الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Approach of Dealing with Patents When Register Generic Drugs in SFDA

In cooperation with the Saudi Authority for Intellectual Property (SAIP)

Version No. 2

Date of Issue	28 November 2022
Date of Implementation	1 January 2023

Only the Arabic version of this Regulation is authentic and it is applicable when there are differences with this translation

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Saudi Food and Drug Authority

Drugs Sector

Please visit SFDA's website at for the latest update

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	Publisher	Date	Notes
Draft 1	Executive Directorate of Regulatory Affairs	21 September 2020	-
Draft 2	Executive Directorate of Regulatory Affairs	1 June 2021	-
Draft 3	Executive Directorate of Regulatory Affairs	30 May 2022	-
Version no. 1	Executive Directorate of Regulatory Affairs	28 November 2022	Final version
Version no. 2	Executive Directorate of Regulatory Affairs	8 October 2025	Final version

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Objectives

1. Enhance transparency of the Saudi Food and Drug Authority (SFDA) procedures.
2. Promote trust in the procedures for dealing with patents related to pharmaceutical products.
3. Facilitate the registration of generic products.

Stages of the Approach process

First Stage: Regarding Innovator Companies

1. Innovator companies must include a copy of the patent document for their innovative product, issued by the Saudi Authority for Intellectual Property (SAIP), within the registration file submitted to SFDA.
2. If the patent document is not issued at the time of submitting the registration file, the company is obligated to provide upon its issuance, and the company will bear the consequences of any delay in submission.
3. For innovative products protected by a patent issued by SAIP or by the Gulf Cooperation Council Patent Office and already registered at SFDA, the company must provide the patent document. Submitting the patent document does not imply that SFDA bears any responsibility for protecting it.
4. If the innovator company claims that the generic product infringe the patent of its product, the company may submit its claims to the Commercial Court
5. SFDA shall comply with any final and enforceable judgment issued by the competent judicial authorities in favor of the innovator company
6. SFDA shall provide the generic company with the patent number(s) of the innovated product upon the generic company's request, provided that the request is accompanied by a supporting letter from an intellectual property agent.

Second Stage: Regarding generic companies that plan to register a generic product in SFDA

1. The generic company applies for registration of its product in SFDA, and if there is a patent in the innovated product file in SFDA, then SFDA will request a Freedom to Operate (FTO) letter from the generic company.
2. Generic companies must obtain the FTO letter from an intellectual property agent licensed by SAIP who is authorized to provide such assessments.
3. The FTO letter shall include the following:

   "I (name of an intellectual property agent licensed by SAIP) hereby certify that the generic product (name of the generic product, strength and dosage form does not infringe any patent of an innovator product registered in the Kingdom.
4. The FTO letter and a copy of the intellectual property agent's license, issued by SAIP, must be submitted to SFDA within 60 working days from the date of the request.
5. The generic company shall also submit a formal declaration, as specified in Appendix No. 1, that its generic product does not infringe any intellectual property rights protected within the Kingdom of Saudi Arabia.
6. Based on the FTO letter and the submitted declaration, SFDA shall proceed with the registration of the generic product. However, the registration of the generic product does not constitute the SFDA's approval of the contents of the FTO letter issued by the Intellectual Property Agent, nor does the SFDA bear any responsibility based on its contents.
7. The generic company has the right to apply for the registration of a generic product of an innovative product without submitting FTO Letter 24 months prior to the patent expiry. However, the generic product will be registered after the patent has expired.

Appendix No. 1

إقرار

إشارة إلى طلبنا المقدم للهيئة العامة للغذاء والدواء لتسجيل المستحضر –*الاسم العلمي والتركيز والشكل الصيدلاني* – برقم (.....) وتاريخ / / .

تُقر الشركة – اسم الشركة المسوقة في حال كانت محلية واسم المكتب العلمي أو الوكيل في حال كانت الشركة أجنبية –بأن المستحضر – الاسم العلمي والتركيز والشكل الصيدلاني – لا ينتهك أي حق من حقوق الملكية الفكرية المتمتعة بالحماية في المملكة العربية السعودية، كما تتعهد الشركة بأنه في حال كان المستحضر -كلياً أو جزئياً- متعدي على أي من تلك الحقوق فإن الشركة مسؤولة مسؤولية تامة عن ذلك التعدي وعما ينشأ عنه من دعاوى وتعويضات.

المقر بما فيه:

الشركة: اسم الشركة

العنوان:

ممثل الشركة: بموجب وكالة معتمدة أو تفويض مصدق من جهة تقبل بها الهيئة العامة للغذاء والدواء (اسم الممثل + بياناته)