KINGDOM OF BAHRAIN
MINISTRY OF HEALTH

REGISTRATION GUIDELINES
2002

PHARMACY & DRUG CONTROL DIRECTORATE

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This new edition of registration guidelines is issued with the hope of coping with all the changes that have taken place in drug manufacturing, marketing, licensing, co-marketing, under-license manufacturing, contract manufacturing and registration requirements.

In addition, the establishment of a central drug registration committee in the six Gulf States has created prospects for many changes in the registration process.

If you have any comments or queries please do not hesitate to contact:

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1.Drug

Any substance(s) for internal or external use for the purposes of treatment, prevention or diagnosis of any disease, ailment, disorder, deformity, defect or injury to the human body

2.Pharmaceutical equivalents

Two medicinal products are pharmaceutically equivalent if they contain the same active ingredient(s), are of the same dosage form and are identical in strength or concentration, and route of administration and they meet the same compendial or other applicable standards like strength, quality, purity and identity but they may differ in characteristics such as shape, scoring configuration, packaging, excipients (including color, flavors, preservatives) expiration time and within certain limits labeling. They are not necessarily bioequivalent.

3.Country of Origin (CoO)

It is the final destination from which the finished product is dispatched after completing the final steps of manufacture.

4.Marketing Authorization Holder (MAH)

This document refers to the pharmaceutical company which holds the right to market the product in Bahrain and it should be a holder of a manufacture licence, granted by the health authorities in its country. This will exclude exporting offices and wholesale offices

5.Registration Scope

Registration covers the following:

- Pharmaceutical manufacturers as sites of manufacture or marketing authorization holders with manufacture licence.
- Pharmaceutical products and this includes:

a) All solid and liquid dosage forms
b) Blood products, substitutes and expanders
c) All medicated dermatological preparations
d) Opthalmological preparations
e) Intravenous fluid replacement therapy and TPN fluids
f) Contraceptives and intrauterine devices containing hormones
g) Dialysis solution
h) Disinfectants and antiseptics
i) Moisturizing, lubricating and emollient preparations
j) Irrigation fluids
k) Transdermal patches
l) Immunological products and vaccines
m) Spermicidal and viricidal devices
n) Medicated and non-medicated enemas, douches, laxatives
o) medicated aerosols, sprays, inhalers
p) Vitamins and supplements in therapeutic concentrations
q) Medicated mouthwashes and lozenges

The agent or the company representative should provide the following documents for the registration of a pharmaceutical manufacturer or its site

Item 1

1. Full profile of the Company including kinds and scope of activities.

2. Number of manufacturing sites owned by the company and their addresses.

3. The kind of legal and commercial relationship the company holds with these different sites.

4. Manufacturing licence number and its date in country of origin

5. List of all products marketed by the company

6. Agency Contract

7. GMP certificate from the health authorities in the country of the site

8. Number of employees in the different sections and their qualification.

9. Graphic design of the site and flow of manufacturing lines

10. List of all products the site produces either on its vicinity or through contract manufacturing with or for other marketing authorization holders(MAH's)

11. Clarification of the relationship with the MAH.

12. Any inspection visit report by GCC health authorities or Arab Health Authorities, except for country of origin if it is an Arab country/site. Otherwise, a GMP inspection visit should be arranged.

Registration does not cover wholesalers and distributors. Marketing authorization holders should have a manufacture licence issued by the health authorities in country of origin.

Item 2

In case of failure to meet GMP requirements after a GMP inspection visit, a 12-month period should elapse before reconsidering the case.

Item 3

MOH authorities should be informed about any sale, merge, take over or any legal or commercial action concerning the company or its site within 90 days of the action

PRODUCTS

The applicant should submit a description of the submitted documents as follows:

1. Number of submitted files
2. Number of samples submitted along with a brief description of these
3. Full index of contents of the files

The files should contain the following:-

1. A CPP form according to WHO certification scheme authenticated by health authorities in the country of origin. If for any reason the certificate cannot be provided from that particular EU country then from any EU country where the product is marketed with clarification for the reason. Legalisation of this certificate by any GCC embassy is required.

The CPP should contain the following:

- registration number in country of issue
- name and address of the applicant
- name of the country issuing the certificate
- name of the country for which the certificate is issued.
- name and address of the manufacturing licence holder
- the proprietary name of the product if available.
- non-proprietary name (rINN or any common name)
- pharmaceutical formula (in details – attachments)
- name and address of manufacturer of finished product
- commitment of health authorities signatory to the certificate to GMP periodic inspection
- statement specifying if the leaflet is the same in country issuing the certificate, and the reason(s) if different
- date and number of registration of the product in the country issuing the CPP, and if this not available then the reason
- name and address of health authority issuing the certificate

2. Summary of Product Characteristics (SPC). This should contain the following:-

-Proprietary name of the medicinal product
-Qualitative and quantitative composition of product stating the generic names or common names of the active ingredient and important ingredient(s)
-pharmaceutical form

-Clinical particulars such as:-
    -therapeutic indication(s)
    -Posology and method of administration
    -Contraindications
    -Special warnings and precautions
    -interactions with other medicaments and other forms of interactions
    -Use during pregnancy and lactation
    -Effects on ability to drive and operate machinery
    -Undesirable effects
    -Overdose

-Pharmacological properties
    -Pharmacodynamic properties
    -Pharmacokinetic properties
    -Pre clinical Safety data

-Pharmaceutical particulars such as
    -list of excipients
    -incompatabilities
    -shelf life
    -Special precautions for storage
    -Nature and content of containers
    -Instructions for use/handling
    -Manufacturing authorization holder
    -Manufacturing authorization number
    -Date of first authorization/renewed authorization
    -Date of revision of the text
    -Legal category

3. A separate file for the quality control laboratory including the following:

-Method of analysis for finished product
-Certificate of analysis for finished product (physical, chemical, biological and microbiological)
-Finished Product Specifications
-Validation of analytical test methods
-Certificate of analysis of standards and specifications
-Safety measures
-Reference standards (sufficient quantity)
-Related substance reference standards (sufficient quantity)

4. Full description of the active ingredient(s) and excipients including colouring agents, flavouring agents, presentations, emulsifiers, and other pharmaceutical means.

5. Full description of vehicles and carriers of the product e.g., gelatin capsules, pessaries, rectal enemas etc.

6. Method of manufacture of the finished product

7. Names and addresses of any pharmaceutical manufacturing site involved in any step(s) of manufacturing of the finished product

8. Products that are still protected by patent rights will not be registered if submitted by other than the holder of the patent rights

9. Full description of the outer pack and all accessories included to give the proper dose such as syringes, pipettes etc.

10. The concentration of the product should be clear and specific per unit mass or volume.

11. Pharmacological studies including pharmadynamics and pharmacokinetic studies

12. Toxicological studies (new products including newly introduced generics)

13. Clinical studies (new products including newly introduced generics) (For well established generic products reference articles and documents are enough)

Item 4

Source of starting material should be clarified.

Item 5

The product label should carry the following information on external and internal pack in English/Arabic.

-Proprietary name followed by common name of active ingredient(s)
-Pharmaceutical form and strength
-Contents by common name and quantities per dose
-Pack size by weight, volume, or number of doses.
-list of excipients with certain pharmaceutical function
-For injectables, eye drops, and external use products all excipients should be mentioned
-method of use
-warnings
-expiry date by month & year
-Special storage requirements
-Marketing authorization holder
-manufacturer of the finished products
-batch number
-In case of OTC drugs, clear method of use should be specified.
-In case of blisters, proprietary name, common name, marketing authorization holder, batch number and expiry date should be mentioned
-In case of small containers such as ampoules the following should appear on the label (as minimum requirement)
    -name of drug, strength, route of administration
    -manufacturer name and/or logo
    -method of use
    -expiry date
    -batch number
    -contents by weight, volume or units

Item 6

The product patient leaflet should contain the following in English/Arabic

-brand name followed by common name
-pharmaceutical form and concentration or strength
-qualitative and quantitative information about active ingredient(s) and excipients in common name
-pack size and contents by volume, weight or number of dosage
-pharmacotherapeuetic group in clear understandable language.
-MAH and manufacturing licence holder
-therapeutic indication(s)

-contra indication(s)
-precautions
-drug-drug interaction, food interaction, alcohol –drug interaction and others.
-any special precautions
-use during pregnancy, lactation, elderly, children and other patient categories
-effect on driving and machinery operating
-probable allergy-producing additives
-dose and dose regimens
-clear description of administration method
-antidote and treatment of overdose
-any information related to period of use, skipping or forgetting doses, abrupt withdrawal, best time of administration of doses, etc.
-side effects and advice on reporting any adverse reaction to doctors and pharmacists
-warning against use after expiry date on pack
-number of leaflet and date of last revision

Item 7

A full bioequivalence study report or equivalent, from an independent lab should be submitted whenever a generic product is submitted for registration
For registration of under-licence products for out-of-patent molecules a bioequivalence study comparing it with the parent product is required.

Item 8

Products imported for government outlets and in large pack sizes should carry the full medical profession leaflet.

In case this could not be met and patient leaflets are supplied in the pack, extra medical profession leaflets should be submitted to the Ministry of Health for distribution upon request.

Item 9

If the pharmaceutical product contains an animal product the source and kind of animal should be specified.

Item 10

Only approved colouring substances, flavouring substances, diluents and additives should be used in the manufacturing process as approved by major drug regulatory agencies, WHO and other international organizations.

Item 11

Price certificate authenticated by the health authorities in country of origin stating the following:-
-ex-factory price.
-wholesale price in country of origin
-public sale price in country of origin
-CIF price GCC countries
-suggested CIF price to Bahrain

Item 12

1. Stability studies should be attested by quality assurance section and authorized by manufacturer. Stability studies should be conducted on the product in the same container-closure system intended for marketing in Bahrain.

2. Stability studies should be provided for at least 3 production batches, The following should be clarified at the beginning of the document
   -batch numbers, dates of manufacture and dates of expiry of batches tested
   -Storage conditions of T & RH used during the study protocols
   -temperature and relative humidity
   -Samples should be taken for analysis at certain points of time i.e. every 3 months at least during the first year and every six months thereafter
   -analysis method
   -parameters tested
   -conclusion of the studies pertinent to stability and suggested shelf-life and storage condition (the conclusion could be added at the end of the document)

3. Tests should cover physical, chemical, biological and microbiological attributes.

4. For accelerated stability studies, testing should be done at certain time points: initial, 3 and 6 months at least.
   If there is a change in the specifications, then testing should be done at intermediate conditions at four points of time:
   Initial, 6,9 and 12 months (this includes initial and final readings)

5. Real time should cover at least 12 months duration at long term and at least 6 months data at intermediate storage condition
   For zones I and II, long term conditions are 25ºc±2ºc and 60%±5%RH
   For Zones III and IV, long term conditions are 30ºc±2ºc and 65% ± 5%RH
   Which is the same as the intermediate conditions

6. Stability studies conditions
Long-term

GENERAL CONDITIONS FOR LONG TERM STABILITY STUDIES

Study	Storage Condition	Minimum time period covered by data at submission
Long Term for Zones III & IV For Zones I & II	30ºc±2% and 65% RH±5% 25ºc±2% and 60% RH±5%	12 months 12 months
Accelerated	40ºc±2ºc and 75%RH±5%	6 months

CONDITIONS FOR REFRIGERATED DRUGS

Study	Storage Condition	Duration
Long Term	5ºc±3%	12 months
Accelerated	25ºc±2ºc% and 60%RH±5%	If change occurs between 3-6 months of accelerated stability testing then retest should be done. Period should be based on real time data. If change occurs within the first 3 months of accelerated test, more frequent testing at a shorter period should be done. No need for retesting through the 6 months period if a significant change occurred within the first 3 months.

DRUGS STORED IN A FREEZER

Study	Storage Condition	Duration
Long Term	20ºc±5ºc	12 months

Single batch testing at 5ºc±3ºc for studies of effects of change of temperature during shipping on at least 3 production batches should be used.

7. If container-closure system to be registered is superior to the one in the stability studies, then comparative stability data may not be required

8. If the product is to be registered in moisture-permeable container such as PVC or same grades of polyethylene or if the closure system allows moisture permeation, the high humidity conditions should be considered in the stability studies at the recommended temperature.

9. Stability data should be generated on 3 production batches. In case data is incomplete, a commitment to update the requirements for full term stability studies on 3 production batches should be made.

10. Accelerated stability studies are useful in predicting the probable stability of a new product but it should be verified by studies on production batches in the pack intended for registration at the maximum recommended storage temperature for the full term proposed eg. at 30 degrees, if the recommended storage temperature statement is "Store below 30 degrees."

11. Accelerated studies are done with the purpose of increasing the rate of chemical degradation and physical change of a drug by exaggerating the normal storage conditions. They include elevated temperature, high humidity, intense light and when appropriate low temperature, freeze/thaw cycles.

12. These accelerated studies help in equivalence tests of multi-source products and they are determined by the climate zone whereby the product is intended for distribution, and uses of the product and by the type of dosage forms.

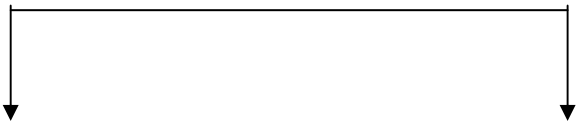
13. They are less suitable for semi-solid and heterogeneous formulations like emulsions. For climate zones III & IV, the conditions mostly accepted are 40 degrees C±2 degrees and 75% R.H ±5% for 6 months period.

14. Lower temperature may be used for temperature-sensitive drug substance or product. In such case accelerated studies are carried for six months at a temperature at least 15 degrees C above its designated long term storage conditions with appropriate RH.

15. It should be noted that whenever the accelerated stability studies show significant changes at (refer to the four conditions below) then an additional 12 month study at 30 degrees C and 60% RH condition is required i.e. Less aggressive conditions.

16. If again at 30 degrees C there is still a significant change (refer to the four conditions below) then normal room temperature labeling is not supported and special labeling may be required e.g. Store below 25 degree C is the long term storage conditions.

Significant change at 40 degrees C/75% R.H.



Significant change at 30ºC and 65% R.H.

Label with normal room temperature Labeling e.g. 15-30 degrees C

Requires a "Store below 25ºC" label or more cautionary labels are required

17. Significant changes for a drug substance is defined as failure to meet its specifications such as the following:

    1.5% Potency change of initial assay value of a batch
    2.A degradant exceeding its specification value
    3.pH change outside its limits
    4.Dissolution outside the limits for 12 caps or tablets

18. If storage and transportation may occur outside the storage criteria then 3 months stability studies at 45-50ºC and 75% RH are required

19. Stability studies should include testing of these attributes of the drug product that are susceptible to change during storage and are likely to influence quality/safety and or efficacy (Please see the table on the next page)

Dosage Form	Physical attributes to be tested
Tablets and capsules	Dissolution rate or disintegration Appearance Odour Hardness Friability Moisture content And for hard gelatin capsules brittleness
Liquid formulation and injections	Appearance Colour Odour PH Clarity for solution Freedom from visible particulate Contamination Size range of particulate Contamination for large volume Parenterals Particle size distribution for suspensions Resuspendability for suspensions Viscosity Moisture content for powders for reconstitution Phase separation for emulsions Micelle size distribution for micellar solutions
Ointments and creams	Appearance Odour Viscosity Softening range Loss of water Physical and chemical Homogeneity Particle size distribution Particle formation Ph
Freeze Dried material (including materials for reconstitution	Appearance of both freeze dried and reconstituted material pH water content rate of solution

Aerosols	Leak test Particulate contamination Valve function and appearance Weight loss Uniformity of dose and number of doses per container for the metered dose aerosols
Suppositories and pessaries	Appearance Softening temperature for the moulded products Dissolution rate for the compressed products
Transdermal patches	Appearance In vitro release rates

20. For multi-dose injectables containing antimicrobial preservative, a microbial challenge test at the end of shelf life is required in addition to the chemical assay of the preservative during the studies.

21. **<u>Storage conditions under certain conditions</u>:-**

    After constitution or dilution, if applicable, stability studies should be conducted to provide information for the labeling on the preparation, storage condition and in-use period of the constituted or diluted product.

    Such studies should be performed at initial and final time points or 12 months if full data is not available

	Variations	Action or requirements
1	Alternative or additional manufacturing site	If the new site is responsible for the final release of the product and its marketing, then full registration documents for the new site should be submitted. -If the new site is involved with one or more intermediary steps of manufacturing or packaging, then an attested GMP certificate from the health authorities in the country of the site
2	Change of manufacturing site releasing the finished product	-A new CPP if the site is located in a country other than the originally registered product site. -New stability studies from the new source -New packs from the new site -Statement from the MAH indicating that no change in finished product specification, method of manufacture, source of raw material, validation, control tests etc. -If a change in the above has taken place then all related documents should be submitted.
3	Change/addition of a new pack size of the registered product	If the change in size is consistent with the approved uses of the product then a new price certificate if a change in price is expected. -If the change is not consistent with the approved uses then requirements as per change of indications and uses -Old and new packs should be submitted. If not pack is not yet available, then the artwork should be submitted.
4	Adding a new indication, warning or changing the dose regimens	-Documents of clinical studies to support the addition or changes and to show the effectiveness and safety under the new recommended conditions -New labeling of the product and new information insert

5	Change in the route of administration	New registration documents are required including the following:- a)Description of the plant and equipments used in all processes of manufacture b)Control tests for the different characteristics of potency, purity, safety and stability c)Clinical studies d)Comparison studies with the previously registered drug product
6	New pharmaceutical characteristics	a) New registration documents are required including the following:- a)Description of the plant and equipments used in all processes of manufacture b)Control tests for the different characteristics of potency, purity, safety and stability c)Clinical studies d)Comparison studies with the previously registered drug product e)Bioequivalence studies or equivalent studies such as limited clinical studies f)New labeling and insert leaflet
7	Addition or removal of one API from a multi-component product	-New registration as a new product. All requirements for such process are needed
8	Change in the dosage form	-New product registration requirements including the followings:- a)bioequivalence/bioavailability studies b)clinical documentation c)description of the manufacturing method d)New labeling and insert leaflet
9	Change from immediate release product to a slow or delayed-release dosage form or vice versa	As above
10	Change from a liquid formulation to a powder for reconstitution or vice versa	As above

11	Change in the analytical method of the finished product	-Validation to show that the new method is equivalent or better than the existing method -full description of the method -full information about major changes in the method
12	Additional tests and limits for starting materials or finished product	-Statement that no effect or change on processing -Description of tests
13	Change in methods of manufacturing and/or equipments except for slow or modified release product	Description of method -Stability studies on 2 batches of altered product
14	Change in on excipient of up to ± 5%	Description of change
15	Change to flavouring, colouring or essence of finished product	Altered additives should be on list of permitted substances -Description of change -accelerated stability studies on 2 batches for 3 months at least or real time stability studies for one year -full term stability studies on 2 batches should start for full duration
16	Change in the quantitative composition of the coating of tablets or capsules amounting to less than 2% of the total weight of the tablet or capsule	-The coating should have no modified release properties -No API in the coating -Only permitted colors are allowed. -Description of the change
17	Change to the volume of the granulating fluid upto ±15%	Description of the change
18	Change in batch size	-Stability studies should commence on at least one batch full scale production -Description of change
19	Changes to the quantitative content of viscosity producing agents in the product	Validation that any solid material present is at least equally well suspended -Stability studies has commenced on at least 2 batches of the altered product

20	Changes to the container/Closure system in immediate contact with the product	The product should be a non-sterile product -Validation of equal or better protection to the product -Accelerated stability studies available on 2 batches in the new container for 3 months or one year real time stability studies. -Stability studies has commenced on 2 batches for the full duration of shelf life -Description of the change
21	Additional types of container/closure systems in immediate contact with the product	The product should be a non-sterile product -Validation of equal or better protection to the product -Accelerated stability studies available on 2 batches in the new container for 3 months or one year real time stability studies. -Stability studies has commenced on 2 batches for the full duration of shelf life -Description of the change
22	Change to parts of the container not in contact with the product	As above
23	Changes to layout, logos, diagram or pictures	Full description of the changes -Samples of artwork
24	Changes in imprints or marks in solid dosage forms	Full description of the changes provided the following:- -all colours are on the permitted list -no implication of unapproved indication or patient population -any changes to the scoring of tablets are consistent with dosage schedules

25	Change in the marketing authorization holder	-full description of the administrative change -full accounts of the legal responsibilities involved -Description of any change that affect the manufacturing method of products such as site, method, raw material source, validation, control test. Any such changes should be dealt with according to the kind of change as above
26	Change in shelf-life (extension or reduction)	-Stability studies according to requirements to justify an extension of shelf life -analytical method and validation methods -Any scientific reason for reduction of shelf life -Approval of health authorities in country issuing the CPP and approving the SPC
27	Change in the specification of the finished product	-If the purpose is to tighten the existing specification limits, then only description of the new ones. -Stability studies are needed in the following conditions a)Change in the synthesis method of the active material(s) b)Change in the pH specification of liquid preparation c)Change in the container system from bottle to PVC blisters
28	General Changes in the leaflet, not applicable to any of the above	-Old and new leaflets -Comparison table for both leaflets highlighting all the changes.

ISTRATION

Item 12

The cancellation of a manufacturer's registration is done under any of the following conditions:

1.If it has not submitted any of its products for registration within a year of the company registration.
2.If forgery in its papers and documents has been proven.
3.If it has violated the regulations and guidelines of GMP.

VII- SUSPENSION AND REVOCATION OF A DRUG MARKETING UTHORIZATION

conditions:-

1.If studies have proven its toxicity or it has serious side-effects or it has been banned by WHO or major drug authorities
2.The product is strongly suspected to be unsafe in the normal conditions of use
3.The qualitative and quantitative composition is not as agreed in the MA.
4.The product is not in compliance with the conditions of MA
5.The product is being promoted in an inappropriate or unethical manner.
6.If health authorities in Bahrain have enough data to show serious adverse reactions or for technical reasons agreed on by Drug Registration Committee
7.If its marketing authorization has been cancelled or suspended or its production has been stopped in the CoO.

VIII- RE-REGISTRATION OF A DRUG PRODUCT REQUIREMENTS

Item-14

1) A new legalized CPP from health authorities in country of origin.
2) 3 Pieces of finished product and 3 copies of the latest insert leaflet
3) A copy of the latest composition formula already on the market
4) Any new documents and materials as required by Pharmacy & Drug Control Directorate
5) Enough samples
6) Renewal of licence is done 3 months, at least, before the expiry of licence
7) The license validity is 5 years.
8) Finished product Specification
9) Reference Standards

FEES

Company Registration/Re-registration	BD.5/- 5 yrs
New product registration & Re-registration	BD.5/- 5 yrs
Laboratory Analysis	BD.50/- Battery of tests
Pharmacy Registration -Importer -Non-Importer	 BD.50/annum BD.25/annum
Health food licence	BD.100/annum
Health Product license	BD.5/-5yrs
Clearance of any item in invoices	BD. ½ per item
Destruction of any item in invoice	BD. ½ per item
Pharmacist or Technician	BD.20/annum

PENALTIES

Delay in renewal of pharmacist or Technicians licence	BD.3/- per month of delay upto 3 months then the fee is doubled if no renewal is done upto 6 months of its expiry. After the 6 month period, the license is cancelled.
Delay in renewal of a drug licence	BD.3/- per month of delay up to 6 months after which the licence would be cancelled
Delay in renewal of a pharmacy licence	BD.10/- per month of delay upto 3 months after which the licence is cancelled
Delay in renewal of health food licence	BD.10/- per month of delay upto 3 months after which the licence is cancelled
Other Violations	According to pharmacy law, section on penalties.

N.B: The renewals and follow up on licenses is the full responsibility of the agent and the directorate holds no responsibility in this field.

Samples

The following should apply to importation of samples of pharmaceutical products.

-The product should carry a valid licence.

-The exporting source should be the same registered source.

-The packaging material, leaflet, labeling and shelf life should be similar to the registered product specification

-Lot number, expiry date and preferably manufacturing date should be on the label

-For reduced size samples, the size should be identified clearly.

-The outer and inner package should carry the sentence "free medical sample, not for sale' or similar.

-Samples for narcotics, psychotropics, drugs under control and steroidal preparations are released for registration purposes and tender only

-Injectable product samples should be accounted for and a record of distribution should be presented to the directorate upon request

-Injectable antibiotic product samples are allowed for hospitals only.

-Fees for clearance of sample is collected for 10 pieces or more of each product presentation i.e., size, strength.

Invoices

P & DC Directorate takes the responsibility of releasing drug items from all ports of entry for government and non-government approved establishments
The invoices should be for a party that is allowed by government laws and pharmacy laws to import drugs into Bahrain. Manufacturing date, expiry date, batch number of the goods should be present on the invoice. Source address and other specifications should meet the registration documents with p & DC.
Invoices of blood products, biologicals, vaccines and sera derivatives should be accompanied by HIV and Hepatitis free certificates from responsible authorities in exporting country

-Batch certificate should be included for every batch in the consignment
-Samples of imported items may be requested upon release
-A fee against clearance of each item in the invoice is collected.

Destruction of expired product

The local agents should forward to P & DC list of items that are either expired or spoiled. The drug inspectors after comparing the actual quantities with the documents can proceed with the destruction procedures in collaboration with the Ministry of Municipalities. After the submission of municipality clearance letter to P & DC certificate of destruction will be provided to the local agents.

A fee is charged against each item

Personal Parcels

These require pre-approval by pharmacy & Drug Control directorate.
The Pharmacy law prevents any person to import drugs for personal use except according to prior approval from Ministry of Health. Any parcel not meeting the requirements of the law and guidelines of P & DC is subject to confiscation. Please follow ministerial decrees.

Veterinary Drugs

According to Pharmacy law these are dealt with in the same way as drugs for human use.

Recall of Drugs

If due to national or international information a recall of a drug item is mandatory, then it is the duty of the agent to recall all the stock from the local market and forward such information to P & DC directorate either for confiscation , destruction, follow-up or for any measure seen by MOH authorities

REGISTRATION OF HEALTH PRODUCTS

Health product

Health product is the product that is marketed in any of the common pharmaceutical forms for oral and topical use. The product contains substances of natural origin (herbal, animal or mineral).

Only oral and topical preparations are accepted within this classification. Opthalmic, otic and nasal drops, all injectables, rectal and vaginals preparations are considered pharmaceutical preparations that undergo full registration procedure. Non-medicated nasal and vaginal washes could be classified as health products depending on documents submitted.

The following documents should be submitted for registration of a health product (in a dossier)

1.Insert leaflet clarifying the following:
- -Quantitative and qualitative composition of the product. Names in the leaflet of all herbal products must be in Latin names and names in Common English. Arabic names is an additional advantage
- -General indications without any hint of medical action.
- -Dose and method of administration
- -Warnings, cautions, contra-indications.
- -All excipients and additives such as colouring and flavouring agents must be mentioned
- -Side Effects
- -Treatment of overdose
- -Interactions with commonly used drugs, food and alcohol
- -Storage conditions

2.Any post marketing surveillance reports
3.Source and kind of animal if the preparation contains an animal product.
4.Certificate from the health authorities (or concerned authorities) in the country of origin regarding the status of the manufacturer and the product in the country of origin.

5.The clear quantitative and qualitative composition of the preparation. All additives and excipients should be mentioned. If percentages are used it should be clear enough to indicate the amount of ingredient per specified unit of size

6.Samples (4 pieces of each)
7.Method of manufacture of the product

8.Labels and artwork of the outer pack
9.Scientific medical reference monograph or/and articles about the product or its components
10.Storage conditions
11.Laboratory identification methods i.e. method of analysis
12.Reference standard materials and enough samples required for the Laboratory analysis
13.Side effects
14.Shelf life of the product

Labeling

The outer and inner label of the product should contain the following information:

-Name of the product
-All excipients in the preparation should be identified on the label.
-Full quantitative and quantitative formula of the preparation
-Contra-indications, warnings, cautions, dose and method of administration
-Any precautions and interaction

-The general indication of the product should be clarified without any indication of a specific medical action.
-Date of manufacture, date of expiry and batch number should appear on the label.
-Pack size should be on the label as per number of oral doses, capsules, tablets, milliliter etc.
-Storage Conditions

Additional requirements:-

1.Contents of herbal product preparation should not exceed 4 herbal components, unless a very strong scientific justification is provided.

2.Paediatric formulas are not accepted.

3.No hormonal, steroidals, psychotropics or chemotherapeutics substances are accepted.

4.No medical claims should be made

5.No claim of absence of side effect should be made

6.Validity of license is 5 years

7.P & DC Directorate holds the right to delete, suspend or revoke the license if scientific data about the danger, change of classification or side effects were obtained from international, regional or local authorities.

8.Supportive medical information from non-scientific websites is not accepted.

GENERAL RULES

1.Licences to import and sell health products are given to pharmacies and special outlets.

2.The area provided for display and sale of such products should be at least 6 sq.meters

3.An application for this activity should be submitted to P & DC Directorate indicating the address where the activity is to be practiced

4.The directorate inspector organizes with the applicant the inspection visit before granting the preliminary approval.

5.After granting the preliminary approval the applicant should complete the ministry of trade and commerce-commercial register requirement.

6.An annual fee of BD.100 is collected against the license

7.A fee of BD.5/- is collected against every licenced product

8.The product licenses are renewed every 5 years

9.An annual fee of ½ BD is collected against every item in the invoice upon clearance.

10.A fee of BD.50/- is collected whenever a laboratory analysis is preformed on any product