

**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: