**Revision of the EU General Pharmaceutical Legislation**

**Policy Area 1: Security of Supply / Shortages**

**November 2023**

Stakeholder Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Stakeholder Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**RE: Submission to the Department of Health and the Pharmaceutical Strategy Working Group (PSWG) on the Revision of the EU General Pharmaceutical Legislation - Policy Area 1 - Security of Supply / Shortages**

Dear Stakeholder,

The Department of Health (‘the Department’) and the Pharmaceutical Strategy Working Group (‘PSWG’) are seeking submissions to assist in informing Ireland’s position on the EU Commission’s revision of the general pharmaceutical legislation.

The PSWG was established by the Minister for Health in May 2022 on foot of the EU Commission’s launch in November 2020 of a Pharmaceutical Strategy for Europe. The Group is tasked to inform the national position of the proposal.

Specifically, at this stage, we are seeking submissions in relation to the **proposed provisions regarding security of supply / shortages** and in response to this communication, are **only** seeking submissions on this policy topic at this time. Information provided by way of submissions in response to this communication, that is not related to this topic, will not be considered.

Your organisation has been identified as a relevant stakeholder in relation to the above.

The Department and PSWG are seeking a targeted submission which adheres to a specific format on this policy topic. Please see below guidelines.

Submissions should contain information which you deem relevant to the provisions / articles identified in both the proposed Regulation and proposed Directive on the policy topic of **security of supply / shortages only**.

The Department and PSWG would ask you to consider the following questions when providing your feedback and submission on this policy topic:

1. **Do you/your organisation agree with the principles of these provisions? Please refer to specific provisions and proposed text as relevant.**
2. **Are there any challenges that you/your organisation anticipate/s with these provisions and/or the actors involved?**
3. **Is there anything that you/your organisation believes is omitted from these provisions? Please refer to specific provisions and proposed text as relevant.**
4. **Are there any policy gaps in these provisions from you/your organisation’s perspective?**

Submissions should be emailed to [EUpharmastrategy@health.gov.ie](mailto:EUpharmastrategy@health.gov.ie). The period for submissions to be received on this topic will close at end of day on **8th December 2023**.

Yours sincerely,

PSWG Secretariat.

**How to send your submission:**

* Please email an electronic document (searchable PDF or equivalent) for the attention of the Department of Health and PSWG to the above email addresses.
* Please do not send hard copies of your submission.

**What should I include with and in my public consultation submission?**

* Your submission should comprise the submission document and a separate covering letter.
* Keeping personal information such as home/business address, email address or telephone number in a separate covering letter facilitates the publishing of a submission document, should the Department decide to do so at some point, without revealing personal details.
* Please advise in your covering letter if you would prefer that the Department did not publish your name so that the Department can take this into account when deciding on how your submission should be treated, including if your submission should be published. Please note that the decision to publish your submission with or without your name is a decision of the Department and while the Department may take your preference into account, there is no obligation to do so.

**In the covering letter, please include:**

* Your organisation’s name, email address and contact telephone number.
* A brief outline of why you are making the submission.
* If you prefer your name and any other personal details not to be published, please state this clearly in your covering letter. However, as already indicated, your full name may be published with any submission you make, if decided by the Department.

**In the submission document, please include:**

* A brief introduction, for example, explaining your company / membership group / area of expertise (if applicable).
* The main points you wish to make on this policy topic, answers to the proposed questions above, positions, recommendations, objections and proposed amendments to the text as drafted, for consideration by the Department and PSWG. We would ask that in providing this information, you are as succinct as possible.
* Any facts or information (evidence) that you have to offer from which the Department might be able to draw conclusions, or which could be put to other parties for a response.
* Links to any publications referred to; there is no need to send as attachments also.
* Any proposed recommendations; be as specific as possible and summarise your observations at the end of the document.

**Tips on writing your submission:**

* Keep your submission concise and to the point. Please do not include any unnecessary or superfluous material that does not relate directly to the topic - security of supply / shortages.
* Avoid including any details in your submission that you would have reservations about, if published.
* Avoid arriving at conclusions or making recommendations without indicating the supporting facts or evidence.
* If you refer to other publications, include links to the publications. There is no need to send them as attachments.
* Please remember to number your pages and it is helpful to number paragraphs also.
* Ensure your submission is in MS Word format or searchable pdf format.
* Please spell out any abbreviations that you use.

**Important information:**

* The Department cannot consider submissions which deal with matters outside its remit.
* The Department cannot consider submissions which deal with cases relating to individuals.
* You should not criticise or make charges against any person(s) or entity, by name or in such a way as to make him, her or it identifiable or otherwise include anything that might be regarded as damaging to the person’s or entity’s good name.
* You should be careful not to comment on matters currently before a court of law, or on matters in respect of which court proceedings are imminent.
* Anonymous submissions should not be submitted and are likely to be rejected.
* The Department and PSWG is not a forum for making personal representations or promoting a product, service, or business, and you should not attempt to do so. Making a submission is a public process. You should be aware that any submissions made in response to this process, including your name may be published, in whole or in part, if the Department decides to do so.
* Note also that the Department reserves the right not to accept your submission, and it is not obliged to publish any part of it.

**How your submission will be dealt with:**

* You should expect to receive acknowledgement of receipt of your submissions within 2 working days.
* The Department will circulate your submission to members of the PSWG.
* Your submission will form part of the considerations of the legislative proposals on the topic of security of supply/shortages by the Department and PSWG.
* The Department and/or the PSWG may decide that further action is to be taken in relation to the submission. This may include writing to you for further information, forwarding your submission for a response elsewhere or inviting you to make an oral presentation before it.
* In the normal course of events, you will be kept updated of any such decisions.