DISCLAIMER

• The information contained in this presentation does in no way constitute a representation or warranty of Cinfa Biotech regarding the accuracy and or completeness thereof. This relates in particular but not limited to the non-infringing character of any third party IP relating to the products or technology as described herein unless otherwise explicitly agreed upon. Accordingly, Cinfa Biotech assumes no liability whatsoever for any damages occurring from the reliance on such information by any recipient.
AGENDA

- SPC manufacturing waiver
- Manufacturing in Europe
- Manufacturing and R&D
SPC EXTENDS PATENT PERIOD

- SPC = Supplementary Protection Certificate
- Prolongs patent period for up to five years
- Rationale: long periods for product development/registration restrict market exclusivity period

NO GLOBAL SPC REGULATION

- SPC regulations are national
- Many countries have implemented SPC regulation, e.g. EU countries, US
- Some countries have not implemented SPC regulation, e.g. Brazil, India, Russia, China
- Patents in non-SPC countries expire up to five years earlier as compared to SPC countries
SPC REGULATIONS DISADVANTAGE EUROPEAN MANUFACTURERS

- Manufacturers from non-SPC countries can manufacture and market in non-SPC countries immediately after patent expiry
- EU manufacturers cannot manufacture for non-SPC markets during SPC period
- Manufacturers from non-SPC countries can launch earlier in SPC countries (manufacture during SPC period)

SPC REGULATIONS DISADVANTAGE EUROPEAN MANUFACTURERS

- Product marketing in non-SPC countries

<table>
<thead>
<tr>
<th>Manufacturers from non-SPC countries</th>
<th>Patent</th>
<th>Manufacturing</th>
<th>Marketing</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Manufacturers from EU</th>
<th>Patent</th>
<th>SPC</th>
<th>Manufacturing</th>
<th>Marketing</th>
</tr>
</thead>
</table>

⚠️ Up to five years delay in market entry
SPC REGULATIONS DISADVANTAGE EUROPEAN MANUFACTURERS

- Product marketing in SPC countries
  - Manufacturers from non-SPC countries
    - Patent
    - SPC
    - Manufacturing
    - Marketing
  - Manufacturers from EU
    - Patent
    - SPC
    - Manufacturing
    - Marketing

SPC HURDLES MIGHT ENCOURAGE EUROPEAN MANUFACTURES TO LEAVE

- Current SPC regulations in Europe represent a significant competitive disadvantage
- Might cause European manufacturers to move production to non-SPC countries
- Represent a substantial risk for long-term sustainability of manufacturing in Europe
INITIATIVE FOR SPC MANUFACTURING WAIVER FOR EXPORT WAS STARTED

- European Commission, with support of Medicines for Europe, considers targeted SPC manufacturing waiver

SPC MANUFACTURING WAIVER CREATES COMPETITIVE CONDITIONS

- Product marketing in **non-SPC countries**
  
<table>
<thead>
<tr>
<th>Manufacturers from non-SPC countries</th>
<th>Patent</th>
<th>Manufacturing</th>
<th>Marketing</th>
</tr>
</thead>
</table>

- Manufacturers from SPC countries
  
<table>
<thead>
<tr>
<th>Manufacturers from SPC countries</th>
<th>Patent</th>
<th>SPC</th>
<th>Manufacturing</th>
<th>Marketing</th>
</tr>
</thead>
</table>

Up to five years delay in market entry
SPC MANUFACTURING WAIVER CREATES COMPETITIVE CONDITIONS

- Product marketing in **non-SPC countries**

<table>
<thead>
<tr>
<th>Manufacturers from non-SPC countries</th>
<th>Patent</th>
<th>Manufacturing</th>
<th>Marketing</th>
</tr>
</thead>
</table>

| Manufacturers from SPC countries    | Patent | SPC           | Manufacturing | ✔ Marketing |

SPC MANUFACTURING WAIVER CREATES COMPETITIVE CONDITIONS

- Product marketing in **SPC countries**

<table>
<thead>
<tr>
<th>Manufacturers from non-SPC countries</th>
<th>Patent</th>
<th>SPC</th>
<th>Manufacturing</th>
<th>Marketing</th>
</tr>
</thead>
</table>

- Delay due in market entry

<table>
<thead>
<tr>
<th>Manufacturers from SPC countries</th>
<th>Patent</th>
<th>SPC</th>
<th>Manufacturing</th>
<th>Marketing</th>
</tr>
</thead>
</table>

Delay due in market entry
SPC MANUFACTURING WAIVER CREATES COMPETITIVE CONDITIONS

- Product marketing in **SPC countries**

  Manufacturers from non-SPC countries
  - Patent
  - SPC
  - Manufacturing
  - Marketing

  Manufacturers from SPC countries
  - Patent
  - SPC
  - Manufacturing
  - Marketing

AGENDA

- SPC manufacturing waiver
- Manufacturing in Europe
- Manufacturing and R&D
EUROPE IS THE WORLDWIDE LEADER IN BIOSIMILARS

- Mature regulatory pathway for market authorisation of biosimilars
- Established market mechanics for biosimilars
- Many years of experience with biosimilars

THE EUROPEAN BIOSIMILARS INDUSTRY IS AT HIGHEST LEVEL

- Almost 20 years of industrial biosimilars development
- 10 years of biosimilars market experience
- Proven highest quality
- Developed infrastructure and technology for manufacturing, efficient and reliable
- Highly qualified experts
INDUSTRIAL EXPERIENCE CREATES BENEFIT TO PATIENTS AND SOCIETY

• Product quality
• Increased patient access to biological medicines
• Economic effect on healthcare systems

WORLDWIDE BIOSIMILARS INDUSTRY IS STRONGLY GROWING

• Market is evolving on global level
• Many new players from several regions, supported by national support programs in some countries
• Ex-EU products entering the market
• Competitive pressure is increasing
STRENGTHENING THE EUROPEAN BIOSIMILARS INDUSTRY IS CRUCIAL

- Maintain worldwide leadership
- Thousands of new high-tech jobs
- Boost SMEs
- Build and maintain technology and competence
- Investments in R&D
- Economic growth

COMPETITIVE ENVIRONMENT REQUIRED FOR EUROPEAN MANUFACTURERS

- Establish competitive conditions for, remove competitive disadvantages
- Local support programs for start-up of manufacturers and R&D
- Make the European biosimilars industry sustainable
AGENDA

• SPC manufacturing waiver
• Manufacturing in Europe
• Manufacturing and R&D

"RESEARCH FOLLOWS FERMENTER"*

• Manufacturing requires technological infrastructure
• Technological infrastructure triggers innovation
• Innovation attracts experts

*M. Leyck-Dieken, Biosimilars, Berlin, 29 September 2015
“RESEARCH FOLLOWS FERMENTER”*

- Manufacturing as a major factor for R&D
- Strong economic impact, mid- and long-term
- Strengthening manufacturing results in growth and sustainability

*M. Leyck-Dieken, Biosimilars, Berlin, 29 September 2015