

NOTICE OF INTENTION TO WITHDRAW A MEDICINAL PRODUCT FROM THE MARKET IN IRELAND



This form has been prepared to enable manufacturers, importers or their agents to notify the HSE Corporate Pharmaceutical Unit of the withdrawal of a pharmaceutical product and to fulfil their obligations under the 2021 Agreements between the HSE and the IPHA/APMI.

At least 3 months is required where there is a reimbursed therapeutic alternative for the approved indication available on the market.

At least 12 months is required where there is no reimbursable therapeutic alternative for the approved indication available on the market.

This is in the interest of maintaining an uninterrupted supply of medicines to patients

1.	Name, Strength, Form and Pack Size of medicinal product being discontinued:	
2.	GMS/High Tech Code:	
3.	Indicate if product is confined to Hospital usage only:	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
4.	Marketing Authorisation number:	
5.	ATC Code:	
6.	Expiry date of last manufactured batch:	
7.	Proposed date for product discontinuation:	
8.	Date (month and year) when it is estimated that stocks of product will be depleted:	
9.	Where the product discontinuation is of a particular pack size, strength or dosage form within a range of products provide details of those products that will continue to remain available:	
10.	Proposals for informing all stakeholders, i.e. the HPRA, Healthcare Professionals and Hospitals if relevant:	
11.	Give reasons for the proposed product discontinuation of the product(s) with appropriate substantiating information:	
12.	If there a reimbursed therapeutic alternative to the product being discontinued please provide details:	
13.	Provide an evaluation of likely impact that the proposed discontinuation will have on the quality of patient care, including an estimate of the number of patients it will affect:	

14.	Provide details of the current status and availability of the product in the various Member States of the European Union:	
15.	A copy of any letter(s) sent or proposed to be sent to Health Care Professionals in relation to the discontinuation of the product.	
16.	Enclose a copy of the most recent Summary of Products Characteristics for the product or a direct link to same:	
17.	Company Name:	
18.	Company Address:	
19.	Contact Name:	
20.	Telephone Number:	
22.	Email Address:	

[Please ensure that the form is signed](#)

<p>Signed: _____ Date: _____ Managing Director/General Manager</p> <p>The completed form should be returned to: Corporate Pharmaceutical Unit HSE Primary Care Reimbursement Service Exit 5 M50 North Road Finglas Dublin 11</p> <p>Tel No: 353/1/8915725 E-mail: CPU@hse.ie</p>	
--	--

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

CPU Office Use Only - Date Stamp