

IMPACT ON GENERIC & BIOSIMILAR MEDICINES WITHOUT SPC MANUFACTURING WAIVER

MISSED OPPORTUNITIES¹:

- **25.000** additional direct jobs (100.000 indirect)
- **€9.5 billion** net sales for the EU pharmaceutical industry
- **€3.1 billion** savings to EU pharmaceutical spending

PATENT: IP PROTECTION 20 YEARS

EU SPC: EXTRA 5 YEARS PROTECTION

IP EXPIRY



DELOCALISATION OF MANUFACTURING OUTSIDE THE EU



DELAYED START OF EU MANUFACTURING



DELAYED EXPORT



DELAYED PATIENT ACCESS IN EU



START OF MANUFACTURING



EU & non-EU manufacturers compete on the same level



EXPORT TO NON-EU



DAY 1 PATIENT ACCESS IN EU

IMPACT ON GENERIC & BIOSIMILAR MEDICINES WITH SPC MANUFACTURING WAIVER



SPC MANUFACTURING WAIVER WILL NOT REDUCE INTELLECTUAL PROPERTY (IP) PROTECTION

¹EU publications: Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe