



## 4b. Activities on security of supply

Unit B4 – Medical products: quality, safety, innovation  
DG Health and Food Safety  
**European Commission**



# Study on shortages

- Study objectives
  - *Provide data on the types of medicines in shortage and their root causes*
  - *Assess the current legal obligations (Article 23a, Article 81, MS measures)*
  - *Identify and benchmark possible future actions that could address risks of shortages.*
- Final report due 30 September
  - Quantitative data on shortages in the EU and their causes.
  - An assessment of current legal provisions
  - Identification of potential policy solutions to shortages
- Next Steps
  - Presentation to the Council Working Party in September
  - Informal EPSCO 12-13 October
  - Will feed into revision of the pharmaceutical legislation



## Structured dialogue

- Overall objective to gain knowledge and understanding (phase 1) in order to put forward (in a phase 2) a set of possible measures and formulate policy options to be considered by the Commission and other authorities in the EU to ensure the security of supply.
- Phase 1
  - Number of meetings with stakeholders process ongoing since 26 February (12 meetings organised by Commission, including 2 high level events) within 4 workstreams with representatives of industry, patients' and health professionals' representatives, Member States and academia;
  - Reports delivered on 20 July
- Phase 2
  - Analysis of reports and discussion within COM in order to present a policy paper on security of supply
- Next Steps
  - Workshop planned for 29 September
  - Meeting with ad-hoc group planned in October