# **European Critical Medicines 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.





**Critical** 

Medicines

Act

### **INVEST IN BUILDING ROBUST & RESILIENT SUPPLY CHAINS**

 EU funds & State Aid rules for essential medicines and API production



Open trade & multilateral cooperation with non EU countries should be supported to create a level playing field



### **REFORM OFF-PATENT MEDICINES MARKET**

European guidance on medicines public procurement to integrate security of supply, multi-winner tenders, MEAT criteria



## **ENCOURAGE 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)







