmaceutical form presented has Systemic side effects.

According to modern global protocols, it is preferable to use sprays as they have a local effect and have fewer side effects than other pharmaceutical forms.

* It has many precautions in use according to the leaflet of the reference preparation, and this does not apply to inhalers, which are considered safer.

Decisions of the Technical Committee for Drug Control at its session on 14/04/2022

*- Not approving the reception of new veterinary preparations and not approving to complete the registration procedures for veterinary preparations under registration that contain:

Cefquinome (as Sulphate) 4.5% W/V.

In pharmaceutical form, Powder and solvent for solution for injection, based on the decision of the Specialized Scientific Committee for Veterinary Medicines and Feed Additives on 28/02/2022

Note: -

It was presented to the Specialized Scientific Committee for Veterinary Medicines and Feed Additives, which decided at the session of 28/02/2022:

Not approving due to the absence of the formulation in its current form (Powder and Solvent) in any reference country, provided that this decision applies to all similar preparations.

*-Initial approval to receive this pharmaceutical form, Bag on Valve (BOV), and it is placed in Box X: Non-Traditional Topical preparation and Registration licenses are not issued unless the studies required by the Quality Committee are completed and approved.

Note: -

It was presented to the Quality File Evaluation Committee on 23/03/2022, which decided:

There is no objection to using the Bag on Valve (BOV): Packaging system, provided that companies submit the required studies that are conducted during the stages of developing the product (Pharmaceutical development), which prove that this packaging does not affect the quality specifications of the method of use (eg. delivery rate and delivery amount) as well as the specifications for the quality, effectiveness and stability of the preparation according to each

pharmaceutical form and according to the specifications set in the reference pharmacopoeias, with the need to clarify how to control the degree of homogeneity and viscosity (homogeneity and viscosity) of the preparation during packaging and use.

Decisions of the Technical Committee for Drug Control at its session on 21/04/2022

*-Not approving the reception of new preparations containing this composition

Pipradrol HCL.	0.044 mg
Thiamine HCl	0.222 mg
Riboflavin Vitamin B_2	0.111 mg
Pyridoxine HCl	0.042 mg
Nicotinamide	1.111 mg
Choline	2.222 mg
Inositol	2.222 mg

And not approving to complete the registration procedures for the preparations under registration based on the decision of the Combined Specialized Scientific Committee for Internal Medicines Diseases at its session on 30/11/2021.

Note: -

The preparations were presented to the Combined Specialized Scientific Committee for Internal Medicines Diseases at its session on 30/11/2021:

Which recommended not approving the registration of the preparations, as there is no scientific rationale for combining Multivitamins with Pipradrol, which has a CNS stimulant effect, and therefore it may lead to misuse of the preparation.

Decisions of the Technical Committee for Drug Control at its session on 12/05/2022

*- Not approving the reception of new preparations and canceling the preparations under registration that contain Hydrocodone Bitartrate as There is no need to provide products containing this substance in Egypt, based on the decisions of the Specialized Scientific Committee for Chest Diseases at its two sessions on 11/02/2020 and 19/01/2021, and the decisions of the Non-Reference Medicines Committee at its two sessions on 26/07/2020 and 08/04/2021, and the decision of the Pharmacology Committee at its session on 25/02/2021.

Note: -

-**The preparation was presented to the Combined Specialized Scientific Committee for Chest Diseases at its session on 11/02/2020**:

It recommended rejecting the product due to discontinuing Circulation of the product at the FDA

And also, according to the FDA Risk Benefit Assessment

-**The preparation was presented to the Combined Specialized Scientific Committee for Chest Diseases at its session on 19/01/2021**:

The specialized scientific committee for chest diseases decided not to approve the preparation for the following reasons:

* Discontinuing the product by the FDA

*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

- **The preparation was presented to the Non-Referenced Medicines Committee at its session on 26/07/2020**:

Which recommended refusing to register the preparation Due to stopping its Circulation at the FDA and to avoid the many problems resulting from the misuse of Hydrocodone, in support of the decision of the Chest Committee on 11/02/2020.

-**The preparation was presented to the Non-Reference Medicines Committee at its session on 08/04/2021**:

Which recommended rejecting the registration of the preparation due to the serious side effects of Hydrocodone, according to the FDA leaflet for the preparation, 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

-**The preparation was presented to the Pharmacology Committee at its session on 25/02/2021**:

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

Decisions of the Technical Committee for Drug Control at its session on 26/05/2022

*-Approval to grant a period of 3 months from the date of the committee for the Circulation of preparations containing Halothane, after which the Circulation of the preparations in Egypt will be stopped in accordance with the rules, and the central Administration of operations will follow up on this, with companies obligated to do Dear Dr letter explaining the risks of using the preparation and the categories for whom its use is prohibited by the Central Administration of Pharmaceutical Care with applying the rules and allowing registered and under-registered preparations to be converted into export only, and not approving the reception of new preparations.

*-Regarding the decision of the Technical Committee at its session on 01/04/2021, which state that (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 Lidocaine solvent in a volume different from the quantity that will be dissolved. (provided that the solvent is registered as a separate preparation) Provided that a commitment is made to write the quantity with which the solvent will be dissolved - according to the approved leaflet - on the packaging and leaflet, with follow-up inspection, for a period of only one year from the date of the committee in order to reconcile the situation and to preserve the availability of preparations to the Egyptian patient, especially in the era of the Corona crisis and the need for antibiotics, with a referral to the Human medicines Registration Department to apply the rules. The Technical Committee for Drug Control at its session on 26/05/2022, decided to approve extending the deadline granted by the decision of the Technical Committee at its session on 01/04/2021 for another year ending on 01/04/2023.

*- Regarding registered veterinary preparations: In the case of that the pharmaceutical form is identical (the pharmaceutical form in accordance with the decision of the Technical Committee for Drug Control at its session on 12/01/2012) and differ the concentrations of the same company's preparations containing the same active substance, a commitment is made to unifying the names of these preparations and the company is given a year from Date of the committee to reconcile the situation and choose the name.

Decisions of the Technical Committee for Drug Control at its session on 02/06/2022

*- Not approving to complete the registration procedures for the product containing Sodium Picosulfate at a concentration of 10 mg in the pharmaceutical form tablets, and not approving the reception of new preparations based on the decision of the Specialized Scientific Committee for Internal Medicine at its session on 22/02/2022.

Note:

***The Specialized Scientific Committee for Internal Diseases decided at its session on 22/02/2022**: not to approve the registration of the preparation for the following reasons:

1. High concentrations of Sodium Picosulfate may cause severe diarrhea and imbalance of salts in the blood, especially in the elderly.
2. The availability of reference concentrations used in the Egyptian market (5 mg - 7.5 mg) that serve the same therapeutic purpose.
3. There are alternatives that have fewer side effects, such as Lubiprostone

*- Initial approval to complete the procedures for registering preparations containing Gefapixant 45 mg in the pharmaceutical form of tablets, provided that the registration procedures of the preparation by FDA is followed up and the developments are re-presented to the technical committee before issuing the registration license of any preparation containing this substance based on the decision of the combined specialized scientific committee for chest diseases. At its session on 23/02/2022.

Note:

***The Specialized Scientific Committee for Chest Diseases at its session on 23/02/2022, decided**: to postpone and address the company to present the results of the complete clinical studies for the reference preparation, especially since the

FDA has concerns about its efficacy despite the completion of the third phase of clinical studies in October 2020.

*- As for preparations containing Oxytocin, when they submit to receive registration license, their circulation is limited to hospitals only.

Decisions of the Technical Committee for Drug Control at its session on 21/07/2022

*- Not approving the reception of new preparations containing Theophylline & Ephedrine, not approving to complete the registration procedures for preparations under registration, and not approving to complete the procedures for re-registering registered preparations, based on the decision of the Combined Specialized Scientific Committee for Chest Diseases at its session on 23/02/2022.

Note: -

-**The Combined Specialized Scientific Committee for Chest Diseases decided at its session on 23/02/2022**:

not to approve the re-registration of the preparation because:

- The combination of theophylline and ephedrine has many dangerous side effects, such as heart arrhythmia
- The presence of Drug interaction Category C between the two substances Ephedrine & Theophylline, which requires close monitoring of the patient.
- Ephedrine is not mentioned in the guidelines for treating asthma, and its use in cases of bronchial asthma was stopped a long time ago.
-There are no studies indicating the safety and effectiveness of the formula

*- Not approving the reception of new preparations containing Aprocitentan and not approving to complete the registration procedures for preparations under registration, based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 27/04/2022

Note: -

The Combined Specialized Scientific Committee for Cardiovascular Diseases decided at its session on 27/04/2022: Rejection of the preparation due to incomplete clinical studies of the reference preparation, Phase 3 Active, not recruiting, which prove the safety and effectiveness of the preparation.

*- Not approving the reception of new preparations containing Betahistine in the form of Sustained Release Tablet, and not approving to complete the registration procedures for preparations under registration, based on the decision of the Specialized Scientific Committee for Ear, Nose, and Throat Diseases at its session on 09/02/2022.

Note: -

The Combined Specialized Scientific Committee for Ear, Nose and Throat Diseases decided at its session on 09/02/2022: not to approve the preparation for the following reasons:

1. The company did not submit approved scientific papers indicating the effectiveness of this pharmaceutical form.
2. The presented pharmaceutical form, Sustained Release Tablet, does not offer any advantage over the pharmaceutical form registered in the Egyptian market, Immediate Release, as the dose provided by the company is twice daily and the usual dose for registered preparations is twice daily as well.
3. The pharmacokinetics of this pharmaceutical form are unknown.
4. The composition is not referenced in this pharmaceutical form.

*-Not approving the reception of new preparations containing the combination (Betamethasone + Loratadine) in the form of Oral Liquid dosage forms, and not approving to complete the registration procedures for preparations under registration, based on the decision of the combined Specialized Scientific Committee for Pediatric Diseases at its session on 08/03/2022.

Note: -

-**The Combined Specialized Scientific Committee for Pediatric Diseases decided at its session on 08/03/2022**: to reject the preparation for the following reasons:

-The presence of Betamethasone in the preparation has a harmful effect on the growth of children during their development stages and a harmful effect on immunity and osteoporosis when used in children.
- Fear of preparation misuse, as allergy medications are widely used in children, and adding betamethasone to them will increase the side effects on children.
-The composition is not found in any scientific reference or any reference country.

*-Not approving the reception of new preparations containing the combination Bacitracin + Papain + Lysozyme in the form of Lozenges, and not approving to complete the registration procedures for preparations under registration, based on the decision of the Specialized Scientific Committee for Ear, Nose, and Throat Diseases at its session on 09/02/2022.

Note: -

-The Combined Specialized Scientific Committee for Ear, Nose and Throat Diseases decided at its session on 09/02/2022 the following:

The Committee still stick by its previous decision not to approve the registration of the preparation because it contains Bacitracin as local antibiotics, according to the Pharmacovigilance report dated 06/08/2020 which It includes the recommendation of the drug regulatory authority in France to withdraw preparations containing local antibiotics that are used in the treatment of diseases of the nose and throat.

Decisions of the Technical Committee for Drug Control at its session on 28/07/2022

*-For preparations containing Gemifloxacin in oral dosage forms:
Not approving the reception of new preparations, cancellation of preparations under registration, and suspension of the registered preparations production. A period of 3 months is given from the date of the committee for Circulation and reconcile the situation.

A recommendation will be submitted to the head of the Drug Authority to withdraw the preparations from the market and cancel the registration of the registered preparations after the expiry of this period, due to the loss of their scientific reference and based on a reply of The Egyptian Pharmacovigilance Center and the decision of the Combined Specialized Scientific Committee for Chest Diseases at its session on 20/07/2022.

Note:

-**The Vigilance Center was contacted about the safety of the product in the Egyptian market, and the reply was as follows**: The balance of risks and benefits is not in favor of the active substance, according to what was published by EMA, and the substance has lost its scientific reference.

-**The Combined Specialized Scientific Committee for Chest Diseases, in its session on 20/07/2022, recommended**: to refuse the preparation registration, as there are safer alternatives to Quinolones in the Egyptian market, as follows:
1- Since the balance of benefits to risks is not in favor of the product, according to the EMA report issued on 25/06/2009, which states that the balance of risks to benefits is not in favor of the active substance, according to what was published by EMA, and that the substance has lost its scientific reference:

The CHMP was concerned that Gemifloxacin may be more genotoxic (harmful to the DNA, the genetic material in cells) and that it may therefore cause more damage to the DNA than other fluoroquinolones. The Committee was also concerned there was not enough evidence of effectiveness of Gemifloxacin in patients with moderate community-acquired pneumonia when given as a five-day treatment. The seven-day treatment was not considered acceptable because of the risk of side effects. The Committee also noted that the information presented did not support the use of Gemifloxacin for chronic bronchitis because no studies were carried out to investigate whether Gemifloxacin was better than other treatments for this type of infection and because there were problems with the studies that were performed. Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Gemifloxacin in the treatment of community-acquired pneumonia and acute exacerbation of chronic bronchitis caused by bacterial infection did not outweigh its risks. The company informed the CHMP that there are no clinical trials or compassionate use programmes for Gemifloxacin in Europe.

2- Through the practical experience of the Chest Committee doctors, it was found that the use of Gemifloxacin causes: Severe skin rash

*-Not approving the reception of new preparations containing the formula (Beta -Sitosterol +Silver (Nano solution) in the form of Topical dosage forms and cancelling the preparations under registration based on the decision of the Combined Specialized Scientific Committee for Dermatology, Venereal Diseases and Andrology Diseases at its session on 30/05/2022 and the decision of the combined Specialized Scientific Committee for general surgery at its session on 19/06/2022.

Note:

- **The Combined Specialized Scientific Committee for Dermatology, Venereology and Andrology, at its session on 30/05/2022**, recommended: Not approving the registration of the preparation for the following reasons:

1. The studies presented do not contain a clinical study indicating the feasibility of the presented formula in terms of Efficacy, Pharmacokinetics & Pharmacodynamics.
2. The studies presented were conducted on a limited number of patients, and the study that was conducted in Japan (a reference country) was on animal cells.

-**The Combined Specialized Scientific Committee for General Surgery at its session on 19/06/2022, which decided**: to reject the preparation from a scientific point of view, as:

1- The studies presented do not include Efficacy, Pharmacokinetics & Pharmacodynamics.
2- The studies presented do not indicate the clinical stage (phase) that the study reached, and some studies do not indicate the number of patients on whom the study was conducted.
3. Some of the presented studies did not go beyond the stage of experimentation on animals.

Accordingly, it is not possible to decide on the composition based on the studies presented.

*-For preparations containing Chlorpheniramine at a concentration of 10 mg in the form of injection: approving to complete the procedures for registering the preparations, and their use is limited to hospitals only based on the decision of the Combined Specialized Scientific Committee for Internal Diseases at its session on 22/02/2022 and the decision of the Vigilance Committee at its session on 07/07/2022.

Note:

- **The Combined Specialized Scientific Committee for Internal Diseases, in its session on 22/02/2022**, recommended: Approving the re-registration of the preparation, provided that it is used in hospitals only, as it may lead to a disturbance in the heart rhythm and a drop in blood pressure that may lead to death, according to what was stated in the MHRA leaflet.

-**The Vigilance Committee held its session on 07/07/2022**, which decided: Limiting the use of Chlorpheniramine Maleate in the pharmaceutical form (injection) at a concentration of 10 mg to hospitals only due to the possibility of serious side effects such as heart rhythm disturbances and a drop in blood pressure that may lead to death and hypersensitivity (anaphylaxis). Which is difficult to deal with outside the hospital.

*-For preparations containing Proteolytic enzymes in oral dosage forms:
In continuation of the decision of the Technical Committee at its session on 04/06/2020, the following is added: "Preparations containing Proteolytic enzymes in the form of Oral Dosage Forms provided for the following therapeutic purpose are approved: as enzymes for digestion in the pharmaceutical form of tablets or capsules that give their effect in the stomach.

Note:

- **The Technical Committee for Drug Control, at its session on 04/06/2020**, decided based on what was presented: approval of the registration of preparations containing Proteolytic enzymes in the oral dosage form and approval to receive new preparations containing them, provided that the preparations are adhered to the pharmaceutical form and the leaflet of the reference preparation.

In the case of non-reference, adhering to the pharmaceutical form Enteric coated or Gastro resistant for preparations indicated for the therapeutic purpose of treating swelling and infiltration and as an adjuvant treatment for infections, based on the decision of the Non-reference Medicines Committee at its session

on 07/05/2020 and the decision of the Pharmacology Committee at its session on 16/04/ 2020 and the decision of the Scientific Committee for Rheumatology at its session on 02/04/2020. The application will begin from the month following the issuance of the decision.

Decisions of the Technical Committee for Drug Control at its session on 18/08/2022

*- For registered human preparations, in case of adding a raw material source, the company is allowed to conduct a dissolution rate study as follows (provided that the company has previously approved the bioequivalence study):

- Compared to the reference preparation and is allowed to be performed in the factory or one of the approved bioequivalence centers.

Or

- Compared to a production/pilot batch that was previously produced with the same composition and the same specifications of active and inactive materials and in the same factory, provided that withdrawal is through the central administration of operations and the company is committed to conducting it in the Egyptian Drug Authority's laboratories.

Decisions of the Technical Committee for Drug Control at its session on 25/08/2022

*- Approving the reception of new preparations containing the combination (Paracetamol + Ibuprofen) solution for intravenous infusion, for referenced concentrations only, starting from 01/09/2022, as an exception to the decision of the Technical Committee on 01/04/ 2010, and not exceeding the box number.

*-Not-approving to complete the registration procedures of the preparations under registration and not approving the reception of new preparations containing the combination (Crystalline Trypsin + Neomycin) in the Topical dosage form based on the decision of the Combined Specialized Scientific Committee of Dermatology and Venereology at its session on 30/05/2022.

Note: -

The Combined Specialized Scientific Committee for Dermatology and Venereology, at its session on 30/05/2022, recommended not approving the registration of the preparation because the company did not fulfill the committee's requests to submit studies indicating the effectiveness and safety of the formulation and did not clarify the therapeutic purpose of the submitted formulation.

*-Not- approving to complete the registration procedures of the preparations under registration and not approving the reception of new preparations containing the combination (Diethylamine + Flufenamic acid + Myrtecaine + Salicylic acid) in the Topical dosage form based on the decision of the Combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics at its session on 20/07/2022.

Note: -

The Combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics at its session on 20/07/2022:

It recommended not to approve the product for the following reasons:

1. There is no scientific reason to combine more than one NSAID substance in one formula, which leads to an increase in side effects.
2. The composition does not offer any therapeutic advantage over the alternatives available in the Egyptian market.
3. The company did not submit scientific files proving the effectiveness and efficiency of the formula.

*- Not-approving to complete the registration procedures of the preparations under registration and not approving the reception of new preparations containing Dyphylline in the form of tablets with a concentration of 200 mg, based on the decision of the combined Specialized Scientific Committee for Chest Diseases at its session on 20/07/2022.

- Note: -

The Combined Specialized Scientific Committee for Chest Diseases, at its session on 20/07/2022, recommended not approving the preparation due to non-commitment to submitting a scientific file or any studies on the preparation.

*- Not-approving to complete the registration procedures for preparations under registration and not approving to receive new preparations containing Proglumide based on the decision of the combined Specialized Scientific Committee for Internal Medicine at its session in
30/11/2021.

- Note: -

The Combined Specialized Scientific Committee for Internal Diseases, at its session on 30/11/2021, recommended not approving the registration of the preparation, as this active substance is not included in the international Guidelines for the treatment of stomach ulcers, and the company has not submitted sufficient scientific studies indicating the effectiveness and safety of the preparation, as well as the availability of alternatives in the Egyptian market for the same therapeutic purpose such as:

Proton Pump Inhibitors, Mucosal Protective & H2 Antagonists

*-For registered preparations containing the combination (Paracetamol + Chlorpheniramine + Pseudoephedrine) in the form of Syrup or Suspension, must be adhered to the reference concentrations and the reference form Suspension on re- registration.

Decisions of the Technical Committee for Drug Control at its session on 22/09/2022

*- Not approving to complete the registration procedures for preparations under registration and not approving to receive new preparations containing Evogliptin based on the decision of the Combined Specialized Scientific Committee for Endocrinology and Metabolism at its session on 29/08/2022.

Notes:

The Specialized Scientific Committee for Endocrinology and Metabolism, at its session on 29/08/2022, recommended not to approve the preparation from a scientific point of view, as follows:

- The company did not provide studies proving the effectiveness and safety of the formula.

- There are not enough approved studies for Evogliptin, as it is not referenced and is not traded in the Egyptian market.

*- Not approving to complete the registration procedures for preparations under registration that contain (Itopride + Esomeprazole) in the form of Sustained Release Capsule and not approving the reception of new preparations containing this composition until studies are conducted that confirm the effectiveness and safety of the preparation based on the decisions of the Combined Specialized Scientific Committee for Liver and Digestive System Diseases at its two sessions on 31/05/2021 and 23/05/2022.

Notes:

• **The combined specialized scientific committee for diseases of the liver and digestive system, at its session on 31/05/2021**: recommended not to approve the preparation for the following reasons:

1- The lack of a scientific rationale that combines two substances, one of which is short-acting, taken 3 times daily, and the other is long-acting, taken once.
2- Itopride, at a concentration of 150 mg, if taken once, severe side effects appear more clearly, such as its effect on cardiac arrhythmia and signs of Parkinson's paralysis.

•**The combined specialized scientific committee for diseases of the liver and digestive system, at its session on 23/05/2022**: recommended not to approve the preparation for the following reasons:
1- The company did not submit studies indicating the effectiveness and safety of the formulation in this pharmaceutical form, as Itopride is given in the form of immediate release and Esomeprazole is given in the form of Gastro-resistant or delayed release.
2- There are no scientific studies approved by scientific bodies that indicate the pharmacodynamics and pharmacokinetics of the presented formulation.

*- Not approving to complete the registration procedures for preparations under registration that contain Sodium Chloride 10% in the form of Inhalation Solution and not approving to receive new preparations based on the decision of the combined Specialized Scientific Committee for Chest Diseases at its session on 20/07/2022.

Note: -

The Combined Specialized Scientific Committee for Chest Diseases at its session on 20/07/2022:
It recommended not approving to register the concentration of 10% because the company did not submit studies supporting the use of this concentration and there was no need to use this high concentration for the therapeutic purpose provided by the company.

*- Not approving to complete the registration procedures for preparations under registration that contain (Levodopa + Carbidopa + Opicapone) and not approving to receive new preparations containing this combination based on the decision of the Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 31/08/2022.

Note: -

The Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases, at its session on 31/08/2022, recommended not approving the registration of the preparation for the following reasons:

1. The scientific file submitted by the company did not meet the committee's requirements in terms of the effectiveness and safety of the presented formula.
2. There is no scientific basis for combining Opicapone, which is given once a day, while Levodopa + Carbidopa, which is taken 6-8 times a day, depending on the patient's condition.

*- Not approving to complete the registration procedures for preparations under registration that contain Glibornuride and not approving to receive new preparations containing this substance based on the decision of the Combined Specialized Scientific Committee for Endocrinology and Metabolism at its session on 06/06/2022.

Note: -

The Combined Specialized Scientific Committee for Endocrine and Metabolism Diseases, in its session on 06/06/2022: recommended not to approve the preparation from a scientific point of view, because it is old generation sulfonyl urea and no longer marketed in any country in the world, and there are many alternatives in the Egyptian market of new sulfonyl urea generation, which Proven efficiency and safety.

Decisions of the Technical Committee for Drug Control at its session on 29/09/2022

*-Allowing companies to apply to Administration of Human Pharmaceuticals Variations for requesting the addition of a fourth source for a single active raw material, with applying the rules (provided that the physical properties and specifications of the fourth source analysis certificate match all registered sources for the same active raw material).

Decisions of the Technical Committee for Drug Control at its session on 20/10/2022

*- Limit the use of all preparations containing Chlorpheniramine maleate in the form of injection to hospitals only.

*- Emphasizing that the vigilance monitoring of any product means periodic follow-up of it unless otherwise stated in the decision.

Decisions of the Technical Committee for Drug Control at its session on 03/11/2022

*- Not approving to complete the registration procedures for preparations containing Ibacitabine 10 mg/gm in the topical dosage form, and not approving the reception of new preparations, based on the decision of the Combined Specialized Scientific Committee of Dermatology, Venereology and Andrology at its session on 26/09/2022.

Note:

- **The Combined Specialized Scientific Committee for Dermatology, Venereal and Andrology Diseases, at its session on 26/09/2022**., recommended: Not approving the registration of the preparation, as the company did not submit scientific files indicating the effectiveness and safety of the formulation.

*- Not approving to complete the registration procedures for preparations containing Dolasetron Mesylate (as monohydrate) at a concentration of 100 mg in the oral dosage form, and not approving the reception of new preparations, based on the decisions of the Combined Specialized Scientific Committee for Internal Diseases at its session on 29/03/2022 and the Combined Specialized Scientific Committee for cancer and radioisotopes at its session on 21/09/2022.

Note:
- **The Combined Specialized Scientific Committee for Internal Diseases at its session on 29/03/2022, which decided**: The committee still stands by its previous decision at its session on 21/04/2021, where it decided not to approve the preparation for the following reasons:

1. Serious side effects of dolasetron mesylate, according to FDA Drug Safety Communication, are: 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

- **The Specialized Scientific Committee for Cancer and Radioisotopes at its session on 21/09/2022, recommended:** not to approve the registration of the preparation, as it does not provide any therapeutic advantage over the alternatives available in the Egyptian market, Ondansetron & Granisetron, in addition to withdrawing the active ingredient from many Reference countries.

Decisions of the Technical Committee for Drug Control at its session on 17/11/2022

*- Not approving the reception of new preparations containing the formula Acetylsalicylic Acid and Proton pump inhibitor even if they are reference and cancelling the preparations under registration, and cancelling the decision of the Technical Committee on 10/01/2013.

Decisions of the Technical Committee for Drug Control at its session on 08/12/2022

*- Not approving the reception of new preparations and not approving to complete the registration procedures for preparations under registration that contain Colestilan (Colestimide) at a concentration of 3 gm in oral dosage form.

*- Approval to receive new preparations containing Silymarin or Milk Thistle Extract for local Circulation, or to receive requests to transfer any preparations containing Silymarin or Milk Thistle Extract from export to local Circulation as herbal medicines, with cancelling the decision of the Technical Committee at its session on 01/11/2012.

Note: -

The Technical Committee decided at its session on 01/11/2012: not to approve the reception of new preparations containing Silymarin or Milk Thistle Extract for local Circulation and not to approve requests to transfer any preparations containing Silymarin or Milk Thistle Extract from export to local Circulation due to the availability of similars & alternatives.

*-Approval to exclude herbal drug preparations from the decision of the Technical Committee for Drug Control at its session on 25/08/2011, similar to nutritional supplement preparations that were previously excluded from this decision in accordance with the decision of the Technical Committee for Drug Control at its session on 26/06/2014.

Note: -

The Technical Committee decided at its session on 26/06/2014 not to implement the decision of the Technical Committee at its session on 25/08/2011 regarding not approving packaging for tablets or capsules containing more than three strips on nutritional supplement preparations.

Decisions of the Technical Committee for Drug Control at its session on 22/12/2022

*- Not approving the reception of new preparations and not approving to complete the registration procedures for preparations under registration that contain the formula Pantoprazole + Sodium Bicarbonate in the form of Delayed Release Granules for Oral Suspension based on the decision of the combined specialized scientific committee for diseases of the liver and digestive system at its session on 23/05/2022.

Note: -

The combined Specialized Scientific Committee for Liver and Digestive System Diseases recommended, at its session on 23/05/2022, not to approve the registration of the preparation for the following reasons:

1. The Company not applied Scientific Rationale for such a pharmaceutical form for the formulation provided.
2. This pharmaceutical form will cause the inactivation of Sodium Bicarbonate, which is required to be effective at the beginning of taking the dose in order to neutralize stomach acid and maintain the effect of Pantoprazole.

*- Not approving the reception of new preparations and not approving to complete the registration procedures for preparations under registration that contain the combination Ticagrelor 90 mg + Aspirin 81 mg based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 11/09/2022.

Note: -

The Combined Specialized Scientific Committee for Cardiovascular Diseases recommended in its session on 11/09/2022 not to approve the preparation from a scientific point of view due to the incompatibility of the doses of the two substances in the presented formulation, as according to the approved

scientific references (FDA, BNF 83) the dose of Ticagrelor is 90 mg twice daily and The maximum dose for Aspirin is one tablet daily, as it should not exceed 100 mg daily.

Acc. to FDA:

-Initiate treatment with Ticagrelor 180 mg (two 90 mg tablets) oral loading dose.
-Continue treatment with 90 mg twice daily.
-Use Ticagrelor 90 mg twice daily with a daily maintenance dose of aspirin of 75-100 mg.
- Maintenance doses of aspirin above 100 mg decreased the effectiveness of Ticagrelor.
- Avoid maintenance doses of aspirin above 100 mg daily

*- Not approving the reception of new preparations and not approving to complete the registration procedures for preparations under registration that contain the combination Mosapride + Rabeprazole based on the decision of the combined Specialized Scientific Committee for Liver and Digestive System Diseases at its session on 23/05/2022.

Note: -

The combined Specialized Scientific Committee for Liver and Digestive System Diseases recommended, at its session on 23/05/2022, not to approve the registration of the preparation for the following reasons:

1- There is no scientific basis for using the two active ingredients together.
2- Rabeprazole Sodium is given in the form of an enteric coated tablet or cap, and there is no reference product in the form of SR.
3- There is no scientific evidence to combine the two substances together as a fixed dose combination in terms of Pharmacokinetics.
4- The presented composition does not offer any new therapeutic advantage over using each substance individually.

*- Not approving the reception of new preparations and not approving to complete the registration procedures for preparations under registration that contain the combination Lovastatin + Niacin based on the decisions of the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 11/09/2022 and the Pharmacovigilance Committee on 27/06/2019.

Note:

- The Combined Specialized Scientific Committee for Cardiovascular Diseases recommended in its session on 11/09/2022 not to approve the preparation and The committee believes that there is no objection to using niacin and Lovastatin separately in the cases that require that, in accordance with the approved international protocols, but the committee refuses to use them together in one tablet, according to what was published in the Federal Register, regarding the withdrawal of the original product Advicor (Lovastatin 20 mg + Niacin 500 mg ER tablets) from the FDA because it did not reduce the incidence of cardiovascular disease risks.

- **On 27/06/2019, the Pharmacovigilance Committee recommended** rejecting the formulation as it has no additional benefit in exchange for its risks, according to the FDA circular 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

Decisions of the Technical Committee for Drug Control at its session on 29/12/2022

*-Approval to receive new preparations containing the formulation (Amlodipine +Bisoprolol Fumarate) at the following reference concentrations 5/10,10/10,10/5, based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 18/12/2022.

Note:
the Combined Specialized Scientific Committee for Cardiovascular Diseases At its session on 18/12/2022, recommended the following: Approval of this formulation at the concentrations provided because it is used in the treatment of high blood pressure patients in accordance with international guidelines.