Session 4 - Manufacturing Europe – Thriving as a Global Competitor

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Chemo Group

• Thank you – to our Business Partners in Europe and International Markets

• Chemo Group is open for business 😊

* "IMS Health Forecasts Global Drug Spending to Increase 30 Percent by 2020, to $1.4 Trillion, As Medicine Use Gap Narrows", Tor Constantino, 18 Nov. 2015
The Pharmaceutical Sector by 2020

- Global medicine use in 2020 will reach **4.5 trillion doses**
- By 2020: Generic medicines to account for **88% of total medicine use** in pharmerging markets*
- **Patent expiries** are expected to result in **$178 billion** in reduced spending on branded products, incl. **$41 billion** in savings on biologics as **biosimilars** become more widely adopted*
- Development and manufacturing of generic, biosimilar and value added medicines is vital for public health sustainability*

* "IMS Health Forecasts Global Drug Spending to Increase 30 Percent by 2020, to $1.4 Trillion, As Medicine Use Gap Narrows”, Tor Constantino, 18 Nov. 2015

The European Experience
Generic Medicines, a Cornerstone of Healthcare Sustainability

**KEY FIGURES ON GENERIC MEDICINES**

- **56%** of dispensed medicines
- **22%** of pharmaceutical expenditures
- **€100BN** less spending through generic competition
- **350,000** manufacturers’ turnover in the EU
- **High quality medicines to over 500 million patients**
- **+160,000 employees**
- **+100% employee retention over 10 years**
- Cardiovascular, Hypertension, Diabetics, Depression, Epilepsy, Mental disorders, Gastrointestinal

Biosimilar Medicines, a Cornerstone of Healthcare Sustainability

**KEY FIGURES ON BIOSIMILAR MEDICINES**

- **400 million patient days** in approved biosimilar medicines
- **2006** first biosimilar approved in the EU
- **+44%** patient access in the EU (2006-2013)
- **€78Bn** savings from 2011 to 2013
- **15 European countries** have made biosimilars available for medicine or biologics in oncology and development evaluation

patients • quality • value • sustainability • partnership
How to stimulate competitiveness of the sector?

- Efficient regulatory approvals
- Competition from day 1 of the IP expiry in Europe and worldwide
- Pro-competition pricing and procurement policies
- Education and incentives for healthcare professionals
- Objective, reliable and scientifically up-to-date information to stakeholders about generic and biosimilar medicines

Strong Manufacturing Sector
The Supplementary Protection Certificate (SPC)

- Patent protection lasts 20 years
- The Supplementary Protection Certificate (SPC) extends exclusivity of patented products by up to 5 years
- To compensate originators for Marketing Authorisation delays in Europe
- Unintended effect: EU manufacturers forced to outsource to export to unprotected markets

Who is impacted?

- Bigger multinationals: produce in non-EU plants
- SMEs: outsource production to third party manufacturers abroad – long contracts (often beyond SPC expiries)

The biggest loser is the European economy
How it works today for launch in EU

SPC Manufacturing Waiver
The Benefits of an SPC Manufacturing Waiver in Europe

- High skill pharmaceutical **R&D and manufacturing** back into the EU
- **Avoid relocation** of production capacities
- Create **high skill jobs**
- Develop **EU manufacturing science**
- Boost **European SMEs** (reduce costs – spur growth)
- Support the **European API industry**
- Create **economic growth in Europe**
- Ensure **high quality and continuity of supply in third countries** (faster & increased access)
- Increase the **EU trade balance** (more export)
- **Will NOT undermine or change existing IPR equilibrium** in the EU
- Give opportunity to compete for **global leadership**

### What an SPC waiver would trigger in Europe

In 2014-2022, the European generic medicine industry would create:

- 64,000 high skill jobs in EU
- 36 new companies
- €5.2 billion business value*

*Manufacturing and export provisions: Impact on the competitiveness of European pharmaceutical manufacturers and on the creation of jobs in Europe, study by Vanda Vicente and Sergio Simoes, 2015*
Latest Developments

• EU-Canada CETA (Sept 2014)
  • Introduces patent extension in Canada
  • Allows export waiver

• EP Resolutions call for SPC manufacturing waiver to stimulate competitiveness of EU industry
  • on re-industrialising Europe (Jan 2014 - Butikofer); and
  • on IPR protection in non-EU countries (June 2015 - Mosca)
  • on Single Market Strategy (May 2016 - Comi)

• European Commission Single Market Strategy of 28 October 2015 proposes introduction of SPC Manufacturing Waiver (legislative proposal by 2017)

The way forward

• Next steps:
  • Launch of public consultation (lasting 12 weeks) - summer 2016
  • Final impact assessment
  • Legislative proposal

• Need for targeted SPC manufacturing waiver to be introduced in the EU SPC Regulation by 2019
Opportunity to boost development and manufacturing of generic, biosimilar and value added medicines in Europe