**نموذج طلب إلغاء تسجيل مستحضر**

**Permanent Cessation of Marketing of a Medicinal Product**

All fields are mandatory

|  |  |
| --- | --- |
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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 | | | | | | | | □ 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 | | | | | |
| □ 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 |
|  | | | | | | | | | | | | | |
| **Amount of product imported to Saudi Arabia during 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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