medicines for europe
better access. better health.

Factsheet

Medicines Shortages:
root causes and policies recommendations

MEDICINE SHORTAGES HAVE **MULTIFACTORIAL ROOT CAUSES:**

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

ECONOMIC CAUSES:

- [x] Increasing cost of goods, energy crisis and inflation
- [x] Cost containment measures following the 2009 financial crisis:
  - → Price-cuts
  - → Clawback and payback
  - → Reference pricing
- [x] Unsustainable tender practices (single-winner, price-only)

EXTERNAL FACTORS:

- [x] Consolidation of Active Pharmaceutical Ingredients (API) industry production in third countries
- [x] Less medicines manufacturers on the market
- [x] Accidents or natural disasters, pandemic, war...

REGULATORY BURDEN:

- [x] Falsified Medicines Directive
- [x] Inefficient Variations Regulation
- [x] Increase of costs (i.e. proposal for EMA fees)
- [x] Annex 1 for sterile products
- [x] Environmental policy not tailored to benefit-risk of medicines
- [x] Ineffective stockpiling obligation and penalties to prevent shortages

IMPLEMENTING SUSTAINABLE POLICIES:

- [x] Adjust the price of medicines to the inflation, protecting the economic viability of essential medicines
- [x] Ensure predictable pricing & reimbursement policies and sustainable market
- [x] Targeted guidelines on medicines procurement under the current EU directive

STIMULATING INVESTMENT IN MANUFACTURING AND SUPPLY FOR EUROPE:

- [x] "Medicine security act" 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
  - → Allowing the off-patent medicine industry to participate to the EU funds (via RRF, health IPCEI, soveregnity fund)

OPTIMISING THE REGULATORY PROCESSES:

- [x] Regulatory flexibility (e.g. e-leaflets / multi-country packages / lower fees for low-price medicines / fast-track regulatory procedures)
- [x] Digitalisation (use of telematic tools)
- [x] Reduction of regulatory fees for older molecules
- [x] Amend the EU variations legislation to optimise systems and manage information via digital means
- [x] Environmental policy adapted to benefit-risk of medicines for patients

MEASURES TO **PREVENT** SHORTAGES

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