Decisions of the Technical Committee at its session on 02/01/2020

*- Regarding preparations that contain the composition (Sofosbuvir + Daclatasvir) in the form of Bilayer Tablets:

Approval of the exemption from conducting clinical studies, provided that the remaining requirements of the Drug Development Committee on 12/08/2018 are adhered to.

- Note:

1-The Technical Committee for Drug Control decided at its session on 15/11/2018:

Approval to receive new preparations containing the combination (Sofosbuvir + Daclatasvir) while adhering to the decision of the Drug Development Committee on 12/08/2018 and the decision of the Specialized Scientific Committee for Gastrointestinal and Liver Diseases on 18/10/2018.

2-It was presented to the Pharmaceutical Development Committee at its session on 12/08/2018:

Which recommended that from a scientific and pharmaceutical standpoint, there is no objection to completing the registration procedures, but on the condition that the company submits the following:

1-Composition certificate.

2-Accelerated stability study at 40ºC & 75 ºC relative humidity including determination of all related and degradation substances identified by the reference product.

3-Comparative dissolution study in pH 1.2, pH 4.5, pH 6.8 & the most suitable media for both products (Sovaldi & Daclanza) at the initial and final time intervals of the stability study.

If these studies are accepted, the company will conduct a Fast and Fed bioequivalence study and clinical studies based on the decision of the Specialized Scientific Committee for Gastrointestinal and Liver Diseases.

*- Canceling the preparations under registration and not approving the reception of new preparations containing the composition (Asunaprevir + Daclatasvir) Based on the decision of the Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 22/11/2018 and the Pharmacology Committee on 14/11/2019.

Note:

1- The Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 22/11/2018:

Which recommended rejecting the preparation due to the lack of sufficient studies on the formulation proving its safety and effectiveness in treating Genotype 4 C virus.

2- The Pharmacology Committee at its session on 14/11/2019:

Which recommended refusing to register the preparations because there is no evidence of the effectiveness and safety of the formulation in treating HCV Genotype 4.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Ipragliflozin + Metformin) Based on the decision of the Specialized Scientific Committee for Endocrinology and Metabolism at its session on 25/12//2017 and 04/12/2019 and the Pharmacology Committee at its session on 12/10/2017.

Note:

1- The Specialized Scientific Committee for Endocrinology and Metabolism at its session on 25/12/2017:

Which recommended rejecting the preparations because there is no scientific reference for combining the two substances in one formula.

2- It was represented to the specialized scientific committee for Endocrinology and Metabolism at its session on 04/12/2019:

Which decided that it still stuck to its previous opinion on 25/12/2017

3- The Pharmacology Committee at its session on 12/10/2017:

Which considered that the preparation contains the full usual dose of Ipragliflozin with half the recommended daily dose of Metformin, in violation of the rules followed in the treatment of type 2 diabetes, so the committee recommended rejecting the preparation.

*- Canceling the preparations under registration and not approving the reception of new preparations containing the composition (Calcium dobesilate + Lidocaine) In the form of Rectal Suppository based on the decision of the Specialized Scientific Committee for General Surgery at its session on 21/11/2018 and the Pharmacology Committee at its session on 14/02/2019.

Note:

1- The Specialized Scientific Committee for General Surgery at its session on 21/11/2018:

Which recommended refusing to register the product due to its stop circulation in Portugal and Italy and the lack of sufficient studies proving the safety and effectiveness of the product.

2- The Pharmacology Committee at its session on 14/02/2019:

Which recommended refusing to register the aforementioned formulation due to the lack of evidence proving the effectiveness and safety of its use in this pharmaceutical form.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Troxerutin in pharmaceutical form Ophthalmic preparations based on the decision of the Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 04/03/2019 and the Pharmacology Committee at its session on 07/05/2019.

Note:

1- The Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 04/03/2019:

Which recommended refusing to register the preparation due to the lack of sufficient studies on the use of this substance in this pharmaceutical form.

2- The Pharmacology Committee at its session on 07/05/2019:

Which recommended rejecting the registration of the preparation, as there is no evidence of the effectiveness and safety of using Troxerutin in this pharmaceutical form.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Atropine with concentration 0.1 mg/ml in the pharmaceutical form Ophthalmic preparations based on the decision of the Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 24/06/2019 and the Pharmacology Committee at its session on 07/11/2019.

Note:

1- The Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 24/06/2019:

Which recommended rejecting the preparation due to the ineffectiveness of the provided concentration.

2- The Pharmacology Committee at its session on 07/11/ 2019:

Which recommended rejecting the registration of the preparation, as this formulation is not registered in any reference country, and the presented studies do not provide sufficient information proving the effectiveness and safety of use.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Citicoline at a concentration of 100 mg/10ml in the form of Oral Solution based on the decision of the Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 06/11/2019 and the Pharmacology Committee at its session on 28/11/2019.

Note:

1-The Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 06/11/2019:

It recommended Rejecting the preparation because the provided concentration is less than the therapeutic dose: (Sub therapeutic) as the daily dose based on international recommendations is 1000-2000 mg/day.

2-The Pharmacology Committee at its session on 28/11/2019:

Refusal to register the preparation, as the usual daily dose of this medicine is 500 mg to 2000 mg, and the concentration of the preparation provided by the company is one tenth of the concentration of the reference preparation, which requires taking large quantities of the medicine (which may reach more than one package per dose) to reach the required dose.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Ginkgo Biloba in the form of Ophthalmic Preparations based on the decision of the Specialized Scientific Committee for Eye Diseases at its session on 23/09/2019 and the Pharmacology Committee at its session on 28/11/2019.

Note:

1- The Specialized Scientific Committee for Eye Diseases at its session on 23/09/2019:

The formulation was rejected due to the lack of sufficient accredited scientific studies proving the effectiveness and safety of Ginkgo Biloba in the pharmaceutical form provided as eye drops.

2- The Pharmacology Committee at its session on 28/11/2019:

Ginkgo biloba is not registered in any of the reference countries as an Ophthalmic solution or for use in the indications provided by the company. Rather, it is registered only as Oral dosage forms for various indications of use, and the safety or effectiveness of its use in the eye has not been proven. Therefore, the committee recommended refusing to register the product.

*- Regarding preparations that contain the composition (Sofosbuvir + Velpatasvir):

Approval of the decision of the committee assembled from members of the Pharmacovigilance Committee and the members invited in accordance with the approval of the Head of Administration at its session on 02/05/2019, which states:

"Obligating companies to own products containing Sofosbuvir + Velpatasvir by fulfilling the standards stipulated in the Guidelines of Good Pharmacovigilance Practice GVP-Arab followed by the center, including: for Additional monitoring (Inverted Black Triangle).

As for the study, the committee recommends making Registry in cooperation with the National Anti-Virus Committee, provided that the following is done to ensure the success of the Registry:

1) Some information should be added to the data that is already collected in order to serve the purpose of the Registry:

-Trade name of the preparation.

-Efficacy data.

-Serious and non-serious adverse effects.

-Safety concerns included in the risk management plan.

-Relapse rate.

-Where the Registry goals are the evaluation of preparations containing Sofosbuvir + Velpatasvir in Clinical practice in terms of effectiveness, adverse effects and relapse rate for cases that have already been treated.

2) Obligating companies to own products containing Sofosbuvir + Velpatasvir by continuing to collect information with the National Anti-Virus Committee.

3) Obligating companies to own products containing Sofosbuvir + Velpatasvir by collecting safety information from the Private market Providing it to the Pharmacovigilance Center and presenting it in accordance with the Guidelines of Good Pharmacovigilance Practice GVP-Arab.

4) The preparations containing Sofosbuvir + Velpatasvir must have been added to the committee's treatment protocol.

5) Its continuation should be reconsidered after one year from its commencement.

With a recommendation to consider the rest of the new DAAs preparations for the treatment of HCV to evaluate them individually, guided by experiencing The Registry In preparations containing: "Sofosbuvir + Velpatasvir"

The Committee recommends to conduct a retrospective study for all cases; First Line & Relapsers for 100 patients in each of the following: Cairo Liver Institute - Menoufia Liver Institute - Al-Rajhi Hospital, Assiut - Kasr Al-Aini Center. The study results shall be submitted to the Pharmacovigilance Center in accordance with follow-up with the Hepatitis Virus Control Committee.

Decisions of the Technical Committee at its session on 30/01/2020

*- Canceling the preparations under registration and not approving the reception of new preparations containing the composition
(Gabapentin+ Cyanocobalamine + Thiamine) Based on the decision of the Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 03/10/2018 and the Pharmacology Committee at its session on 31/10/2019.

Note:

1- The Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 03/10/2018:

Which recommended rejecting the combination as it does not provide a therapeutic advantage in Neuropathy treatment over the alternatives available in the Egyptian market as well as the lack of need for it.

2- The Pharmacology Committee at its session on 31/10/2019:

Which recommended rejecting the registration of the preparation for the same reason mentioned in the Specialized Scientific Committee decision on 03/10/2018, as the formulation does not add any therapeutic advantage over the use of Gabapentin individually for the treatment of Peripheral Neuritis.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Clascoterone in the form of Topical Dosage forms based on the decision of the Specialized Scientific Committee for Dermatology,

Venereology and Andrology at its session on 23/12/2019 and the Non-Reference Medicines Committee at its session on 12/12/2019.

Note:

1-The Specialized Scientific Committee for Dermatology, Venereology and Andrology at its session on 23/12/2019:

Which recommended not approving the registration of the preparation due to the lack of sufficient studies indicating the safety and effectiveness of this preparation, as the innovator preparation is still under clinical studies in international bodies.

2-The Non-Reference Medicines Committee at its session on 12/12/2019:

Which recommended not approving the registration of the preparation due to the absence of any information in the known scientific references confirming its effectiveness and safety, with the possibility of considering registering the preparation after completing the procedures for registering the substance in the FDA.

*- Canceling the preparations under registration and not approving the reception of new preparations containing the composition (Amoxicillin 500mg + Clavulanic acid 62.5mg) at these concentrations and in pharmaceutical form sachet, based on the decision of the Specialized Scientific Committee for Pediatric Diseases at its session on 23/04/2019, the Specialized Scientific Committee for Internal Medicine Diseases at its session on 31/12/2019, and the Pharmacology Committee at its session on 22/08/2019.

***Note*:**

1-The Specialized Scientific Committee for Pediatric Diseases at its session on 23/04/2019:

Which decided that it still adheres to its previous opinion of rejecting the preparation for the following reasons: The dose must be calculated and divided according to the child's weight, and this does not apply to this pharmaceutical form.

2-The Pharmacology Committee held its session on 22/08/2019:

Which recommended rejecting the registration of the preparation, since the dose used in the age group (Adult & Children more than 40 kg) acc. to the company, is the same dose of 1000 mg/125 mg, and therefore there is no advantage to using the preparation under study.

3-The Specialized Scientific Committee for Internal Medicine at its session on 31/12/2019:

Which recommended rejecting the preparation because it has no therapeutic advantage over the alternatives available in the Egyptian market, and in support of the Pharmacology Committee decision at its session on 22/08/2019.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Fursultiamine in the form of injection based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 30/07/2019 and the Pharmacology Committee at its session on 02/01/2020.

Note:

1-The Specialized Scientific Committee for Internal Medicine at its session on 30/07/2019:

Which recommended not approving the preparation because there are many preparations in the Egyptian market that contain Vitamin B1, furthermore, its use by intravenous injection may reduce its use and do not add benefit to the treatment.

2-The Pharmacology Committee at its session on 02/01/2020:

Which recommended refusing to register the preparation for the same reasons mentioned in the of the Specialized Scientific Committee for Gastrointestinal Diseases decision on 30/07/2019.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Obeticholic acid with concentration 25 mg based on the decision of the Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 29/03/2018 and the Pharmacology Committee at its session on 26/12/2019.

Note:

1-The Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 29/03/2018:

Which recommended rejecting the preparation because there is no scientific reference for this concentration and the lack of sufficient studies proving the safety and effectiveness of the preparation.

2-The Pharmacology Committee at its session on 12/26/2019:

Which recommended rejecting the registration of the preparation due to the lack of a reference concentration, as the maximum dose of this substance is 10 mg once daily. Moreover, the studies submitted by the company indicated that there is no additional effectiveness of the concentration of 25 mg over the reference concentration of 10 mg, which exposes the patient to additional unjustified side effects.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Mepenzolate based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 31/12/2019 and the Pharmacology Committee at its session on 14/02/2019.

Note:

1-The Specialized Scientific Committee for Internal Medicine Diseases held its session on 31/12/2019, which recommended:

Rejecting the preparation for the following reasons:

1- Mepenzolate has no therapeutic role in stomach and duodenal ulcers.

2-The presence of more effective and safer modern alternatives.

3- Serious side effects of acetylcholine antagonists that may reach the point of paralysis.

2-The Pharmacology Committee held its session on 14/02/ 2019, which recommended:

Not approving the registration of the preparation due to the lack of information indicating the effectiveness or safety of the preparation, especially with the suspension of circulating similar preparations in both Sweden and FDA.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Mometasone 50 mcg + Olopatadine 665 mcg) at these concentrations based on the decision of the Specialized Scientific Committee for Ear, Nose and Throat Diseases on 07/05/2019.

Note:

The Specialized Scientific Committee for Ear, Nose and Throat Diseases on 5/7/2019 decided:

The formulation was not approved due to the lack of completion of clinical studies that indicate the safety and effectiveness of the formulation and the full presentation of its results.

Decisions of the Technical Committee at its session on 13/02/2020

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Chloramphenicol in the form of Vaginal preparations based on the decision of the Pharmacology Committee at its session on 02/01/2020 and the Specialized Scientific Committee for Obstetrics and Gynecology at its session on 26/03/2019 and also for not submitting sufficient scientific studies.

Note:

1-The Specialized Scientific Committee for Obstetrics and Gynecology at its session on 26/03/2019:

Which recommended rejecting the preparation due to the lack of sufficient accredited scientific studies indicating the effectiveness and safety of the preparation

2-The Pharmacology Committee at its session on 02/01/2020:

Which recommended rejecting the registration of the preparation, as the substance Chloramphenicol has side effects and is only used in specific and precise medical cases that do not include the indications for use provided by the company that owns the product

*- Cancellation of preparations under registration and not approving the reception of new preparations containing them Acotiamide based on the decision of the

Specialized Scientific Committee for Internal Medicine at its session on 11/04/2017, and also due to the lack of sufficient scientific studies.

Note:

The Specialized Scientific Committee for Internal Medicine held its session on 11/04/2017:

The committee still stands by its previous decision not to approve the preparation due to the lack of sufficient scientific studies indicating efficiency and effectiveness, in addition to the fact that this preparation has serious side effects, as it leads to the accumulation of Acetylcholine which leads to a decrease in heart rate and constriction of the bronchi.

Decisions of the Technical Committee at its session on 20/02/2020

*- Approval to receive new preparations containing the formulation (Rosuvastatin 40 mg + Ezetimibe 10 mg) based on the decision of the Pharmacology Committee on 30/01/2020.

*- Approval to receive new preparations containing the formulation (Omeprazole + Sodium Bicarbonate) based on the decision of the Pharmacovigilance Committee on 16/01/2020.

Decisions of the Technical Committee at its session on 27/02/2020

*- Regarding the controls and procedures for registering Oncology preparations and Immunosuppressive:
Approval of the following proposal submitted by the General Administration of Registration:

First: All Oncology and Immunosuppressant preparations - manufactured locally or imported - under registration or registered and not yet marketed - at the time of issuance of this decision - the following shall be submitted for approval as a condition for completing registration procedures or as a condition for release for production batches:

- Accelerated stability study for 6 months on a pilot or first production batch.
- Quality file Module 3 (S-part & P-part) for evaluation.
- Study the dissolution rate and study the bioequivalence of the preparations that require this, and in accordance with what is determined by the specialized scientific committee to evaluate studies of availability and bioequivalence.

Second: All Oncology and Immunosuppressive preparations - manufactured locally or imported - registered - and actually marketed at the time of issuance of this decision - must adhere to the following:

- Follow up with the Egyptian Pharmaceutical Vigilance Center for these preparations to monitor safety and adverse effects. The company is committed to

following up with the center at least every 3 months or according to the time limits specified by the center.

- Preparing records showing the places where these preparations are dispensed, as well as compiling reports on the effectiveness of the preparations. Especially those disbursed through institutes, hospitals, medical centers specialized in treating Oncology, or private hospitals, for evaluation by the competent departments upon request.
- Submit Quality File Module 3 (S-part & P-part) for evaluation and approval when making any change to the registered product or when re-registering.

Third:

- Commitment to all conditions and requirements necessary to complete registration procedures, as well as studies and conditions contained in the marketing authorization license in accordance with what is determined by ministerial decisions and the rules governing this.
- The following are considered as an additional feature when evaluating the quality profile of the active substance (S-part):

The active substance must be imported from one of the reference countries, or the production line in the factory from which the active substance is imported has been inspected or obtained a valid GMP certificate from one of the reference countries, or approved by the FDA or obtained EUDRA GMP & to be considered, the certificate of the CEP issued from EDQM.

- Registration file CTD requests is allowed to be completed on one pilot or production batch according to the condition of each product.
- Follow-up by the inspection to meet the requirements.

*- Approval to receive new preparations containing Ibuprofen Lysine in pharmaceutical form injection excluding it from the Technical Committee's decision on 01/04/2010 concerning NSAIDs.

Decisions of the Technical Committee at its session on 05/03/2020

*- Canceling the preparations under registration and not approving the reception of new preparations containing the composition (Metoprolol + Ticagrelor) based on the decision of the Specialized Scientific Committee for Cardiovascular Diseases on 21/11/2018 and the Pharmacology Committee at its session on 06/02/2020.

Note:

1-The Specialized Scientific Committee for Cardiovascular Diseases at its session on 21/11/2018:

Which recommended to reject the combination for the following reasons:

1-There are not sufficient studies proving the safety and effectiveness of the formula.

2- It is not included in the international guidelines for the treatment of Acute Coronary Artery Disease.

2-The Pharmacology Committee at its session on 06/02/2020:

Which recommended refusing to register the product for the same reasons mentioned in the decision of the Specialized Scientific Committee for Cardiovascular Surgery.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Levonadifloxacin in the form of Oral dosage forms based on the decision of the Specialized Scientific Committee for

Dermatology, Venereology and Andrology at its session on 11/03/2019 and the Pharmacology Committee at its session on 06/02/2020.

Note:

1-The Specialized Scientific Committee for Dermatology, Venereology and Andrology at its session on 11/03/2019:

It recommended rejecting the preparation as the innovator preparation is still under clinical studies and not providing complete studies indicating its efficacy, safety and effectiveness.

2-The Pharmacology Committee at its session on 06/02/2020:

It recommended refusing to register the preparation, as the submitted studies did not prove the effectiveness and safety of using the preparation.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Befunolol in the form of Ophthalmic Dosage forms based on the decision of the Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 23/09/2019 and the Pharmacology Committee at its session on 20/02/2020.

Note:

1-The Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 23/09/2019:

It recommended rejecting the preparations due to lack of need and the presence of other alternatives available in the Egyptian market, and stopping its circulation in France and Italy.

2-The Pharmacology Committee at its session on 20/02/2020:

Which recommended refusing to register the preparations, as the substance Befunolol is not circulated in any reference country and has been withdrawn from the only countries where it is registered, which are France and Italy, and therefore the safety of its use has not been proven.

*- Cancellation of preparations under registration and not approving the reception of new preparations with the formulation:
(Magnesium aspartate + L Lysine Hcl + L Leucine + L Phenylalanine + Valine + Ascorbic acid) in the form of Oral dosage forms based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 31/12/2019 and the Pharmacology Committee at its session on 06/02/2020.

Note:

1-The Specialized Scientific Committee for Internal Medicine Diseases held its session in 31/12/2019:

Which recommended rejecting the preparation for the following reasons:

1-The presented composition has no clear therapeutic purpose.

2- Misuse of the presented composition may lead to kidney damage, and in the case of minor liver dysfunction, it may lead to hepatic coma.

3- The presence of magnesium and its oral use may lead to diarrhea and blood salt disturbances.

2-Pharmacology Committee at its session on 06/02/2020:

Which recommended refusing to register the preparation in support of the decision of the Specialized Scientific Committee for Internal Medicine Diseases on 31/12/2019, as the preparation does not have a clear therapeutic purpose and the formulation misuse may lead to harm to some kidney or liver patients.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Oliceridine based on the decision of the Specialized Scientific Committee for Pain Diseases and Anesthesia at its session on 03/03/2020 and the Pharmacology Committee at its session on 24/12/2015.

Note:

1-The Specialized Scientific Committee for Pain Diseases and Anesthesia at its session on 03/03/2020:

The committee recommends rejecting Oliceridine substance as it is still under clinical studies and complete studies have not been provided indicating the effectiveness and safety of the substance.

2-The Pharmacology Department reported the implementation of the decision of the Pharmacology Committee at its session on 24/12/2015:

Regarding the preparations that are still under clinical studies, the committee refused to approve the registration of the preparations, as the effectiveness and safety of these materials are not yet known.

The decision applies to all similar cases of preparations that apply for registration with the Egyptian Ministry of Health and the active ingredients included in their composition are still under clinical studies globally.

*- The substance N-acetylcysteine is recorded according to its classification by reference.

Decisions of the Technical Committee at its session on 16/04/2020

*- Regarding cases of Pack addition for export purposes, which require requirements approved by the Variation Committee:

A commitment is made to submit a 6-month accelerated stability study on a production batch, and release will only take place after the approval of 3-month accelerated stability study.

Decisions of the Technical Committee at its session on 23/04/2020

*- Approval to receive new products containing the formula (Bromelain + Trypsin + Rutoside Trihydrate) with reference concentrations, based on the decision of the Specialized Scientific Committee for Rheumatic Diseases at its session on 02/04/2020 and the decision of the Pharmacology Committee at its session on 31/01/2019.

Decisions of the Technical Committee at its session on 30/04/2020

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Anaprazole based on the decision of the Specialized Scientific Committee for Internal Medicine at its session on 27/11/2018 and the Pharmacology Committee at its session on 24/12/2015.

Note:

1-It was presented to the Specialized Scientific Committee for Internal Medicine Diseases at its session on 27/11/2018:

Which recommended not approving the product.

2-The Pharmacology Committee decided at its session on 24/12/2015:

A general decision on all preparations submitted for registration based on the presence of preparations submitted for registration in the reference countries that are still in the stages of clinical studies:

Not approving the registration of the preparations, as the active ingredients included in their composition are still in the stages of clinical studies, and therefore the safety of these substances is not yet known. Therefore, the committee doesn't approve to register these preparations, and the decision applies to all similar cases of preparations that are submitted for registration with the Egyptian Ministry of Health and the active ingredients included in its composition are still under clinical studies worldwide.

*- Cancellation of the preparations under registration and not approving the reception of new preparations containing the combination (Etoricoxib

+Tizanidine) based on the decision of the Specialized Scientific Committee for Rheumatic Diseases and Rehabilitation at its session in 02/08/2018 and the Pharmacology Committee held its session on 24/12/2015.

Note:

1-It was presented to the Specialized Scientific Committee for Rheumatology and Rehabilitation Diseases at its session 02/08/2018:

The committee recommends rejecting the preparation because:

1-Each material is available separately in the Egyptian market.

2-Using the two substances together is used in limited cases.

3- The presence of Tizanidine prevents gradation in dosage, as this concentration causes drowsiness and dizziness.

2-The Pharmacology Committee decided at its session on 24/12/2015:

A general decision on all preparations submitted for registration based on the presence of preparations submitted for registration in the reference countries that are still in the stages of clinical studies:

Not approving the registration of preparations, as the active ingredients included in their composition are still in the stages of clinical studies, and therefore the safety of these substances is not yet known. Therefore, the committee doesn't approve to register these preparations, and the decision applies to all similar cases of preparations that are submitted for registration with the Egyptian Ministry of Health and the active ingredients included in its composition are still under clinical studies worldwide.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the combination (Paracetamol + Lignocaine) in the form of injection based on the decision of the Specialized Scientific Committee for Pediatric Diseases at its session on 04/02/2020, the Specialized Scientific Committee for Internal Medicine Diseases at its session on 03/03/2020, the Specialized Scientific Committee for Anesthesia at its session on 03/03/2020 and the Non-Reference Medicines Committee at its session on 02/01/2020.

Note:

1-It was presented to the Specialized Scientific Committee for Pediatric Diseases at its session on 04/02/2020

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

1- There is no use of Lignocaine in pediatrics for the therapeutic purpose provided by the company.

2- There is no use of Paracetamol IM in pediatrics.

2-It was presented to the Specialized Scientific Committee for Internal Medicine at its session on 03/03/2020:

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

1. Using lignocaine intravenously may cause a heart rhythm disorder and may be fatal.

2. The safety of giving Paracetamol intramuscularly hasn't been proven in scientific references or reference countries.

3. The preparation was previously rejected by the Specialized Scientific Committee for Pediatric Diseases on 04/02/2020 and the Non-Reference Medicines Committee on 20/02/2020.

3-It was presented to the Specialized Scientific Committee for Anesthesia at its session on 03/03/2020:

It recommended rejecting the preparation for the following reasons:

1- The concentration of Lignocaine is unjustified and may represent a risk with repeated use.

2- Not providing sufficient studies on the composition and not providing approved recommendations for the use of Paracetamol IM or IV (bolus).

4-The following was presented to the Non-Reference Medicines Committee at its session on 02/01/2020:

It recommended not approving the registration of the preparation because there is no scientific basis for combining Paracetamol & Lidocaine in the form of an IV ampoule, as Lidocaine can cause side effects in the administration of the route. In the case of the IM route, there is also no need to add Lidocaine, as Paracetamol does not cause irritation

Decisions of the Technical Committee at its session on 14/05/2020

*- Approval of the following proposal submitted by the Human Medicines Registration Department, which includes:
Regarding the decisions of the Technical Committee approving the reception of some products for which a decision had previously been issued by the Technical Committee to refuse to receive them: The decision will be applied to inquiry requests submitted starting from the month following the issuance of the decision in order to achieve the principle of equal opportunities between companies and to allow time to modify the program for receiving inquiry requests.
(The decision applies to veterinary preparations and biological preparations).

*- Approval to receive new preparations containing Meloxicam in the form of IV Injection & exclude them from the Technical Committee decision on 01/04/2010 regarding NSAIDs, provided that the decision application takes place starting from the month following the issuance of the decision.

Decisions of the Technical Committee at its session on 04/06/2020

*- Approval for the registration of preparations containing Proteolytic enzymes in the form of Oral dosage form. Approval to receive new preparations containing them, provided that adhering to the reference product's pharmaceutical form & leaflet. In case that there is no reference, the pharmaceutical form Enteric coated or Gastro resistant dosage form is adhered to. This is for preparations used 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, the decision of the Pharmacology Committee at its session on 16/04/2020 and the decision of the Scientific Committee for Rheumatology Diseases at its session on 02/04/2020. Applying this decision will take place starting from the month following the issuance of the decision.

Decisions of the Technical Committee at its session on 18/06/2020

*- Regarding preparations containing Diclofenac in the form of suppositories: Confirmation of the Technical Committee decisions dated 28/10/2010 and 22/09/2011 to commit to placing the warning "Not for use for children under 6 years" on the outer package and leaflet.

Note:

The Technical Committee decided at its session on 22/09/2011:

Regarding preparations that contain Diclofenac in the form of suppositories: "The committee still adheres to its previous decision in its session dated 28/10/2010 to write the warning on the outer packaging: "Not for use for children under 6 years" in a clear place on the outer packaging and in the inner leaflet, because it is not permitted for use in children under 6 years of age except in the case of Juvenile Idiopathic Arthritis, according to the reference (BNF for children 2010-2011) and the widespread use of these preparations to reduce fever without a prescription. The indications for use are mentioned in detail in the inner leaflet, and this applies to all preparations; registered and under registration.

Decisions of the Technical Committee at its session on 25/06/2020

***- Regarding the substance Sodium Metabisulfite:**

1- With regard to preparations; Large Volume Parentrals: The presence of inactive ingredients Sodium Metabisulphite is not allowed in the composition statement, unless the innovator composition statement contains this substance.

2- With regard to Paracetamol (Acetaminophen) Solution for Infusion:

A) Registered preparations: Sodium Metabisulphite substance is removed from the composition statement in accordance with applying variation rules to registered pharmaceutical preparations. A period of 18 months is given from the committee date to reconcile the situation. Production and circulation are stopped after the termination of this period.

B) Preparations under registration: Sodium Metabisulphite substance is removed from the composition statement. In case the product is in the final stages of registration (obtained stability approval, or pilot batches were manufactured) before the technical committee date on 25/06/2020, then the registration license is allowed to be issued and a period of 18 months is given from the committee date (in a manner that does not conflict with any other periods granted to the product) to reconcile the situation and remove Sodium Metabisulphite substance from the composition statement in accordance with variation rules for registered pharmaceutical preparations. Production and circulation shall be stopped after the termination of this period.

*- Not approving the re-registration of preparations containing Minoxidil in the form of gel.

*- Concerning registered preparations containing: Di-iodohydroxyquinoline; Addressing companies to conduct a study to confirm efficacy & safety against placebo. The study protocol must be submitted and presented to the Non-Reference Medicines Committee.

*- Approval to re-register registered preparations containing Bambuterol & approval to receive new preparations from 01/08/2020, while adhering to the warnings issued by the Pharmacology Committee for Long acting B_2 agonist in the leaflet, based on the decision of the Pharmacology Committee on 31/03/2016 and the Pharmacovigilance Committee on 15/03/2020.

- Note:

1- Decision of the Pharmacology Committee at its session on 31/03/2016:

Approval of the registration of the product, with emphasis on adding the warnings previously issued by the Pharmacology Committee regarding Long acting B_2 agonist in the product leaflet, which states:

It is forbidden to use these preparations alone, and an inhaled corticosteroid derivative must be used with them

- Long-term use of these preparations is limited to cases that do not respond to corticosteroid preparations alone.

- If used, it will be for the shortest possible period to control the symptoms of a respiratory crisis, provided that treatment is then continued with a corticosteroid preparation.

- For children and those in their teenage years, a pharmaceutical formula containing these substances should be used in addition to a corticosteroid preparation.

2- Decision of the Pharmacovigilance Committee on 15/03/2020 is as follows:

There is no objection to registering (bambuterol) substance with applying warnings and uses for long acting B_2 agonists group.

Decisions of the Technical Committee at its session on 09/07/2020

*- Cancellation of the preparations under registration and not approving the reception of new preparations containing the combination (Esomeprazol + Rebamipide) based on the Pharmacology Committee decision on 09/04/2020 and the Specialized Scientific Committee for Internal Medicine decision on 15/05/2018.

Note:

1-It was presented to the Specialized Scientific Committee for Internal Medicine Diseases at its session on 15/05/2018

Which recommended not approving the preparation because Rebamipide requires a high degree of acidity, and at the same time Esomeprazole reduces stomach acidity and thus negatively affects the absorption of Rebamipide.

2-The preparation was presented to the Pharmacology Committee at its session on 09/04/2020

Which recommended not approving the registration of the preparation due to the lack of sufficient studies proving the effectiveness and safety of the preparation.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Vilaprisan based on the decision of the Specialized Scientific Committee for Gynecology on 22/04/2020 and the Pharmacology Committee on 24/12/2015.

Note:

1-It was re-presented to the Specialized Scientific Committee for Gynecology at its session on 22/04/2020:

Which recommended rejecting the preparation as it is still under clinical studies and not providing sufficient studies indicating the effectiveness and safety of the preparation.

2-The Pharmacology Committee decided at its session on 24/12/2015:

The Committee considers not approving the registration of preparations that are still in the phases of clinical studies, Phase 2, and therefore the effectiveness and safety of these materials are not yet known. Therefore, the Committee refuses to register these preparations, and the decision applies to all similar cases of preparations that are submitted for registration with the Egyptian Ministry of Health and the active ingredients included in its composition are still under clinical studies globally.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Bupropion+Zonisamide) based on the decision of the Scientific Committee for Psychiatric and Neurological Diseases at its session on 26/12/2018 and the decision of the Pharmacology Committee on 09/04/2020

Note:

1-It was presented to the Scientific Committee for Psychiatric and Neurological Diseases at its session on 26/12/2018:

Which recommended rejecting the preparation because there was no scientific basis for combining the two substances together in one formulation.

2-It was presented to the Pharmacology Committee on 09/04/2020

Which decided not to approve the registration of the product due to the lack of sufficient studies.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Ammonium Chloride+ Cetylpyridinium+ Dextromethorphan + Menthol+ Sodium Citrate) based on the decision of the Specialized Scientific Committee for Chest Diseases on 23/04/2019 and the decision of the Pharmacology Committee on 30/04/2020

Note:

1-The preparation was presented to the Specialized Scientific Committee for Chest Diseases on 23/04/2019:

Which recommended not approving the preparation due to the lack of formulation reference.

2-The preparation was presented to the Pharmacology Committee on 30/04/2020:

Which recommended rejecting the preparation due to the lack of evidence regarding the preparation effectiveness and safety in the presence of these ingredients together, as well as the absence of specific doses for different age groups, and the lack of indications clarity regarding the use of these ingredients together.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the combination (Dexamethasone+Dextromethorphan+Sodium Benzoate+ Guaiacol glyceryl ether (Guaifenesin)) based on the decision of the Specialized Scientific Committee for Chest Diseases at its session on 10/05/2018 and the decision of the Pharmacology Committee on 23/04/2020

Note:

1-The preparation was presented to the Specialized Scientific Committee for Chest Diseases, at its session on 10/05/2018:

Which recommended not approving the preparation due to the lack of a scientific basis for combining a cough suppressant with an expectorant and cortisone.

2-The preparation was presented to the Pharmacology Committee on 23/04/2020:

Which decided not to approve the registration of the preparation because there is no scientific basis for the presence of Dexamethasone in this formulation, and the concentration of other substances in the formulation is less than the therapeutic dose.

*- Approval to print the factory name and address using inkjet if they are not present on the labels of imported products.

Decisions of the Technical Committee at its session on 16/07/2020

*- Approval to receive new preparations containing Celecoxib in the form of Oral Solution.

It is excluded from the Technical Committee decision on 01/04/2010 regarding NSAIDs. Applying this decision will take place starting from the month following the issuance of the decision.

Decisions of the Technical Committee at its session on 06/08/2020

*- Limit the use of preparations containing Methylergometrine substance for only hospitals, hospital pharmacies, and the Egyptian Company for Pharmaceutical Trade pharmacies. The preparations must be disbursed according to a medical prescription.

Decisions of the Technical Committee at its session 13/08/2020

*- Approval to receive new preparations containing Etofenamate in pharmaceutical form Depot Injection excluding it from the Technical Committee's decision dated 01/04/2010 regarding not receiving new preparations of NSAIDs. The decision application will take place starting from the month following the issuance of the decision.

*- Cancellation of preparations under registration, not approving the re-registration of registered preparations, and not approving the reception of new preparations containing Telaprevir based on the decision of the Pharmacovigilance Committee at its session on 18/06/2020 and the Specialized Scientific Committee for Liver and Digestive System Diseases at its session on 10/08/2020.

Note:

1-The Pharmacovigilance Committee decided at its session on 18/06/2020:

Refusal to register Telaprevir for the following reasons:

1- Telaprevir is not marketed in any concentration or any pharmaceutical form in the regulatory authorities.

2-This substance has serious adverse effects, the most important of which are: Serious Skin Reactions: Fatal and non-fatal serious skin reactions, including Stevens Johnson Syndrome (SJS), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), and Toxic Epidermal Necrolysis (TEN), have been reported

in patients treated with Telaprevir combination treatment. Fatal cases have been reported in patients with progressive rash and systemic symptoms who continued to receive Telaprevir combination treatment after a serious skin reaction was identified.

3- The emergence of newer and safer effective materials to treat the same uses for which the Telaprevir substance is used.

2-The following was presented to the Specialized Scientific Committee for Liver and Digestive System Diseases at its session on 10/08/2020:

Which recommended rejecting the preparation for the following reasons:

1- Telaprevir has been withdrawn from international guidelines of Chronic hepatitis C treatment.

2- It is not marketed by accredited international regulatory bodies.

3- The availability of alternatives in the Egyptian market that are safer, more effective and belong to the therapeutic group (direct acting antiviral (DAAs) which are newer than Telaprevir, such as Sofosbuvir.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Pinoxacin based on the decision of the Specialized Scientific Committee for Endocrinology and Metabolism at its session on 17/12/2018 and the testimony of the Pharmacology Department.

Note:

1- The Specialized Scientific Committee for Endocrinology and Metabolism decided at its session on 17/12/2018:

The preparation was not approved due to the lack of studies indicating the safety and effectiveness of the preparation.

2- Pharmacology Department reported*:*

The active substance is still in the stages of clinical studies (Phase I), and therefore the effectiveness and safety of this substance is not yet known.

Decisions of the Technical Committee at its session 27/08/2020

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Dehydroepiandrosterone (Prasterone) in the form of Oral Dosage Forms based on the decision of the Specialized Scientific Committee for Gynecology and Obstetrics at its session on 22/04/2020 and the decision of the Pharmacology Committee at its session on 09/07/2020.

Note:

1-The the Specialized Scientific Committee for Gynecology and Obstetrics recommended at its session on 22/04/2020:

Rejecting the preparation due to the lack of sufficient studies proving the effectiveness and safety of the preparation.

2-The Pharmacology Committee recommended at its session on 09/07/2020

Not approving the registration of the product because it has not been registered in this pharmaceutical form in any of the reference countries.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Minoxidil + Finasteride) based on the decision of the Specialized Scientific Committee for Dermatology, Venereology and Andrology at its session on 24/06/2019 & the decision of the Non-Reference Medicines Committee at its session on 26/07/2020.

Note:

1-The Specialized Scientific Committee for Dermatology, Venereology and Andrology decided at its session on 24/06/2019:

Rejecting the preparation because it is still under clinical studies as well as the lack of completed studies results proving the effectiveness and safety of this preparation.

2-The Non-Reference Medicines Committee recommended at its session on 26/07/2020:

Rejecting the presented preparation until there are sufficient clinical studies indicating the safety and effectiveness of using this preparation.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Ondansetron in Extended Release form based on the decision of the Specialized Scientific Committee for Cancer and Radioisotopes at its session on 21/04/2020 and the decision of the Non-Reference Medicines Committee at its session on 11/06/2020.

Note:

1- It was presented to the Specialized Scientific Committee for Cancer and Radioisotopes at its session on 21/04/2020, which recommended:

Not approving the registration of the preparation due to the lack of completion of studies indicating the safety and effectiveness of the preparation (Extended Release).

2-The Non-Reference Medicines Committee recommended at its session on 11/06/2020:

Not approving the registration of the preparation due to the lack of clear scientific evidence for the use of Ondansetron in the form of Extended Release Tablet.

Decisions of the Technical Committee at its session 03/09/2020

*- Cancellation of 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 dated 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 10/08/2020 & to be submitted to the head of the Egyptian Drug Authority for approval and approval to cancel the registered preparations.

Note:

1-The issue was presented to the Pharmacovigilance Committee on 26/03/2020, and the committee reported the following:

Due to the damage that may occur to the liver, according to the regulatory authorities EMA, MHRA, ANSM

2-The following was presented to the Specialized Scientific Committee for Gynecology and Obstetrics at its session on 10/06/2020.

Which decided not to approve preparations containing Ulipristal acetate 5mg for the following reasons:

1- In support of the decision of the European Medicines Agency, France, and the United Kingdom to suspend and withdraw preparations containing Ulipristal acetate at a concentration of 5 mg used in the treatment of Uterine Fibroid due to its harmful effects on the liver.

2- The large number of liver patients in Egypt, in addition to the difficulty of monitoring patients' liver functions.

3- The availability of other safer preparations for treating fibroids, such as Triptorelin Acetate

3-The following was presented to the Specialized Scientific Committee for Liver and Digestive System Diseases at its session on 10/08/2020:

Which decided to support the decision of Specialized Scientific Committee for Gynecology and Obstetrics Committee at its session on 10/06/2020.

*- Regarding the validity of raw materials bearing Retest:

Approval of the Supreme Inspection Committee's proposal that the company bring declaration of new retest date/ expiry date based on stability study done by manufacturer of raw material

The following must be done:

1 - Sending the letter from the supplier to the General Department of Inspection directly via the inspection email.

2- A certificate of analysis for the material must be sent with an updated expiry date of the material.

The analysis is carried out in the Egyptian Drug Authority laboratories every 6 months at a maximum, provided that the shelf life is taken for a maximum of one year, renewable within the limits of the period extended by the manufacturer of raw material.

*- The period for transferring temporary manufacturing shall be for one year, for emergency and exceptional cases only and after the approval of the General Department of Inspection. With adhering to submit the requirements for the new factory to the competent departments in accordance with the rules during this year. As for the approvals for the transfer of temporary manufacturing previously given to companies, with adhering to submit the requirements for the new factory to the competent departments in accordance with the rules within one year from the date of the committee, with the cancellation of any previous decisions that contradict this.

Decisions of the Technical Committee at its session 10/09/2020

*- Approval to receive new preparations containing Thiocolchicoside at a concentration of 4 mg only, with a commitment to write the warning (not to be used for more than 7 days only at a dose of 1-2 tablets daily) on the outer packaging and to adjust the dose in the leaflet, based on the decision of the Specialized Scientific Committee for Rheumatology, Rehabilitation & Orthopedic surgery at its session on 28/07/2020. The decision application will take place starting from the month following the issuance of the decision.

Note:

The Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedic surgery decided at its session on 28/07/2020 the following:

There is no objection to approving the preparation in concentration 4 mg only because the risk of using the preparation at this concentration is less than 8 mg concentration. Also, concentration 4 mg is marketed in the reference countries Italy, France and Portugal, provided that a warning is written on the outer packaging (do not use for more than 7 days only at a dose of 1-2 daily) in order to avoid side effects, if the daily dose exceeds 8 mg, such as Severe Hepatitis, Teratogenicity, Male Infertility and may be carcinogenic. It should only be dispensed with a medical prescription.

Decisions of the Technical Committee at its session 17/09/2020

*- Canceling the preparations under registration and not receiving new preparations containing Bendazac, based on the decision of the Pharmacovigilance Committee on 27/08/2020.

Note:

The preparation was presented to the Pharmacovigilance Committee on 27/08/2020, and it decided based on what was presented:

The Committee recommends rejecting the registration of the preparation for the following reasons:

1- There are not sufficient studies on the effectiveness of the active ingredient in the pharmaceutical form, Coated tablet, for the mentioned use;

(Early presenile and senile idiopathic cortical cataract; juvenile cataract; cataract diabetic; pacification of the cortex or lens nucleus of any etiology)

2- There are safety concerns regarding the active ingredient in the pharmaceutical form, Coated tablet, the most important of which is Hepatotoxicity, which led to stopping its use in the reference countries.

Decisions of the Technical Committee at its session 24/09/2020

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Doxylamine + Folic acid + Pyridoxine) based on the decision of the Specialized Scientific Committee for Internal Medicine at its session on 25/06/2019 and the decision of the Pharmacology Committee at its session on 07/05/2020.

Note:

1-The preparation was presented to the Specialized Scientific Committee for Internal Medicine Diseases at its session on 25/06/2019, which recommended the following:

The committee still stands by its previous decision on 18/06/2012 when presenting the formulation of (Doxylamine + Pyridoxine) which after extensive study of the preparation recommended rejecting the preparation for the following reasons:

1) The indications for use mentioned by the company are not found in scientific references.

2) According to scientific references, Doxylamine should not be used by pregnant women as it may cause fetal deformities.

**Also, adding folic acid to the formula does not protect the fetuses from deformities resulting from the presence of doxylamine.*

2-It was presented to the Pharmacology Committee at its session on 07/05/2020, which decided:

Not approving the registration of the preparation due to the lack of scientific significance for combining (Doxylamine + Pyridoxine) with Folic acid, which can be used alone, and the concentration of Pyridoxine as an antiemetic is less than the therapeutic dose.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Azanidazole based on the decision of the Specialized Scientific Committee for Gynecology and Obstetrics at its session on 22/04/2020 and the decision of the Non-Reference Medicines Committee at its session on 25/06/2020.

Note:

1-The preparation was presented to the Specialized Scientific Committee for Gynecology and Obstetrics at its session on 22/04/2020:

Which recommended rejecting the preparation for the following reasons:

- Not providing sufficient accredited scientific studies on the effectiveness and safety of the preparation.

- It was withdrawn from Italy.

-There are alternatives available in the Egyptian market that have been proven to be safe, such as Metronidazole.

- The preparation was presented to the Non-Reference Medicines Committee at its session on 25/06/2020:

Which recommended refusing to register the submitted preparation due to the lack of sufficient recent studies proving its effectiveness and safety in the provided indications for use, despite its lack of inclusion in the modern guidelines for the treatment of Trichomonas Vaginalis.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Fermagate based on the decision of the Specialized Scientific Committee for Kidney and Urinary Tract Diseases at its session on 24/08/2020 and the decision of the Pharmacology Committee at its session on 24/12/2015.

Note:

1-The preparation was presented to the Specialized Scientific Committee for Kidney and Urinary Tract Diseases at its session on 24/08/2020:

Which recommended not approving the preparation due to the lack of completion of clinical studies proving the safety and effectiveness of the preparation.

2-The Pharmacology Department reported that this preparation is subjected to the decision of the Pharmacology Committee at its session on 24/12/2015:

It decided on a general decision on all preparations submitted for registration based on the presence of preparations submitted for registration in the reference countries that are still in the stages of clinical studies: By not approving the registration of preparations, as the active ingredients included in their

composition are still in the stages of clinical studies, and therefore the safety of these substances is not yet known. Therefore, the committee refuses to register these preparations, and the decision applies to all similar cases of preparations that are submitted for registration with the Egyptian Ministry of Health and the active ingredients included in its composition are still under clinical studies globally.

*- Cancellation of preparations under registration and refusal to receive new preparations containing the composition (Brimonidine + Dorzolamide + Timolol) based on the decision of the Specialized Scientific Committee for Eye and Retina Diseases at its session on 21/07/2020 and the decision of the Non-Reference Medicines Committee at its session on 26/07/2020.

Note:

1- The preparation was presented to the Specialized Scientific Committee for Eye and Retina Diseases at its session on 21/07/2020:

Which recommended not approving the preparation due to the lack of completion of clinical studies indicating the safety and effectiveness of the formulation.

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

Which recommended rejecting the presented combination. This is because there is no information regarding the Pharmacokinetics of the 3 active components in one fixed dose combination.

*- Approval to receive new preparations containing Edaravone 30 mg/20 ml in the pharmaceutical form of Injection, based on the decision of the Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 01/07/2020, and the application is effective as of 01/11/2020.

Note:

1- The preparation was presented to the Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 01/07/2020:

Which recommended the following:

Approving the preparation from a scientific standpoint for the following reasons:

1- Because of its importance in treating Amyotrophic Lateral Sclerosis.

2- The lack of alternatives in the Egyptian market.

3- Referenced composition.

Decisions of the Technical Committee at its session 01/10/2020

*- Regarding preparations containing Cefotaxime 0.5g Injection:

The solvent volume of 2 ml is adhered to; & if a solvent of another size is used, write “Dissolve in 2 ml Solvent" on the package and leaflet, with inspection follow-up. A period of 6 months from the date of the committee is given to reconcile the situation.

Decisions of the Technical Committee at its session 22/10/2020

*- Canceling the preparations under registration and not approving the reception of new preparations containing the combination (Hydrocodone Bitartrate + Guaifenesin) based on the decision of the Specialized Scientific Committee for Chest Diseases at its session on 11/02/2020 and the Non-Reference Medicines Committee at its session on 26/07/2020.

Note:

1-It was presented to the Specialized Scientific Committee for Chest Diseases at its session on 11/02/2020:

Which recommended rejecting the preparation due to stop circulation the preparation at the FDA and in accordance with the Risk Benefit Assessment mentioned in the FDA

2-It was presented to the Non-Referenced Medicines Committee at its session on 26/07/2020:

Which recommended rejecting the registration of the preparation due to stop its circulation in 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.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Lemborexant at a concentration of 20 mg based on the decision of the Specialized Scientific Committee for Psychiatric and

Neurological Diseases at its session on 23/09/2020 and the Non-Reference Medicines Committee at its session on 09/07/2020.

Note:

1 -The preparation was presented to the Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 23/09/2020:

Which recommended rejecting the preparation due to the lack of reference in the concentration provided since the maximum dose of Lemborexant is 10 mg per day.

2-The preparation was presented to the Non-Reference Medicines Committee at its session on 09/07/2020:

Which recommended refusing to register the preparation due to exceeding the maximum daily dose of 10 mg for Lemborexant, according to scientific references.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Azimilide based on the decision of the Specialized Scientific Committee for Cardiology at its session on 09/09/2020 and the testimony of the Pharmacology Department.

Note:

1-The preparation was presented to the specialized scientific committee for cardiology at its session on 09/09/2020*:*

Which recommended not approving preparations containing Azimilide in concentration 125 mg due to the lack of completion of clinical studies proving the effectiveness and safety of the preparation.

2-The Pharmacology Department reported that:

The decision of the Pharmacology Committee at its session on 24/12/2015 regarding the preparations submitted for registration while the original preparations are still in the stages of clinical studies in international bodies shall be applied to the preparation, which states: Not approving the registration of preparations where the active ingredients included in their composition are still in the stages of clinical studies and therefore the safety of these substances is not yet known, so the committee refuses to register these preparations, and the decision applies to all cases similar to the preparations that are submitted for registration with the Egyptian Ministry of Health and the active ingredients included in their composition are still under clinical studies globally.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Sodium Gualenate hydrate in the form of Ophthalmic Preparations based on the decision of the Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 19/11/2018.

Note:

The preparation was presented to the Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 19/11/2018:

Which recommended rejecting the preparation due to the lack of sufficient studies indicating the effectiveness and safety of the substance, the lack of need for it and the availability of alternatives.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Lysozyme (Leftose) in the form of syrup based on the decision of the Specialized Scientific Committee for Pediatric Diseases at its session on 01/09/2020 and the decision of the Specialized Scientific Committee for Ear, Nose and Throat Diseases at its session on 01/10/ 2019.

Note:

1-The preparation was presented to the Specialized Scientific Committee for Pediatric Diseases at its session on 01/09/2020:

Which recommended rejecting the preparation due to the lack of studies indicating the safety and effectiveness of the preparation.

2-The preparation was presented to the Specialized Scientific Committee for Ear, Nose and Throat Diseases held its session on 01/10/2019:

Which recommended rejecting the preparation from a scientific standpoint; since Lysozyme is used topically as lozenges in cases of sore throat, and not providing studies indicating the effectiveness of its use in the provided pharmaceutical form as syrup.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Ademetionine in the form of injection based on the decision of the Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 13/01/2020, the decision of the Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedic surgery at its session on 24/02/2019 and the decision of the Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 20/03/2019.

Note:

1-The preparation was presented to the Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 13/01/2020:

Which recommended that the preparation cannot be registered as a pharmaceutical preparation for the following reasons:

1- Lack of approved studies supporting the use of Ademetionin in treating liver diseases.

2- Most clinical studies of this substance were conducted on laboratory animals.

2-The preparation was presented to the Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedic surgery at its session on 24/02/2019:

Which recommended rejecting the preparation due to the lack of sufficient studies on the use of this substance in the treatment of Osteoarthritis.

3-The preparation was presented to the Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 20/03/2019:

Which recommended rejecting the preparation due to the lack of sufficient studies on the use of this substance in the treatment of depression.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Rebamipide in the form of Ophthalmic Preparations based on the decision of the Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 21/07/2020.

Note:

The preparation was presented to the Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 21/07/2020:

Which recommended not to approve the preparation *as the studies were submitted by places that are not accredited or well-known.*

Decisions of the Technical Committee at its session 19/11/2020

*- With regard to registered preparations containing the composition (Piperazine + Hexamine (Methenamine) + Khellin) in pharmaceutical form Effervescent granules:

Approval to complete the procedures for re-registering preparations containing the old formulation containing Piperazine based on the decision of the Non-Reference Medicines Committee at its session on 05/11/2020 while keeping the previous name and price. For companies that have committed to implementing the decision of the Technical Committee on 05/12/2017 and also wish to keep the new formulation without Piperazine; the name is changed and the price is revised.

Note:

The Technical Committee for Drug Control decided at its session on 05/12/2017:

"With regard to registered preparations traded/marketed in the local market in pharmaceutical form Effervescent granules containing the composition (Piperazine + Hexamine (Methenamine) + Khellin):

Piperazine is removed and Hexamine+ Khellin are kept. Companies are obligated to amend the composition statement for these preparations, and they are considered new preparations, while retaining the price and their place in the box, and adding the letter N For the name. The companies are given a period of one year from the date of the committee to reconcile the situation".

*- Approval for the re-registration of registered preparations containing...Pamabrom and approval to receive new preparations containing the substance Pamabrom on the condition of being referenced, based on the decision of the Pharmacology Committee at its session on 01/10/2020 and the decision of the Specialized Scientific Committee for Gynecology and Obstetrics at its session on 28/10/2020, the decision will be applied from the beginning of the month following the issuance of the decision.

*- Regarding preparations that contain Meclofenoxate 500 mg:
Approval to complete the procedures for registering and re-registering preparations containing it, based on the decisions of the Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 01/07/2020, the Pharmacovigilance Committee at its session on 16/07/2020, and the Non-Reference Medicines Committee at its session on 18/01/2018.

*- Amending the decision of the Technical Committee on 18/06/2020 to read: "With regard to preparations that contain substance Diclofenac in the form of suppositories with a concentration of 50 mg and lower concentrations: the warning is written "Not for use in children under 6 years", and for higher concentrations: the warning is written "Not for use in children" on the outer packaging and leaflet according to the reference preparations leaflet.

Note:

The Technical Committee for Drug Control decided at its session on 18/06/2020:

"With regard to preparations that contain Diclofenac in the form of suppositories: Confirmation of the decisions of the Technical Committee on 28/10/2010 and 22/09/2011 to commit to placing the warning "Not for use on children under 6 years" on the package and leaflet.

Decisions of the Technical Committee at its session 26/11/2020

*- Approval to receive new preparations containing the formula (Acetylsalicylic acid 100 mg + Clopidogrel 75 mg) This is for reference, and the decision will be applied starting from 01/01/2021.

*- Approval to receive new preparations containing the substance Minocycline in pharmaceutical form Topical Foam with reference concentrations, and the decision will be applied starting from 01/01/2021.

Decisions of the Technical Committee at its session 03/12/2020

*- Approval of the following proposal submitted by the Variation Section for Registered Human Pharmaceutical Preparations in order to approve the rules regulating the addition/transfer of a manufacturing location for registered human pharmaceutical preparations, provided that the decision is applied to batches produced or imported starting from 01/03/2021:

The company is committed to performing the following on products from the new factory:

1- Analysis of the first 3 consecutive production runs of the new factory's production in the Egyptian Drug Authority's laboratories in the Inspection Division (if the analysis was done in the Registration Division before) or analysis of the first batch in the Registration Division and the second and third batches in the Inspection Division in case that the analysis was not done in the Registration Division before and is not done. The Release will be only after receiving the matching result.

2- Submit a Comparative study In-Vitro Dissolution at 3 different PH media (1.2/4.5/6.8) and the most suitable medium (D3/4) in comparison with a batch produced in the old factory or a comparison with the reference preparation, and the first production batch is not released until the study is approved by the Bioavailability and Equivalence Department.

Note:

- ***In the event that the active substance has Narrow Therapeutic Drug:***

A bioequivalence study is requested instead of a dissolution rate study in accordance with the rules regulating that.

- In the event that the active substance: BCS Class (IV)

A request is made to conduct a dissolution rate study in one of the licensed bioequivalence centers.

3- For locally manufactured preparations: submitting an accelerated stability study (for a period of 6 months) on the first 3 consecutive production runs of the preparation produced by the new factory, provided that this is done within thirty months from the production date in the new factory, after which production of the preparation is stopped until all requirements are met. The three production runs will be released only after an accelerated stability study for 3 months has been approved on the first production run.

- For imported preparations: submitting an accelerated stability study (for a period of 6 months) on 3 consecutive production runs of the product produced by the new factory. The imported batches will not be released until after the accelerated stability study is approved.

4- Submission of Process validation for the preparation produced by the new factory and followed up by pharmaceutical inspection.

With the amendment of the internal leaflet and the external card, this is followed up by the General Administration of Pharmaceutical Inspection.

*- Approval of the following proposal submitted by the Variation Section for Registered Human Pharmaceutical Preparations regarding the Lidocaine solvent, provided that the decision will be implemented after approval by the Chairman of the Egyptian Drug Authority:

1- Allowing companies to register Lidocaine solvent for intramuscular injection only in sizes (1-2 - 3.5 - 4 - 5 ml) at a concentration of 1% and 2%, without being restricted by the number specified in the box. It will not be allowed to be sold except as a solvent only, with the phrase "Not sold alone or Not to be sold separately" clearly and in a clear color on the solvent bottle.

2- Obliging companies that own (preparation + solvent) registered with one registration number to apply to register the solvent with a separate registration number, while giving the companies a period of two years from the date of the technical committee to obtain the solvent registration license the, after which, production will be stopped and the company is obligated to add a registered solvent. While allowing the benefit of all studies that were conducted on the Lidocaine solvent before, whether the product was registered or under registration (provided that these studies were conducted on the same batch) and exemption from approving the internal leaflet and the external label for the solvent.

3- It is allowed to add a maximum of three solvent suppliers, provided that the type of solvent packaging is unified for one product and on the condition that the solvent is registered, considering the compatibility of the shelf life of the solvent with the shelf life of the drug and applying the rules of variation for registered human pharmaceutical preparations.

4- Commitment is made to adding the solvent in the same container as the Vial, with the exception of preparations that are proven through scientific references to be used in hospitals or inside the operating room or without a limited amount of solution.

5- As for imported preparations, the packaging marketed in the country of origin is adhered to in the event of a conflict with this decision.

6- Cancel all previous decisions that contradict this.

*- Amending the decision of the Technical Committee for Drug Control at its session on 07/03/2013 to read: "With regard to imported preparations: allowing the use of a leaflet approved by a reference country, provided that the preparation is registered and traded, with a commitment to applying the rules and decisions related to warnings.".

Note

The Technical Committee decided at its session on 07/03/2013 regarding imported preparations: *The leaflet shall be approved as it is marketed in the country of origin.*

*- Approval to receive new preparations containing Buprenorphine in implementation of the Minister of Health's Resolution No. (640) of 2020 regarding the treatment program with alternative drugs to opioids in

pharmaceutical form Sublingual Tablets and in concentrations Buprenorphine 2 mg alone, or in combination (Buprenorphine 8 mg + Naloxone 2 mg) while adhering to the circulation requirements in accordance with the decision of the Minister of Health. The decision application will be implemented starting from the month following the issuance of the decision.

*- Amending the decision of the Technical Committee at its session on 24/09/2020 to read: "Cancelling the preparations under registration and not approving the reception of new preparations containing the formulation (Doxylamine + Folic acid + Pyridoxine) based on the decision of the Pharmacology Committee at its session on 07/05/2020 and the confirmation that the formulation (Doxylamine + Pyridoxine) is referenced and used for treatment of nausea and vomiting of pregnancy in women who don't respond to conservative management.

Note:

The Technical Committee decided at its session on 24/09/2020:

To cancel the preparations under registration and not to approve the reception of new preparations containing the composition (Doxylamine + Folic acid + Pyridoxine) based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 25/06/2019 and the decision of the Pharmacology Committee at its session on 07/05/2020.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Casopitant based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 18/09/2018, the Specialized Scientific Committee for Cancer and Radioisotopes at its session on 30/10/2018, and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Internal Medicine Diseases decided at its session on 18/09/2018:

It recommended not approving the preparation due to its withdrawal from EMA & as the safety of the preparation has not been proven.

***2- The Specialized Scientific Committee for Cancer and Radioisotopes, at its session on 30/10/2018**:*

It recommended rejecting the preparation, as it was withdrawn from the EMA Since 2009, at the request of the mother company, due to the need for more studies proving the safety of the product.

3- The Pharmacology Committee decided at its session on 01/10/2020:

It recommended not approving the preparation due to the failure to submit studies indicating the effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Clinafloxacin based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 25/12/2018 and the Pharmacology Committee at its session on 01/10/2020.

Note:

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

It recommended not approving the preparation, as this group of 3rd Generation fluoroquinolone has serious side effects and there is no scientific reference for its use.

2- The Pharmacology Committee decided at its session on 01/10/2020*:*

It recommended not approving the preparation due to the lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Saxagliptin + Vitamin D) based on the decision of the Specialized Scientific Committee for Endocrinology and Metabolism at its session on 11/03/2019 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1-The Specialized Scientific Committee for Endocrinology and Metabolism at its session on 11/03/2019:

It recommended rejecting the formula due to the lack of sufficient scientific studies proving the feasibility of the formula in diabetics.

2- The Pharmacology Committee decided at its session on 01/10/2020:

It recommended not approving the preparation, due to the lack studies indicating the effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Rosuvastatin + Metformin) based on the decision of the Specialized Scientific Committee for Cardiology at its session on 23/01/2019 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Cardiology decided at its session on 23/01/2019:

It recommended not approving the preparation due to the lack of results of clinical studies proving the safety and effectiveness of the preparation.

2- The Pharmacology Committee decided at its session on 01/10/2020:

It recommended not approving the preparation due to the lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Lucinactant based on the decision of the Specialized Scientific Committee for Chest Diseases at its session on 23/04/2019, the Specialized Scientific Committee for Pediatric Diseases at its session on 02/07/2019, and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Chest Diseases, at its session on 23/04/2019:

It recommended not approving the preparation due to its suspension in the FDA.

2- The Specialized Scientific Committee for Pediatric Diseases, at its session on 02/07/2019:

It recommended rejecting the preparation in order to stop its marketing in FDA. It is not marketed anywhere in the world for newborns and premature infants, and it has no preventive role in RDS treatment.

3- The Pharmacology Committee decided at its session on 01/10/2020:

It recommended not approving the preparation due to lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Carbutamide based on the decision of the Specialized Scientific Committee for Endocrine Diseases and Diabetes at its session on 19/03/2019 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1-The Specialized Scientific Committee for Endocrine Diseases and Diabetes at its session on 19/03/2019:

It recommended rejecting the preparation due to stopping its circulation in France.

2- The Pharmacology Committee decided at its session on 01/10/2020:

It recommended not approving the preparation due to lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Captodiame based on the decision of the Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 19/02/2020 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 19/02/2020:

It recommended rejecting the preparation based on the Vigilance Center's report, which included the following:

***In France, an article was found containing the cancellation of Covatine preparation Containing a substance Captodiame HCl whereas, after re-evaluating it, it became clear that the balance of risks and benefits was not in favor of the product due to the lack of data related to effectiveness, and the*

Vigilance Center recommended not to register preparations containing the substance...Captodiame HCl and withdraw it if any.

2- The Pharmacology Committee decided at its session on 01/10/2020:

It recommended not approving the preparation due to lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Ceforanide based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 18/09/2018 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Internal Medicine Diseases, at its session on 18/09/ 2018:

It recommended rejecting the preparation, as it belongs to second-generation Cephalosporin antibacterial group. This group has become useless and there are alternatives available from a Third-generation Cephalosporin antibacterial group which are more effective.

2- The Pharmacology Committee decided at its session on 01/10/2020:

Not to approve the preparation due to lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Abaloparatides based on the decision of the Specialized Scientific Committee for Rheumatic Diseases at its two sessions on

28/09/2017 and 19/12/2018 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Rheumatic Diseases at its session on 28/09/2017:

It recommended rejecting the preparation due to the lack of sufficient studies proving the effectiveness and safety of the preparation.

2- The Specialized Scientific Committee for Rheumatic Diseases recommended at its session on 19/12/2018:

It recommended not approving the preparation due to EMA refusal to grant the marketing license for the innovator preparation Eladynos. This is according to EMA report Issued on 26/07/2018 regarding Abaloparatide.

3- The Pharmacology Committee decided at its session on 01/10/2020:

It recommended not approving the preparation due to lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Apremilast in the form of Injection based on the decision of the Specialized Scientific Committee for Rheumatology at its session on 09/06/2019 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Rheumatic Diseases, at its session on 09/06/2019:

It recommended rejecting the preparation due to the lack of studies supporting the safety and effectiveness of this substance in its form as Injection form.

2- The Pharmacology Committee at its session on 01/10/2020:

It recommended not approving the preparation due to the failure to submit studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Glycyrrhizin in the form of Injection based on the decision of the Specialized Scientific Committee for Liver and Digestive Diseases at its session on 18/10/2018 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Liver and Digestive System Diseases, at its session on 18/10/2018:

It recommended rejecting the preparations as the active ingredient is not mentioned in the Therapeutic Guidelines approved by scientific societies for the liver (AASLD, EASL, APASL).

2- The Pharmacology Committee decided at its session on 01/10/2020:

It recommended not approving the preparation due to the failure to submit studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Dexlansoprazole in the form of Injection based

on the decision of the Specialized Scientific Committee for Internal Medicine at its session on 12/12/2017, the Pharmaceutical Development Committee at its session on 23/06/2019, and the Pharmacology Committee at its session on 05/11/2020 and 01/10/2020.

Note:

1-The Specialized Scientific Committee for Internal Medicine at its session on 12/12/2017 recommended rejection for the following reasons:

- There is no scientific reference or reference country for using Dexalansoprazole by intravenous injection.

- The difficulty of preparing the compound, as it is lyophilized powder. It may be exposed to contamination and there are alternatives that are easier and safer to use.

2- The Pharmaceutical Development Committee on 23/06/2019 recommended rejection for the following reasons:

- There is no importance in preparing it in this case, as safer alternatives are available.

- The company has not submitted any scientific studies regarding this pharmaceutical form.

- There is no scientific reference or reference country in which intravenous injection is available.

3- The Pharmacology Committee decided on 05/11/2020:

Not to approve the preparation due to the lack of studies indicating the effectiveness and safety of the preparation in this pharmaceutical form.

4-The Pharmacology Committee decided at its session on 01/10/2020:

Not to approve the preparation due to the failure to submit studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Domperidone + Simethicone) based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 25/12/2018 and the Pharmacology Committee at its session on 01/10/2020.

Note:

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

It recommended not approving the preparation due to the lack of Scientific Rationale to combine the two materials together and the availability of each of them separately in the Egyptian market.

2- The Pharmacology Committee decided at its session on 01/10/2020:

It recommended not approving the preparation due to the lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Ammonium Chloride + Carbinoxamine + Citric Acid +Ephedrine + Menthol + Sodium Citrate) in the form of Syrup based on the decision of the Specialized Scientific Committee for

Chest Diseases at its session on 23/04/2019 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1 - The Specialized Scientific Committee for Chest Diseases, at its session on 23/04/2019:

It recommended not approving the preparation due to the non-reference of the formula.

2- The Pharmacology Committee decided at its session on 01/10/2020:

It recommended not approving the preparation due to the lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Ambroxol + levocetirizine) This is based on the decision of the Specialized Scientific Committee for Pediatric Diseases at its session on 05/02/2019 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Pediatric Diseases, at its session on 05/02/2019:

It recommended rejection due to the lack of reference of the formulation and the absence of feasibility or therapeutic advantage for combining an expectorant and an anti-allergy in one formulation.

2- The Pharmacology Committee decided at its session on 01/10/2020:

It recommended not approving the preparation due to the lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Chlorpheniramine + Diphenhydramine + Phenylephrine) based on the decision of the Specialized Scientific Committee for Pediatric Diseases at its session on 05/02/2019 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Pediatric Diseases, at its session on 05/02/2019:

It recommended rejecting the preparation due to the non-reference of the formula and the presence of more than one anti-allergic substance and the presence of phenylephrine that causes side effects in children, such as high blood pressure.

2- The Pharmacology Committee decided at its session on 01/10/2020:

Not to approve the preparation due to the lack of studies indicating effectiveness and safety.

*- Cancellation of the preparations under registration and not approving the reception of new preparations containing the combination (Clopidogrel + Metoprolol) based on the decision of the Specialized Scientific Committee for Cardiology at its session on 21/11/2018 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Cardiology at its session on 21/11/2018:

It recommended rejecting the formula for the following reasons:

1-There are not sufficient studies proving the safety and effectiveness of the formula.

2- It is not included in the International Guidelines for treatment of Acute Coronary Artery Disease.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Lansoprazole + Omeprazole) based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 27/11/2018 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Internal Medicine Diseases, at its session on 27/11/2018:

It recommended not approving the preparation due to the lack of Scientific Rational To combine two substances that serve the same therapeutic purpose.

2- The Pharmacology Committee decided at its session on 01/10/2020:

Not to approve the preparation due to the lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Paracetamol 500 mg + Chlorpheniramine 2 mg + Dextromethorphan 15 mg) with these concentrations based on the decision of the Specialized Scientific Committee for Chest Diseases at its session on 23/04/2019 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Chest Diseases, at its session on 23/04/2019:

It recommended not approving the preparation due to the non-reference of the formula.

2- The Pharmacology Committee decided at its session on 01/10/2020:

Not to approve the preparation due to the lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Ipecacuana extract + promethazine Hcl + Potassium Guaiacolsulfonate)

This is based on the decision of the Specialized Scientific Committee for Chest Diseases at its session on 07/08/2018 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- The Specialized Scientific Committee for Chest Diseases at its session on 07/08/2018:

It recommended not approving the preparation due to the lack of a scientific reference and its withdrawal from Spain.

2- The Pharmacology Committee decided at its session on 01/10/2020:

Not to approve the preparation due to the lack of studies indicating effectiveness and safety.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition
(Calcium carbonate + Magnesium Metasilicate Aluminate + Methionine Methyl Sulfonium Chloride +Precipitated Magnesium Carbonate)
This is based on the decision of the Specialized Scientific Committee for Internal Medicine Diseases at its session on 30/07/2019 and the Pharmacology Committee at its session on 01/10/2020.

Note:

1- the Specialized Scientific Committee for Internal Medicine at its session on 30/07/2019: *It recommended not approving the preparation, as the company did not provide any information about the indications for use and the doses of the medication to be used.*

2- The Pharmacology Committee decided at its session on 01/10/2020:

Not to approve the preparation due to the lack of studies indicating effectiveness and safety.

Decisions of the Technical Committee at its session in 17/12/2020

*- Excluding preparations containing Tacrolimus in the pharmaceutical form Topical Ointment from applying the Technical Committee decision at its session on 27/02/2020 regarding the controls and procedures for registering Oncology and Immunosuppressant preparations.

Note:

The Technical Committee decided at its session on 27/02/2020 regarding the controls and procedures for registering Oncology and Immunosuppressant preparations:

Approval of the following proposal submitted by the General Administration of Registration:

First: *All Oncology and Immunosuppressant preparations - manufactured locally or imported - under registration or registered and not yet marketed - at the time of issuance of this decision - the following shall be submitted for approval as a condition for completing registration procedures or as a condition for release for production batches:*

- *Accelerated stability study for 6 months on a pilot or first production batch.*
- *Quality file Module 3 (S-part & P-part) for evaluation.*
- *The dissolution rate study and the bioequivalence study of the preparations that require this, and in accordance with what is determined by the Specialized Scientific Committee to evaluate Studies of Availability and Bioequivalence.*

Second: *All Oncology and Immunosuppressive preparations - manufactured locally or imported - registered - and actually marketed at the time of issuance of this decision - must adhere to the following:*

- *Follow up with the Egyptian Pharmaceutical Vigilance Center for these preparations to monitor safety and adverse effects. The company is committed to following up with the center at least every 3 months or according to the time limits specified by the center.*
- *Preparing records showing the places where these preparations are dispensed, as well as compiling reports on the effectiveness of the preparations. Especially those disbursed through institutes, hospitals, medical centers specialized in treating Oncology, or private hospitals, for evaluation by the competent departments upon request.*
- *Submit a Quality File Module 3 (S-part & P-part) for evaluation and approval when making any change to the registered product or when re-registering.*

Third:

- *Commitment to all conditions and requirements necessary to complete registration procedures, as well as studies and conditions contained in the registration notification in accordance with what is determined by ministerial decisions and the rules governing this.*
- *The following are considered as an additional feature when evaluating the quality profile of the active substance (S-part):*

The active substance must be imported from one of the reference countries, or the production line in the factory from which the active substance is imported has been inspected or obtained a valid GMP certificate from one of the reference countries, or approved by the FDA or obtained EUDRA GMP & to be considered, the certificate of the CEP issued from EDQM.

- *Registration file CTD requests is allowed to be completed on one pilot or production batch according to the condition of each product.*
- *Follow-up by the inspection to meet the requirements.*

Decisions of the Technical Committee at its session in 31/12/2020

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Betrixaban based on the decision of the Pharmacovigilance Committee at its session on 01/10/2020 and the decision of the Specialized Scientific Committee for Cardiology at its session on 04/11/2020.

Note:

1-It was presented to the Pharmacovigilance Committee at its session on 01/10/2020, and the committee's decision was as follows:

The registration of the Betrixaban substance was refused for the following reasons:

1- Refusal to register the substance Betrixaban in EMA for the following reasons:

-The efficacy of Dexxience in the proposed indication has not been robustly demonstrated. Evidence presented was based on a single pivotal study without confirmation of efficacy for Betrixaban in other indications.

-Treatment with Dexxience was associated with an increased risk of bleeding events compared to the comparator in the trial.

2- The American Food and Drug Administration FDA stopped marketing the product for unclear reasons so the product has become non-referenceable to date.

2- It was presented to the Specialized Scientific Committee for Cardiology at its session on 04/11/2020:

Which decided not to approve the concentrations of 40 mg & 80 mg according to the report of the Pharmacovigilance Center, and the side effects of the active substance according to EMA.

-The efficacy of Dexxience in the proposed indication has not been robustly demonstrated. Evidence presented was based on a single pivotal study without confirmation of efficacy for betrixaban in other indications.

-Treatment with Dexxience was associated with an increased risk of bleeding events ((major or clinically relevant non-major bleedings) compared to the comparator in the trial.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Cefroxadine based on the decision of the Specialized Scientific Committee for Pediatric Diseases at its session on 13/02/2020 and the decision of the Pharmacology Committee at its session on 22/10/2020.

Note:

1-The following was presented to the Specialized Scientific Committee for Pediatric Diseases at its session on 13/02/2020:

Which recommended rejecting the preparation because the company had not provided sufficient studies on the preparation.

2-The following was presented to the Pharmacology Committee at its session on 22/10/2020:

Which recommended rejecting the preparation, as the studies submitted by the company are old and were conducted on a limited number of patients, and therefore they do not prove the effectiveness and safety of the preparation.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Rolapitant with concentration 200 mg based on the decision of the Specialized Scientific Committee for Cancer and Radioisotopes at its session on 21/04/2020 and the decision of the Pharmacology Committee at its session on 05/11/2020.

Note:

1-It was presented to the Specialized Scientific Committee on Cancer and Radioisotopes at its session on 21/04/2020:

Which decided not to approve the registration of the preparation due to the lack of completion of studies indicating the safety and effectiveness of the presented concentration.

2-The following was presented to the Pharmacology Committee at its session on 05/11/2020:

Which decided not to approve the registration of the preparation due to the lack of sufficient studies that support this dose.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing the composition (Ceftazidime + Sulbactam) based on the decisions of the Specialized Scientific Committee for Chest Diseases at its sessions on 09/01/2018 and 25/12/2018 and the decision of the Pharmacology Committee at its session on 18/06/2020.

Note:

1-The following was presented to the Specialized Scientific Committee for Chest Diseases at its session on 09/01/2018:

Which recommended not approving the preparation for the following reasons:

- There is no scientific background on this formulation and no scientific experiments have been conducted to prove the effectiveness of this formulation.

- The only presented study on this composition was just In Vitro.

2-The following was presented to the Specialized Scientific Committee for Chest Diseases at its session on 25/12/2018:

Which recommended not approving the preparation for the following reasons:

- There is no scientific background on this formulation and no scientific experiments have been conducted to prove the effectiveness of this formulation.

- The only presented study on this composition was just In Vitro.

3-The two preparations were re-presented to the Pharmacology Committee at its session on 01/10/2020:

The committee recommends rejecting the two preparations for not completing the required study dated 18/06/2020.

*- Cancellation of preparations under registration and not approving the reception of new preparations containing Pemirolast in pharmaceutical form Oral Dosage Forms based on the decision of the Specialized Scientific Committee for Pediatric Diseases at its session on 12/12/2017 and the decision of the Pharmacology Committee at its session on 22/10/2020.

Note:

1-It was presented to the Specialized Scientific Committee for Pediatric Diseases at its session on 12/12/2017:

The committee recommends rejecting the preparation as there is no scientific research indicating the use of this substance in pediatrics.

2-It was presented to the Pharmacology Committee at its session on 22/10/2020:

The committee recommends refusing to register the preparation due to the lack of sufficient studies indicating the effectiveness and safety of the preparation for the uses provided by the company.

*- Cancellation of preparations under registration and not approving 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.

Note:

It was presented to the Specialized Scientific Committee for Internal Medicine Diseases at its session on 26/02/2019, which recommended:

Not approving the registration of the preparation for the following reasons:

1- The product circulation was stopped in France without knowing the reasons.

2-It is not a vital medicine that the Egyptian market needs in the current time.

2-The following was presented to the Pharmacology Committee at its session on 01/10/2020:

The committee recommends rejecting the preparation due to the lack of sufficient studies indicating the effectiveness and safety of the preparation.