



**(BIO)PHARMA IRELAND HIGH-LEVEL SEMINAR:  
THE FUTURE OF (BIO)PHARMACEUTICAL MANUFACTURING**

# **Commission's work on patent exemptions and the SPC framework**

**Alfonso CALLES SÁNCHEZ**

**European Commission**

**DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROWTH)**

**Unit F5: Intellectual Property and Fight Against Counterfeiting**



# Current policy initiatives in the EU Institutions related to pharmaceutical patents

1. Commission's Single Market Strategy (COM(2015)550), October 2015
2. EPSCO Health Council conclusions, June 2016
3. Commission's "*Inception impact assessment*" on SPCs + exemptions related to patents/SPCs, 16 February 2017
4. EP's INI initiative on access to medicines

# Commission's Single Market Strategy & I.I.A.

- We are working on these issues:
  - 1) Evaluation of the SPC legislation
  - 2) Unitary-SPC (fragmentation)
  - 3) SPC so-called "manufacturing waiver" for export purposes
  - 4) Bolar scope
- Next steps
  - ✓ Studies
  - ✓ Public consultation



*Thank you for your attention!*

Alfonso CALLES SÁNCHEZ  
[alfonso.calles-sanchez@ec.europa.eu](mailto:alfonso.calles-sanchez@ec.europa.eu)

**European Commission**

DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROWTH)  
Unit F5: Intellectual Property and Fight Against Counterfeiting