

NOTICE OF INTENTION TO RENAME A PHARMACEUTICAL PRODUCT CURRENTLY APPROVED UNDER THE GMS & COMMUNITY DRUG SCHEMES



This form has been prepared to enable manufacturers, importers or their agents to notify the HSE Corporate Pharmaceutical Unit of a Name Change of an approved Pharmaceutical Product.

1.	Name, strength, form and pack size of a pharmaceutical product currently:	
2.	GMS/High Tech code:	
3.	Proposed new name: <i>(Give full name, strength and pack size)</i>	
5.	Marketing Authorisation number:	
7.	Proposed date for name change:	
8.	Proposals for informing all stakeholders, i.e. the HPRA, Healthcare Professionals and Hospital Pharmacies, if relevant:	
9.	Give reasons for the proposed name change of the product(s) with appropriate substantiating information:	
10.	Provide details of the current status and availability of the product in the various Member States of the European Union:	
11.	A copy of any letter(s) sent or proposed to be sent to Health Care Professionals in relation to the name change of the product:	
12.	A copy of the Summary of Products Characteristics of the old and proposed new name of the product:	
13.	Company Name:	
14.	Company Address:	
15.	Contact Name:	
16.	Telephone No:	
17.	Email Address:	

Please ensure that the form is signed

Signed: _____ Date: _____
Managing Director/General Manager

The completed form should be returned to:
Corporate Pharmaceutical Unit
HSE Primary Care Reimbursement Service
Exit 5 M50
North Road
Dublin 11
D11 XKF3

Tel No: 353-1-8915725
Fax No: 353-1-8915757
E-mail: CPU@hse.ie

Copies of this form are available on www.hse.ie/eng/about/Who/cpu

CPU Office Use Only - Date Stamp

The following documents must be enclosed with this form:

- | | |
|--|--------------------------|
| 1) Company Cover Letter | <input type="checkbox"/> |
| 2) Patient Information Leaflet | <input type="checkbox"/> |
| 3) Product Artwork | <input type="checkbox"/> |
| 4) Licence (EU and/or HPRA) | <input type="checkbox"/> |
| 5) Summary of Products Characteristics | <input type="checkbox"/> |
| 6) Letter to Healthcare Professionals | <input type="checkbox"/> |
| 7) Application Fee - €100 | <input type="checkbox"/> |