

Frequently Asked Questions (FAQs)

This document contains answers of the most frequently asked questions about SDR system and drug file submissions. The questions are grouped by category to make search easier and the answers are cross-referenced with other information on the topic available on this document or linked websites. The categories are:

- [Where to start?](#)
- [Application form in SDR](#)
- [Submitting Drug Application](#)
- [Data Requirements](#)
- [General Questions](#)

If you have any comments, or if you have a question about SDR that was not answered here, please send it to: sdr.drug@sfda.gov.sa

This FAQ is created and maintained by Regulatory Affairs Department – Drug Sector – SFDA.

Where to start?

1. How to register a product?

The applicant should be familiar with the product type by comparing the product with the published drug lists. If the product is not available in the drug lists, then can choose to either classify it or apply directly. Please follow the figure below for more information.

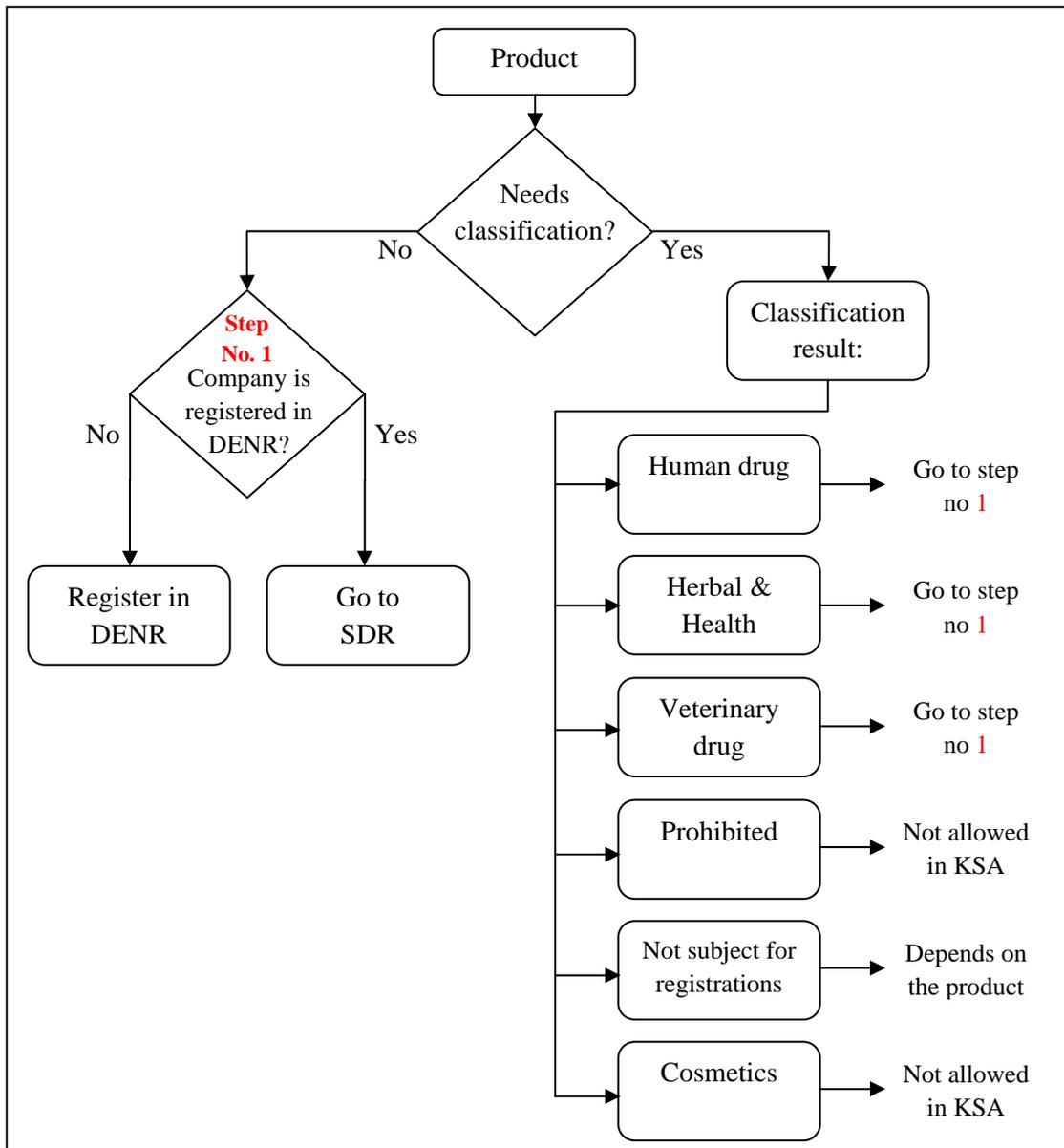


Figure 1: schematic diagram for how to register a product

2. How to register my Pharmaceutical Establishment in Drug Sector?

Visit the DENR website at the link: <http://denr.sfda.gov.sa>

3. I have created a user ID and a password from DENR system, can I start applying in SDR?

No, you cannot. You need to activate the account by following the instructions in the email and the DENR guidance.

4. How long it will take to register my Pharmaceutical Establishment in DENR?

Usually around 7 days.

5. How I can create a subaccount?

By choosing the “*Add sub account*” menu in the main account page.

6. When I can log in to SDR?

You can when you receive an email from DENR containing the approval of the account and the DENR number. Moreover, the DENR user ID and password can be used for the Drug Sector e-services, such as SDR, IBRCS and others.

7. Who should apply in SDR, the agent (MAH) or the scientific office manager?

This is done by an agreement between the two. Taking into consideration that once one of them started, the other cannot continue or step in the middle of the registration process (per application).

Application form in SDR

8. What types of applications are available in SDR?

There are three types:

- Marketing Authorization Application of Medicinal Product for *Human Use*
- Marketing Authorization Application of Medicinal Product for *Veterinary Use*
- Marketing Authorization Application of *Herbal & Health Product*

Type of Application

9. What does the following means?

a. Is Saudi Arabia the Country of Origin (COO)?

It means, is the manufacturer a local establishment located in Saudi Arabia?

b. Marketing Authorization holder?

It means the MAH holder in the country of origin.

Names and ATC Code

10. What is the Pharmacotherapeutic group (ATC code)?

The Anatomical Therapeutic Chemical (ATC) Classification System is used for the classification of drugs. It is controlled by the WHO Collaborating Centre for Drug Statistics Methodology (WHOC).
Please, visit the website: http://www.whocc.no/atc_ddd_index/

11. How to choose the right ATC code?

The active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties. Drugs are classified in groups at five different levels. The drugs are divided into fourteen main groups (1st level), with pharmacological/therapeutic subgroups (2nd level). The 3rd and 4th levels are chemical/pharmacological/therapeutic subgroups and the 5th level is the chemical substance. It is available in the WHO website at the previous website. For example, vancomycin has 2 codes. One is (J01XA01) as glycopeptide antibacterials under the pharmacological/therapeutic subgroups of

Antiinfectives for systemic use. The other one is (A07AA09) as antibiotics under the pharmacological/therapeutic subgroups of antidiarrheals, intestinal anti-inflammatory / antiinfective.

Product Information

12. How to fill the package size, volume and unit fields?

It depends on your product, such as tablet or a liquid dosage form. Below table shows some examples:

Dosage Form	Package Size	Volume	Unit
Ampoule or Vial	5	3	mL
Cartridge	50	1.8	mL
Cream or ointment	1	10	g
Enema	1	133	mL
Eye/ear drops	1	10	mL
Inhaler	1	200	DF ¹
Powder	1	500	g
Syrup	1	100	mL
Tablet or Capsule	30	Leave it blank	Leave it blank

Contact Information

13. What does “Proposed marketing authorization holder/person legally responsible for placing the product on the market in KSA” mean?

This is the MAH in KSA, i.e. the agent.

Manufacturers

14. What does the field “Activity” mean?

The activity can be anything from manufacturing, primary packaging, secondary packaging, batch release, or other activities.

15. If a product has two manufacturing sites, where to include the 2nd site in the application form for new registration?

Both the two manufactures should be included in the “Finished Product Manufacturer” section, and the activity can be to one of them as “secondary source”.

¹ DF: Dosage Form

Fees

16. How to pay the required amount for registering a drug?

Under “Fees” page, choose the proper application type then generate a SADAD bill. Please make sure you have chosen the right type in order to generate a bill with the right fee amount.

Scheduling

17. How to schedule and reschedule an appointment?

SDR Guidance explains the procedure in details.

18. Do I have to notify for cancelation? What the minimum time for notification?

Yes, it is recommended to notify SFDA by email at least two days prior to the scheduled day.

19. If I am (as applicant) late for the appointment, what is the procedure?

You will have the remaining time for checking, then by the end of meeting time the unrevised parts of your application will be considered missing, and another appointment is needed.

Submitting Drug Application

20. What is a “Drug Application”?

A drug application is a term used to describe the combination of: the application form in SDR, the product file, and drug samples.

21. How to present the product file to SFDA?

Simply, follow the “Guidance for Submission” (*latest published version*).

22. Can non-Saudi pharmacist make the delivery of the product file?

According to the government law, the person should be Saudi.

23. In module 1, if I missed a signature or a stamp or a copy of a certificate, is it acceptable?

No it is not. The file will be returned with an acknowledgement letter with deficiency.

24. If any information or documentation is missing/incorrect, would SFDA receive it until I complete it?

The Drug Sector will not accept the Drug Application and will be returned back to the applicant.

25. Would providing a valid legalized CPP copy issued to any other country a possibility, or should the CPP be issued to Saudi Arabia by the related health authorities?

The CPP should be issued to Saudi Arabia by the related health authorities.

26. How would I receive an inquiry? What to do then?

An auto-email will be sent from SDR notifying you of an inquiry. For full details, please read the “Guidance for Submission” (*latest published version*). However, Drug Sector does not recommend that the applicant sending a further clarifications or questions regarding the query in SDR system. If the applicant have any question or need clarifications, he/she should send an e-mail to sdr.drug@sfd.gov.sa.

27. When the samples (batch number) is different, what to do?

This is not acceptable. All samples, its letter (1.3.5), and the certificate of Analysis (1.7.3) must have the same batch number and expiry date.

28. In case the Drug Samples are *different* than the Artwork, e.g. no Arabic trade name, different design or different pack size...etc, what is the procedure?

SFDA will accept the provided samples as long as they meet the conditions in module 1 (1.3.5) and the certificate of Analysis (1.7.3).

29. What is NeeS? What are the differences between NeeS and eCTD?

NeeS is defined as Non-eCTD electronic Submission.

The difference from an eCTD is that the two relevant XML files, the *index.xml* and *gc-regional.xml* for the backbone of Modules 2 to 5 and Module 1 for the GCC, respectively and the *util* folder are not present, so navigation through a NeeS is based on electronic Tables of Content, bookmarks and hypertext links. The XML backbone (recognizable as 'index.xml' at the root level of the submission folder) of the eCTD provides two useful functions:

- It provides a hyperlinked table of contents to the entire submission when viewed in web browser with a suitable stylesheet
- It provides descriptive information ('meta-data') on the files that make up the actual content of the eCTD

30. Is the NeeS accepted for Herbal and health products? Veterinary products?

For the time being, they are *excluded*.

31. How to prepare a NeeS?

Simply, follow the "Guidance for Submission" (*latest published version*).

32. Does a NeeS application cover all dosage forms, strengths, and pack sizes of a product?

Yes it does.

33. Are the folders and the folders' naming mandatory?

For Modules 1-5: the folder structure and names must follow the GCC or ICH defined structure and names.

34. In case of empty folder, should we put "not applicable" or "not available"?

No, these folders should be deleted.

35. If we have a pdf file size above 100MB, what to do?

Files larger than 100 MB should be avoided. If there is a need to exceed this limit, please contact the Drug Sector.

36. When I can submit a NeeS or eCTD?

A timeline has been published in the Drug Sector website.

Data requirements

37. How to prepare the drug file?

The drug file should be prepared according to the “*Data Requirements for Human Drugs Submission - Content of the Dossier*” published in the website.

38. Where should I include the certificate of suitability (COS)?

In the folder name “32r-reg-info”.

39. What do we have to submit in (2.3.R) & (3.2.R) Section?

Refer to the “*Data Requirements for Human Drugs Submission - Content of the Dossier*” guideline.

40. Following are recommendations for the presentation of the information in the *Quality Module* for different scenarios that may be encountered:

- *For a drug product containing more than one drug substance:* one complete “3.2.S” section should be provided for one drug substance, followed by other complete “3.2.S” sections for each drug substance.
- *For a drug substance from multiple manufacturers:* one complete “3.2.S” section should be provided for the drug substance from one manufacturer, followed by other complete “3.2.S” sections for each drug substance manufacturer.
- *For a drug product with multiple strengths:* one complete “3.2.P” section should be provided with the information for the different strengths provided within the subsections. One complete copy of the dossier should be provided for each strength.
- *For a drug product with multiple container closure systems (e.g. bottles and unit dose blisters):* one complete “3.2.P” section should be provided with the information for the different presentations provided within the subsections.
- *For multiple drug products (e.g. tablets and a parenteral product):* a separate dossier is required for each drug product.
- *For a drug product supplied with reconstitution diluent(s),* the information on the diluent should be provided in a separate part “3.2.P” if the diluent is co-packaged with the drug product. However, if the diluent is not co-packaged with the drug product, the compatibility of the diluent with the drug product should be discussed in 3.2.P.2.6.

41. Where should the information on bioequivalence studies for a generic application be included?

Bioavailability study reports should be included in Module 5, under section 5.3.1 “Reports of Biopharmaceutical Studies”. More specifically, reports of comparative Bioavailability/Bioequivalence studies should go under section 5.3.1.2.

42. For a registered product, how to register the following:

a. A new pack size.

Follow the “*Guidelines for Variation Requirements*”, specifically the section “Change in pack size of the finished product”.

b. A new package type (for example from aluminum blister to tablet container, or from plastic bottle to a glass bottle).

Apply for a new registration.

c. A new strength.

Apply for a new registration.

General Questions

43. How can we submit the Herbal & Health products? Veterinary drugs?

As mentioned in the “Guidance for Submission” (*latest published version*).

44. Is SFDA offering pre-submission meetings?

In the time being, no.

45. After registering a product, who is the MAH?

The MAH in KSA is then the agent. However, the MAH for the product worldwide is the license holder.

46. How to contact the Drug Sector regarding registration?

There are several ways:

Phone: +966-1-203-8222 Extensions: 5171, 5169

Fax: +966-1-205-7643

Email: sdr.drug@sfda.gov.sa

Mail: 3292 Northern Ring Road – An nafal District

Riyadh 13312-6288

Kingdom of Saudi Arabia

Website: www.sfda.gov.sa