Ministerial Decision
No 1214/20/M on 17/6/1409H

Regarding Alteration of Medicine Companies and their Products Registration Resolution

The Minister of Health,

Based on the authorities conferred to him, and

After reviewing the Law of practicing pharmaceutical profession, medicines and medicine formulation and trading issued by the Royal Decree No. 18 dated 18/3/1398H and the executive regulations for practicing pharmaceutical profession issued by the Ministerial Decision dated 26/11/1398H, and

Based on the public interest requirement,

Decide the following:

Article (1):

To substitute chapter (3) of the part (2) of the mentioned regulations by the following:

Firstly, Registration Committee: to be formed by a Ministerial decision specifying its number of members, its work period and its decisions will be effective after the approval of the Minister.

Secondly, registration of companies and subsidiary: the Agent shall submit the application and attach to it, the following documents:

1- An original authenticated copy of agency registration in the Saudi Ministry of Commerce.

2- Copy of medicines wholesale trading license.

3- To fill in the registration form (annex A) attached to this regulation.

4- A certificate issued by the health authority in the Country of origin showing clearly the following:

a- That the Company is permitted to manufacture pharmaceutical medicines in the country of origin, number of registration in the country of origin and date to be mentioned.

b- That the Company is following the basis of good practicing of production.

c- That the formulation which will be exported to the Kingdom

will be identical in constitution to the formulation which is registered and marketed in the country of origin.

5- A certificate from the Company authenticated from the concerned authorities in the country of origin in a list showing by order the following information about the Company's formulation:

a- Trade or scientific name of the formulation.

b- Constitution, effective substances and quantities.

c- Medication group.

d- Registration number and date in the country of origin.

e- Starting marketing date in the country of origin.

f- Names of other countries where the formulation was registered and marketed.

6- Summary of Research:

a- Summary of Company activities in the field of research explaining the formulation under research in the different stages and the formulations already marketed which were discovered, or developed by the Company.

b- Copy of invention patent or known international scientific bulletins which will support correctness of the above mentioned information in (6-A).

7- The following certificates from the mother Company duly authenticated by the competent authorities shall be added in case a subsidiary is to be registered:

a- To specify its responsibility as to guarantee the availability of formulations produced by the subsidiary.

b- Warranty of the subsidiary to be registered with respect to technical, financial and legal.

Thirdly, formulation registration pricing condition:

It is not allowed to register any formulation for a registered Company as per this Resolution unless the following documents are attached to the registration application:

1- Index of contents.

2- Application for registration duly filled in (Annex B) attached

to this Regulation.

3- Specification and complete analysis methods of the formulation including stability study and storage conditions.

4- Analysis certificate from the Company duly authenticated by the competent authorities for the samples submitted for registration.

5- A certificate issued by the health authorities of free trade of the formulation in the country of origin.

6- A certificate issued by the health authorities showing that the colored and dilution substances available in the formulation composition are allowed in the country of origin and if the marketing certificate contains these substances will be enough.

7- A certificate duly authenticated by the competent authorities in the country of origin showing the source of animal, if the formulation is containing any substance of animal source.

8- The rate of alcohol in the formulation (if any) to be specified and the justification of availability in such a rate.

9- A certificate from the health authorities showing that the leaflet attached to the formulation pack or the information printed on the pack are the same approved and circulated with the formulation in the country of origin.

10- The inside leaflet in Arabic and/or English, and the Company is obliged to add and/or delete the information which may require the formulation to be circulated in the Kingdom including the translation of the leaflet into Arabic according to the decision of the Committee.

11- Formulation label.

12- Six samples of the formulation including specimen of outer cover.

13- Other countries names where the formulation is registered and marketed at present duly authenticated.

14- Selected international scientific writings about the formulation and also neutral issues about its effectiveness and safety use.

15- Summary of studies on clinical, poisonous and medication and also supervision studies of the formulation after marketing in cases so require.

16- Studies of the biological availability and biological equality.

17- Analytical procedures to define the formulation veterinary remains in animal foods.

18- Prices certificate duly authenticated by the competent authorities in the country of origin.

19- Any comments or additional documents which the Company wishes to attached.

Fourthly, General Provisions:

1- It is prohibited to circulate the medicine, either locally formulated or imported from outside before being registered in the Ministry of Health.

2- An amount of SR 1,000 is levied from each Company or subsidiary to be registered and SR 200 for every concentrate of the pharmaceutical formulation type which is registered.

3- The registered formulation shall be listed in special files in the Ministry under consecutive numbers and the Company agent shall be officially notified and the name of the agent, number of registration and the price shall be printed on the formulation packs.

4- It is prohibited to make any change in the ingredients, specification, method of manufacturing, reasons for use after the registration of the formulation without the prior consent of the registration committee, but if a change in the formulation pack or wrapping, or validity, the approval of the General Administration for medical and pharmaceutical licenses in the Ministry must be obtained.

5- It is necessary to write the concentration and the basic information in the pack clearly so that it can be read by the eye only, also it is necessary not to repeat the color and type of pack in others of the Company's formulation, especially in the aid medicine.

6- It is necessary that the wording of the information, leaflets, notices and its means must agree with the contents of the formulation from substances and peculiarity treatment as per rules set by the Committee.

7- If the ownership of the Company or the formulation is changed, it is necessary that the old owner and the new owner inform the Ministry within 30 days from transfer of ownership.

8- The Committee has the right to delay or refuse or cancel the registration of any Company or subsidiary or formulation mentioning

the reasons, in case of refusal or cancellation, the agent has the right to mention his objection within two months of notifying of the Committee decision, otherwise it shall be considered final.

9- The Company and its agent are obliged to avail the registered formulation with all concentrations and pharmaceutical types continuously and without cessation whatever price lowering, otherwise the Ministry will take what is necessary to avail the formulation.

10- The Company or subsidiary registration shall be cancelled in the following cases:

a- If no application for registration of any of its formulations is submitted within one year of notifying the agent of registration.

b- If forging is proved or cheat in the certificates.

c- If it is enlisted in the boycott and any of the formulation is not excluded from the boycotting.

d- If repeated violation or did not continue to apply the good basis of manufacturing practices.

11- The formulation registration shall be cancelled in the following cases:

a- If poisonous is proved or had dangerous side-effects, or stopped to be used upon recommendation from World Health Organization or other international organizations.

b- If reports are available to the Registration Committee from the health authorities in the Kingdom proving that it has harmful side-effects or any technical reasons concerned with the Kingdom to be decided by the Committee.

c- If the registration is cancelled or production in the country of origin is stopped.

d- If forgery or cheat in the certificates.

12- The agent to submit to the General Administration of medical and pharmaceutical licenses with an authenticated list of imported, issued and remaining of medicines of all formulation registered periodically every six months as per the attached specimen.

Fifthly, General Provisions:

1- Companies manufacturing medicines in the trade name and/or scientific shall be registered if the registration justification is fulfilled and marketing of its medicines in the same name in the country of

origin and other advanced countries.

2- The Ministry shall make sure that the Companies are applying the basis of good practice of the medical manufacturing through visits and reports of whom entrusted for this purpose.

3- The Company shall be considered researcher if it discovered a new substance of clinical effectiveness or had developed a known substance, or it was able to find a new formulation that may add clear characteristics to the circulated formulation.

4- Arabian Companies shall be excluded from research and marketing condition in other advanced countries and also international Companies which are necessary medicines of limited alternate which are not subjected to the prescription, if it is not available from research companies.

5- Registered companies and subsidiary to submit a newly file to consider their registration every five years.

6- The formulation shall be analyzed in Laboratories specified by the Ministry to make sure of their conformity with the specifications and information available in the registration file, and also periodical analysis on random samples of the formulation to make sure of their continuity in conforming with the specifications and there is no change, and the agent shall avail the standard substances, chemicals and special requirements needed to analyze the formulation.

7- An authenticated certificate by the competent authorities in the country of origin showing the reasons and justification, if:

a- The formulation submitted for registration is marketed in the country of origin in a trade name different from that marketed in other than marketed in other than the country of origin.

b- The formulation is marketed in the country of origin under the name of a marketing section of the manufacturing Company, explaining clearly the relation between.

8- Priority for registration shall be given to formulation according to its therapy importance and as per the standards put by the Committee.

9- The Committee shall specify the medicines which no application for registration is submitted, and which availability is necessary for specified medical parties and shall put the standards that control the importation.

10- Entering of not boycotted medicines with limited quantities shall be allowed for personal use vide a prescription or for hospitals through prior consent for treatment of special cases.

11- Hospitals shall be allowed to avail the formulation:

a- From the parent company or one of its registered subsidiaries on condition that the formulation is registered for either one of them

b- Registered by concentration or different pharmaceutical type as of that registered in the same required manner in the manufacturing Company country.

12- Veterinary medicines packs shall show, in Arabic and/or English Languages, the following:

a- Period of stopping the use of medicine before slaying the animal or consumption of the animal products

b- The phrase for animal use only or veterinary use only.

13- Subjected to Registration:

a- Herbal formulation, health and supplementary foods, cosmetics, medical instruments which have medical allegations or contain effective substances that have effective medication, and also disinfectant used for human according to standards specified by the Committee

b- Diagnosis substances which enter the body by any way.

14- Biological formulation including vaccines shall be subjected to the same conditions of registering the formulation, and the manufacturing Company specialization in producing such formulation and marketing in advanced countries shall be confirmed, and random samples shall be analyzed to make sure of its purity, effectiveness and safety use.

15- The chemical substances used in the composition of the pharmaceutical formula or imported for medicine manufacturing, and also medical instruments, detergents .. etc must be permitted for use in the country of origin vide an authenticated certificate by the competent authorities, and the necessary certificates and the analysis ways, and also constancy studies to be submitted to approve clearance.

16- The Committee shall revise the formulation after the elapse of 3 years of registration or whenever need arises to consider the re-registration of formulation and submitting of documents mentioned under paragraphs (5-6-9-12-13) of Article (thirdly) (registration of formulation and pricing), will be enough, and any information or other studies required by the Committee.

Sixthly, Directions to complete the registration requirements:

Annex © attached to the Resolution.

Article (2):

This decision shall effective as from the date of publication in the official newspaper.

Minister of Health
Faisal Al-Hijalan

Kingdom of Saudi Arabia
Ministry of Health

For Ministry of Health use only

Date received:
Application No.
Unit assigned:

General Directorate of Medical Licenses and Pharmaceutical Affairs

Application for registration of Pharmaceutical Co./Subsidiary

1- Name, address & telephone of Company/Subsidiary

2.Date of submission:

2.A: type of application (check one)

( ) new

( ) revised

2/B. application Number if previously submitted:

3- Name, address & tel. No. of agent in the Kingdom:

4.Registration of agency in the Saudi Ministry of Commerce::

4.A- Number:

4.B- Date:

5- Company statistics:

5/A-Commercial statistics:

Government ( )

Private ( )

Stock Company ( )

Other (specify) ( )

5.B- Date established

5/C: Capital Assets

5/D: Annual sales
(last five years):

5/E: No of employees with their qualifications in various departments in the Company:
(research, production, packaging, quality control ..etc)

5/F: Addition activities of the Co. other than pharmaceutical manufacturing

6- Products of the parent Co.

Products of Company research

6/A- Developed substance:

Propriety name

Scientific name

Chemical name

6/B: Check one or more boxes

( ) Known drug substance

( ) New chemical entity discovered by the Company:

( ) New development

(Process, formula, etc.)

6/C: Finished product:

Dosage form:

Strength

Therapeutic category

6/D: Patent number.

6/E: Patent date

6/F: Country granting the patent:

6/G: References:

7- Subsidiaries of the Company:

7/A: Name of Subsidiary:

7/B: Full address of subsidiary:

7/C; Telephone number:

7/D:Relationship to parent Company:

( ) Affiliate

( ) Original Branch

( ) Division

( ) Other (specify)

7/E: Functions performed by subsidiary:

( ) Production

( ) Manufacturing

( ) Packing

( ) Other (specify)

7/F: Products of the subsidiary (other than human pharmaceuticals)

( ) raw materials

( ) veterinary products

( ) chemicals

( ) cosmetics

( ) others (specify)

8- Certification by responsible official:

8/A: I certify that the information submitted in the application form is true and correct that all products marketed by this Company are manufactured under good manufacturing practices

8/B: Name and title of responsible official in the Company:

8/C: Signature of responsible official in the Company

8/D: Date

8/E: Full address

(POB, City, Postal Code, Country)

Note: all information included in this application should be attested by the Saudi Embassy in the Country of origin

For Ministry of Health only Kingdom of Saudi Arabia

Date received:

Unit assigned:

Application No.:

Ministry of Health

General Directorate of Medical licenses and Pharmaceutical Affairs

Application for registration of a human or animal drug product

1. Name, address and telephone number of manufacturer:

2. Date of submission:

2.a. Application (check one)

( ) new

( ) revised

3. application number (if previously submitted)

5. Type of product (check one):

( ) human drug

( ) animal drug

( ) if animal drug state

a) species (bovine, equine ..etc)

b) withdrawal time:

(meat) (milk)

(days) (hrs)

6. Chemical

7. Nonproprietary name (generic)

8. Proprietary name (brand/trade name)

9. Dosage form

10. Strength

11.Therapeutic category (s)

12. Route of administration

13. Type of application (check one)

( ) for control drug products (CD)

( ) for a prescription product (RX)

( ) for an over-the-counter product

14. Full composition (active ingredients)

15. If product in compendium or has official standard state source.

16. Package size and type

17. Shelf life (month/year) and storage condition

18. Indication use

19. Pharmaceutical effect/mode of action

20. Dosage and route of administration

21. Duration of treatment

22. Warnings/precautions

23. Contraindications

24. Side effects, toxic reactions and antidotes, if any

25. Name of other countries in which the product is registered and currently marketed. (indicate date of marketing)

26. State the registration number and date of other dosage forms, strength, package size (if

previously approved in the Kingdom)

27. I certify that information submitted in the application form is true and that the product is manufactured under good manufacturing practice.

Name and title of the responsible official in the Company.

Signature of the responsible official in the

Company

Date:

Address (POB, city, postal code, country)

28.Check of application form and enclosures by the Ministry of Health officials:

Application form filled correct:

( ) no ( ) yes

( ) enclosures complete

( ) comments

Name Signature Date