

#EuropeanBiotechWeek2021

EUROPEAN BIOTECH WEEK 2021

27 SEPTEMBER – 3 OCTOBER

EUROPEAN
BIOTECH
WEEK



INNOVATION IS IN OUR GENES



INVEST
EUROPE

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

YOUR ROLE TODAY

- ✓ Webinar will be recorded and slides available
- ✓ Q&A for direct questions to panellists
- ✓ Chat for comments to share with all delegates



@BiotechWeekEU



@europa.bio



@biotechweek



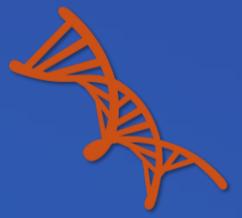
@EuropaBio – the European
Association for Bioindustries

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SPEAKERS

INVEST
EUROPE



Juozas Olekas, EP



Stefan Gijssels, SEBOIO



Ingrid Maes, Inovigate



Oskar Slotboom, BGV



Isabelle Schubert, Novartis



Bernard Grimm, EuropaBio

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Bernard GRIMM

Healthcare Biotechnology
Director at EuropaBio

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Juozas OLEKAS

Member of the European
Parliament, S&D, Lithuania



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Stefan GIJSSELS

SEBOIO Health Policy
Consulting and Co-founder
of Digestive Cancer Europe



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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

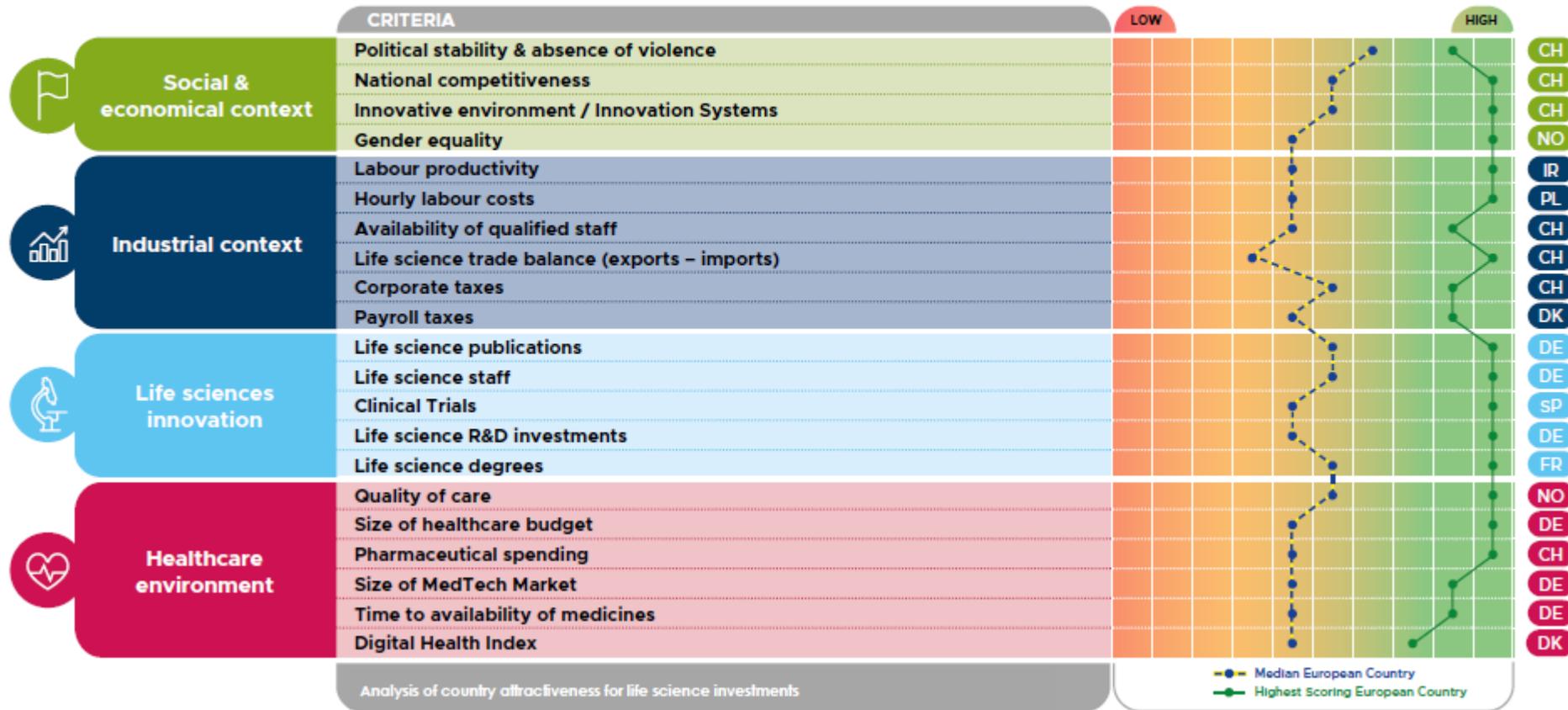


- To provide a set of **key indicators** and **policy recommendations** for a coherent life science ecosystem
- To identify how selected **European countries score** on these life science indicators (Belgium, France, Germany, Ireland, Italy, the Netherlands, Spain, Sweden, Denmark, Finland, Poland, Norway, 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

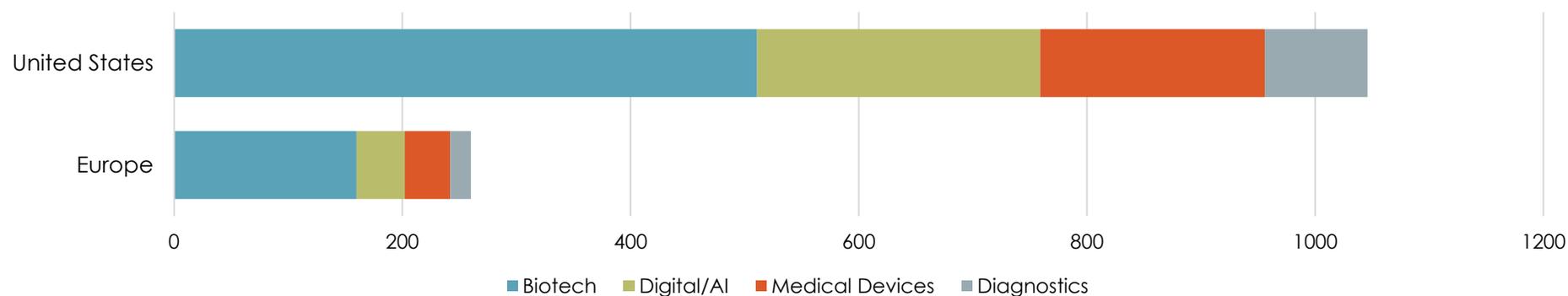
Overview of the selected criteria



Comparison with the US

	EU	US
Public health research	6.9 billion €	28.4 billion €
Pharma patent registration growth rate	1	x 3
Life Science Venture Capital	11 billion \$	30 billion \$
Life Science Staff	479,530	2,296,000

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





- 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

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Ingrid MAES

Co-founder of Inovigate





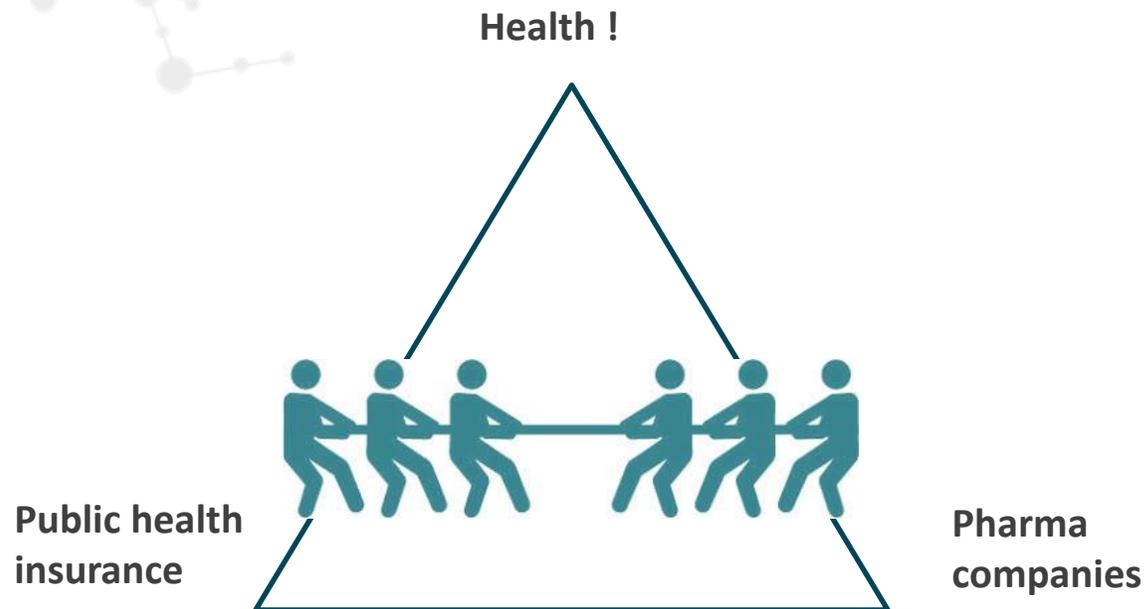
How could the pharmaceutical strategy in the EU serve innovation in health?

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

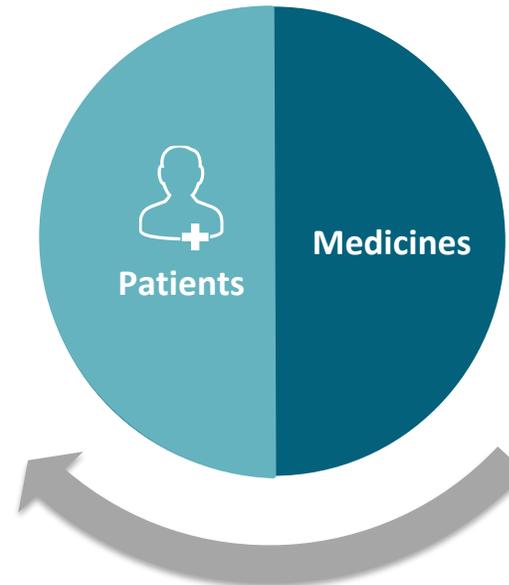
- Motor of innovation

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

EU Pharmaceutical strategy

Ensuring access to affordable medicines

Addressing unmet medical needs, supporting competitiveness, innovation and sustainability of EU's pharmaceutical industry and development of high quality, safe, effective and greener medicines,

Digitization and new technologies to support innovation across the whole value chain

Enhancing crisis preparedness and response mechanisms, diversified and secure supply chains, address medicines shortages.

- 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

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

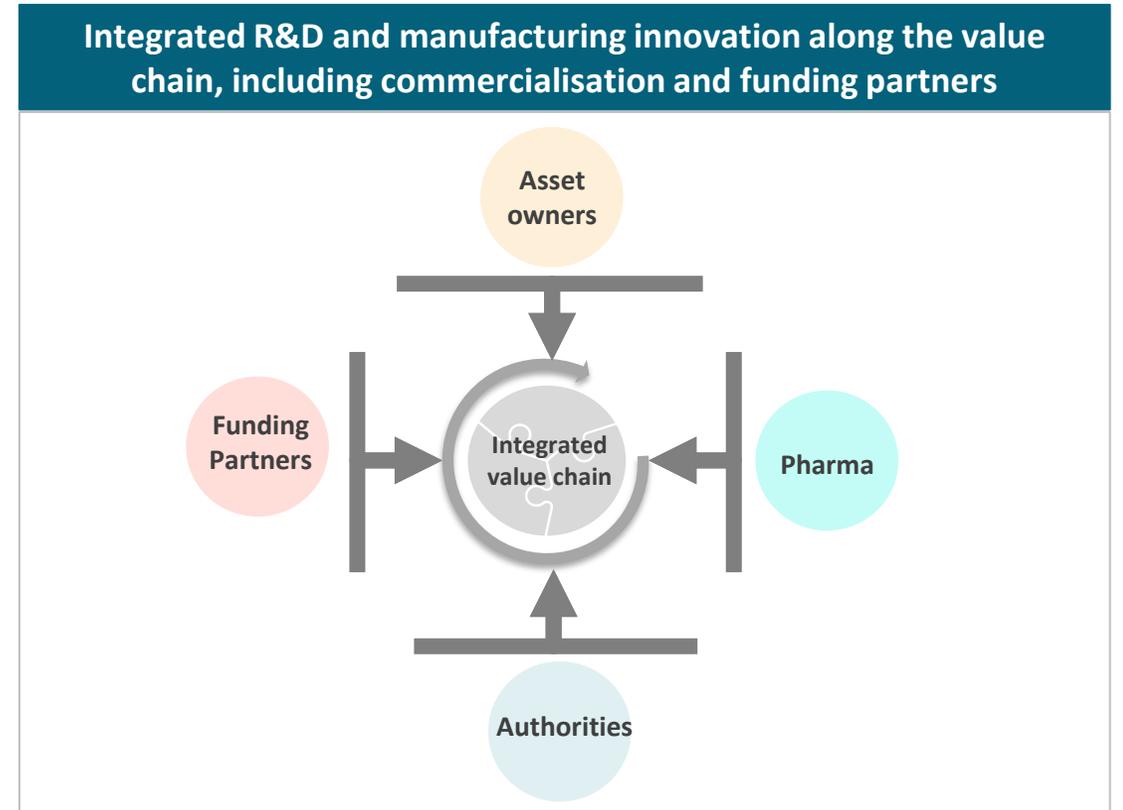
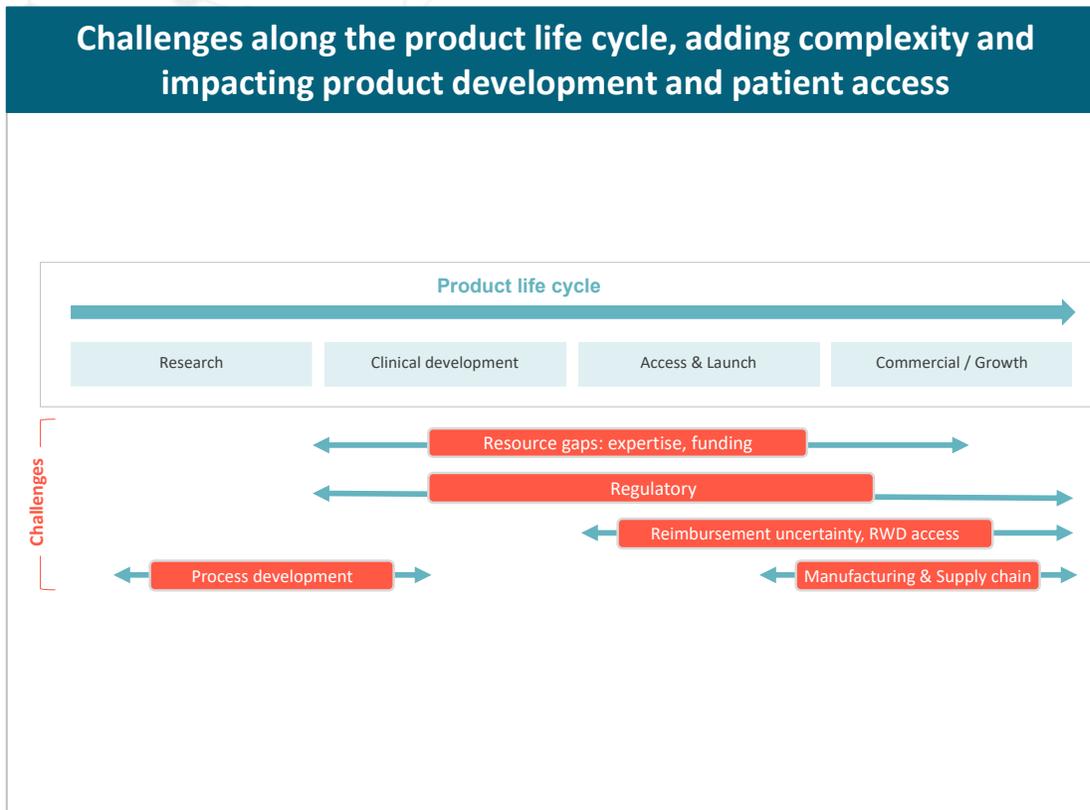
To build the EU value chain of the future, authorities must drive the priorities towards the industry based on the societal needs

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



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



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

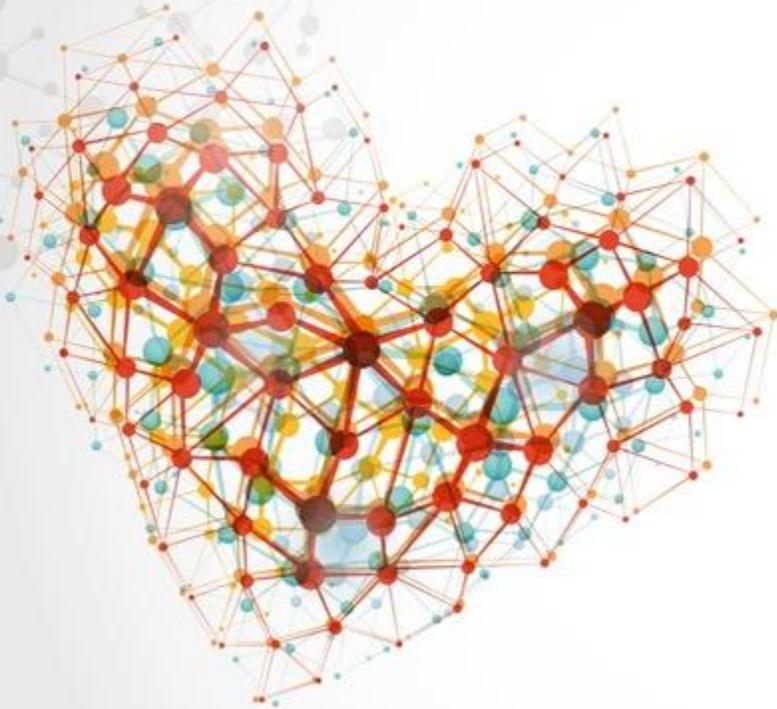
Income of marketed innovation allows companies to continue to develop new innovations



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

ingrid.maes@inovigate.com

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Oskar SLOTBOOM

General Partner at
BioGeneration VC





Biotechweek event

29 September 2021

The logo for BGV, consisting of the letters 'B', 'G', and 'V' in a bold, sans-serif font. The 'B' and 'G' are dark blue, while the 'V' is a lighter blue. The letters are slightly overlapping and have a modern, geometric feel.

Europe is second to none in science production

1B. World-class science and innovation in Europe



High academic quality of innovation

32%

Top talent creation. 32% of the top-50 Universities are located in Europe (vs 44% in the US, and 24% in RoW)

1.2x/3.1x

Top science production. Comparable or higher publication output versus the US (1.2x) and China (3.1x)



Challenges in translating innovation into patents

0.29x

Lost in translation vs. the US Europe generates 3.5x fewer patents than the US (i.e. 0.29x)

0.11x

在翻译中丢失了 vs. China. Europe generates significantly less patents (8.7x fewer patents than China, i.e; 0.11x)



Strong contributions to (some) approvals

13%

Some contributions to FDA drug approvals. 13% of biotech-originated FDA new drug approvals originate from European biotechs

32%

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 4.5x 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 80mn) 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)

McKinsey & Company 53

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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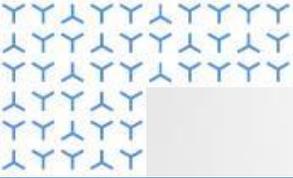
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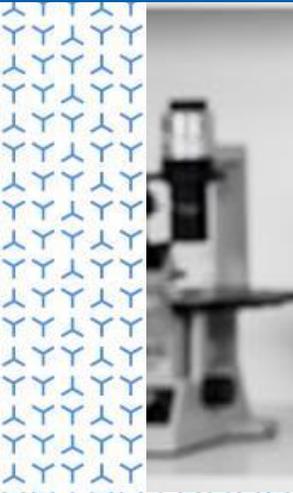
Isabelle SCHUBERT

Global Head IP Strategy
at Novartis



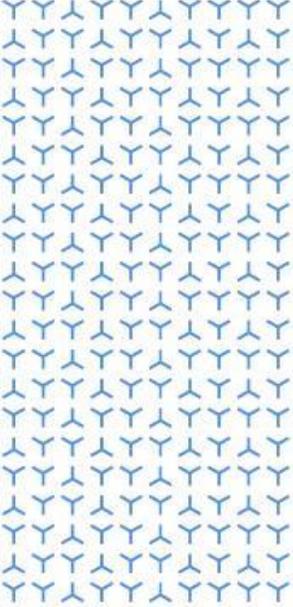


Novartis AG



IP – the basis for pharmaceutical innovation – Biotech Week

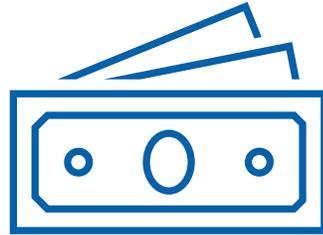
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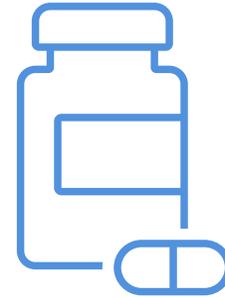
From intellectual property protection to a better quality of life



**Patents,
SPCs, RDP,
OME, PED**



**R&D
investments**

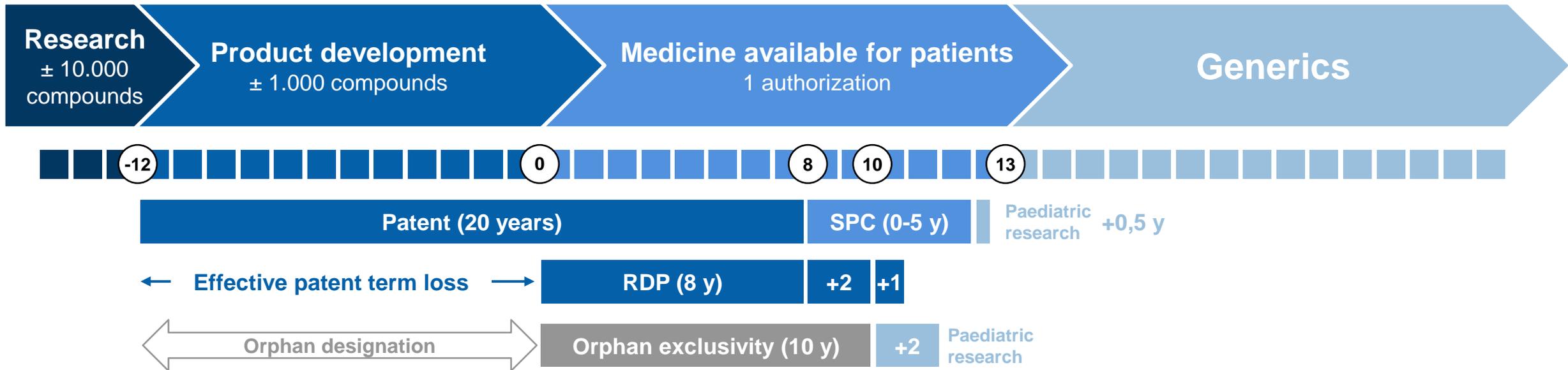
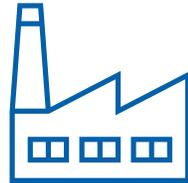
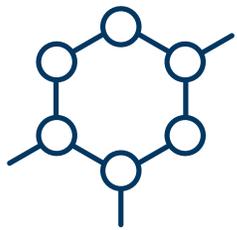


Supply
(Innovative and
generic medicines)



**Better quality
of life**

Innovation cycle in the pharma sector



Geographic comparison of IP environment

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

*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

A faint, light-colored map of Europe is visible in the background of the right side of the image, with the text overlaid on it.

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

slido.com
#EBWHC



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

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