European Medicines Security Act

The EU's off-patent medicines manufacturers are committed to providing equitable access to essential medicines in Europe. For that, they need a favourable and sustainable policy framework in place.





Medicines

Security

Act

INVEST IN BUILDING ROBUST & RESILIENT SUPPLY CHAINS

- EU funds & State Aid rules for essential medicines and API production
- Extend the scope of the EU sovereignty fund to essential medicines and API production



ENCOURAGING A WELL FUNCTIONING IP SYSTEM FOR TIMELY COMPETITION

Clarification of the Bolar provision to allow Day 1 generic
& biosimilar medicines launch after IP expiry (this should include all regulatory and administrative procedures)



ACHIEVE EFFICIENCY AND DIGITALISATION OF THE MEDICINES REGULATORY NETWORK / HARNESS THE DIGITAL REVOLUTION FOR MEDICINES SUPPLY AND DEMAND PREDICTABILITY

- Digitalisation & harmonisation of data requirements, building on existing IT systems
- Fast implementation of regulatory flexibilities (ePI, pack sizes, labelling, etc)









