

Session 4: Withdrawals

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Setting the scene

- Member States acknowledge majority of withdrawals are for commercial reasons (Technopolis study on shortages)
- Recent experiences show that Industry exogenous factors (several from legislation) are driving withdrawals
 - e.g., FMD (manufacturing lines), Northern Ireland (Brexit), Romania (clawback), France (clawback)
- How can Member States and authorities better collaborate on Products and Processes sustainability to prevent withdrawals?



Some positive examples

1. **Commission "Brexit amendment"** for Northern Ireland, Republic of Ireland, Malta and Cyprus – FMD and national licensing flexibilities.
2. **Forthcoming German "generic medicines law"**: increase of the prices of critical medicinal products on the basis of a decision process involving BfArM and MoH to counter supply bottlenecks
3. Possible EU guidance on **medicines procurement: multi-winner tenders** and **criteria beyond the price** can prevent market consolidation and decrease the risk of withdrawals

Will early notification deadline (6-12 months) have an impact?

- Not for prolonging products availability on the market: because manufacturers cannot "threaten" a withdrawal to seek a price increase (ASPEN Competition law decision)
- Withdrawal decisions usually linked to low sales/profitability → Supply chain contracts will not be extended.
- Shortages notification is already allowing demand changes capture and remediation actions like import authorisations