Notice to applicant

**Central Administration for Pharmaceutical Products**

**General Administration of Veterinary Pharmaceuticals**

# Decisions of the Organizing Committees of Veterinary Pharmaceuticals' Registration

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- **Decisions of the Technical Committee for Drug Control and the Specialized Scientific Committee for Veterinary Products and Feed Additives:**

**Decision of the Technical Committee for Drug Control issued at the session dated 8/9/2012, regarding veterinary pharmaceuticals containing the following substance:**

*Sulphaquinoxaline

The Technical Committee for Drug Control has decided to approve the recommendation of the Scientific Committee for Veterinary Medicines, which permits the registration of products containing this substance, along with writing a warning on the outer package that reads: "This substance shall not be used for egg-laying birds or dairy cattle, and its use must be stopped for a period of 10 days before the animal slaughter if the animal is meat producing intended for human consumption.

**Decision of the Technical Committee for Drug Control issued at the session dated 2/12/2020, regarding veterinary pharmaceuticals containing the following substance:**

*Chlortetracycline Hydrochloride

The Technical Committee for Drug Control has decided not to approve the use of these pharmaceuticals as feed additives, along with reviewing the leaflets for similar pharmaceuticals and placing a warning in a clear place on the outer package.

**The Technical Committee's decision issued at the session regarding veterinary pharmaceuticals containing the following substance:**

* Quinapyramine

The Technical Committee for Drug Control has decided that pharmaceuticals containing this substance shall not be re-registered and new similar pharmaceuticals shall not be received.

**Decision of the Technical Committee issued at the session dated 27/10/2011 regarding veterinary pharmaceuticals that contain the following two substances:**

*(Tylosin + Colistin)

The Technical Committee for Drug Control has decided not to approve the re-registration of pharmaceuticals containing these two substances together and not to receive similar pharmaceuticals.

**Decision of the Technical Committee for Drug Control issued at the session dated 24/11/2011:**

- The Technical Committee for Drug Control has decided that for veterinary pharmaceuticals, line extension shall be allowed only if it does not conflict with box capacity.

**Decision of the Technical Committee for Drug Control issued at the session dated 27/10/2011:**

- The Technical Committee for Drug Control has decided that veterinary pharmaceuticals containing only vitamins and minerals without any other active substances shall be excluded from the application of the Similars' Box system.

**Decision of the Technical Committee for Drug Control issued at the session dated 24/5/2011 regarding veterinary pharmaceuticals containing the following substance:**

* Difloxacin (Oral Solution)

The Technical Committee for Drug Control has decided containers for veterinary pharmaceuticals containing Difloxacin in the form of Oral Solution shall be limited to 100 ml only.

**Decision of the Technical Committee for Drug Control issued at the session dated 28/6/2012 regarding veterinary pharmaceuticals containing the following substance:**

*Tilmicosin (Premix)

- The Technical Committee for Drug Control has decided to approve the recommendation of the Scientific Committee for Veterinary Products and Feed Additives on 23/5/2012, which states that veterinary pharmaceuticals containing Tilmicosin in the form of Premix shall not be received and that similar veterinary pharmaceuticals shall not be re-registered.

**Decision of the Technical Committee for Drug Control issued at the session dated 14/7/2011 regarding the re-registration of veterinary pharmaceuticals:**

The Technical Committee for Drug Control has decided that veterinary pharmaceutical products shall be re-registered every ten years based on a request submitted by the Applicant to the Central Administration for Pharmaceutical Affairs during the last year of the validity period of the product registration License. Accordingly, requests for re-registration shall not be accepted after the period of ten years ends.

**Decision of the Technical Committee for Drug Control issued at the session dated 18/10/2012 regarding veterinary pharmaceuticals containing the following composition:**

*(Bromhexine Hcl + Trimethoprim + Sulphadimidine)

- At the session dated 18/10/2012, the Technical Committee for Drug Control has decided not to approve the receiving of veterinary pharmaceuticals containing this composition or similar ones in the form of feed additives.

**Decision of the Technical Committee for Drug Control issued at the session dated 13/12/2012 regarding veterinary pharmaceuticals containing the following substance:**

*Disodium Methyl Arsinate

The Technical Committee for Drug Control has decided not to approve receiving of new veterinary pharmaceuticals containing this substance and not to approve the completion of registration procedures for pharmaceuticals under registration. The decision applies to registered analogues upon re-registration.

**Decision of the Technical Committee for Drug Control issued at the session dated 13/12/2012 regarding veterinary pharmaceuticals containing the following substance:**

*Pefloxacin

The Technical Committee for Drug Control has decided not to approve the receiving of new veterinary pharmaceuticals containing this substance.

**Decision of the Technical Committee for Drug Control issued at the session dated 21/1/2013 regarding veterinary pharmaceuticals containing the following substance:**

*Doxycycline

The Technical Committee for Drug Control has decided to approve the recommendation of the Scientific Committee for Veterinary products and Feed Additives, which states that its withdrawal period shall be increased to 10 days in poultry, its use shall be limited to broilers only, and it shall not be used for dairy cattle. Companies shall be given a period of 6 months from the date of the committee 21/1/2013 to implement this decision.

**Decision of the Technical Committee for Drug Control issued at the session dated 21/1/2013 regarding veterinary pharmaceuticals containing the following substance:**

* **Fosfomycin**

The Technical Committee for Drug Control has decided not to approve the completion of registration procedures for any veterinary pharmaceuticals containing Fosfomycin, not to approve the re-registration of registered veterinary pharmaceuticals containing this substance, and not to produce any new batches thereof, while not receiving any veterinary pharmaceuticals containing this substance.

**Decision of the Technical Committee for Drug Control issued at the session dated 27/2/2024 regarding veterinary pharmaceuticals containing the following substance:**

* Fosfomycin

The Technical Committee for Drug Control has decided not to approve the registration of veterinary pharmaceuticals containing this substance for export.

**Decision of the Technical Committee for Drug Control issued at the session dated 21/1/2013 regarding veterinary pharmaceuticals containing the following substance:**

*Clindamycin

The Technical Committee for Drug Control has decided to approve that pharmaceuticals containing this substance shall be registered for cats and dogs only and their pharmaceutical form shall be limited to oral solution, tablets (bolus) and capsules. Meanwhile, the registration of these pharmaceuticals that are under

registration shall be cancelled and the re-registration of pharmaceuticals containing Clindamycin in any other form that differs from this decision shall not be approved. Companies producing and importing pharmaceuticals containing this substance shall be notified of the fact that their use shall be limited to cats and dogs only, and these companies shall be warned against using this substance for birds and farm cattle due to its negative effects. Meanwhile, these companies shall be granted a period of 6 months from the date of the committee to implement the decision.

**Decision of the Technical Committee for Drug Control issued at the session dated 21/1/2013 regarding veterinary pharmaceuticals containing the following two substances:**

*Clindamycin & Spectinomycin

- The Technical Committee for Drug Control has decided that the re-registration of registered pharmaceuticals shall not be approved; the under-registration pharmaceuticals containing this composition shall be cancelled; any new veterinary pharmaceuticals containing this composition shall not be received.

- At the session dated 13/6/2013, the Technical Committee for Drug Control has decided not to produce any new batches or import any new consignments of veterinary pharmaceuticals registered in the composition of Clindamycin + Spectinomycin, after the expiration of a six-month deadline from the date of the committee on 13/6/2013.

**Decision of the Technical Committee for Drug Control issued at the session dated 21/1/2013 regarding veterinary pharmaceuticals containing the following substance:**

*Lincomycin (Premix)

- At the session dated 21/1/2013, the Technical Committee for Drug Control has decided to approve the amendment to the recommendation regarding veterinary pharmaceuticals containing Lincomycin in the form of Premix. The committee states that there is no objection to using Lincomycin as a feed additive in the case stipulated by the FDA, which is the use of this substance in treatment of Necrotic Enteritis caused by Clostridium microbe in broilers.

**Decision of the Technical Committee for Drug Control issued at the session dated 21/1/2013 regarding veterinary pharmaceuticals containing the following substance:**

*Gentamycin (Injection)

The Technical Committee for Drug Control has decided that the registration of new veterinary pharmaceuticals containing this substance in containers exceeding 50 ml shall not be approved, and that the concentration of this pharmaceutical product shall not exceed 10%. This decision shall be applied to registered pharmaceuticals. Concerned companies, the General Administration of Inspection, and the General Authority for Veterinary Services shall be notified that producing any new batches and importing any new consignments of this substance in containers whose volume exceeds 50 ml and whose concentration exceeds 10 shall be suspended as of the date of notification to the companies and the General Authority for Veterinary Services

- At the session dated 2/5/2013, the Technical Committee for Drug Control has decided to approve veterinary pharmaceuticals containing Gentamycin in the form of injections in containers of more than 50 ml for export only, with a commitment to write the phrase “for export only” clearly on the outer label.

**Decision of the Technical Committee for Drug Control issued at the session dated 7/3/2013 regarding veterinary pharmaceuticals containing the following substance:**

*Danofloxacin (W.S.P)

- The Technical Committee for Drug Control has decided not to approve the re-registration of similar pharmaceuticals, not to receive new veterinary pharmaceuticals containing this substance in the form of (W.S.P), to cancel the registration of under-registration pharmaceuticals containing this substance, and not to produce or import any new batches or consignments of registered pharmaceuticals, after six months from the date of the committee.

**Decision of the Technical Committee for Drug Control issued at the session dated 7/3/2013 regarding veterinary pharmaceuticals containing the substance:**

*Ciprofloxacin

- At the session dated 7/3/2013, the Technical Committee for Drug Control has decided not to approve the re-registration of similar pharmaceuticals, and not agreeing to receive new veterinary pharmaceuticals containing Ciprofloxacin, and to cancel under-registration pharmaceuticals containing this substance. As for registered pharmaceuticals, their use shall be limited to cats and dogs. No importation or production of new batches shall take place after six months from the date of the committee.

**Decision of the Technical Committee for Drug Control issued at the session dated 28/2/2013 regarding veterinary pharmaceuticals containing the following two substances:**

*(Tylosin + Oxytetracycline)

- The Technical Committee for Drug Control has decided not to receive new veterinary pharmaceuticals containing this composition, not to approve the re-registration of registered pharmaceuticals, to cancel under-registration pharmaceuticals, and not to produce any new batches or import any new consignments of registered pharmaceuticals, after the expiration of a six-month deadline from the date of the committee.

**Decision of the Technical Committee for Drug Control issued at the 2/5/2013 session regarding veterinary pharmaceuticals containing the following substance:**

* Florfenicol (Premix)

- At the session dated 2/5/2013, the Technical Committee for Drug Control has decided to approve the recommendation issued by the Specialized Scientific Committee for Veterinary products and feed additives on 6/3/2013, which states that the registration and reception of veterinary pharmaceuticals containing Florfenicol in the form of a premix shall not be approved.

**Decision of the Technical Committee for Drug Control issued at the session dated 13/6/2013 regarding veterinary pharmaceuticals containing the following substance:**

*Spiramycin

- The Technical Committee for Drug Control has decided to approve the recommendation of the Specialized Scientific Committee for Veterinary products and Feed Additives regarding veterinary pharmaceuticals containing this substance, which states that the use of veterinary pharmaceuticals containing Spiramycin in the form of W.S.P shall be limited to pigs only, provided that the packages do not exceed 100 grams per package. Meanwhile, its use as injection shall be permitted in non-dairy cows and pigs, provided that the containers do not exceed 100 cm. It can also be used in cats and dogs in the form of tablets only. Moreover, approval is given to the use of these pharmaceuticals in the form of oral solution in pigs only. The decision shall also apply to under-registration pharmaceuticals, and a grace period shall be granted until 31/12/2013 for registered pharmaceuticals to redress the balance of their situations.

**Decision of the Technical Committee for Drug Control issued at the session dated 26/9/2013 regarding veterinary pharmaceuticals containing the following substance:**

*Benzyl alcohol

- The Technical Committee for Drug Control has decided to approve the recommendation of the specialized Scientific Committee for Veterinary products and feed additives on 29/7/2013 and add the warning of not using veterinary pharmaceuticals containing Benzyl alcohol in the form of injections in newborn domestic animals, provided that the warning shall be added to under-registration pharmaceuticals and registered pharmaceuticals, taking into consideration that companies shall be granted a 6-month period from the date of the committee to implement the decision.

**Decision of the Technical Committee for Drug Control issued at the session dated 26/9/2013 regarding veterinary pharmaceuticals containing the following substance:**

*Ceftazidime

The Technical Committee for Drug Control has decided to approve the recommendation of the Specialized Scientific Committee for Veterinary products and Feed Additives at the session, which states that the registration of veterinary pharmaceuticals containing this substance shall not be approved due to the lack of

similar pharmaceuticals in the veterinary field and that veterinary pharmaceuticals containing this substance shall not be received.

**Decision of the Technical Committee for Drug Control issued at the session dated 12/6/2014 regarding veterinary pharmaceuticals containing the following two substances:**

* (Amoxicillin +Flumequine)

The Technical Committee for Drug Control has decided not to receive new veterinary pharmaceuticals containing this composition.

**Decision of the Technical Committee for Drug Control issued at the session dated 28/8/2014 regarding veterinary pharmaceuticals containing the substance of Arsenic:**

The Technical Committee for Drug Control has decided not to approve the re-registration of veterinary pharmaceuticals containing the substance of Arsenic in its organic and inorganic forms, not to receive new pharmaceuticals containing this substance, to cancel the registration of under-registration pharmaceuticals, and not to produce or import any new batches of registered pharmaceuticals as of the date of the committee.

**Decision of the Technical Committee for Drug Control issued at the session dated 29/1/2015 regarding veterinary pharmaceuticals containing the following substance:**

*Norfloxacin

The Technical Committee for Drug Control has decided not to receive new veterinary pharmaceuticals containing this substance. As for the registered pharmaceuticals and those whose registration is valid, they shall be given a grace period of 6 months, after which their production and importation shall be suspended.

**Decision of the Technical Committee for Drug Control issued at the session dated 19/2/2015 regarding veterinary pharmaceuticals containing the following substance:**

* Kitasamycin

The Technical Committee for Drug Control has decided not to receive new veterinary pharmaceuticals and not to approve the re-registration of registered pharmaceuticals containing this substance, provided that the production and importation of these pharmaceuticals shall be suspended after six months from the date of the committee.

**Decision of the Technical Committee for Drug Control at the session dated 2/7/2015 regarding veterinary pharmaceuticals containing the following substance:**

*Bicozamycin

The Technical Committee for Drug Control has decided not to receive new pharmaceuticals containing this substance.

**Decision of the Technical Committee for Drug Control at the session dated 3/9/2015 regarding veterinary pharmaceuticals containing the following two substances:**

*(Colistin+Flumequine)

- The Technical Committee has decided not to approve the re-registration of registered pharmaceuticals and not to receive new pharmaceuticals containing this composition based on the decision of the Specialized Scientific Committee for Veterinary products and Feed Additives on 5/8/2015 and the report of pharmacovigilance.

**Decision of the Technical Committee for Drug Control at the session dated 7/4/2016 regarding veterinary pharmaceuticals containing the following substance**

*Mirosamycin

- The Technical Committee for Drug Control has decided not to approve the receiving of new pharmaceuticals containing this substance based on the decision of the Pharmacovigilance Committee and Specialized Scientific Committee for Veterinary products and Feed Additives.

**Decision of the Technical Committee for Drug Control at the session dated 9/5/2016 regarding veterinary pharmaceuticals containing the following substance**

*Zilpaterol hydrochloride

The Technical Committee for Drug Control has decided not to approve the receiving of new pharmaceuticals containing this substance to be used as a growth promoter.

**Decision of the Technical Committee for Drug Control at the session dated 9/5/2016 regarding veterinary pharmaceuticals containing the following substance**

*Ractopamine Hydrochloride

The Technical Committee for Drug Control has decided not to approve the receiving of new pharmaceuticals containing this substance to be used as a growth promoter.

**Decision of the Technical Committee for Drug Control at the session dated 9/5/2016 regarding veterinary pharmaceuticals containing the following substance**

*Avilamycin

The Technical Committee for Drug Control has decided not to receive new veterinary pharmaceuticals containing this substance.

**Decision of the Technical Committee for Drug Control at the session dated 29/8/2017 regarding veterinary pharmaceuticals containing the following substance**

*Carnidazole

The Technical Committee for Drug Control has decided not to receive new veterinary pharmaceuticals containing this substance.

**Decision of the Technical Committee for Drug Control at the session dated 29/6/2016 - 2/10/2017:**

The Technical Committee for Drug Control has decided that the injectable veterinary pharmaceuticals shall be required to put a solvent in the package of the pharmaceutical product along with the vial or the ampoule containing the powder, provided that the shelf life of the solvent shall correspond to that of the pharmaceutical product, and companies shall be given a 6-month period from the date of the Technical Committee to redress the balance of their situations.

- At the session dated 2/10/2017, the Technical Committee for Drug Control has decided to grant veterinary pharmaceuticals a 6-month period from the date of the committee to implement the decision of the Technical Committee for Drug Control at the session dated 29/6/2016.

**Decision of the Technical Committee for Drug Control at the session dated 10/11/2016:**

- The Technical Committee for Drug Control has decided not to approve the issuance of registration licenses containing a factory that is not listed on the company's toll card. As for companies that have obtained registration licenses, they shall be given a 3-month period, as from the date of the committee, to add the factory listed in the registration license to the company's toll card. After the expiration of the deadline, manufacture of the product shall be suspended in this factory until this factory is included in the toll card of the company that owns the product.

**Decision of the Technical Committee for Drug Control at the session dated 23/5/2017:**

- The Technical Committee for Drug Control has decided that regarding the veterinary pharmaceuticals whose approval for proceeding with their registration procedures has expired, the company's request to complete the registration procedures shall be accepted in the event of completing all the required registration procedures in terms of analysis at the National Organization for Drug Control and Research, receiving of the stability report from the Stability Department during the year following the expiration of the approval for proceeding with the registration procedures and payment of the prescribed service fees of 5,000 pounds, and no other petitions shall be accepted. The approval was made by the Minister of Health and Population on 19/7/2017.

**Decision of the Technical Committee for Drug Control at the session dated 5/12/2017 regarding veterinary pharmaceuticals containing the following substance:**

*Niclosamide (powder)

The Technical Committee for Drug Control has decided to cancel under-registration pharmaceuticals and not to approve the receiving of new pharmaceuticals or the re-registration of registered pharmaceuticals containing Niclosamide in powder form.

**Decision of the Technical Committee for Drug Control at the session dated 5/12/2017 regarding veterinary pharmaceuticals containing the following substance:**

*Oxolinic acid

The Technical Committee for Drug Control has decided not to receive new pharmaceuticals and to cancel the under-registration pharmaceuticals containing this substance.

**Decision of the Technical Committee for Drug Control at the session dated 17/1/2018 regarding veterinary pharmaceuticals containing the following substance:**

* Orbifloxacin 25gm/100gm (W.S.P)

The Technical Committee for Drug Control has decided to commit to one of the reference pharmaceuticals in terms of concentration in the form of tablets or oral suspension, while abiding by the FDA's decision which states that this substance shall not be used in meat producing animals and that it shall be limited to cats and dogs only.

**Decision of the Technical Committee for Drug Control at the session dated 5/4/2018 regarding veterinary pharmaceuticals containing the following substance:**

* Ofloxacin

The Technical Committee for Drug Control has decided not to approve the receiving of any new pharmaceuticals containing this substance and to cancel under-registration pharmaceuticals.

**Decision of the Technical Committee for Drug Control at the session dated 14/5/2018 regarding registered veterinary pharmaceuticals that are similar to Kenafur.ini containing Ceftiofur Sodium in the form of Powder for Injection:**

- The Technical Committee for Drug Control has decided that all volumes registered with different registration numbers shall be considered as one pharmaceutical product and other numbers shall be canceled upon re-registration, since all volumes give the same concentration after dissolution (mg ceftiofur/ml 50).

**Decision of the Technical Committee for Drug Control at the session dated 4/10/2018:**

- The Technical Committee for Drug Control has decided that the veterinary pharmaceuticals, shall commit to production or importation within 3 years from the date of the registration license issuance. In the event of non-compliance, the registration license shall be cancelled. regarding pharmaceuticals for which a deadline extension is refused, they shall be granted another grace period of one year from the date of the committee in the event that there is an available place in the similars' box.

**Decision of the Technical Committee for Drug Control at the session dated 4/10/2018 regarding veterinary pharmaceuticals containing the two substances of Colistin and Neomycin that are orally- administered (Oral Route):**

- The Technical Committee for Drug Control has decided to cancel under-registration pharmaceuticals, not to receive new pharmaceuticals, and to submit a memorandum to the Minister to approve the cancellation of the registered pharmaceuticals, based on the decision of the Specialized Scientific Committee for Veterinary products and Feed Additives at the session dated 6/8/2018.

**Decision of the Technical Committee for Drug Control at the session dated 4/10/2018 regarding veterinary pharmaceuticals containing the following substance:**

* Boldenone

The Technical Committee for Drug Control has decided not to receive any new pharmaceuticals containing this substance and to approve the recommendation of the Scientific Committee, which states the following:

"The registration of veterinary pharmaceuticals containing Boldenone shall not be approved due to the danger of local abuse beyond their registration purpose and the appearance of negative aspects as a result of illegal use."

**Decision of the Technical Committee for Drug Control at the session dated 20/12/2018 regarding veterinary pharmaceuticals containing Colistin with other antimicrobials added to and which are used orally:**

The Technical Committee for Drug Control has decided to cancel under-registration veterinary pharmaceuticals containing Colistin with other antimicrobials added to it that are used orally and not to approve the receiving of new pharmaceuticals containing them. A memorandum shall be submitted to the Minister of Health to approve the cancellation of the registered pharmaceuticals, based on the decision of the Specialized Scientific Committee for Veterinary Medicines and Feed Additives at the session dated 26/11/2018.

**Decision of the Technical Committee for Drug Control at the session dated 11/4/2019:**

The Technical Committee for Drug Control has decided that regardig the petitions submitted against the decision of the Technical Committee for Drug Control issued at the session dated 20/12/2018 regarding veterinary pharmaceuticals containing Colistin with other antimicrobials added to it that are used orally, the Technical Committee for Drug Control has decided at the session dated 11/4/2019 that the petitions of companies shall not be approved.

* As for the registered and under-registration pharmaceuticals that contain Colistin substance only and that are used orally, the Technical Committee for Drug Control has decided to approve the recommendation of the Scientific Committee regarding the generalization of the attached leaflet based on the recommendations of the EMA, while giving a 6-month period from the date of the committee to redress the balance of their situations.

**Decision of the Technical Committee for Drug Control at the session dated 10/10/2019 regarding veterinary pharmaceuticals containing the following two substances:**

* Streptomycin + Dihydrostreptomycin Sulphate (Injection)

The Technical Committee for Drug Control has decided to cancel the under-registration pharmaceuticals, not to approve the receiving of the new pharmaceuticals, and not to approve the re-registration of the registered pharmaceuticals containing this composition in the form of injections, based on the decision of the Specialized Scientific Committee for Veterinary products and Feed Additives at its two sessions dated 8/7/2019 and 5/11/2018 and based on the response of Pharmacovigilance Department.

**Decision of the Technical Committee for Drug Control at the session dated 31/3/2022 regarding veterinary pharmaceuticals containing the following substance:**

*Enrofloxacin

The Technical Committee for Drug Control has decided to approve the registration of veterinary pharmaceuticals containing Enrofloxacin submitted for export-only registration shall be approved, and the scientific data of the product shall correspond to the scientific data of the reference product.

**Decision of the Technical Committee for Drug Control issued at the session dated 14/4/2022 regarding veterinary pharmaceuticals containing the following substance:**

*Cefaquinome (as Sulphate) 4.5% W/V

- The Technical Committee for Drug Control has decided not to approve the receiving of new veterinary pharmaceuticals and not to approve the completion of registration procedures for under-registration veterinary pharmaceuticals containing this composition in the pharmaceutical form of powder and solvent for solution for injection, based on the decision of the Specialized Scientific Committee for Veterinary products and Feed Additives on 28/ 2/2022.

**Decision of the Technical Committee for Drug Control issued at the session dated 12/1/2023 regarding the sources of raw materials for veterinary pharmaceuticals:**

The Technical Committee for Drug Control has decided to allow the addition of a fourth source to a single active raw material while applying the rules (provided that the physical properties and specifications of the fourth source analysis certificate shall be identical to all registered sources of the same active raw material).

**Decision of the Technical Committee for Drug Control issued at the session dated 12/1/2023 regarding imported veterinary pharmaceuticals used for pigs only:**

- The Technical Committee for Drug Control has decided not to approve proceeding with registration procedures for all imported under-registration pharmaceuticals that are used for pigs only, and not to approve the re-registration of similar imported pharmaceuticals that are used for pigs only.

**Decision of the Technical Committee for Drug Control issued at the session dated 23/2/2023 regarding veterinary pharmaceuticals containing the following substance:**

*Framycetin

- The Technical Committee for Drug Control has decided not to approve the completion of registration procedures for under-registration veterinary pharmaceuticals containing Framycetin in the form of injections and not to approve the receiving of new veterinary pharmaceuticals based on the decision of the Specialized Scientific Committee for Veterinary products and Feed Additives at its session dated 23/1/2023.

**Decision of the Technical Committee for Drug Control issued at the session dated 12/6/2023 regarding veterinary pharmaceuticals containing one of the following two substances:**

*Dimetridazole or Metronidazole

The Technical Committee for Drug Control has decided not to use veterinary pharmaceuticals containing one of the two substances (Dimetridazole or Metronidazole) in animals and birds used for human consumption, provided that this decision shall apply to registered, under registration pharmaceuticals, or submitted for re-registration. Regarding registered pharmaceuticals, companies shall be given a 6-month period from the date of the committee to redress the balance of their situations, based on the recommendation of the Specialized Scientific Committee for Veterinary products and Feed Additives at its session dated 12/6/2023.

**Recommendation of the Specialized Scientific Committee for Veterinary products and Feed Additives issued at the session 28/8/2023 regarding the registration of non-reference veterinary pharmaceuticals for export:**

Approval in principle for registering non-reference compositions for export purposes only, provided that the company shall submit the following:

1. A list of countries to which exports will be made.

2. A similar registered product in one of these countries.

Each pharmaceutical product shall be studied separately, with the possibility of requesting the necessary scientific documents that reinforce and confirm the safety and security of the composition for animals used for human consumption in order to preserve human health.

**Recommendation of the Specialized Scientific Committee for Veterinary products and Feed Additives at the session dated 23/10/2023 regarding the carrier substance used in veterinary pharmaceuticals:**

- The committee still stands by its previous decision which states that Sucrose substance shall not be used as a carrier for veterinary pharmaceuticals that are dissolved in water to treat poultry diseases. The committee recommends the possibility of using the two substances: Dextrose and Maltodextrin in addition to Lactose as carrier substances for veterinary pharmaceuticals that are dissolved in water, since a study conducted by the committee has revealed that these substances have neither risks to human and animal health nor any risks to the environment and they have been approved by the FDA as completely safe materials that do not have any toxicity. Nevertheless, pharmaceuticals using these substances shall be committed to undergo a stability study (In-use stability).

**Decision of the Technical Committee for Drug Control issued at the session dated 4/1/2024 regarding veterinary pharmaceuticals containing the following substance:**

***Colistin**

The Technical Committee for Drug Control decided to approve the recommendation of the Specialized Scientific Committee for Veterinary Products

and Feed Additives at the session dated 25/12/2023 regarding veterinary pharmaceuticals containing Colistin, which states:

• Not approving the import of raw materials used in the production of local pharmaceuticals containing colistin.

• Not approving the import of finished pharmaceuticals of the same substance.

•Not approving the re-registration of veterinary pharmaceuticals containing colistin.

• Not approving to complete the registration procedures for pharmaceuticals under registration and canceling the registered pharmaceuticals within one year from the date of the committee.

• Giving companies a period of six months to redress the balance of their situation to manufacture pharmaceuticals from raw materials available in the market, after which production of all pharmaceuticals containing that substance will be stopped.

• Sales and marketing of any pharmaceuticals containing colistin will be stopped and all pharmaceuticals containing colistin will be withdrawn within a maximum of one year from the date of the committee's decision.

The deadlines will be calculated from the date of the Technical Committee's session on 4/1/2024.