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. 1

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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 & 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 History

Version	Publisher	Date	Notes
Draft 1	Executive Directorate of Regulatory Affairs	21 September 2020	-
Draft 2	Executive Directorate of Regulatory Affairs	1 June 2021	-
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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.

First: 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 shall assign an intellectual property agent licensed by the Saudi Authority for Intellectual Property (SAIP) to conduct such studies.
3. SFDA shall be provided with a FTO letter within sixty (60) working days, along with a copy of SAIP's license for the intellectual property agent.
4. In addition, the generic company shall submit a declaration that its generic product does not infringe a patent of any product as described in Appendix No. 1.
5. The FTO letter shall include the following:

   "I (the name of an intellectual property agent licensed by SAIP) hereby certify that the generic product (the name of the generic product) does not infringe any patent of an innovator product registered in the Kingdom."
6. Based on the FTO letter, SFDA shall register the generic product.
7. SFDA will provide the generic company the patent number(s) of innovative product upon request. The Generic company should submit a letter from the intellectual property agent to support the request.
8. The generic company has the right to apply for the registration of a generic product of an innovative product without submitting FTO Letter six months before the expiry of the patent, taking into consideration that the marketing of the generic product will not be allowed before patent expiration[1].

[1] This term exclude the SFDA's memo number 7448

Second: Regarding Innovator Companies

1. Innovator companies must submit a copy of the patent document issued by SAIP in the registration file for product submitted to SFDA.
2. If the patent document of the innovated product has not been issued at the time of submitting the registration file, the innovator company shall submit such document to SFDA within (30) days from its date of issue.
3. With regard to innovated products protected by a patent issued by SAIP or the GCC Patent Office and currently registered with SFDA, the company must provide SFDA with the patent document within (30) days from the date of publishing of this document.
4. If the innovator company claims that the generic product infringe the patent of its product, the company may process their claims in the Commercial Court
5. In case a final judgment is issued by the court in favor of the innovator company, SFDA shall comply with that judgment.

Appendix No. 1

تعهد

إشارة إلى طلبنا المقدم للهيئة العامة للغذاء والدواء لتسجيل المستحضر –*الاسم التجاري للمستحضر الصيدلاني الجنيس* – برقم (.....) وتاريخ / / .

تُقر الشركة –*اسم الشركة صاحبة المستحضر الصيدلاني الجنيس* –بأن المستحضر –*الاسم التجاري للمستحضر الجنيس* – 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- يعد كتعدي على أي من تلك الحقوق فإن الشركة مسؤولة مسؤولية تامة عن ذلك التعدي وعما ينشأ عنه من دعاوى وتعويضات.

المقر بما فيه:

اسم الشركة:

العنوان:

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

Generic Product Registration Path