الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guidance on Publication of Public Assessment Reports for Medicinal Products for Human Use (Saudi-PAR)

Version 1.0

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Saudi Food & Drug Authority

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Please visit SFDA's website at
https://www.sfda.gov.sa/en/regulations?tags=2

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
Draft	Executive Directorate of Benefit & Risks Evaluation	28 June 2022	-
1.0	Executive Directorate of Benefit & Risks Evaluation	27 October 2022	Final

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List of abbreviations

CCI: Commercial Confidential Information

MAA: Marketing Authorization Applicant

MAH: Marketing Authorization Holder

Saudi-PAR: Saudi Public Assessment Report

SFDA: Food and Drug Authority

WDs: working days

Introduction

As part of the commitment to transparency, the Saudi Food and Drug Authority (SFDA) publishes information relating to the evaluation of applications via public assessment reports, hereinafter 'Saudi Public Assessment Report (Saudi-PAR)'.

Purpose

This guidance for the Marketing Authorization Applicants (MAA) is intended to provide the rationale, approach, and procedure for publishing the Saudi Public Assessment Report (Saudi-PAR) with clarification of SFDA's policies for developing Saudi-PAR from the Original Assessment Reports, which were generated during the quality, safety and efficacy evaluation for the medicinal products submitted to SFDA. This guidance contains the clarification of the commercially confidential data and personal data that will be deleted from the report in accordance with the Saudi system and relevant international agreements.

Scope

All human medicine applications after the SFDA decision on authorization.

Transparency

1.1 SFDA publishes Saudi-PAR for medicinal products for human use within 90-120 working days of authorization on the website; the public assessment report shall include a summary of information that has a certain value for healthcare providers, pharmaceutical manufacturers and the public.

1.2 Saudi-PAR may include information about any conditional approval applications with details of their respective due dates for submission of post-approval obligations.

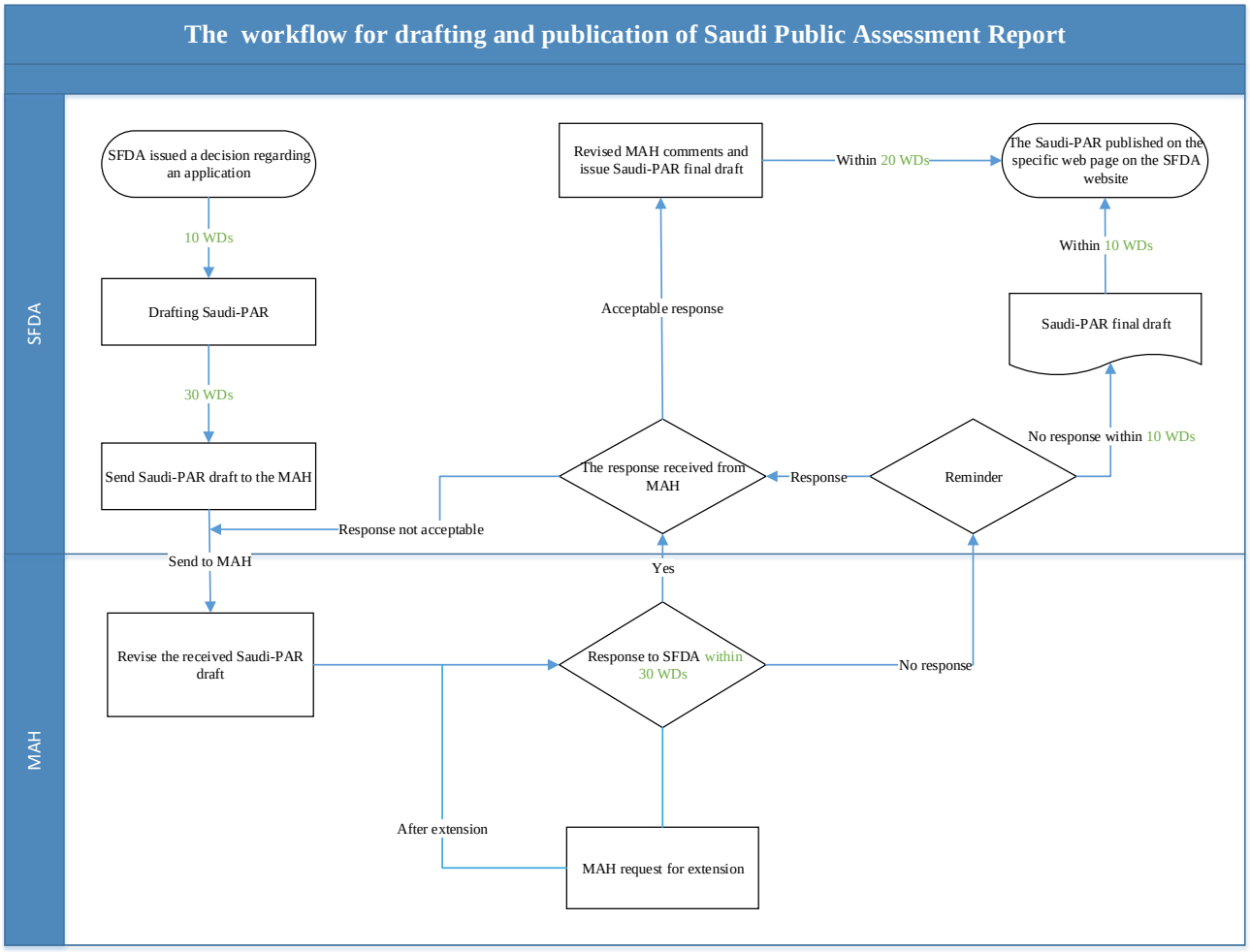
Responsibility

The Drug Sector is responsible for preparing the Saudi-PAR after removing the Commercial Confidential Information (CCI) and personal data from all reports prior to publication, i.e., information that comes into the public domain after the publication of Saudi-PAR is not considered commercially confidential upon the confidential intellectual property and trade secrets.

Structure of report

The reports summarize assessments of the data provided on the quality, safety, and efficacy of applications. In addition, each report outlines the outcomes of the evaluation process and provides scientific reasoning on decisions made to approve an application for marketing authorization. The published report is composed of administrative information, complete quality data, nonclinical and clinical data based on applicants' own tests and studies and/or bibliographic literature substituting/supporting certain test(s) or studies unless those data are protected with a copyright.

Publication process flow chart



Commercially Confidential Information Background:

For the purposes of Saudi-PAR preparation, the SFDA adopting the information in accordance with the national principles and agreements stated hereafter:

- follows the Regulations For the Protection Of Confidential Commercial Information *(issued by the decision of the Minister of commerce and industry no.(3218) dated 25/03/1426h (May 4, 2005))*
- TRIPS Agreement
- Kingdom of Saudi Arabia E-Government Implementation Rules, Council of Ministers Resolution No. 40 Dated 27/2/1427H (27/3/2006) statement no.8, which clarifies the confidential data protected as per Confidential intellectual property, 'know-how' and trade secrets (for example formulas, programs, process or information contained or embodied in a product, unpublished aspects of trademarks, patents and similar); Commercial confidences (for example, details of commercial arrangements, development plans of a company)

For more clarification on the commercial confidentially data, please go to Appendix 1.

References

- SA008: Regulations for the Protection of Confidential Commercial Information. May 4, 2005 https://wipolex.wipo.int/ar/text/129523
- World Trade Organization: the TRIPS Agreement https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm#standards
- 2001L0083 EN 16.11.2012, 011.001 chapter 2 Article 106.
- DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use, Article 21(3, 4).

Appendix1

The confidentiality principles contained below apply to the new pharmaceutical and biological products.

Quality information

- **Drug substance:**

CTD section	Confedintial	Public data
3.2.S.1 Structure	detailed information concerning the particular studies or specific structure identity	General information on structure of the active substance
3.2.S.2 Manufucture	Name of the manufacturer of the drug substance ,detailed information on manufucturing process, process validation parameters and all information about new development	General overview of the process with statements confirming that the manufacturing process and control had been validated.
3.2.S.3 Characterization	details of characterization methods	General information on the characterization with a statement confirming that the drug substance is appropriately characterized
3.2.S.4 Control of drug substance	detailed information on the in-house test methods used and specification parameters with its established acceptance criteria	A general description of the types of test methods used and the appropriateness of the specifications
3.2.S.5 Reference materials	All data related to in-house references	compandial references or reasons for acceptance if in-house
3.2S.6 Container closure system	Dimensions of the container, suppliers name, and detailed information related to the container	General information about the composition of the container
3.2.S.7 Stability studies	All data related to stability studies	General statement support approval

- **Finished product:**

CTD section	Confedintial	Public data
3.2.P.1 Composition	Quantitative composition unless it is necessary for public health	Description of the product with qualitative composition
3.2.P.2 Pharmaceutical development	All data	No data
3.2.P.3 Manufacture	Details of the manufacturing process and process validation	Statement confirming that the manufacturing process is controlled and validated
3.2.P.5 Control of drug product	Detailed information on the test methods used and specification parameters with its established acceptance criteria	A general description of the types of test methods used and the appropriateness of the specifications
3.2.P.6 Reference materials	All data related to this section	No data
3.2.P.7 Container closure system	Dimensions of the container, suppliers name, and detailed information related to the container	General information about the container closure system and suitability for use
3.2.P.8 Stability studies	Details of stability studies, batches, and if any deviation events and corrective action	Information on the outcome of stability studies (real-time condition)

Nonclinical and clinical information

Information encompassing nonclinical and clinical development and its subsequent assessment by SFDA is generally not commercially confidential that includes:

- Data generated by the sponsor using another sponsor's product, for example, comparative studies against the reference medicinal product. However, the commercial confidentiality of such data shall be assessed in accordance with the related Saudi principles set out in this document.
- Published references submitted in support of an application to register a prescription medicine.
- Information related to environmental risk assessments and risk management plans.

Examples of nonclinical and clinical information that is considered a CCI include:

- Specific details on a method used in a study, which, upon justification from the sponsor, could be regarded as a trade secret.
- Development plan from the company, for example, for a different indication, when it is neither requested by SFDA nor related to the safety of the product, would also be CCI.

Pharmacovigilance information

Generally, a quantitative description of the sponsor's proposed pharmacovigilance activities is not considered CCI.

However, detailed descriptions of the pharmacovigilance system can sometimes be considered confidential if they contain individual patient data or business strategies such as planned studies or commercial agreements involving other companies or organizations.

N.B:

The published pharmacovigilance information will be assessed to meet the "Kingdom of Saudi Arabia E-Government Implementation Rules, Council of Ministers Resolution No. 40 Dated 27/2/1427H (27/3/2006) statement no.8, which clarifies the confidential data protected as per confidential intellectual property, 'know-how' and trade secrets"