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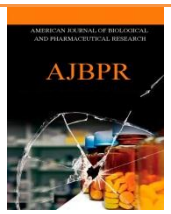

A REVIEW ON OMAN DRUG REGULATORY POLICY AND eCTD SPECIFICATIONS

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ABSTRACT

The review article describes the drug regulatory process of medicines in Oman. The aim of this document is to compile all relevant, existing information on the pharmaceutical sector and make it available to the public in a user-friendly format. Recently Oman MOH Introduced the electronic Common Technical Document format (eCTD) form for submitting the submissions instead of paper format. It provides assistance with the submission of regulatory information in eCTD to the Directorate General of Pharmaceutical Affairs & Drug Control (MOH-DGPA&DC). The document covers general guidance on how to organize electronic application information submitted to the directorate in accordance with eCTD specifications. Guidance on the information to be included in each section of the applications and submissions is based on the International Conference of Harmonization (ICH) and Oman MOH regulatory framework for drug approval. Applicants submitting eCTD applications must comply with this guidance documents as well as the "GCC Module 1 Specifications for eCTD" made available on the Ministry website.

INTRODUCTION

The Sultanate of Oman, situated on the east southern part of the Arabian Peninsula, has a population of 2,325,460 of whom 596,130 are foreign nationals (1999 census) and has an annual population growth rate of 2.7%. 44.4 percent of the population is under 15 years of age and 71% of the population lives in urban areas. There has been tremendous progress in the past 30 years in all spheres of national activity [1]. The goal of a national drug policy is to develop, within the resources of a country, the potential that drugs have to control common diseases and alleviate suffering. This goal can only be achieved if there is an adequate and reliable supply of safe and cost effective drugs of acceptable quality, which are rationally used by prescribers, dispensers and consumers in both the government and private sectors. A number of key components of a national drug policy are already in place within the Sultanate of Oman as a result of the actions of the Ministry of Health. These actions have concentrated on developing and implementing relevant legislation, on stabilizing regulatory procedures for drugs, on selecting a list of drugs for use in government. Institution following effective procurement practices, controlling quality of imported products and distributing supplies to ministry of health institutions. This National Drug Policy document seeks, within the context of the National Health Policy, to unite those existing components with some additional components, to produce a comprehensive policy document with recommendations which will enhance the

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achievements already, made in the pharmaceuticals area [2].

Pharmaceutical Sector

Pharmaceutical affairs are administered by two Directorate Generals one for Pharmaceutical Affairs and Drug Control (DGPA&DC) reporting to the Under Secretary for Health Affairs ,the other for Stores (DGS)in the Ministry of Health. The DGPA&DC is subdivided into three Directorates and headed by a Director General while DGS is subdivided into five Directorates and headed by a Director General. All offices including the medical supplies stores are on the same compound [3].

DGPA&DC

The Directorate of Drug Control (DDC) is responsible for the registration of drugs and clearance of imported/exported drugs for the private Sector also they work in collaboration with the Directorate of Central Laboratory for Drug Analysis (CLDA) which is responsible for the activities of the quality control laboratory. The Directorate of Pharmacy (DP) implements regulations relating to the licensing of Pharmacists and Assistant Pharmacists; licensing and inspection of wholesale or retail premises in the Private Sector.

DGS

The Directorate of Specifications and Supplies (DSS) procures Drugs, Medical, Laboratory supplies and Miscellaneous but is not responsible for the procurement of equipment. The Directorate of Drug Stores (DDS) and The Directorate of Medical Supplies Stores (DMSS) both directorates are distributed drugs and medical supplies directly to Hospitals, which in turn distribute to health centers. The Directorate of Miscellaneous Stores is distributed Medical Printing items, Stationary items, Office supplies and others directly to Hospitals. The Fifth Directorate is for Finance and Administration (DFA). Pharmacists head each of the technical directorates as well as the various technical sections under each Directorate. All Pharmacists working in the country have been trained abroad. An Assistant Pharmacy Institute (OAPI) started graduating Omani assistant pharmacists in 1991 to meet the ongoing demand for assistant pharmacists in the Ministry of Health and other governmental institutions. At present there are no plans to train Pharmacists in the country.

Country Drug Strategy [4]

Objective

- To ensure that all legislation and related regulations are up-to-date to ensure that the general public has access to safe, effective, affordable drugs and medicines which meet approved standards and specifications and that these drugs are used rationally.
- To ensure that all drugs and medicines imported or manufactured in the Sultanate of Oman are evaluated and registered by DGPA&DC according to the established procedures with adequate provisions for emergency registration when required with the ultimate goal that the general public obtains the maximum benefit from a particular product, accompanied by the appropriate professional device.
- To ensure that the selection of drugs are those necessary for the health care of the nation and that they are available to communities and individuals at an appropriate level where they can be safely and effectively used.
- To support the procurement system in making available cost-effective drugs of accepted quality at the needed time.
- To provide Pharmaceutical quality assurance so that the quality of any drug product manufactured in or imported for use in the Country is maintained and complies with established specifications and standards throughout its self-life.
- To improve the use of drugs by health providers through rational prescribing and dispensing and to promote the appropriate use of drugs by the individual and the Community.

Legislation and Regulation

The DP is responsible for licensing Pharmacists and Assistant Pharmacists and for monitoring their performances in the Private Sector. The licensing procedure for expatriate Pharmacists and Asst. Pharmacists involves written examination and an interview by a Technical Committee [5]. The DP responsible for licensing of the premises of wholesale and private Pharmacies also carry out inspection with particular attention paid to the records of the prescriptions and supply of Psychotropic drugs. Random samples are collected for analysis by DCLDA.

Provisions

- Licensing for drug storage and dispensing within private clinics will be limited to those cases where no pharmacy services are available within a limit to be defined by the Ministry.
- A list of drugs for over-the-counter sales in Pharmacies will be developed, published and updated regularly.
- The list of drugs to be sold in supermarkets will be revised and published regularly.

Registration and Drug Control

To ensure that all drugs and medicines imported or manufactured in the Sultanate of Oman are evaluated and registered by the DGPA&DC according to the established procedures with adequate provisions for emergency

registration when required with the ultimate goal that the general public obtains the maximum benefit from a particular product, accompanied by the appropriate professional advice.

- The revenue of registration fees will be collected and retained by the MOH to enable the DDC to employ enough staff to function more efficiently.
- Criteria for the registration of drugs to be up dated to ensure that drugs will only be registered if they meet recognized health needs, have proven effectiveness and safety profiles, meets quality standards and are being used in the country of origin. The cost of the drug will also be considered with the aim to limit the unnecessary proliferation of different brands of the same drug.
- Prominent generic name labelling requirement for registration.
- Reporting of adverse drug reactions be further supported and promoted.

Drug Procurement

To support the procurement system in making available cost effective drugs of accepted quality at the needed time.

- Tender documents will include a specification for the size of generic name to be printed on product and package labels.
- The cost price of procured items will be monitored and their comparison with international price indicators be recorded. Potential savings will be quantified, with a view to widening the tender and increasing the value for money.
- Pharmacists will devise computerized systems of indenting with an aim to reduce the amount of hand-written orders.

Drug Quality Assurance

The Central Laboratory for Drug Analysis started physicochemical analysis in 1981 and microbiological analysis in 1992. It has 19 professional staff, eight pharmacists, two chemists, two biologists, two-pharmacy assistant and six technicians who analyzed 3213 samples from Govt. & Private facilities in 1996. In the experience of the laboratory, only a small fraction - approximately 3% of the samples have problems. Many of the problems are due to chemical and physical defects. This is a reflection of a good procurement process, which selects products by Companies already registered in the Country [6]. About 80% of the analysis refers to stocks from the Central Medical Store and the remaining 20% is for the Private Sector. All drugs purchased by MOH (except biological products - 7%) are analyzed before distribution to Government Health units. Additional staff and resources will be required if all the supplies to private pharmacies and other government institutions are to be analyzed. At the moment, the Private Sector does not pay for analysis.

- The number of pharmacists will be increased to match the workload in case all the supplies to private pharmacies and other government institutions are to be analyzed
- Ways of charging fees to the private sector for analysis of their imported items will be explored
- The income from these fees will be retained by the MOH to improve and run the laboratory services to provide and maintain the human resources, training, buildings and sophisticated equipment necessary to cover the analysis of all drugs that enter into the Country.

Distribution and Storage

The Directorate of Drug Stores (DDS) and Directorate of Medical Supplies Stores (DMSS) are responsible for deciding the quantities to be procured and for storage and distribution of pharmaceutical and medical supplies in coordination with inventory control section [7]. There is only one Central Medical Store (CMS) located in Muscat. The CMS is made up of many buildings, which are well equipped with air-conditioning and cold rooms in appropriate places. The three main sections: Medical, Laboratory and Surgical supplies are each headed by a Pharmacist assisted by Assistant Pharmacists, Laboratory Technicians, Nurses and other supporting staff.

Both directorates are responsible for supplies to all MOH hospitals through indent forms, which are received from each institution. This form includes information on stock in hand, rate of use, and the requested supply. There are no institutional drug budgets except for the Royal Hospital. Supplies are made as per the storage capacities and facilities in every Health unit. Monthly distribution system is used for all Health units except for two remote regions where it is quarterly. Health centers in the regions get their drug supplies from the Regional Hospitals. The quantities issued are based on the consumption which can be increased to 10% to avoid shortages. There are, at the moment, no systems in place for the safe disposal of unwanted drugs and medicines.

- The functions of Central Medical Stores will be re-evaluated and strengthened by modern equipment, in-service training for the medical stores staff in material management and storage administration systems.
- An incinerator system will be developed to safely dispose of expired medicines and unused pharmaceutical products.

eCTD Specifications

This guidance is intended to provide recommendations to applicants wishing to register medicines in eCTD (electronic Common Technical

Document) format [8]. It reflects the current position and will be regularly updated with changes in legislation and policies. It is important that applicants adhere to administrative requirements to avoid delays in processing and evaluating applications. Guidance and application forms are available on the Ministry website (www.moh.gov.om)

The document is intended to provide assistance with the submission of regulatory information in electronic Common Technical Document format (eCTD) to the Directorate General of Pharmaceutical Affairs & Drug Control (MOH-DGPA&DC). It covers general guidance on how to organize electronic application information submitted to the Directorate in accordance with eCTD specifications. Guidance on the information to be included in each section of the applications and submissions is based on the International Conference of Harmonization (ICH) and Oman MOH Regulatory framework for drug approval. This guidance is intended for Registration, Re-registration & Variation applications for human pharmaceutical products. It should be stressed that it reflects the current situation and will be regularly updated in light of changes.

Applicants submitting eCTD applications must comply with this guidance documents as well as the "GCC Module 1 Specifications for eCTD" made available on the ministry website.

1. Types of submissions

- New registration.
- Re-registration.
- Variations.

2. Types of products

The scopes of products to be submitted in eCTD format are the following:

- New Chemical Entities.
- Generics.
- Biologics.

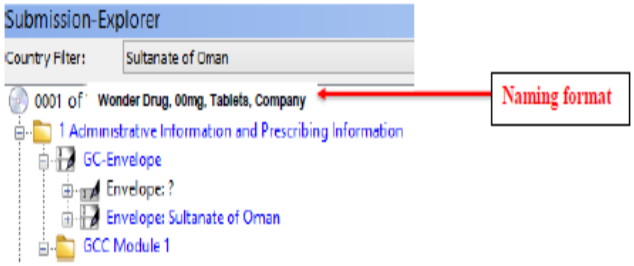
3. Content and structure of eCTD Submissions [8,9]

Structure

In terms of dossier content, the compiled scientific information enclosed in an eCTD is identical to that of CTD submissions. The difference between CTDs and eCTDs lies in the type of media used, and the method of structuring documents. An eCTD submission is an electronic dossier built using an XML backbone with a unified pattern of arranging documents into branches and leaves. It allows better accessibility and therefore improving the overall review process. The structure of an eCTD dossier is viewed graphically via an XML viewing tool as seen in the Fig. 1.

Labeling of the Sequence Number Folder

The Sequence Number Folder (0000) must be labeled in the following format: "Trade Name, Strength, Dosage Form, Company Name."



4. Hard Copies for Module I

eCTD dossiers are submitted electronically. Nonetheless, for legal reasons, specific documents of Module 1 that are listed in Appendix I must be available in hard and soft copies. Both copies must be identical.

5. Specifications of hard copy Documents

Legibility and Size

All documents including tables should be legible and the page size should be A4 Norm.

Page divider/tab

A page divider or tab (with the header of the section printed) should be used to separate selected section in module1.

Language

Information and documents supporting a drug application-such as certificates and approval letters must be either in Arabic or English. If documents are neither in Arabic nor English, a translation to English (from an authorized translation office) are required.

Authentication

Authentication also known as legalization- refers to the process whereby the origins of the document are attested. Authentications of documents are made to MOH-DGPA&DC by the Health authority and/or the Ministry of Foreign affairs in the country of origin, in addition to Oman Embassy or Consulate where the document was issued, refer to appendix- I.

6. Letter of Application (Cover letter)

Submissions as well as additional information in eCTD format should be accompanied by a cover letter of application in both paper and portable document format (PDF). The PDF should be a scan of the originally signed document and must be searchable (OCR scanned) including the following:

- Local Agent:
- Company Name and address
- ATC code(if available)
- Dosage form
- Dosage strength(s)
- The International Non-proprietary Name (INN) of the product
- Number of CDs/DVDs provided
- Application Number

- Validation Tool used
- Validation Specification Version
- MD5 checksum:
- The tracking table of the submitted sequences.

7. Qualifications of the Product File

Softcopy Requirements

For the softcopy, each CD or DVD and its hard plastic cover submitted should include the following label information, clearly presented and printed on the media with font size "12 Times New Roman":

- The company name (Manufacturer name and/or MAH).
- The product Trade name.
- INN name.
- The submission type.
- The sequence number of the submissions contained on the CD/DVD (e.g. 0002).

Media

The electronic submission may only be submitted in CD or DVD (single or dual layer). The disc must not be bootable or have auto-start programs. Currently both CD-ROM and DVD ISO 9660 are considered an acceptable media standard.

System compatibility

The electronic submission (as provided) must be directly readable and usable on MOH-DGPA&DC hardware and software.

Validation confirmation

It is the Applicant's responsibility to ensure that their electronic submission is free of viruses. The applicant must scan the submission via competent antivirus software and produce a certificate proving that the submission is free of viruses. Applicants must use an eCTD validation tool that checks the submission for technical interoperability before submission. The applicant must submit the results of the validation report along with the number generated by the MD5 checksum.

Security

There are various aspects related to security. The physical security of the submission during transportation/transmission is the responsibility of the applicant. Once received by MOH-DGPA&DC, security and submission integrity will become the sole responsibility of the Directorate. In this respect, it should be noted that we will take appropriate measures to prevent loss, unauthorized duplication and/or access or theft of regulatory information presented both on paper and electronic media that are distributed throughout the Directorate.

Password protection

One-time security settings or password protection of electronic Submissions for security purposes is not acceptable during transportation/transmission from the applicant to MOH-DGPA&DC. Applicants should also not include any file level security settings or password protection for individual files in the electronic submission. Applicants should allow printing, annotations to the documents, and selection of text and graphics. The Internal security and access control processes in MOH-DGPA&DC maintain the integrity of the submitted files.

8. Registration Process (New)

Appointments for submitting applications

The applicant must submit an appointment letter to MOH-DGPA&DC to schedule Registration and Re-registration appointments. Appointments will be given to applicants to submit productsthat are manufactured/batch released by companies already registered by MOH-DGPA&DC. The applicant will then be contacted by an assigned staff member to be informed of the designated date and time of submission. In case the applicant did not appear on the scheduled date (no show), a new appointment request has to be made (refer to Appendix II for the format of the appointment request). It is important to note that Variations do not require prior appointments. Applications for variations are received weekly on Tuesdays from 9:00 am till 11:59 Am.

Submission of Application

On the scheduled day of submission, the applicant must be present at the specified time slot. Submitted dossiers are verified against a checklist of all required documents according to MOH-DGPA&DC submission criteria.

Phase- I (Validation)

The submission will be rescanned by MOH-DGPA&DC for viruses. Technical validation of the dossier will be carried out via the Importation tool and the generated 32 digit MD5 checksum will be matched with the one submitted by the applicant. Refer to section 14.0.

Post Phase- I (Validation)

Upon completion of validation, the outcome is either one of the followings:

Valid Drug Applications

The applicant will receive an Acknowledgement letter with the assigned eCTD application number and the validation report attached. The dossier is then forwarded for evaluation and assessment.

Invalid Drug Applications

- A failure letter is issued to the applicant attached to a detailed validation report with all the errors. The applicant is allowed a period of 90 days to rectify the errors from the date of the letter.
- The applicant shall contact the MOH-DGPA&DC requesting an appointment to resubmit the dossier once the errors have been rectified
- If the applicant has provided the requested information within 90 days. The application will forward to the concerned staff member for further processing and assessment.

- If the applicant has provided the requested information within 90 days, but it was found to be still incomplete, the applicant can complete the missing within the rest of the 90 days.
- In case of failure to submit within 90 days, the drug application will be rejected.

Phase II (Evaluation & Assessment)

After successful completion of both validations, technical and content, the submitted dossier will be forwarded for assessment. If deficiencies are identified during assessment, a request is sent to the applicant to provide the required documents within 90 days from the date of the request. Depending on the applicant's response, the subsequent outcomes are

1. Applicant responds within 90 days: submitted documents are assessed.
2. Applicant provides the requirements within 90 days but the response is deemed unsatisfactory: MOH-DGPA&DC will study the case and decide whether to reject the application or grant an extension period not exceeding 30 days.
3. Applicant fails to respond within 90 days: Rejection of application.

9. Re-Registration

- Applicants must submit a renewal request every five years for drug products that have already received marketing authorization – at least six months prior to the end of the 5 year registration period. The followings are required:
- CD/DVD of the required documents in eCTD format (refer to "Sections 12.0").
- Hardcopy consisting of the documents selected in Appendix-I.

The requirements for re-registration are made available on the MOH/MOH-DGPA&DC website.

10. Variations

An applicant can submit a variation application – on drug products that have already received a marketing authorization from MOH-DGPA&DC – through submitting the following:

- CD/DVD of the required documents in eCTD format (refer to "Sections 14.0").
- Cover letter and Hard copies of legalized documents (In case the variation involves legalized documents).
- The requirements variations are made available on the MOH-DGPA&DC/MOH website

11. Correspondence

The eCTD is designed to ensure that assessors have a current view of the submitted information in their designated place in the dossier at all times. Therefore, formal responses to questions should always be submitted in eCTD format, as well as any correspondence that relates directly to the content of the dossier.

12. Submission Considerations for Electronic Version of Module I

Handling of Empty or Missing eCTD Sections

For new applications (Registration) (including generic applications), detailed statements justifying the absence of data or specific eCTD sections should be provided in the relevant Quality Overall Summary and/or Non-Clinical/Clinical Overviews (Module 2.3, 2.4, 2.5).

File formats (General requirements)

Detailed guidance on the specific file formats can be found in the ICH eCTD specification document and GCC Module 1 specifications. The following points have to be taken into consideration:

- The relevant information must be structured according to the requirements of the Common Technical Document (CTD).
- The documents included in electronic submissions should be in PDF format.
- Each PDF file should not exceed 100 megabytes.
- Files must be legible with PDF version 1.4 or higher.
- For graphics: Joint Photographic Experts Group (JPEG), Portable Network Graphics (PNG), Scalable Vector Graphics (SVG) or Graphic Interchange Format (GIF).
- The files referred to above should not be added as leaf elements within the eCTD structure. They should always be provided in a separate folder called 'xxxx-working documents' on the same media containing the electronic dossier, where the number (xxxx) matches the number of the eCTD sequence being submitted (e.g. 0000-workingdocuments)" with a substructure as follows:

Portable Document Format "PDF"

PDF is accepted as a standard for documents defined in this guidance. To ensure that PDF files can be accessed efficiently, each PDF file should not exceed 100 megabytes. For PDF files, the following points must be taken into consideration:

- Files must be legible with PDF version 1.4 or higher.
- PDF files produced from an electronic source document are highly preferred over PDF files produced from scanned paper, since those 'electronic' PDF files provide the maximum functionality to the reviewers in terms of search and print capabilities, and copy and paste functionality. The overviews/summaries in the

CTD Module 2 should always be generated from an electronic source document.

- If scanning is unavoidable, readability and file size must be balanced; the following is recommended: resolution 300 dpi (photographs up to 600 dpi), avoid gray scale or color where possible, use only lossless compression techniques.
- If colors other than black are used, the colored pages must be tested on a black and white printer for acceptable reproduction and legibility prior to submission.
- Print area for pages must fit on an A4 sheet of paper; margins must allow binding in multi-ring binders without affecting readability.
- Landscape-oriented tables must automatically appear in landscape on screen.

Bookmarks and hypertext links

Navigation through an electronic submission is greatly enhanced by the intelligent use of bookmarks and hypertext links. ICH guidance states "It is expected that any document that has a Table of Contents (TOC) will have bookmarks". Documents without TOCs should have bookmarks included where it aids in the navigation around the document content. In general terms, bookmarks and hyperlinks should be used to aid navigation.

Text Searchable Files

Applicants are requested to ensure that all submissions contain the maximum amount of text searchable content. Documents with searchable text will aid the assessor, or any other user, in searching for specific terms and also in copying and pasting information into another document, such as an assessment report. This appendix provides some guidance about what must be text searchable and the ways to ensure that files are created appropriately.

Appendix-I [8]

Module 1 documents that are requested additionally in paper format:

Section	Requirements	1*	2*	3*	4*	HC [a]
1.0	Cover letter	✓	✓	✓		✓
1.1	Comprehensive Table of contents					
1.2	Application Form		✓	✓		✓
1.3	Product Information					
1.3.1	Summary of Product Characteristics (SPC)					
1.3.2	Labeling					
1.3.3	Patient information leaflet (PIL)					
1.3.3.1	Arabic leaflet					
1.3.3.2	English leaflet					
1.3.4	Artwork (Mock-ups)					
1.3.5	Samples					◆[b]
1.4	Information on the experts					
1.4.1	Quality					
1.4.2	Non-Clinical					
1.4.3	Clinical					
1.5	Environmental Risk Assessment					
1.5.1	Non-Genetically Modified Organism (Non-GMO)					
1.5.2	GMO					
1.6	Pharmacovigilance					
1.6.1	Pharmacovigilance System	✓				
1.6.2	Risk Management Plan	✓				
1.7	Certificates and Documents					
1.7.1	GMP Certificate					
1.7.2	CPP or Free-sales [c]				✓	✓
1.7.3	Certificate of analysis – Drug Substance & Finished Product	✓[d]	✓[d]	✓[d]		
1.7.4	Certificate of analysis – Excipients					
1.7.5	Alcohol-content declaration	✓	✓	✓		
1.7.6	Pork-content declaration	✓	✓	✓		
1.7.7	Certificate of suitability (EDQM) + TSE					
1.7.8	The diluents and coloring agents in the product formula	✓	✓	✓		
1.7.9	Patent Information					
1.7.10	Letter of access or acknowledgment to DMF					✓
1.8	Pricing					
1.8.1	Price list	✓	✓	✓	✓	✓[e]
1.8.2	Other documents related-Pricing list					
1.9	Responses to questions					
	Additional data					

* **1:** Company original paper (original hard copy)
* **2:** Signature of authorized person
* **3:** Company official stamp
* **4:** Authentication

a. Hard-copy (HC)
b. Physical Sample
c. Not required for local manufacturers
d. Only for finished products
e. In the initial submission, a price list without authentication can be accepted, but must be provided if requested later on

Appendix-II [9]

Appointment Letter

Ref. No. Date:

Director of Drug Control
Directorate General of Pharmaceutical Affairs & Drug Control
Ministry of Health

Subj: Submission of registration files

After compliments,
We kindly request from you to grant us an appointment for submitting Registration / Re-registration applications for the following product/s:

Sr.#	Type of Application	Trade name, Strength, Dosage form	Generic name	Pack Size	Manufacturer, COO	MAH, COO	GCC status	Registration

Yours Faithfully,
Local Agent signature & stamp

Appendix III [8]

Points to be included in a cover letter:
Local Agent:
Company Name and Address:
Trade Name:
ATC code:
Dosage Form:
Dosage Strength:
International Non-proprietary Name (INN):
Number of CDs/DVDs provided:
Application Number:
Validation Tool used:
Validation Specification:
MD5 checksum:

Sequence Tracking Table

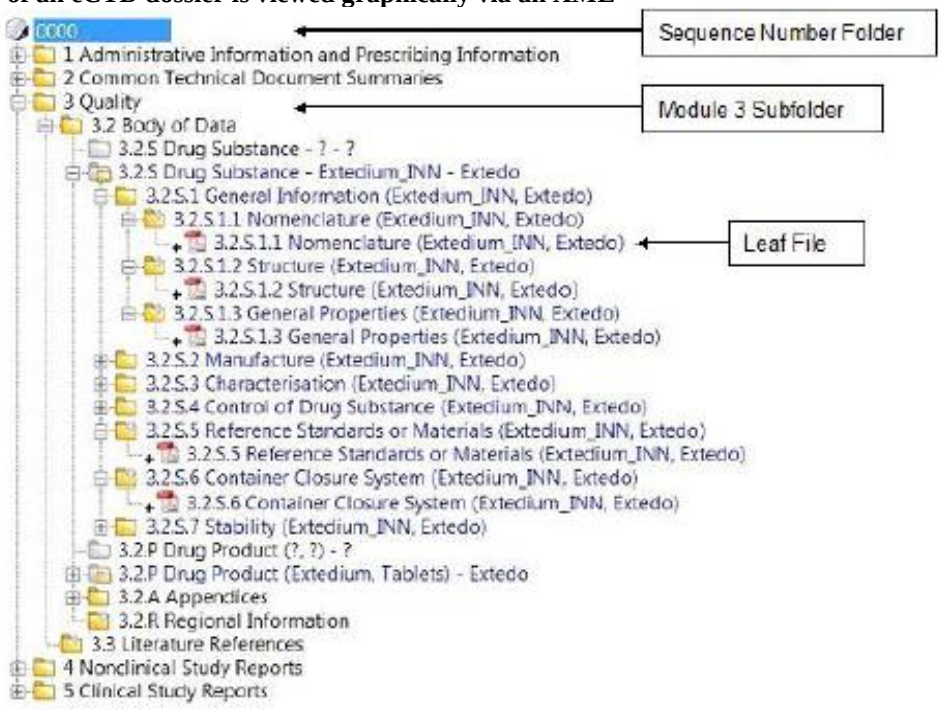
Date of submission	Sequence number	Submission type	Related eCTD sequence	Regulatory activity/ Submission description	Regulatory status (submitted / approved / rejected)

Appendix-IV

References
GCC Reference document
SFDA Reference document
• GCC Module 1 Specifications [10, 11]
Thailand FDA
• TH eCTD Specification Module 1 and Regional Information [12]
Swiss medic
• Guidance for Industry on Providing Regulatory Information in eCTD Format [13]
US FDA

• Guidance for Industry Providing Regulatory Submissions in Electronic Format — Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications [14]
South Africa Medicines Control Council
• South African Specification1 for eCTD2 Regional - Module 1 [15]
EMA
• Harmonized Guidance for eCTD Submissions in the EU [16]
ICH Reference Documents:
• ICH electronic Common Technical Document (eCTD) [17]
• ICH Specification 3.2 (Modules 2 - 5) (Notice to Applicants Vol 2B) [18]
• ICH Q&As [19]
• ICH M4 Granularity [20]

Fig: 1. The structure of an eCTD dossier is viewed graphically via an XML



Documents that must be text searchable

- The PDF should be produced wherever possible from a text source, such as MS Word, but if sourced from a scanned original then they must be OCR'd.
- Key administrative documents in Module 1 including, the cover letter, application form, SPC, labeling and PIL documents
- The main body of text of Risk Management Plans
- Any document in Module 2 of the submission (QOS, Nonclinical Overview and Summaries, Clinical Overview and Summaries).
- The main body of text in any reports, methods, analytical procedures, etc. supplied in Module 3 of the submission
- The main body of text and main tables in modules 4 and 5.

Documents that are recommended to be text searchable

The PDF should be produced wherever possible from a text source, such as MS Word, but if sourced from a scanned original then there is no need for OCR.

- Any original Certificate of Pharmaceutical Product.
- Any original Certificate that confirm that the product is free from BSE/TSE.
- Any original GMP certificate.
- Any original certificate of analysis.
- Any manufacturer's licenses.
- Any certificates of suitability.
- Any Manufacturing Authorization.
- Any literature references sourced from journals, periodicals and books (except when these are used in a bibliographic application so support the main claims of the application).

- Any page with a signature that does not contain other infoinformation key to the understanding of the submission
- Applicants should consider providing signatures on separate pages from key text in reports, overviews, etc.

Module 1: 1.9 Responses to questions

The organization of the submission of electronic information in response to a list of questions should follow the format of the first submission.

Summary & Conclusion:

- Oman is a member of the Gulf Co-operation Council states and International Organization's such as the World Health Organization. Procurement of drugs has been going on through the Saudi based SGH procurement system. The internal policy by the DGPA&DC is that if the SGH prices are higher than those offered on the Oman local tender, then the procurement is done locally.
- To ensure that all legislation and related regulations are up-to-date to ensure that the general public has access to safe, effective, affordable drugs and medicines which meet approved standards and specifications and that these drugs are used rationally.
- To ensure that all drugs and medicines imported or manufactured in the Sultanate of Oman are evaluated and registered by DGPA&DC according to the established procedures with adequate provisions for emergency registration when required with the ultimate goal that the general public obtains the maximum benefit from a particular product, accompanied by the appropriate professional device.
- To ensure that the selection of drugs are those necessary for the health care of the nation and that they are available to communities and individuals at an appropriate level where they can be safely and effectively used.
- To support the procurement system in making available cost-effective drugs of accepted quality at the needed time.
- To establish a well-designed, well-managed, cost-effective drug distribution system, with the aim of maintaining a constant supply of drugs in good condition, minimizing drug losses due to inadequate forecasting of needs, spoilage, expiry or theft.
- To provide Pharmaceutical quality assurance so that the quality of any drug product manufactured in or imported for use in the Country is maintained and complies with established specifications and standards throughout its self-life. To establish criteria for good manufacturing practices for any small-scale manufacturing or repackaging of drugs and to ensure that these products are of a quality appropriate for their intended use.
- To improve the use of drugs by health providers through rational prescribing and dispensing and to promote the appropriate use of drugs by the individual and the Community. To ensure the highest degree of co-operation with other Countries and International Organizations, to improve the supply, distribution and use of drugs to the benefit of the Community.
- To ensure that the traditional medicines of Oman and the imported traditional remedies are safe and effective.
- To accept the all dossier's in electronic format only, which makes the quick review process. The dossier acceptance or rejection will be accurate.

Conflict of Interest

The authors declare that there are no conflicts of interest.

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