## 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 2016 Agreements between the HSE and the IPHA/APMI.

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

At least <u>12 months</u> 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	No	
4.	Marketing Authorisation number:			
5.	Expiry date of last manufactured batch:			
6.	Proposed date for product discontinuation:			
7.	Date (month and year) when it is estimated that stocks of product will be depleted:			
8.	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:			
9.	Proposals for informing all stakeholders, i.e. the HPRA, Healthcare Professionals and Hospitals if relevant:			
10.	Give reasons for the proposed product discontinuation of the product(s) with appropriate substantiating information:			
11.	If there a reimbursed therapeutic alternative to the product being discontinued please provide details:			
12.	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:			

13.	Provide details of the current status and availability of the product in the various Member States of the European Union:	
14.	A copy of any letter(s) sent or proposed to be sent to Health Care Professionals in relation to the discontinuation of the product.	
15.	Enclose a copy of the most recent Summary of Products Characteristics for the product or a direct link to same:	
16.	Company Name:	
17.	Company Address:	
18.	Contact Name:	
19.	Telephone Number:	
20.	Email Address:	
Please	ensure that the form is signed	
The concept of the co	d: Managing Director/General Manager  ompleted form should be returned to: rate Pharmaceutical Unit Primary Care Reimbursement Service M50 Road s 11  o: 353/1/8915725 o: 353/1/8915757 l: CPU@hse.ie	Date:
The concept of the co	d: Managing Director/General Manager  ompleted form should be returned to: trate Pharmaceutical Unit Primary Care Reimbursement Service M50 Road s 111  o: 353/1/8915725 o: 353/1/8915757 I: CPU@hse.ie  Copies of this form are avail	Date:  able on www.hse.ie/eng/about/Who/cpu  Use Only - Date Stamp