

**نموذج طلب إلغاء تسجيل مستحضر**

**Permanent Cessation of Marketing of Medicinal Product form**

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| 7 أغسطس 2022 | تاريخ الاصدار |
| 1 | رقم النسخة |

*للاستفسارات*

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| **Product Information** | | | | | | | | | | | | | |
| **Trade Name** | | | | |  | | | | **Reg. no.** | |  | | |
| **Active Ingredient(s)** | | | | |  | | | | | | | | |
| **Route(s) of Administration** | | | | |  | | | | **Dosage Form** | |  | | |
| **Package Size and Type** | | | | |  | | | | **Strength/Unit** | |  | | |
| **Marketing Authorization Holder (MAH)** | | | | |  | | | | **Price** | |  | | |
| **Name and Site of Manufacturer** | | | | |  | | | | **Agent** | |  | | |
| **Reason(s) for cessation** | | | | | | | | | | | | | |
| **□ Production line shutdown** | | | | | | | | **□ Product have not been marketed since first registration** | | | | | |
| **□ Low price**  **Have you submitted an appeal?**  **☐ No ☐ Yes no. of appeals:** | | | | | | | | **□ Product have not been marketed since ………………** | | | | | |
| **□ Increased production expenses** | | | | | | | | **□ Problems in manufacturing** | | | | | |
| **□ MAH changed (resourced)** | | | | | | | | **□ Reported adverse events** | | | | | |
| **□ Low demand of the product** | | | | | | | | **□ Availability of another pack size of the product, specify** | | | | | |
| **□ Manufacturer changed, specify with address** | | | | | | | | **□ Availability of another concentration of the product, specify** | | | | | |
| **□ Contract termination with the licensor company** | | | | | | | | **□ Availability of another dosage form of the product, specify** | | | | | |
| **□ MAH changed, specify with address** | | | | | | | | **□ Availability of other alternatives marketed by other MAH, specify** | | | | | |
| **Other:** | | | | | | | | | | | | | |
| **Did you attach an official letter from MAH with all required information (The letter should contain a justification for cessation request)**  **If not, a justification for not attaching should be provided:** | | | | | | | | | | | | | **Yes** |
| **No** |
|  | | | | | | | | | | | | | |
| **Consumption (for the last four years)** | | | | | | | | | | | | | |
| **Year** | | | **20..** | | | **20..** | | | | **20..** | | **20..** | |
| **Amount** | | |  | | |  | | | |  | |  | |
| **List of countries that the product is still marketed in** | | | | | | | | | | | | | |
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| **List of countries that ceased the product with dates and reasons for cessation** | | | | | | | | | | | | | |
| **Country** | | | | **Date** | | | **Reasons** | | | | | | |
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**Declaration:**

* I hereby certify that the submitted information is true and accurate.

Title:

Name:

Signature:

Date:

Company stamp: