

SPEAKING THE SAME LANGUAGE

WP5 | Identifying the root causes of observed
shortages of medicines

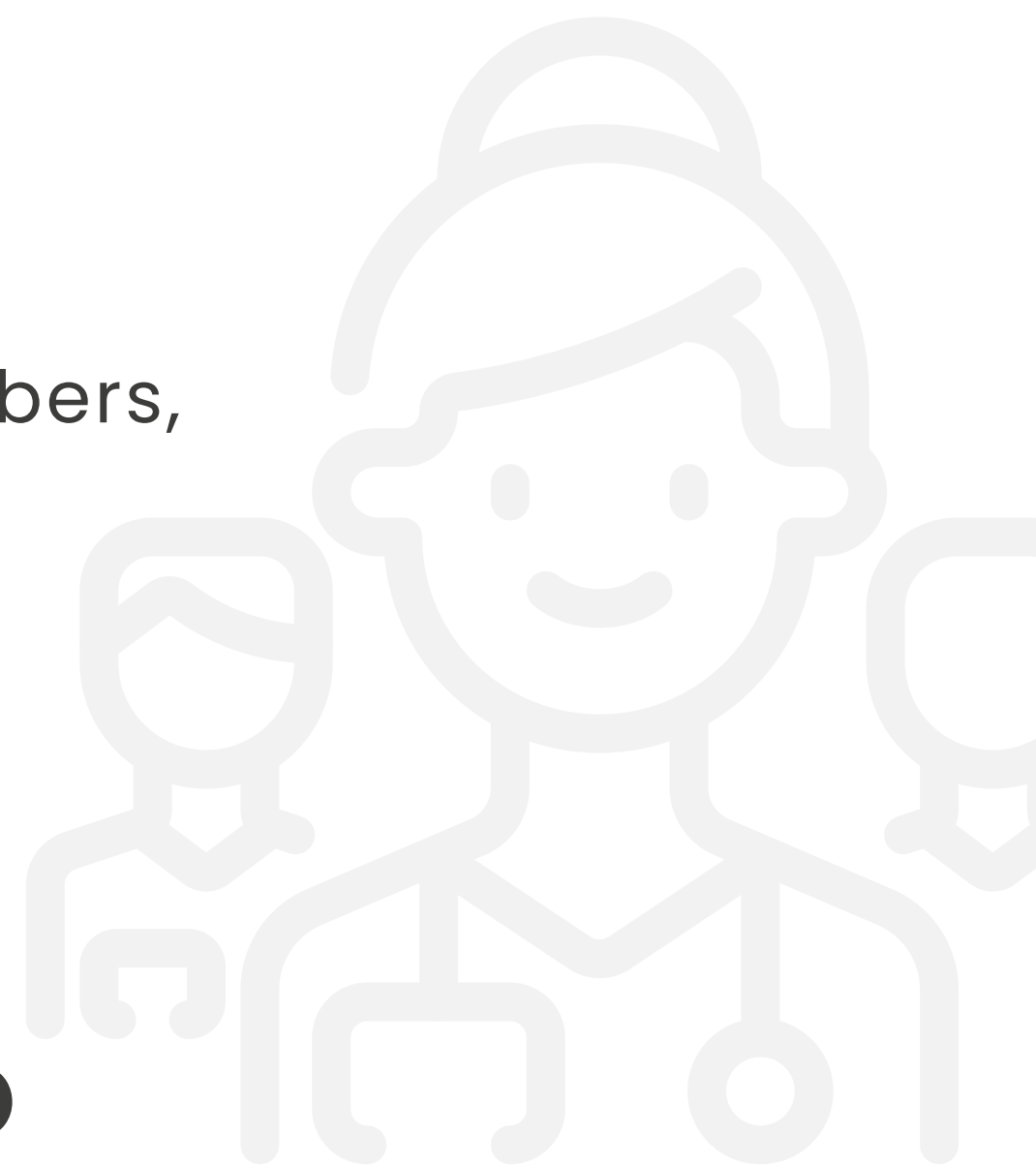
Stakeholders Involved

The terms and definitions presented here are the result of the collaborative work carried out under Work Package 5.

They do not represent official definitions but rather proposed and agreed-upon interpretations that were considered for the work conducted within the project. These proposals aim to support future harmonisation efforts across the EU.

HEALTHCARE PROFESSIONAL

Is a stakeholder that includes prescribers, pharmacists and nurses.



MANUFACTURER

Is a stakeholder that has been authorised to produce medicinal products. The manufacturer may or may not also be the MAH.

REFERENCE

HPRA. (2021) Medicinal product shortages. A framework for a multi-stakeholder approach to handling shortages of human medicinal products. Available at:
<https://www.hpra.ie/docs/default-source/default-document-library/medicine-shortages-framework.pdf?sfvrsn=0>

MARKETING AUTHORISATION HOLDER (MAH)

The MAH is the stakeholder in whose name the marketing authorisation for a medicinal product has been granted. The MAH is responsible for all aspects of the medicinal product, including quality and compliance with the conditions of the marketing authorisation.

REFERENCE

HPRA. (2021) Medicinal product shortages. A framework for a multi-stakeholder approach to handling shortages of human medicinal products. Available at:
<https://www.hpra.ie/docs/default-source/default-document-library/medicine-shortages-framework.pdf?sfvrsn=0>



WHOLESALE DISTRIBUTOR

Is a stakeholder that has been authorised to distribute medicinal products.

REFERENCE

HPRA. (2021) Medicinal product shortages. A framework for a multi-stakeholder approach to handling shortages of human medicinal products. Available at:
<https://www.hpra.ie/docs/default-source/default-document-library/medicine-shortages-framework.pdf?sfvrsn=0>

