

MEDICINE SHORTAGES HAVE **MULTIFACTORIAL ROOT CAUSES:**

ECONOMIC CAUSES:

- ☒ Cost containment measures following the 2009 financial crisis:
 - Price-cuts
 - Clawback and payback
 - Reference pricing
- ☒ Unsustainable tender practices (single-winner, price-only)

INDUSTRIAL FACTORS:

- ☒ Consolidation of Active Pharmaceutical Ingredients (API) industry production in third countries
- ☒ Less medicines manufacturers on the market
- ☒ Accidents or natural disasters

REGULATORY BURDEN:

- ☒ New regulation:
 - Falsified Medicines Directive
 - Brexit
- ☒ Variation Regulation

THE EU SHOULD ESTABLISH A **COOPERATION MECHANISM ON SHORTAGES** COORDINATING POLICIES TO AVOID NATIONAL SPILL OVER EFFECTS BY:

SUSTAINABLE POLICIES:

- ☒ Ensure predictable pricing & reimbursement policies and sustainable market
- ☒ Targeted guidelines on medicines procurement under the current EU directive

STIMULATING INVESTMENT IN MANUFACTURING AND SUPPLY FOR EUROPE:

- ☒ A comprehensive Industrial policy to stimulate APIs and medicines manufacturing for EU by:
 - Creating incentives & competition measures to stimulate investment
 - Targeted guidelines on medicines procurement under the current EU directive

IMPROVING REGULATORY OPTIMISATION:

- ☒ Regulatory flexibility (e.g. e-leaflets / multi-packages / lower fees for low-price medicines / fast-tracks)
- ☒ Digitalisation (use of telematic tools)
- ☒ Reduction of regulatory fees for older molecules
- ☒ Amend the EU variations legislation to optimise systems and manage information

MEASURES TO **PREVENT** SHORTAGES

MEASURES TO **PREVENT & MITIGATE** SHORTAGES AND REACT QUICKLY