

# 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:	
5.	Marketing authorisation number:	
7.	Proposed date for name change:	
8.	Proposals for informing the National Medicines Information Centre:	
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.	Fee for Name change to an existing reimbursed product:	
14.	Company Name:	
15.	Company Address:	
16.	Contact Name:	
17.	Telephone No:	
18.	Email Address:	

Signed: \_\_\_\_\_  
Managing Director/General Manager

Date: \_\_\_\_\_

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](mailto:CPU@hse.ie)

Copies of this form are available on [www.hse.ie/eng/about/Who/cpup](http://www.hse.ie/eng/about/Who/cpup)

**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) Name change fee                     | <input type="checkbox"/> |