Decisions of the Technical Committee for Drug Control at its session on 05/01/2023

*- Not approving the reception of new preparations and not approving to complete the registration procedures for preparations under registration that contain the composition (Paracetamol + Diclofenac potassium + Methocarbamol) Based on the decision of the Combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics at its session on 30/11/2022.

Notes:

The Combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics recommended, at its session on 30/11/2022, the following: The preparation was not approved from a scientific standpoint for the following reasons

1- The file submitted by the company does not provide any scientific evidence that increases the effectiveness and safety of the formula.
2- Combining all the three substances in one formulation may result in increased side effects
3- The presented composition does not offer any therapeutic advantage over the alternatives present in the Egyptian market ((Methocarbamol + NSAID).

*- Not approving the reception of new preparations and not approving to complete the registration procedures for preparations under registration that contain the composition (Tadalafil + Tamsulosin) due to lack of reference.

*- Not approving the reception of new preparations and not approving to complete the registration procedures for preparations under registration that contain the composition (Hyoscyamine sulfate + Hyoscine hydrobromide + Atropine sulfate + Pectin + Kaolin) Based on the decision of the Combined

Specialized Scientific Committee for Internal Diseases at its session on 29/11/2022.

Notes:

The Combined Specialized Scientific Committee for internal medicine recommended, at its session on 29/11/2022: Refusal to register the product due to:

1- The components of the composition are not combined for a specific use

2- The presence of all these anticholinergics combined in a combination increases the side effects of the preparation

3-The company did not provide any studies that indicates the effectiveness and safety of the formula.

Decisions of the Technical Committee for Drug Control at its session on 12/01/2023

*- For veterinary preparations: Allowing the addition of a fourth source for one active raw material while applying the rules (Provided that the physical properties and specifications of the fourth source analysis certificate match those of all registered sources of the same active raw material), This is in line with the decision of the Technical Committee for Drug Control at its session on 29/09/2022 regarding human pharmaceutical preparations.

*- Approval to receive new preparations containing Minoxidil 5% in the pharmaceutical form of Topical gel, starting from the beginning of next month, with a commitment to conduct a comparative study between each submitted preparation and a reference preparation with the same concentration that proves the safety of the preparation (Comparative In-Vitro Permeation study), and it is required to be approved by Bioavailability and Bioequivalence Studies Evaluation Unit to allow the completion of registration procedures.

*- Not approving the reception of new preparations and cancellation of preparations under registration that contain the active ingredient “Bismuth” and all its salts in the Oral dosage form for the indication of irritable bowel syndrome with Diarrhea, based on the decisions of the Combined Scientific Committee for Internal Diseases at its session on 29/11/2022.

Notes:
the Combined Specialized Scientific Committee for Internal Medicine Diseases At its session on 29/11/2022, recommended the following: Refusal of the active ingredient “Bismuth” and all its salts in the Oral dosage form for the indication of Irritable bowel syndrome with diarrhea, due to its serious side effects on the nervous system that may lead to Neurotoxicity, according to

international bodies “FDA and MHRA” Which may be misused without medical supervision, especially in patients with irritable bowel syndrome with diarrhea, who need such medications frequently.
There are also many alternatives in the Egyptian market that are safer and have fewer side effects, such as Loperamide

*- The phrase (used for children from the age of 6-12 years) shall be written in clear writing on the outer packaging of all registered and under-registered preparations containing Ibuprofen 200 mg /5 ml Oral suspension while applying the rules.

*- Approval to receive new preparations containing the following composition starting from the next month in accordance with the rules:

Acetaminophen 325mg

Dextromethorphan Hydrobromide 10mg
Phenylephrine Hydrochloride 5mg
Chlorpheniramine Maleate 2mg

Decisions of the Technical Committee for Drug Control at its session on 19/01/2023

*- The decision of the Technical Committee will be amended at its session on 03/12/2020 to become as follows: “

Approval to receive new preparations containing Buprenorphine in implementation of the Minister of Health decision decree No. (640) of 2020 regarding the program for treatment with alternative drugs to opioids for the Sublingual Tablets Dosage form, in the concentrations 2 mg ,& 8 mg, for Buprenorphine Alone, or in the combination (Buprenorphine 8 mg + Naloxone 2 mg) While adhering to trading requirements in accordance with the decision of the Minister of Health, and the application will be implemented starting from the month following the issuance of the decision.

Decisions of the Technical Committee for Drug Control at its session on 02/02/2023

*- Approval to receive new preparations with the formulas (Dapoxetine 30 mg + Sildenafil 50 mg) and (Dapoxetine 60 mg + Sildenafil 100 mg) with the addition of the warning “must not be taken more frequently than once every 24 hours”, and the application will take place starting from the month following the issuance of the decision in accordance with the rules

Decisions of the Technical Committee for Drug Control at its session on 09/02/2023

*- The decision of the Technical Committee at its session on 14/04/2022 will be amended to be: Initial approval to receive the dosage form Bag on Valve (BOV), and its addition to the Box X : Non Traditional Topical preparation, for the preparation intended for topical use, and If the preparation is for any use other than topical use, it should be added to the appropriate box according to the rules, and Registration Licenses won't be issued unless the studies required by the Quality Committee are completed and approved.

*- Cancellation of preparations under registration that contain the composition (Mometasone 1% + Nadifloxacin 1%) in any dosage form intended for topical use and removing it from the box in accordance with the rules, and not approving the reception of new preparations based on the decision of the Combined Specialized Scientific Committee for Dermatology, Venereal Diseases and Andrology at its session on 26/12/2022.

Notes:

the Combined Specialized Scientific Committee for Dermatology, Venereal and Andrology Diseases At its session on 26/12/2022, recommended the following: Rejection of the preparation for the following reasons:

1- Nadifloxacin is used as an Antibiotic and Mometasone is used as a Corticosteroid. While the indication provided by the company is for Fungal Infections. Accordingly, there is no scientific basis for combining these two substances together for the use provided by the company.

2- The provided concentration of Mometasone 1% is very high, while the concentration listed in scientific references is 0.1%, which leads to an increase in the side effects of the active substance.

*- Cancellation of preparations under registration that contain the composition (Cefepime + Enmetazobactam) and deleting it from the boxes while applying the rules, and not approving the reception of new preparations based on the decision of the combined Specialized Scientific Committee for Internal Medicine Diseases at its session on 29/11/2022.

Notes: the Combined Specialized Scientific Committee for Internal Medicine Diseases At its session on 29/11/2022, recommended the following: refusal to register the preparation from a scientific standpoint due to the failure to provide scientific evidence which proves the effectiveness and safety of the formulation, as the original preparation is still under clinical studies in international bodies.

*- Not approving the reception of new preparations containing Phenazopyridine, and Cancellation of preparations under registration, and registered preparations when applying for re-registration, and deleting these preparations from the boxes while applying the rules, Based on the decision of the Combined Specialized Scientific Committee for Kidney and Urinary Tract Diseases at its session on 24/10/2022.

Notes:

the Combined Specialized Scientific Committee for Kidney and Urinary Tract Diseases At its session on 24/10/2022, recommended the following: Rejecting the preparation due to its severe side effects “Methemoglobinemia”. According to the FDA, this side effect greatly exceeds the desired benefit of the drug, and the committee believes that there is no urgent need for this drug, as the active ingredient is used to relieve pain in cases of urinary tract infection, and There are other active substances with fewer side effects available in the Egyptian market that can be used to treat urethral infections, and thus relieving the pain, as (Fosfomycin, Trimethoprim, Sulphamethazole).

*- Not approving the reception of new preparations and cancellation of preparations under registration containing the composition (Cyclopenthiazide + Oxprenolol) and deleting it from the Box while applying the rules, Based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 18/12/2022.

Notes:

the Combined Specialized Scientific Committee for Cardiovascular Diseases At its session on 18/12/2022, recommended the following: Rejection of the preparation due to:

1- There is no indication of this composition in any of the international recommendations for treating high blood pressure or coronary artery disease.

2- The company did not provide sufficient studies proving the safety and effectiveness of the presented formula

Decisions of the Technical Committee for Drug Control at its session on 23/02/2023

*- Not approving the completion of registration procedures for veterinary preparations under registration containing Framycetin in the form of injections, and not approving the reception of new veterinary preparations containing Framycetin based on the decision of the Specialized Scientific Committee for Veterinary Medicines and Feed Additives at its session on 23/01/2023.

Notes:

The Specialized Scientific Committee for Veterinary Medicines and Feed Additives recommended in its session on 23/01/2023 the following: "Refusing to complete the registration procedures for this preparation and similar preparations due to the lack of a reference for the formulation. There are also controls for the use of this compound in injecting animals used for human consumption due to its high toxicity to the kidneys, in addition to the destruction of the middle ear (Ototoxicity & Nephrotoxicity). It has also been scientifically proven that there are residues of the drug in animal tissues for long periods, which leads to the destruction of human health.

Decisions of the Technical Committee for Drug Control at its session on 09/03/2023

*- Cancellation of preparations under registration that contain the composition (Glutamate+ Promethazine) and deleting it from the box while applying the rules, and not approving the reception of new preparations based on the decision of the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 30/01/2023.

Notes:

the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases At its session on 30/01/2023, recommended the following: “Not approving the preparation for the following reasons:

1- The company did not submit any scientific files that prove the effectiveness and safety of the formula.

2- There is no scientific basis for combining these two substances together in the treatment of insomnia.

Decisions of the Technical Committee for Drug Control at its session on 16/03/2023

*- Regarding the Decision of the Technical Committee for Drug Control at its session on 01/04/2021 that states: Regarding human drug preparations for intramuscular injection containing Lidocaine as a solvent "Approving the proposal submitted by the Human Medicines Registration Department to allow companies to use Lidocaine solvent in a volume different from the quantity with which it will be dissolved (provided that the solvent is registered as a separate preparation), provided that a commitment is made to write the quantity of the solvent with which it will be dissolved - according to the approved leaflet - on the packaging, And the Leaflet, with a follow-up by the inspection, for a period of only one year from the date of the committee, in order to reconcile the situation and to preserve the provision of the products to the Egyptian patient, especially in the era of Corona crisis and the need for antibiotics, with the direction of the Human Medicines Registration Department to implement the rules.

-The Technical Committee for Drug Control decided at its session on 26/05/2022 to approve the extension of the deadline granted by the decision of the Technical Committee at its session on 01/04/2021 for another year ending on 01/04/2023.

-The Technical Committee for Drug Control, at its session on 16/03/2023, decided to approve the extension of the deadline granted by the decision of the Technical Committee at its session on 01/04/2021 for six months for the last time, starting from 01/04/2023, to end on 01/10/2023.

Decisions of the Technical Committee for Drug Control at its session on 23/03/2023

*- Cancellation of the preparations under registration, and deleting them from the boxes in accordance with the rules, and not approving the reception of new preparations containing "Dorzaglitin" Based on the decision of the Combined Specialized Scientific Committee for Endocrine and Metabolism Diseases at its session on 30/01/2023.

Notes:

The Combined Specialized Scientific Committee for Endocrine and Metabolism Diseases recommended at its session on 30/01/2023: Rejection of the preparation, as the original preparation is still under clinical studies that indicate the effectiveness and safety of the formulation in international bodies.

*- Cancellation of the preparations under registration, and deleting them from the boxes in accordance with the rules, and not approving the reception of new preparations containing **Ansofaxine hydrochloride (Toludesvenlafaxine)** Based on the decision of the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 30/01/2023.

Notes:

The Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases, at its session on 30/01/2023, recommended the rejection of the preparation as the original product is still under the clinical studies that indicate the effectiveness and safety of the formulation in international bodies.

*- Not approving the reception of new preparations and Cancellation of the preparations under registration that contain the composition (Ruscogenine + Trimebutine) in the Rectal Dosage form, and deleting them from the Boxes according to the rules, Based on the decision of the Combined Specialized Scientific Committee for General Surgery at its session on 23/11/2022 and the decision of the Pharmacovigilance Committee at its session on 16/02/2023.

Notes:

1-The Combined Specialized Scientific Committee for General Surgery, at its session on 23/11/2022, recommended the rejection of the combination after reviewing the response of the ANSM (the pharmaceutical regulatory body of the State of France) on 29/09/2022, after contacting it regarding discontinuing the rectal cream which indicates that the balance of benefits and risks is not in favor of the product.

This included the following:

> The Commission also found an adverse reaction profile dominated by cutaneous and immunological effects (anaphylaxis and contact dermatitis) and an added risk of cutaneous and immunological manifestations with the combination trimebutine/Ruscogenin.
>
> The benefit/risk ratio of the specialties based on trimebutine and Ruscogenin in rectal form (Proctolog®) was unfavorable in the indication "symptomatic treatment of painful and itchy manifestations, fissurary syndromes, especially in hemorrhoidal crisis".

2- The Pharmacovigilance Committee, at its session on 16/02/2023, Decided:

Commitment to its previous decision in its two sessions on 26/12/2019 and on 20/02/2020 of not to approve the registration of this combination for the following reasons:

- There are no updates regarding the safety of the formulation in question.

- The previous reasons for rejection still present, and these reasons stipulate the following:

According to what was published on the ANSM website of the French regulatory body:

- The benefit /risk ratio of rectal cream is not favorable.
- Immune allergic and cutaneous undesirable effects such as contact dermatitis, urticarial eczema, edematous reaction and anaphylactic shock.

Decisions of the Technical Committee for Drug Control at its session on 06/04/2023

*- Not approving to complete the registration procedures for the preparations under registration containing the Combination (Amoxicillin + Vonoprazan) and removing it from the Boxes and the database of the Egyptian Drug Authority while applying the rules, and not approving the reception of new preparations based on the decision of the Combined specialized scientific committee for Gastrointestinal and Liver Diseases at its session on 13/02/2023.

Notes:

The Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases, at its session on 13/02/2023: recommended, Disapproval of preparations containing "Vonoprazan & Amoxicillin" provided as a Combo Pack, as the provided package does not contain Clarithromycin, and this is not compatible with the therapeutic protocol for treating Helicobacter pylori bacteria, which requires its presence in the treatment protocol, and this may lead to an increase in antibiotic resistance against this infection.

*- Approval of the submitted proposal that states the exception of the preparations submitted for registration for export purposes only, from the decision of the Technical Committee for Drug Control at its session on 04/12/2014.

Notes:

The Technical Committee for Drug Control has decided at its session on 04/12/2014 to determine the number of registration applications submitted for the purpose of export and tenders to be as follows:

- For factories: 2 orders per month

- For Manufacturing for others companies" Toll": 1 order per month.

Decisions of the Technical Committee for Drug Control at its session on 11/05/2023

*- Definition of Large volume parenteral according to USP to become: Preparations containing more than 100 ml.

- For human pharmaceutical preparations that contain Sodium Metabisulphite as an inactive ingredient in pharmaceutical dosage forms given by intramuscular or intravenous injection:

Updating the decision of the Technical Committee for Drug Control on 25/06/2020 to become:

1. For Small Volume Parenteral preparations:

The presence of Sodium Metabisulphite in pharmaceutical forms given by intramuscular or intravenous injection is permitted with a maximum of 40 mg as maximum daily dose as per FDA Inactive ingredient database.

- For Large Volume Parenteral preparations:

The presence of Sodium Metabisulphite in the composition statement is not permitted unless the Innovator composition statement contains this substance in the same concentration.

2. In the Case of production of the pilot batch or issuance of the stability study approval before the date of the Technical Committee on 25/06/2020, the final registration notification will be issued and a period of 18 months is given from the date of the Technical Committee's approval to issue the registration notification in order to reconcile the situation and modify the composition statement in accordance with the rules of variation for registered pharmaceutical preparations, then after the expiry of this period, production and circulation will be suspended until the necessary studies are completed.

Note:

The Technical Committee for Drug Control decided at its session on 25/06/2020: For large volume Parentrals: the presence of the inactive ingredient Sodium Metabisulphite in the composition statement is not permitted unless the Innovator composition statement contains this substance.

1.For Paracetamol (Acetaminophen) Solution for Infusion:

- For Registered preparations: Deletion of Sodium Metabisulphite from the composition statement, and application of the rules of variations to registered pharmaceutical preparations, and a period of 18 months is given from the date of the committee to reconcile the situation, and production and circulation are stopped after the expiry of this period.

- For Preparations under registration: Deletion of Sodium Metabisulphite from the composition statement & If the product is in the final stages of registration (obtained stability approval, or pilot batches were manufactured before the date of the Technical Committee on 25/06/2020), then the registration notification is allowed to be issued and a period of 18 months is given from the date of the committee (in a manner that does not conflict with any other deadlines granted to the preparation) to reconcile the situation and delete Sodium Metabisulphite from the composition statement in accordance with the rules of Variations for registered pharmaceutical preparations, and production and circulation shall be stopped after the expiry of this deadline.

- For paracetamol solution for infusion registered and circulated products that doesn’t contain sodium metabisulphite: Retained samples from previous batches should be withdrawn to analyze the presence of sodium metabisulphite

*- Not approving the reception of new preparations containing the composition (Proton Pump inhibitor + Sodium Bicarbonate) in the form of Gastro-Resistant dosage forms, and cancellation of the preparations under registration and deleting them from the Boxes with applying the rules, based on the decision of the Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 13/02/2023.

Notes:

The Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases, at its session on 13/02/2023, recommended Not approving the registration of the preparation, as the pharmaceutical form of Gastro-Resistant Granules for Oral Suspension will cause the inactivation of NaHCo3, which is required to be effective at the beginning of taking the dose to neutralize stomach acid and reserve the effect of Esomeprazole from the breakdown.

*- Not approving the reception of new preparations containing (Mirabegron + Solifenacin succinate + Tamsulosin) in the oral dosage forms, and cancellation of the preparations under registration and deleting them from the Boxes with applying the rules, based on the decision of the Combined Specialized Scientific Committee for Kidney and Urinary Tract Diseases at its session on 22/02/2023.

Notes:

- The Combined Specialized Scientific Committee for Kidney and Urinary Tract Diseases, at its session on 22/02/2023, recommended the rejection of the preparation as the company didn't submit any recent scientific studies indicating the safety and effectiveness of the presented formulation for using the three ingredients together, in addition to the fact that the concentrations of the active ingredients for this formulation are not compatible according to the therapeutic protocols, which include: The following:

Mirabegron 50 mg + Solifenacin succinate 5 mg

Solifenacin succinate 6 mg + Tamsulosin HCL 0.4 mg.

*- Not approving the reception of new preparations containing the combination (Trypsin-Chemotrypsin complex + Doxycycline) in the oral dosage forms, and cancellation of the preparations under registration and deleting them from the Boxes

with applying the rules, based on the decision of the Combined Specialized Scientific Committee for Internal Medicine Diseases at its session on 28/02/2023.

Notes:

- The Combined Specialized Scientific Committee for Internal Medicine Diseases, at its session on 28/02/2023, recommended the refusal of the preparation for the following reasons:

1- The company did not provide any scientific files proving the effectiveness and safety of the presented formula

2- There is no scientific basis for combining Antibiotic & Proteolytic enzymes

*- Not approving the reception of new preparations containing the substance Anamorelin, and cancellation of the preparations under registration and deleting them from the boxes with applying the rules, based on the decision of the Pharmacovigilance Committee at its session on 03/11/2022 and the decision of the Combined Specialized Scientific Committee of the Cancer and radioactive isotopes at its session on 28/02/2023.

Notes:

- The Combined Specialized Scientific Committee for Cancer and Radioisotopes, at its session on 28/02/2023, recommended: Not approving the registration of this active substance in support of the decision of the Pharmacovigilance Committee at its session on 03/11/2022, which states:

Based on the EMA's refusal to register the substance, as:

- The balance of risks and benefits is not in favor of the product.
- Studies provided by the company show that the preparation has marginal effect on lean body mass and no proven effect on hand grip strength or patient quality life.
- The information provided regarding the safety of the product is not sufficient.

*- Not approving the reception of new preparations containing the substance Zabofloxacin, cancellation of the preparations under registration and deleting them from the boxes with applying the rules, based on the decision of the Combined specialized scientific committee for chest diseases at its session on 20/03/2023.

Notes:

- The Combined Specialized Scientific Committee for Chest Diseases, in its session on 20/03/2023, recommended the following: The committee still stands by its previous decision on 19/09/2017 to refuse to register the substance due to the lack of sufficient studies indicating the safety and effectiveness of this preparation, as the original products are still under clinical studies in Global bodies.

Decisions of the Technical Committee for Drug Control at its session on 01/06/2023

*- Not approving to complete the registration procedures for preparations under registration that contain Gentamicin at a concentration of 0.3% for topical use on the skin and delete them from the boxes with applying the rules, and Not approving the reception of new preparations based on the decision of the Pharmacovigilance Committee at its session on 09/03/2023 and the Combined specialized scientific committee For Dermatology, Venereology and Andrology Diseases at its session on 27/03/2023.

Notes:

- The Pharmacovigilance Committee recommended in its session on 09/03/2023 not to approve a concentration of 0.3 gm of Gentamicin in the pharmaceutical form topical cream, as there is no sufficient information about the safety of this product at this concentration and this pharmaceutical dosage form, given that the reference concentration for topical use is 0.1 gm.

- The Combined Specialized Scientific Committee for Dermatology, Venereology and Andrology, in its session on 27/03/2023, recommended that the concentration of Gentamicin provided at 0.3% is too high for the pharmaceutical form of topical cream, and this concentration is recorded in all health authorities in the form of Ophthalmic preparations. while for Topical preparations, it is registered in health authorities at a concentration of 0.1%, and there is not sufficient information about this concentration in this pharmaceutical form. The committee also supports the decision of the Pharmacovigilance Committee dated 09/03/2023 not to approve a concentration of 0.3 gm of Gentamicin in the pharmaceutical form topical cream.

*- Approval to receive new preparations containing Edaravone at a concentration of 105mg/5ml in the pharmaceutical form of Oral Suspension and to exclude them from the decision of the Technical Committee regarding NSAIDS on 01/04/2010, and the application will be implemented starting from 01/07/2023.

Decisions of the Technical Committee for Drug Control at its session on 22/06/2023

*- Approval of the recommendation of the Specialized Scientific Committee for Veterinary Medicines and Feed Additives at its session on 12/06/2023 not to use veterinary preparations containing one of the two substances (Dimetridazole or Metronidazole) in animals and birds used for human consumption, provided that this decision applies to preparations registered or under registration or submitted for re-registration. With regard to registered preparations, companies are given a period of 6 months from the date of the committee to reconcile the situation.

Notes:

- The Specialized Scientific Committee for Veterinary Medicines and Feed Additives recommended at its session on 12/06/2023 regarding the two substances (Dimetridazole or Metronidazole): Not to use the substances (Dimetridazole or Metronidazole) in animals and birds used for human consumption, provided that this decision applies to preparations registered or under registration or submitted for re-registration in accordance with the following report:

The Specialized Scientific Committee for Veterinary Medicines and Feed Additives studied the effect of Metronidazole and preparations from the same group of Nitroimidazoles and the safety and security of their use in animals used for human consumption... and it concluded the following:

*- The phenomenon of antimicrobial resistance has become accelerating in this era as a result of the expansion of the uncontrolled use of antimicrobials in humans, animals and plants. The result of this is related to current global concerns about the ability of microbes to develop more complex antimicrobial resistance mechanisms, which can ensure their survival and render drugs ineffective in treating serious diseases in humans.

The World Health Organization has declared that antimicrobial resistance is considered one of the ten major global threats, and the misuse and overuse of antimicrobials in humans, animals and plants are the main drivers of the emergence of drug-resistant microbes.

* In 2019, the World Health Organization prepared a revised list of highly important antimicrobials for human use with the intention of using it as a reference to help formulate and prepare risk management strategies to contain the phenomenon of antimicrobial resistance. One of the most important of these decisions is to prevent the use of antimicrobials used for human treatment, which are classified internationally (Important for human medicine) from use in treating animals used for human consumption (Food Animals). The European Medicines Evaluation Agency (EMEA) also classified medicines intended for human use as Very Important for Human Medicine and prevented their use in animals used for human consumption.

* In 2019, the Food and Drug Administration (FDA) announced a ban on the use of medications from the group Nitroimidazoles (Metronidazole - Ronidazole - Tinidazole - Ipronidazole) in all animals used for human consumption, including birds, fish, and horses used for human consumption. This is due to what applies to this group of drugs (Important for human medicine) of utmost importance for human use.

* Also, the European Medicines Evaluation Agency (EMEA) included the Nitroimidazole group and the others (Dimetridazole, Metronidazole, Ornidazole and Tinidazole) among the drugs that are prohibited for use in animals used for human consumption.... (EU by Commission Regulation NO 37 /2010) as a result of the presence of residues of these compounds in the tissues and organs of animals used for human consumption, as well as eggs and tissues of poultry, which threatens humanity with the phenomenon of antimicrobial resistance. This decision has been included in the regulations of the European Agency (EU by

Commission Regulation NO 37/2010), and using these compounds in animals used for human consumption is considered a violation of the regulations and laws.

*The World Health Organization, the Food and Drug Organization, and the European Medicines Evaluation Agency have confirmed that in the event that drugs from the Nitroimidazole group and others are used in animals not used for human consumption, care must be taken not to use them during pregnancy because of the fetal deformities they cause, and not to use them during breastfeeding because of their Carcinogenic effects to tissues, Such as use in cats, dogs, ornamental birds, and parrots.

Decisions of the Technical Committee for Drug Control at its session on 13/07/2023

*- Not approving to complete the registration procedures for the preparations under registration that contain the substance Pentosan in the pharmaceutical form of injection and deleting them from the boxes with application of the rules and not approving to receive new preparations based on the decision of the Combined specialized scientific committee for cardiovascular diseases at its session on 21/05/2023.

Notes:

- The Combined Specialized Scientific Committee for Cardiovascular Diseases, at its session on 21/05/2023, recommended rejecting the preparation because the company had not provided sufficient scientific studies for this pharmaceutical form and for the indications for use presented by the company.

*- Not approving to complete the registration procedures for the preparations under registration that contain the substance Vildagliptin at a concentration of 100 mg and delete them from the boxes with application of the rules and not approving to receive new preparations based on the decision of the Combined Specialized Scientific Committee for Endocrine Diseases at its session on 08/06/2023.

Notes:

- The Combined Specialized Scientific Committee for Endocrine Diseases recommended at its session on 08/06/2023: rejecting the registration of the preparation from a scientific standpoint because:

1- The daily reference dose is 100 mg divided into two equal doses. The dose is taken as follows:

50 mg twice daily for patients with normal kidney function tests

50 mg once daily for patients with kidney dysfunction

It is not recommended to give a dose of 100 mg once daily to a person with healthy kidneys.
2- Not providing sufficient studies indicating the effectiveness and safety of the presented concentration.

*- Approval to receive new reference preparations containing Lactobacillus for use in gynecology based on the decision of the Combined Specialized Scientific Committee for Obstetrics and Gynecology at its session on 12/06/2023, and the application will take place starting from the month following the issuance of the decision.

Notes:

- At its session on 12/06/2023, the Combined Specialized Scientific Committee for Obstetrics and Gynecology recommended approving the preparation from a scientific standpoint, as it is useful in some cases of recurrent infection.

Decisions of the Technical Committee for Drug Control at its session on 10/08/2023

* - Approval to receive new reference preparations containing Mirogabalin starting from the beginning of September 2023& The pharmacovigilance will monitor these preparations and a report on them will be submitted six months after the first preparation is registered and circulated in Egypt.

* - Not approving to complete the registration procedures for the preparations under registration containing the combination (Lidocaine + Diclofenac sodium + Gabapentin) and cancelling them from the Boxes in accordance with the rules, and not approving to receive new preparations based on the decision of the Combined Specialized Scientific Committee of Rheumatology, Rehabilitation and Orthopedics at its session on 21/06/2023.

Notes:

- The Combined Specialized Scientific Committee for Rheumatology, Rehabilitation and Orthopedics recommended at its session on 21/06/2023:

Not approving the product for the following reasons:

1. The company did not submit approved scientific papers proving the effectiveness and safety of the formula.
2. There is no scientific basis for using Gabapentin as a topical dosage form for the therapeutic purpose provided by the company.

*- Not approving to complete the registration procedures for preparations under-registration containing the substance Centanafadine and canceling them from the Boxes in accordance with the rules, and not approving to receive new preparations until the completion of clinical studies and registering them in reference countries based on the decision of the Combined Specialized Scientific

Committee for Psychiatric and Neurological Diseases at its session on 19/07/2023.

Notes:

- The Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases recommended, at its session on 19/07/2023, not to approve the preparation, as the Brand preparation is still under clinical studies that indicate the effectiveness and safety of the formulation in international bodies.

*- Not approving to complete the registration procedures for preparations under-registration containing the substance Nicergoline and cancelling them from the Boxes in accordance with the rules& not approving to receive new preparations, and not approving the re-registration of the registered preparations and they will be cancelled from the Boxes with the application of the rules based on the decision of the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 19/07/2023.

Notes:

- The Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases recommended at its session on 19/07/2023 that: The committee adheres to its previous decision at its session on 13/06/2022, not to approve the preparation, as Nicergoline has become outdated, and new safer drugs have appeared, such as Piracetam. In addition, the uses of ergot derivatives, have become few and limited, according to what was stated in the EMA report.

*- Not approving to complete the registration procedures for preparations under registration containing the substance Hexoprenaline in pharmaceutical forms: oral dosage form, vaginal dosage form, and these preparations will be cancelled from the boxes in accordance with the rules, and Not approving to receive new

preparations, and Not approving to re-register registered preparations and cancelling them from the boxes, with application of the rules, with the continued registration of preparations containing this substance in the pharmaceutical form of injection in hospitals only, with close follow-up of pharmacovigilance based on the decision of the Pharmacovigilance Committee at its session on 16/03/2023 and the Combined Specialized Scientific Committee for Obstetrics and Gynecology at its session on 12/06/2023.

Notes:

- The Pharmacovigilance Committee, in its session on 16/03/2023, stated: Based on the European Regulatory Authority (EMA), the Committee recommends a Reservations on the use of all short-acting β2-agonist in the pharmaceutical form of oral tablets in obstetric use.

- The Combined Specialized Scientific Committee for Obstetrics and Gynecology recommended at its session on 12/06/2023: This substance belongs to the short acting B2 agonist, which may affect the circulatory system and cause severe side effects on the heart.

Therefore, the committee recommends stopping the use of Hexoprenaline in pharmaceutical forms: oral dosage form, vaginal dosage form, for the therapeutic purposes of obstetric indications, in order to avoid misuse, and the balance of benefits to risks is not in favor of the preparation, according to what was published on the EMA website under the title

Restrictions on use of short acting beta agonist in obstetric indications

The committee recommends keeping the pharmaceutical form as injections in hospitals only under careful medical observation, and there are safer alternatives in the Egyptian market for the same therapeutic purpose, such as (progesterone, dydrogesterone).

Decisions of the Technical Committee for Drug Control at its session on 17/08/2023

*- Not approving to complete the registration procedures for the preparations under registration containing the substance Zuranolone and cancelling them from the boxes and the Egyptian Drug Authority database in accordance with the rules, and not approving to receive new preparations containing Zuranolone based on the decision of the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 19/07/2023.

Notes:

- The Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases recommended, at its session on 19/07/2023, not to approve the preparation, as the Brand product is still under clinical studies to indicate the effectiveness and safety of the formulation in international bodies.

*- Updating the decision of the Technical Committee at its session on 12/01/2023 to become: "Approval to receive new reference preparations containing the following composition starting from the next month in accordance with the rules:

Acetaminophen	325 mg
Dextromethorphan Hydrobromide	10 mg
Phenylephrine Hydrochloride	5 mg
Chlorpheniramine maleate	2 mg

*- Not approving to complete the registration procedures for preparations under-registration and cancelling them from the boxes and the Egyptian Drug Authority database in accordance with the rules, not approving to receive new preparations and not approving to complete the procedures for re-registering registered preparations that contain the substance Isoxsuprine and cancelling them from the boxes and the Egyptian Medicines Authority database. This is upon re-registration with the application of the rules based on the decision of the Pharmacovigilance Committee at its session on 18/05/2023 and the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 19/07/2023.

Notes:

The Pharmacovigilance Committee recommended, at its session on 18/05/2023, a Reservations on registering the product for the following reasons:

- No information has been found regarding the safety and effectiveness of the active ingredient Isoxsuprine for use in cases of cerebrovascular insufficiency or peripheral vascular disease.
- It has serious side effects, such as Risk of serious cardiovascular side effects when used as tocolysis, according to what was published by the EMA as well as in the global database of adverse effects.
- It was rejected by both the EMA and the FDA for its ineffectiveness in Obstetric Indication, knowing that the preparation is not registered in any of the reference countries.

The Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases recommended, at its session on 19/07/2023, not to approve the re-registration of the product for the following reasons:

1. The Committee supports the decision of the Pharmacovigilance Committee at its session on 18-05-2023
2. This drug has not been used for a long time because of its serious side effects, including cardiovascular effects.
3. There are safer alternatives available in cases of cerebrovascular insufficiency or peripheral vascular disease, such as Nicardipine, Nitroglycerin & Verapamil.

Decisions of the Technical Committee for Drug Control at its session on 24/08/2023

*- Updating the decision of the Technical Committee on 17/08/2023 to become: "Not approving the completion of the registration procedures for non-reference preparations under registration and canceling them from the Boxes and from the Egyptian Drug Authority database in accordance with the rules and not approving the reception of new non-reference preparations containing the substance Zuranolone based on the decision of the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 19/07/2023.

*- Not approving the reception of new preparations and cancellation of the preparations under registration containing the substance Diquafosol in the form of Ophthalmic Preparations and canceling them from the boxes and the Egyptian Drug Authority database in accordance with the rules, based on the decision of the Combined Specialized Scientific Committee for Ophthalmic and Retinal Surgical Diseases at its session on 31/07/2023.

Notes:

- At its session on 31/07/2023, the Combined Specialized Scientific Committee for Ophthalmic and Retinal Surgical Diseases recommended rejecting the preparation as follows:

• There are many alternatives in the Egyptian market for treating dry eye.

• The studies provided by the company are insufficient to prove the effectiveness and safety of the product, and they require further randomized clinical trials, according to what was stated in the papers submitted by the company.

Decisions of the Technical Committee for Drug Control at its session on 31/08/2023

*- Not approving the reception of new preparations and not approving to complete the registration procedures for the preparations under registration that contain the combination (Acefylline Piperazine + Phenobarbitone) or the combination (Acefylline Piperazine + Phenobarbital) and deleting them from the boxes and canceling them from the Egyptian Drug Authority database with the application of the rules, based on a decision The Pharmacovigilance Committee at its session on 16/02/2023 and the decision of the Combined Specialized Scientific Committee for Chest Diseases on 20/03/2023.

Notes:

- **The Pharmacovigilance Committee, at its session on 16/02/2023, recommended the following:** (The Pharmacovigilance Committee still adheres to its previous decision, which is to delete Phenobarbital from cough formulations that contain Acefylline Piperazine/Phenobarbital because it has many adverse effects and drug interactions and may cause addiction if used for long periods, it also has no scientific basis in treating asthma.)

- **At its session on 20/03/2023, the Combined Specialized Scientific Committee for Chest Diseases recommended the following:**

• Phenobarbital is not present in the treatment guidelines for treating bronchial asthma and chronic cough.

• Its use exposes the patient to side effects without any benefit to the patient, especially when used for a long period in the chronic treatment of asthma, and may cause addiction if used for long periods.

• In the event that some patients need sedatives during treatment, one of the alternative sedative medications available on the market can be used for specific periods and at an appropriate dose.

*- Not approving the reception of new preparations and not approving to complete the registration procedures for under-registered preparations that contain Pholcodine, deleting them from the boxes, and canceling them from the Egyptian Drug Authority database with the application of the rules, based on the

decision of the Pharmacovigilance Committee at its session on 13/04/2023 and the decision of the Combined Specialized Scientific Committee. for Chest Diseases on 29/05/2023.

Notes:

- **The Pharmacovigilance Committee, at its session on 13/04/2023, recommended the following:** "The Committee recommends conservation of all preparations containing pholcodine due to the serious side effects that result from its interaction with NMBAs, according to some regulatory authorities and the absence of effective measures to minimize this risk, especially since the drug has many alternatives, and companies should be obligated to distribute a letter addressed to health care providers explaining the reason for discontinuing preparations containing the active ingredient pholcodine based on the EMA's decision.
- **At its session on 29/05/2023, the Combined Specialized Scientific Committee for Chest Diseases recommended the following:**
  Conservation on all preparations containing pholcodine based on the EMA report on the withdrawal of preparations containing pholcodine, which includes the following:
  "EMA's safety committee, PRAC, concluded its review of medicines containing pholcodine, which are used in adults and children to treat non-productive (dry) cough and, in combination with other active substances, for the treatment of symptoms of cold and flu, and recommended the revocation of the EU marketing authorisations for these medicines. The available data showed that use of pholcodine in the 12 months before general anaesthesia with neuromuscular blocking agents (NMBA) is a risk factor for developing an anaphylactic reaction (a sudden, severe and life-threatening allergic reaction) to NMBAs"

The committee also believes that it is difficult to avoid this risk for pholcodine, in addition to the presence of other alternatives in the Egyptian market that are used as anti-cough medications.

*- Not approving the reception of new preparations and canceling the preparations under registration containing Bacitracin in the pharmaceutical form of Injection based on the decision of the Combined Specialized Scientific Committee for Pediatric Diseases at its session on 30/08/2023.

Notes:

- At its session on 30/08/2023, the Combined Specialized Scientific Committee for Pediatric Diseases recommended the following:

Rejecting the preparation, based on what was stated on the Federal Register website on 15/9/2022 regarding Bacitracin injection preparations.

"The Food and Drug Administration (FDA or Agency) has determined that bacitracin for injection, 10,000 units/vial and 50,000 units/vial, was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for bacitracin for injection."

*- Not approving the reception of new preparations and cancellation of the preparations under registration containing the substance Cyanocobalamin at a concentration of 5 mg based on the decision of the Combined Specialized Scientific Committee for Internal Medicine diseases at its session on 22/08/2023.

Notes:

The combined specialized scientific committee for internal Medicine diseases recommended, at its session on 22/08/2023., the following:

The preparation was not approved, as the concentration of Cyanocobalamin is very higher than the therapeutic dose mentioned in the scientific reference BNF 84, which is Adult: 50–150 micrograms daily.

Decisions of the Technical Committee for Drug Control at its session on 21/09/2023

*- Not approving to complete the registration procedures for preparations under registration that contain Diclofenac Epolamine at a concentration of 0.074% in the Mouth Wash pharmaceutical dosage form and canceling them from the Egyptian Drug Authority database and from the boxes in accordance with the rules, and not approving to receive new preparations due to lack of reference.

*- Approval to receive new reference preparations containing the substance Tramadol, with implementation starting from the beginning of October 2023

Decisions of the Technical Committee for Drug Control at its session on 12/10/2023

*- Not approving to complete the registration procedures for the preparations under registration and canceling them from the boxes and the Egyptian Drug Authority database while applying the rules, and Not approving the reception of new preparations containing the **combination (Clindamycin Phosphate + Benzoyl Peroxide + Adapalene)** until the completion of clinical studies based on the decision of the Combined specialized scientific committee for Dermatology, Venereology and Andrology at its session on 18/09/2023.

Notes:

The preparation was presented to the Combined Specialized Scientific Committee for Dermatology, Venereology and Andrology Diseases at its session on 18/09/2023, which recommended: Not to approve the preparation as there are no sufficient scientific studies proving the efficiency, effectiveness and safety of the combination together. Also, the scientific file submitted by the company stated that the formula is still under clinical studies in Phase 2 & Phase 3.

*- Not approving to complete the registration procedures for the preparations under registration and canceling them from the boxes and the Egyptian Drug Authority database with the application of the rules, and not approving the reception of new preparations containing **Fexuprazan Hydrochloride** until the completion of clinical studies based on the decision of the Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 14/ 09/2023.

Notes:

The preparation was presented to the Combined Specialized Scientific Committee for Gastrointestinal and Liver Diseases at its session on 14/09/2023, which recommended: Not to approve the preparation due to the lack

of completion of clinical studies that indicate the effectiveness and safety of the formulation in accredited international bodies.

*- Amending the decision of the Technical Committee for Drug Control at its session 03/10/2019 to "Not approving the reception of new, non-reference preparations containing the substance **Methylphenidate**, and not approving the completion of the registration procedures for non-reference preparations under registration, and cancelling them from the boxes and the Egyptian Drug Authority database, with the application of the rules.

Note:

The Technical Committee decided on 03/10/2019: to amend the decision of the Technical Committee regarding Methylphenidate on 02/08/2018 to be: "Not approving to complete the procedures for registering preparations, canceling preparations under registration, and not approving to receive new preparations containing **Methylphenidate** at a concentration of 22 mg, based on the decision of the Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 07/09/2017".

Decisions of the Technical Committee for Drug Control at its session on 19/10/2023

*- Not approving the completion of the registration procedures for the preparations under registration and deleting them from the Egyptian Drug Authority database and from the boxes with the application of the rules, and not approving the reception of new preparations containing **Nilvadipine** at a concentration of **16 mg** for use in the treatment of Alzheimer's until the completion of the studies, due to lack of reference.

Decisions of the Technical Committee for Drug Control at its session on 02/11/2023

*- Not-approving the completion of the registration procedures for the preparations under registration and deleting them from the boxes and from the Egyptian Drug Authority database while applying the rules, and not-approving the reception of new preparations containing **Ulotaront** at a concentration of **100 mg** until the end of clinical studies, based on the decision of the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 23/10/2023.

Notes:
The preparation was presented to the Combined Specialized Scientific Committee for Psychiatric and Neurological Diseases at its session on 23/10/2023, which recommended: Not approving the preparation, as the reference product is still under clinical studies indicating the effectiveness and safety of the formulation in International Bodies.

*- Not-approving the completion of the registration procedures for the preparations under registration and deleting them from the boxes and from the Egyptian Drug Authority database while applying the rules, and not-approving the reception of new preparations containing the combination (**Mirabegron 50 mg + Solifenacin 10 mg)** in the pharmaceutical form; **tablets**, based on the decision of the Combined Specialized Scientific Committee for Kidney and Urinary Tract Diseases at its session on 23/10/2023.

Notes:
The preparation was presented to the Combined Specialized Scientific Committee for Kidney and Urinary Tract Diseases at its session on 23/10/2023, which recommended: rejecting the preparation because the company did not submit the studies required by the committee (Pharmacokinetics, pharmacodynamics) for this formulation in this pharmaceutical form (Tablets).

Decisions of the Technical Committee for Drug Control at its session on 23/11/2023

*- Not-approving the completion of the registration procedures for the preparations under registration containing the combination (Empagliflozin + Metformin + Vildagliptin) in the pharmaceutical dosage form of Extended-Release Tablets and to cancel them from the boxes and the database of the Egyptian Drug Authority while applying the rules, and not-approving the reception of new preparations based on the decision of the Combined Specialized Scientific Committee for Endocrinology and Metabolism Diseases at its session on 06/11/2023.

Notes:

The preparation was presented to the Combined Specialized Scientific Committee for Endocrinology and Metabolic Diseases at its session on 06/11/2023, which recommended: Not approving the preparation because the company did not submit the studies required by the committee that prove the safety and effectiveness of the formulation for this pharmaceutical form (Extended Release Tablets), as Vildagliptin is available in reference countries and scientific references in pharmaceutical form " tablet", whether alone or in a combination.

*- Not-approving the completion of procedures for registering under-registration preparations containing Nitroglycerin at a concentration of 9 mg and deleting them from the boxes and the Egyptian Drug Authority database while applying the rules, and not-approving the reception of new preparations, due to lack of reference. This decision will not be reconsidered until studies emerge proving the safety and effectiveness of this concentration, based on the decision of the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 27/09/2023 and the Pharmacovigilance Committee at its session on 26/10/2023.

Notes:

1- The preparation was presented to the Combined Specialized Scientific Committee for Cardiovascular Diseases at its session on 27/09/2023, which recommended: Approval from a scientific standpoint for the concentrations of 2.5 mg and 6.5 mg, since these concentrations are reference concentrations and falls within the therapeutic range, and disapproval of the concentration 9 mg as there is no scientific reference for the use of Nitroglycerin in this large dose, in addition to the fact that the side effects will double with this large concentration and the failure to provide sufficient studies proving the safety and effectiveness of this concentration (9 mg), so the committee recommended rejecting the preparation because the company did not submit the studies required by the committee (pharmacokinetics , pharmacodynamics) for this formulation in this pharmaceutical form (tablets).

2- The preparation was presented to the Pharmacovigilance Committee at its session on 26/10/2023, which recommended: There is no objection to re-register preparations containing the active ingredient Nitroglycerin in the pharmaceutical form “Sustained release capsules”, with concentrations of 2.5 & 6.5 mg, as there is no information that negatively affects the balance of benefits and risks and recommended not approving the 9 mg concentration due to the side effects it has with this concentration based on the decision of the Scientific Committee dated 27/09/2023.

*- Not approving the reception of new preparations and not approving to complete the registration procedures for the preparations under registration that contain the Combination (Bromhexine + Terbutaline + Guaifenesin + Menthol) in the form of Oral syrup, deleting them from the boxes and canceling them from the Egyptian Drug Authority’s database while applying the rules, based on the decision of the Pharmacovigilance Committee at its session on 27/09/2023 and

the decision of the Combined Specialized Scientific Committee for Chest Diseases dated 20/03/2023.

Notes:

1- **The preparation was presented to the Combined Specialized Scientific Committee for Chest Diseases at its session on 20/03/2023, which recommended:** The committee has conservations on the presence of Terbutaline in the formula, as it belongs to the therapeutic group systemic B2 agonist, and the use of cough medicines that contain this substance without medical supervision may lead to side effects such as cardiac arrhythmia.

Therefore, the committee recommends removing Terbutaline from this formulation, which is classified as a cough medicine and can be registered separately in case it is needed as a bronchodilator.

2- **The preparation was presented to the Pharmacovigilance Committee at its session on 27/09/2023, which recommended:** Conservations on the presence of Terbutaline in the form of a fixed dose combination within the Combination (Guaifenesin + Menthol + Bromhexine) and other formulations, and that it is preferable to use it individually in case of need for it as a bronchodilator, according to the research results, and based on the decision of the Scientific Committee dated 20/03/2023 “the use of cough medicines that contain this substance without medical supervision may leads to side effects such as Cardiac arrhythmia”, and the decision applies to similar cases of fixed dose combination of B2 agonists in cough medicines.

*- Not approving the reception of new preparations and not approving to complete the registration procedures for the preparations under registration that contain the combination (Salbutamol + Guaifenesin + Bromhexine) in the form of Oral syrup, deleting them from the boxes, and canceling them from the Egyptian Drug Authority database, while applying the rules based on the decision of the Pharmacovigilance Committee at its session on 27/09/2023 and the

decision of the Combined Specialized Scientific Committee for Chest Diseases dated 28/08/2023.

Notes:

1- The preparation was presented to the Combined Specialized Scientific Committee for Chest Diseases at its session on 28/08/2023, which recommended:

- The committee has Conservations on the presence of Salbutamol in the formula, as it belongs to the therapeutic group systemic β2 agonist, and the use of cough medicines that contain this substance without medical supervision may lead to side effects such as cardiac arrhythmia.

Therefore, the committee recommends removing Salbutamol from this formulation, which is classified as a cough medicine and can be registered separately if needed as a bronchodilator.

2- The preparation was presented to the Pharmacovigilance Committee at its session on 27/09/2023, which recommended: Conservations on the presence of Terbutaline in the form of a fixed dose combination within the combination (Guaifenesin + Menthol + Bromhexine) and other combinations, and that it is preferable to use it individually in case of the need for it as a bronchodilator. This is according to the results of the research, and based on the decision of the Scientific Committee dated 20/03/2023 “the use of cough medicines that contain this substance without medical supervision may lead to side effects such as Cardiac arrhythmia”, and the decision applies to similar cases of fixed dose combination of B2 agonists in cough medicines.

Decisions of the Technical Committee for Drug Control at its session on 07/12/2023

*- Not approving to complete the registration procedures for the preparations under registration and canceling them from the boxes and the Egyptian Drug Authority database while applying the rules, and not approving the reception of new preparations containing Idoxuridine based on the decision of the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 22/11/2023.

Notes:

The preparation was presented to the Combined Specialized Scientific Committee for Eye and Retina Diseases and Surgery at its session on 22/11/2023, which recommended: rejecting the preparation as follows:

- The company did not provide recent studies indicating the safety and effectiveness of Idoxuridine
- This substance has many side effects, such as: epithelial toxicity, potential carcinogen, according to the Lexicomp and PubMed references.
-The preparation has been withdrawn from the reference countries.

Decisions of the Technical Committee for Drug Control at its session on 28/12/2023

* - Not approving the reception of new preparations and canceling the preparations under registration that contain the substance Cefoselis Sulfate, and delete them from the boxes and the Egyptian Drug Authority database, while applying the rules, based on the decision of the Combined specialized scientific committee for chest diseases at its session on 18/12/2023.

Notes:

The preparation was presented to the Combined Specialized Scientific Committee for Chest Diseases at its session on 18/12/2023, which recommended: not approving the preparation from a scientific standpoint, because this active substance is not found in any of the reference countries or scientific references, and according to the scientific file submitted by the company, The substance has severe side effects on the nervous system.