INVESTING IN HEALTHCARE
How can the revision of the general pharmaceutical legislation better attract investors in the future?

29 September 2021
12:00 - 13:30 CEST
Online Event
✓ Webinar will be recorded and slides available
✓ Q&A for direct questions to panellists
✓ Chat for comments to share with all delegates

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27 SEPTEMBER – 3 OCTOBER

Bernard GRIMM
Healthcare Biotechnology Director at EuropaBio
EUROPEAN BIOTECH WEEK 2021

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Juozas OLEKAS
Member of the European Parliament, S&D, Lithuania
EUROPEAN BIOTECH WEEK 2021

Stefan GIJSSELS
SEBOIO Health Policy Consulting and Co-founder of Digestive Cancer Europe
Attracting Life Science Investments in Europe

AN INITIATIVE OF THE BIOMED ALLIANCE, EUROPABIO & JOHNSON & JOHNSON – 22 June 2021
Objectives of the life science attractiveness report

• To provide a set of **key indicators** and **policy recommendations** for a coherent life science ecosystem

• To identify how selected **European countries score** on these life science indicators (Belgium, France, Germany, Ireland, Italy, the Netherlands, Spain, Sweden, Denmark, Finland, Poland, Norway, Switzerland, and the United Kingdom)

• To offer a snap-shot of **Europe’s position vis-à-vis the US and China**

• To present **country dashboards** allowing each of the selected countries to view their position within Europe
EUROPE – the median score
Overview of the selected criteria

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>LOW</th>
<th>HIGH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social &amp; economical context</td>
<td>Political stability &amp; absence of violence</td>
<td>CH</td>
</tr>
<tr>
<td>National competitiveness</td>
<td></td>
<td>CH</td>
</tr>
<tr>
<td>Innovative environment / Innovation Systems</td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Gender equality</td>
<td></td>
<td>PT</td>
</tr>
<tr>
<td>Employment productivity</td>
<td></td>
<td>CH</td>
</tr>
<tr>
<td>Hourly labour costs</td>
<td></td>
<td>CH</td>
</tr>
<tr>
<td>Availability of qualified staff</td>
<td></td>
<td>CH</td>
</tr>
<tr>
<td>Life science trade balance (exports – imports)</td>
<td></td>
<td>CH</td>
</tr>
<tr>
<td>Corporate taxes</td>
<td></td>
<td>CH</td>
</tr>
<tr>
<td>Payroll taxes</td>
<td></td>
<td>DK</td>
</tr>
<tr>
<td>Life science publications</td>
<td></td>
<td>DE</td>
</tr>
<tr>
<td>Life science staff</td>
<td></td>
<td>DE</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td></td>
<td>SP</td>
</tr>
<tr>
<td>Life science R&amp;D investments</td>
<td></td>
<td>DE</td>
</tr>
<tr>
<td>Life science degrees</td>
<td></td>
<td>FR</td>
</tr>
<tr>
<td>Quality of care</td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Size of healthcare budget</td>
<td></td>
<td>DE</td>
</tr>
<tr>
<td>Pharmaceutical spending</td>
<td></td>
<td>DE</td>
</tr>
<tr>
<td>Size of MedTech Market</td>
<td></td>
<td>DE</td>
</tr>
<tr>
<td>Time to availability of medicines</td>
<td></td>
<td>DE</td>
</tr>
<tr>
<td>Digital Health Index</td>
<td></td>
<td>DK</td>
</tr>
</tbody>
</table>

Analysis of country attractiveness for life science investments

- ● Median European Country
- ▓ Highest Scoring European Country
## Comparison with the US

<table>
<thead>
<tr>
<th></th>
<th>EU</th>
<th>US</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public health research</td>
<td>6.9 billion €</td>
<td>28.4 billion €</td>
</tr>
<tr>
<td>Pharma patent registration growth rate</td>
<td>1</td>
<td>x 3</td>
</tr>
<tr>
<td>Life Science Venture Capital</td>
<td>11 billion $</td>
<td>30 billion $</td>
</tr>
<tr>
<td>Life Science Staff</td>
<td>479,530</td>
<td>2,296,000</td>
</tr>
</tbody>
</table>

### Total number of investments by US and European Life Science Actors across sectors (Jan 2019 - Sept 2020)

- United States
- Europe

- Biotech
- Digital/AI
- Medical Devices
- Diagnostics
• The EU and the Member States should have a stronger long-term vision on how its life science ecosystem should develop

• This requires a concerted collaborative and sustained policy effort to which the revision of the pharmaceutical legislation should fully contribute

• All aspects of the ecosystem are connected and should reinforce each other
  – Political stability, industrial policy, life science education
  – The availability of venture capital
  – A welcoming regulatory environment for innovative technologies

• Life science investments create value and contribute to health improvement, they create strong knowledge base, high quality jobs and enhance manufacturing capacity and exports
#EuropeanBiotechWeek2021

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Ingrid MAES
Co-founder of Inovigate
How could the pharmaceutical strategy in the EU serve innovation in health?

EuropaBio – 2021

Investing in healthcare - How can the revision of the general pharmaceutical legislation better attract investors in the future?

Ingrid Maes, Managing director
The current tensions

The ethical trilemma

Current challenges

- Health crisis response
- Effective medicines available at an affordable cost
- Unmet medical needs and market failures
- Unequal access
- Affordable medicines across the EU
- Legislative framework to support innovation
- Regulatory inefficiency and administrative burden
- Supply vulnerability
Shifting roles of healthcare stakeholders, requires a new policy framework

**Industry**

- **Biotech**
  - Motor of innovation

- **Pharmaceutical companies**
  - high value-acquisitions of promising pipeline products
  - From a product towards a service business model
  - Supplying health outcomes

- **FAANG – Companies**
  - entered the health market
  - are fastly generating medical and wellbeing insights,
  - deploying ecosystem business models that do control all aspects of our lives,

**Pricing & reimbursement authorities**

- Become buyers
- Critical evaluators of health benefits
- Uncertainty on the real-life effectiveness of novel medicines, and related overall costs
- Budget sustainability of health systems
- Patient access

Upcoming requirements for affordability of medicines and availability put increased pressure on companies. This puts the actual business model at risk and incentivizes less risky (?) service models, in response to value-based healthcare requirements.
The opportunity

The EU Pharmaceutical Strategy: a new and holistic EU approach regarding the pharmaceutical sector, and medicines policy

- The strategy aims to ensure that Europe’s pharmaceutical policy evolves in line with current changes, remaining relevant tomorrow
- This is an excellent opportunity for national Healthcare- and Health-Insurances to redefine their Pharmaceutical Strategy as well
### The required transformation

**The cornerstones of a future health ecosystem for which the fundamentals are available in EU**

<table>
<thead>
<tr>
<th>Starting from societal focus and purpose</th>
<th>Innovative look at the innovation process</th>
<th>Promoting collaborations on all fronts</th>
<th>Integrated value-chain approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Societal priorities</td>
<td>Data access &amp; re-use</td>
<td>Cross-country collaborations &amp; breaking authority silo’s</td>
<td>Connecting ecosystems and building value chains</td>
</tr>
<tr>
<td>Ensure innovation matching patient and national health system needs</td>
<td>Novel trial designs</td>
<td>Collaborative R&amp;D models</td>
<td>Competitiveness of the sector as an ecosystem</td>
</tr>
<tr>
<td>Tailor incentives to stimulate innovation in unmet medical need areas</td>
<td>Funding of SMEs and academia</td>
<td>Bring stakeholders together from the start</td>
<td>Production networks close to POC</td>
</tr>
<tr>
<td>Ensuring affordability</td>
<td>Innovative manufacturing and supply chains</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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To build the EU value chain of the future, authorities must drive the priorities towards the industry based on the societal needs

Plan for a strong EU health ecosystem focussed on societal demand and relevance

**Society**
- Societal priorities (unmet medical needs)
- Societal willingness to pay

**Industry**
- Innovate the innovation process
- Collaborate on all fronts

**Authorities**
- Affordability
- Access for innovative curing therapies
- Data access & re-use
- Robust IP and targeted incentives
Case: ATMP as a blueprint for the future

Connect the ecosystem to solve key challenges and build integrated value chain to accelerate access for patients and affordability for society

Challenges along the product life cycle, adding complexity and impacting product development and patient access

Integrated R&D and manufacturing innovation along the value chain, including commercialisation and funding partners
3 virtuous circles: The future European Health ecosystem must be focussed on societal demand to be competitive

 Authorities should define societal priorities
 Companies should prioritise those areas
 Income of marketed innovation allows companies to continue to develop new innovations

 Innovation advances the state of art, and serves as a starting point to address unmet medical needs

 What has been developed meets societal needs and is budgeted
 Priorities are required to focus efforts and assure affordability
Connecting for better health

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Oskar SLOTBOOM

General Partner at BioGeneration VC
Biotechweek event
29 September 2021
Europe is second to none in science production

1B. World-class science and innovation in Europe

- **High academic quality of innovation**: 32% of the top-50 Universities are located in Europe (vs 44% in the US, and 24% in RoW)
- **Top science production**: Comparable or higher publication output versus the US (1.2x) and China (3.1x)
- **Challenges in translating innovation into patents**: Europe generates 3.5x fewer patents than the US (i.e. 0.29x)
- **Strong contributions to (some) approvals**: 13% of biotech-originated FDA new drug approvals originate from European biotechs
- **Promising pipeline**: European biotechs do better on emerging modalities, driving 32% of all Phase 3s and registrations

However, investment is lagging far behind the US

2C. The financing gap versus the US remains, and is still growing

- **Increasing funding, but gap versus US grows**
  - **4.6x**
  - **60%**
  - Higher annual venture funding is available in the US versus Europe, growing to 4.6x in 2018 from 3.3x in 2012
  - Growth in funding gap. US early- and late-stage funding rounds are now on average 60% larger than in Europe

- **US public markets yield more**
  - **3x**
  - Smaller IPOs in Europe. The average US IPO size is 3x larger than on European markets
  - No discrimination. European and US biotech IPOs are similar in size (~USD 80 mn) on US exchanges

- **European exchanges not deep enough**
  - **98%**
  - **3.7/10**
  - US finances European biotechs. 98% of follow-on offerings for European biotechs were raised on US markets, as well as half of their total IPO fundraising
  - Few European biotechs are equipped to pursue investments from China (while 82% of Chinese investors are increasingly looking into Europe)

How to boost investment in Europe?

1. **Access to capital:** Create one European ‘Nasdaq’

2. **Mobilize European retail investments:** E.g., French FCPI funds

3. **Direct European Pension Fund investments:** E.g., % to be invested in European designated innovation sectors

4. **Grow life-science hubs:** Expand and concentrate lab space

5. **Remove administrative/regulatory red tape:** E.g., differences between countries for starting companies, simplify and harmonize clinical trial regulations, IP ownership of academics

6. **Onshore critical capabilities/infrastructure:** Pharmaceutical production and clinical trial capabilities

Need at least a 15-year stable stimulus plan and policy
How this creates a win for Europe?

Additional investments will translate into:

1. more innovative therapies for patients with positive impact on national healthcare budgets

2. additional economic activity: jobs, royalty income, taxes
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Isabelle SCHUBERT
Global Head IP Strategy at Novartis
IP – the basis for pharmaceutical innovation – Biotech Week
29 September 2021
From intellectual property protection to a better quality of life

Patents, SPCs, RDP, OME, PED → R&D investments → Supply (Innovative and generic medicines) → Better quality of life
Innovation cycle in the pharma sector

Research
± 10,000 compounds

± 1,000 compounds

Product development
Medicine available for patients
1 authorization

Generics

Patent (20 years)
SPC (0-5 y)

Paediatric research +0,5 y

RDP (8 y)

Effective patent term loss

±2
±1

Orphan designation
Orphan exclusivity (10 y)

±2

Paediatric research

-12

0

8

10

13
### Geographic comparison of IP environment

<table>
<thead>
<tr>
<th>IP Type</th>
<th>EU**</th>
<th>US</th>
<th>JP</th>
<th>CN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enforceable patents</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>(+)*</td>
</tr>
<tr>
<td>SPC/PTE</td>
<td>Up to 5 yrs</td>
<td>Up to 5 years</td>
<td>Up to 5 years</td>
<td>(up to 5 yrs)*</td>
</tr>
<tr>
<td>RDP</td>
<td>8+2+1 yrs for NME</td>
<td>5 yrs NCE / 12 yrs B 3 yrs</td>
<td>8 yrs NME 4-6 yrs</td>
<td></td>
</tr>
<tr>
<td>Orphan Excl</td>
<td>10 yrs</td>
<td>7 yrs</td>
<td>10 yrs</td>
<td></td>
</tr>
<tr>
<td>Paediatric Extension</td>
<td>SPC + 6 months, OME + 2 yrs</td>
<td>all excl + 6 months</td>
<td>RDP + 2 yrs</td>
<td></td>
</tr>
</tbody>
</table>

*could be green +, depends on implementation of the new law*

**Switzerland has 15 yrs orphan exclusivity, provides for an additional 10 yrs RDP for a significant new indication and paediatric extension can also attach to patent, where there is no SPC**
Risks to the predictability of the IP system in Europe

• Predictability at risk both (i) in view of a possible reduction of the pharmaceutical incentives and (ii) in view of conditionalities which may be introduced into the law in an attempt to «control the industry»

• Needed:
  • Maintain a strong and competitive IP system in Europe
  • Predictable incentives as the basis for long-term investment decisions
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PANEL DISCUSSION followed by Q&A

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How can the Revision of the General Pharmaceutical Legislation better attract investors in the Future?

Encourage investment in academic spin-offs
Provide a clear regulatory framework for R&D in Europe
digitalisation

Incentives

innovation Transparency

Regulatory Flexibility
Focus on development bottlenecks

Diversity in composition of working groups to discuss this