



## Notification of medicinal product shortage from marketing authorisation holder

This form is for use by marketing authorisation holders to notify the HPRA and the HSE of a potential or actual medicine shortage (referred to as a 'shortage').

**Companies should notify potential or actual shortages as soon as possible in advance of them occurring, and depending on the impact, at least two months in advance. If there is any information that the company is unable to provide at the time of the initial notification, please state this clearly in the form. For example, if the company is still investigating the reason for the shortage, please specify this under the 'reasons for shortage' section, in the free-text space provided.**

Please return the completed form to both the HSE Corporate Pharmaceutical Unit at [CPU@hse.ie](mailto:CPU@hse.ie) and to [shortages@hpra.ie](mailto:shortages@hpra.ie).

### 1 PRODUCT DETAILS

(Invented) name:

Authorisation or certificate number(s):

Active substance(s):

Pharmaceutical form(s) and strength(s):

Name and address of authorisation holder:

HSE reimbursement code (where applicable):

### 2 DETAILS OF THE SHORTAGE

Has the shortage been notified within the requested timeframe?

*(Notifications should be submitted as soon as possible, but at least two months in advance of a potential medium or high impact shortage, and at least 30 days in advance of a confirmed low impact shortage.)*

Yes  No

If not, please provide justification for the late notification and what steps have been taken to ensure it is not repeated below:

#### IMPACT ASSESSMENT

What is the market share (%) in Ireland for this active/combination of actives in this strength and dosage form?

What is the outcome of the MAH's assessment of the impact on patients?

Low impact       Medium impact       High impact

Justification for the rating of the impact on patients:

*(Please give consideration to the product's market share for this active/combination of actives in this strength and dosage form, and the possible impact of a shortage of a product with a large market share on the subsequent availability of suitable alternatives.)*

Was the HPRA impact assessment method used?

Yes       No

If not, please describe how the impact assessment was determined:

### **REASON FOR SHORTAGE**

Please select the most applicable root cause of the shortage (see Annex A – Examples of Shortage Reasons for examples of each category).

Manufacturing delay       Unexpected increase in demand  
 API shortage/unavailability       Quality issue  
 Regulatory issue       Shipping delay/distribution issue

Please provide further detail on the reason for the shortage in the free-text space below:  
*(Please provide as much information as possible; this helps us understand the impact on possible alternative products. In particular, please state the specific reason for the manufacturing delay or distribution issue.)*

### **COUNTRIES IMPACTED**

What countries are impacted?

*(Please note that this should be completed relating to whether other markets are impacted, not just that the company is reporting for Ireland.)*

Global       Multiple EEA countries       Ireland and UK       Ireland only

### **SHORTAGE DURATION**

What is the expected start date of the shortage?

*(If the product is already short, please specify the date the shortage began.)*

What is the remaining inventory (in terms of weeks) within the entire supply chain?

*(Please also include details of inventory at primary and secondary wholesale level.)*

What is the realistic expected return date *(including the time required by wholesale distributor to complete quality checks)*?

Who is the primary wholesale distributor in Ireland?

### 3 COMPANY RESPONSE TO THE SHORTAGE

Please describe the proposed response to mitigate the impact of the shortage on patients or resolve the shortage (*taking into account the possibility of a batch specific request, use of different strengths or exempt medicinal products as possible mitigation actions*):

What are the alternative medicinal products? (*This could include alternative products, which are placed on the market in Ireland, indicated for the condition from different MAHs.*)

Is the company planning communication with healthcare professionals?  
(*If so, please include the draft communication.*)

Yes       No

Please include any further relevant information if necessary. If the product is specialist use or has limited customers, please identify the customers.

### 4 DETAILS OF PERSON NOTIFYING

Name:

Company:

Email:

Telephone:

Date:

## **ANNEX A      EXAMPLES OF REASONS FOR SHORTAGES**

### **API shortage/unavailability**

- The active ingredient raw material is unavailable.
- Contract manufacturing organisation has ceased production, and the company is seeking a new API source.

### **Manufacturing delay**

- Equipment breakdown
- Site transfers
- Capacity constraints
- Natural disasters
- Cyber attacks

### **Quality issue**

- Recalls
- Issue with product QC testing/sterility

### **Regulatory issue**

- Delay in submission of a variation
- Delay in regulatory approval
- Delay in CD licence application

### **Shipping delay/distribution issue**

- Local delay with order
- Ordering system error
- Industrial action
- Shipment to/from wholesaler in Ireland is delayed

### **Unexpected increased demand**

- The company cannot accommodate an unexpected increased demand (e.g. due to a shortage, or recall of an alternative product, or other unexpected demand such as health policy decision or new infection).