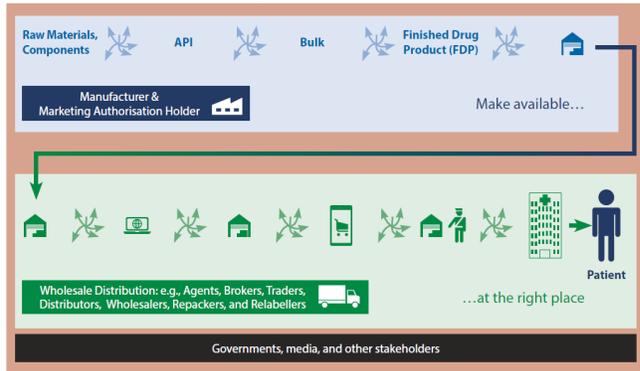


Drug Shortage Prevention

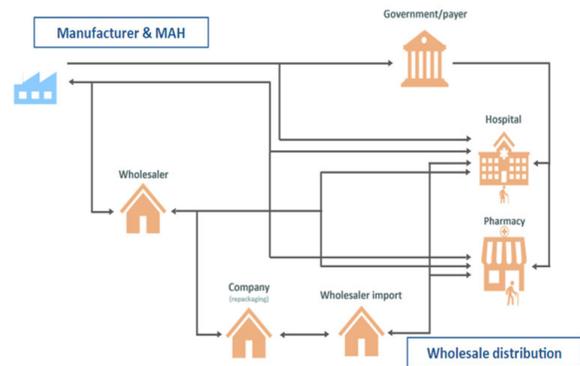
The complexity and responsibility to make a pharmaceutical product available to patients

To enable access to treatment for patients a medicinal product must be manufactured and distributed. This includes all the operations and the quality controls that are required to produce and distribute an Active Pharmaceutical Ingredient (API) and subsequently the drug product¹. This is a highly regulated process ending in the release decision to make the product available. Marketing Authorization Holders (MAH) make sure that the product is ready for wholesale distribution.

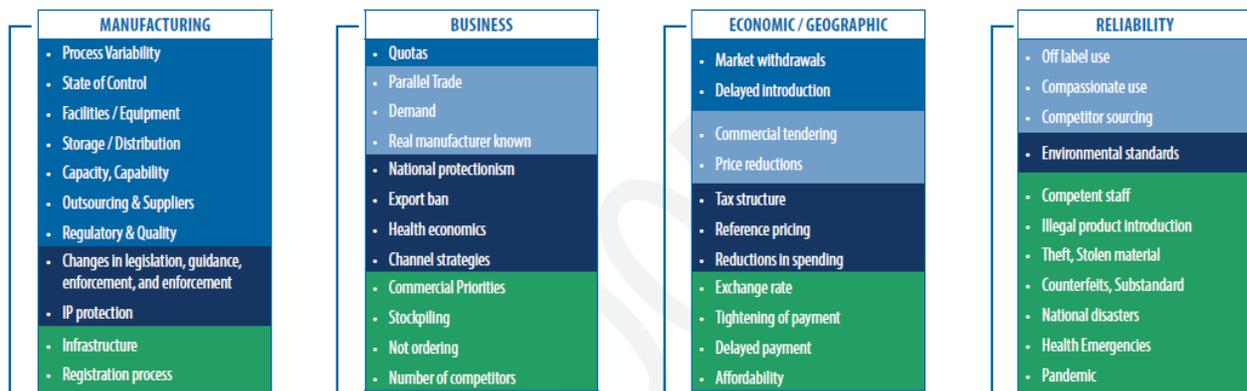
The complexity and responsibility to make the product available to patients²



One product has different marketing channels



Examples of the diversity of factors and stakeholders that could contribute to drug shortage²



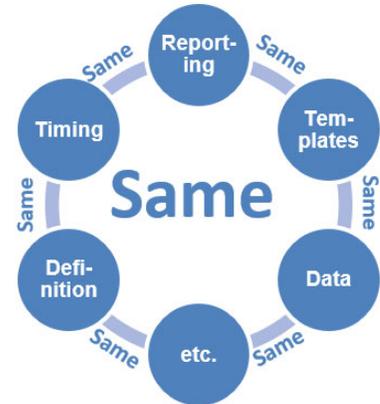
¹ EFPIA infographic on manufacturing https://efpia.eu/media/lsbbeaze/20230914_efpia-leaflet-compressed.pdf

² E. Ramnarine, V. Davoust, K. O'Donnell, S. Rönninger, A. Vinther, **Risk based approach for prevention and management of drug shortages**, PDA Technical Report, 68, 2024. <https://www.pda.org/scientific-and-regulatory-affairs/regulatory-resources/drug-shortage>

Drug Shortage Prevention

Communication drives knowledge and understanding to manage and prevent drug shortages.

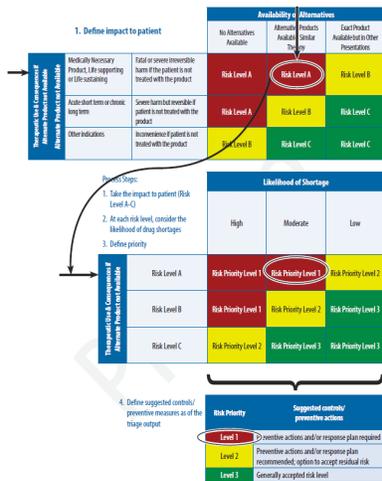
Communication



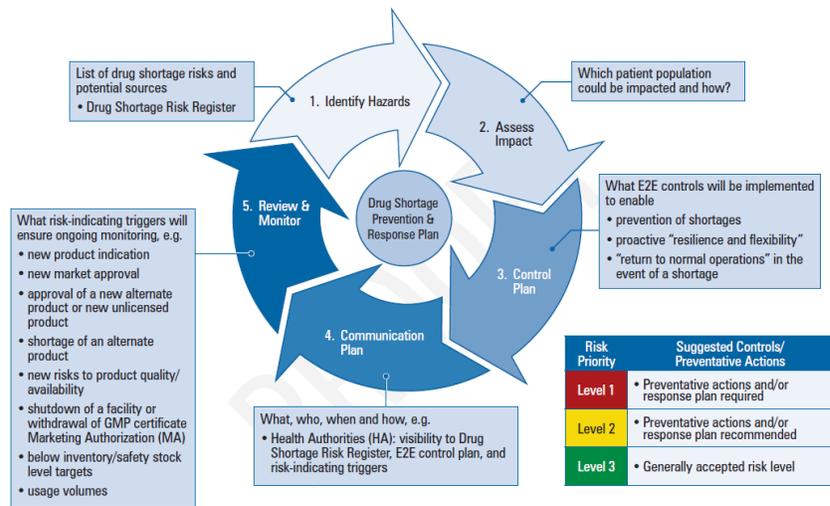
- Bi-directional communication
- Transparency means to understand the impact in the complex environment

Mind the knowledge GAPs due to fragmented data and information from different sources to be collected and analysed.³ Synchronized information flow is necessary for knowledge analysis, decision-making and consistent communication.

Risk Triage model²



Drug Shortage Prevention and Response Plan²



Call to action



² E. Ramnarine, V. Davoust, K. O'Donnell, S. Rönninger, A. Vinther, **Risk based approach for prevention and management of drug shortages**, PDA Technical Report, 68, 2024. <https://www.pda.org/scientific-and-regulatory-affairs/regulatory-resources/drug-shortage>

³ S. Rönninger, **Knowledge Management and ICH**, PDA J. Pharm. Sci. and Tech., 2015, 69, 326-332.