



The European Association for Bioindustries

Emerging Enterprises Council

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BFS Programme - Malaysia

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Emerging Enterprises Council

Looking after Biotech SMEs

- EEC's mission is to ensure that the needs and interests of biotech SMEs are addressed at EU level
- EEC provides advocacy for priority issues with European authorities (i.e. Commission, Parliament, EIB, ...)
- Chairman: Philippe Archinard, PhD (CEO Transgene)
- Director: Laurens G. Theunis, MSc, MFin
- Members: CEOs, investors and other experts
- At least three EEC-meeting per annum

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What are the issues?

- Fragmentation → lack of critical mass:
 - Product markets
 - Financial markets
 - Regulatory frameworks
 - Centers of excellence and clusters
- Business attitude
- “10-year gap”
- Lack of all forms of finance

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What are the issues?

- | | Opportunities |
|--|---------------|
| • Fragmentation → lack of critical mass: | |
| – Product markets | ■ ■ ■ □ □ □ |
| – Financial markets | ■ ■ ■ □ □ □ |
| – Regulatory frameworks | ■ ■ ■ ■ □ □ |
| – Centers of excellence and clusters | ■ ■ □ □ □ □ |
| • Business attitude | ■ □ □ □ □ □ |
| • “10-year gap” | ■ □ □ □ □ □ |
| • Lack of all forms of finance | ■ ■ ■ ■ ■ □ |

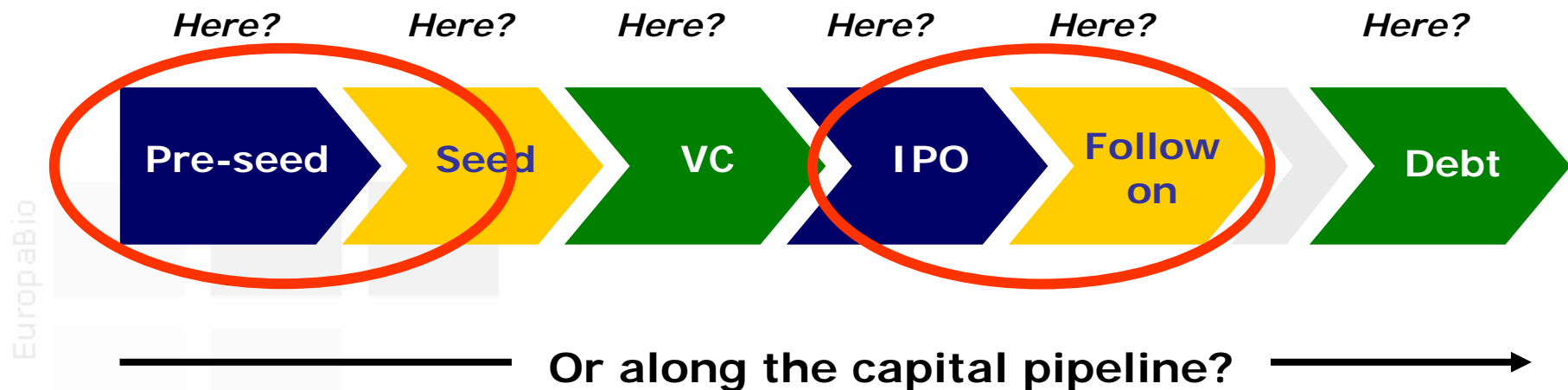
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Overall

*Improving the financial environment for European biotech SMEs to increase their **global** competitiveness*

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But where exactly is the money problem?



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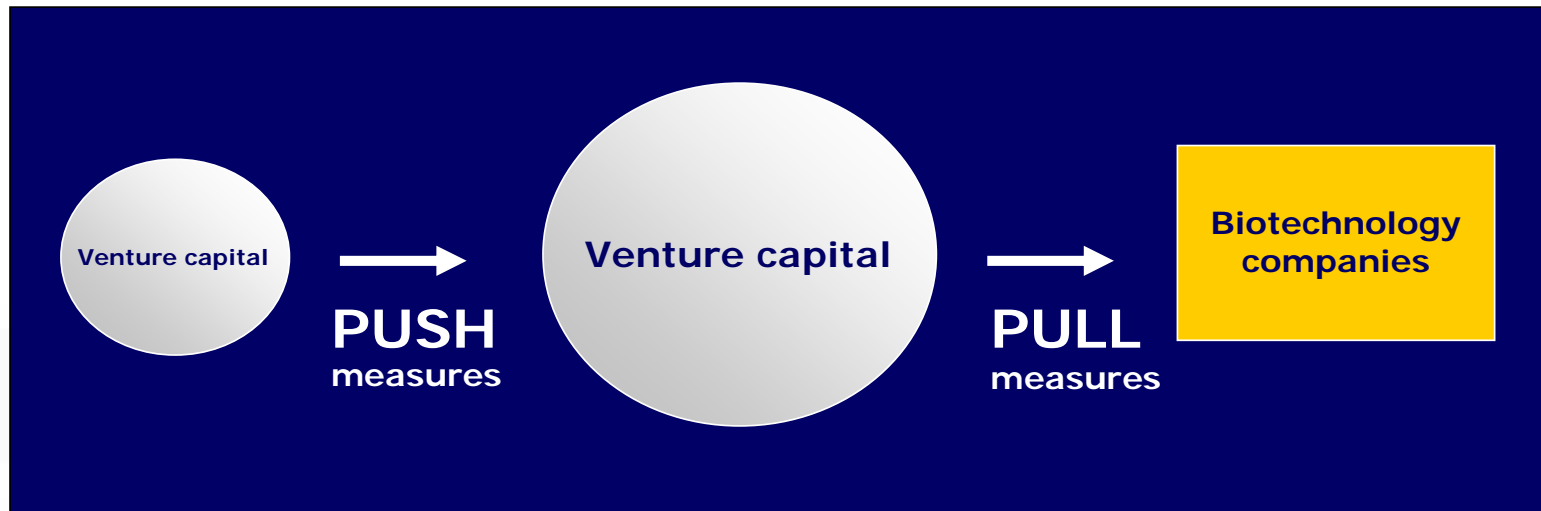
Priorities EEC

Key-remedy: EU-wide IPO market

- Developing a balanced drug portfolio (pre-clinical; Ph I, Ph II) is highly cash intensive (“€100M → € 300M”)
- IPO market is only “independent” avenue to raise this amount of money
- However, European markets highly fragmented, resulting in low liquidity and low market caps
- Underdeveloped European IPO market negatively impacts availability of capital along the capital pipeline
- Consolidation will be key remedy. However, political issues still more important than “economies of scale” effect.

Priorities EEC

Push and Pull strategies



- **PUSH:** aimed at increasing overall availability of capital for European biotechnology companies
- **PULL:** aimed at making European biotechnology companies more attractive for investors to invest in

Priorities EEC

Push and Pull measures

PUSH measures	PULL measures
Increase public spending in R&D: <ul style="list-style-type: none">• CIP• FP7• European Investment Fund	Reduce costs: <ul style="list-style-type: none">• Young Innovative Company status• SME initiative at EPO
Increase spending by institutional investors in the biotech industry: <ul style="list-style-type: none">• Harmonize regulation• Reduce quantitative restrictions	Increase predictability of EU regulatory frameworks: <ul style="list-style-type: none">• Finance• Product approval
Other	Increase critical mass of early stage companies to support future expansion
	Other

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Examples of

PULL measures

- Young Innovative Company status
- SME-initiative at EPO

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Young Innovative Company status

What?

- Fiscal regime based on social cost and tax exemptions
- Allowing companies to invest savings in R&D
- Higher investment in R&D will reduce time-to-market of internal programs and increase productivity
- On short-term, implementation on national level requires initial investment from national governments
- On long-term, tax revenues will significantly increase as new companies and jobs are created
- Resulting in a positive investment balance as well as increased economic growth
- Not only biotech; across all sectors!

YIC status

Criteria and benefits

Criteria

Age < 15 years

R&D expenditures > 15% of total budget

Benefits

- **exemption of 100% on social contributions and other local/regional taxes** (i.e. not linked to profits) for the first 15 years, provided the benefits are reinvested in the company or repayable advances
- **exemption of 100% on tax on revenues** for the first 3 profitable years, of 50% over the next 5 years and of 35% over the next 7 years
- **exemption of 100% on tax on capital gains on shares or stock options** that have been held for a minimum of 3 years
- in addition, the possibility to grant aid of up to €3 million over a 3 year period to a young innovative company, without specific restrictions on eligible costs

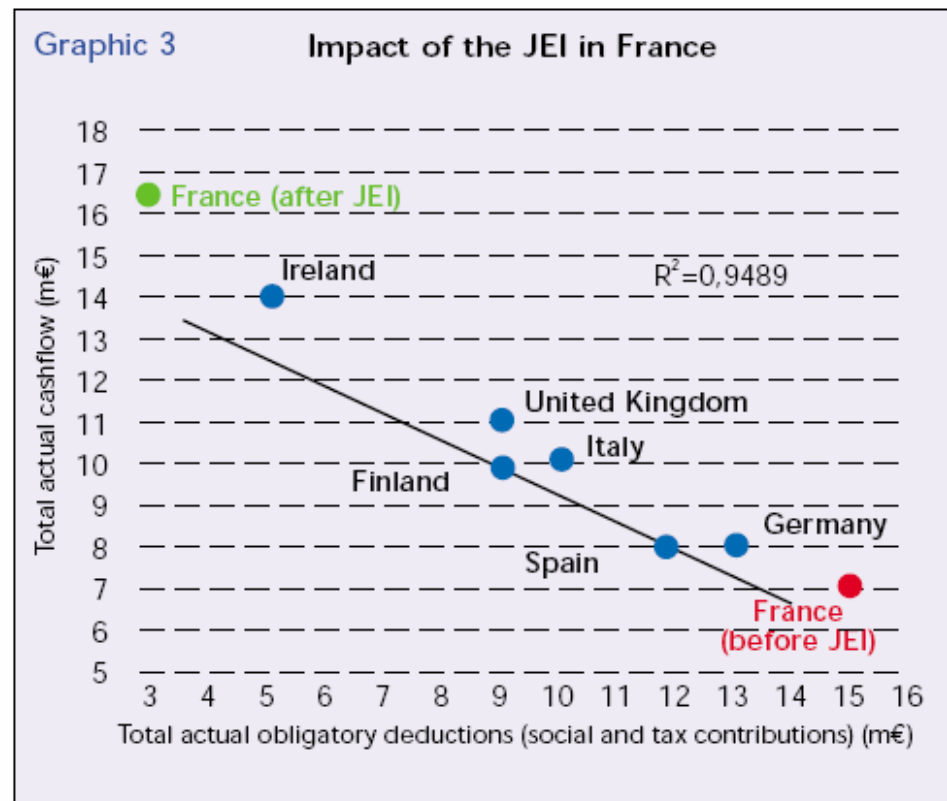
YIC status

Proposal for EU-wide definition

- Implementation of EU-wide definition has two key objectives:
 - Serve as a good practice and inspiration for individual Member States for complete or partial implementation according to national economic standards and/or targeted industries
 - Define a legal framework in which Member States have the freedom to operate (through State Aid rules → ongoing)
- Member States are not obliged to fully implement YIC status
- YIC status should complement existing measures such as the traditional R&D tax breaks
- France first country to implement YIC-based status (2004), Belgium to follow in 2006.

YIC status

France first country to adapt YIC-based regime



YIC status

Very nice... but how much does it cost?

Source: Universities of Pantheon, Sorbonne and Paris XII, and EuropaBio

France: estimated costs / benefits of JEI (€ Million)			
	Year 1	Year 5	Year 10
SOCIAL CHARGES			
- Reference scenario	1016	1869	4429
- JEI scenario	647	2399	9168
Annual gains (+) or losses (-)	-369	+530	+4739
COMPANY TAX			
- Reference scenario	59	108	256
- JEI scenario	22	32	396
Annual gains (+) or losses (-)	-37	-76	+140
INCOME TAX			
- JEI Tax relief	-9	-153	-1677
Capital gains			
- JEI Tax relief	-1	-2	-10
Total Annual gains (+) or losses (-)	-416	+299	+3192

As from year three, positive balance!

YIC status

Contribution to the Lisbon goals

Source: Universities of Pantheon, Sorbonne and Paris XII, and EuropaBio

In blue – situation without the JEI measure			
France: estimate for jobs created with JEI (based on current situation)			
	Year 1	Year 5	Year 10
NO OF INNOVATIVE ENTERPRISES	2800	4460 / 3895 +14%	9985 / 6092 +64%
- Existing	2500	2369 / 2280 +4%	2360 / 2266 +4%
- Newly created	300	2091 / 1614 +30%	7625 / 3826 +99%
NO OF JOBS	58000	135497 / 106799 +27%	731894 / 253062 +189%
- In existing innovative enterprises	55000	85357 / 79220 +8%	183763 / 127244 +44%
- In newly created enterprises	3000	50141 / 27579 +82%	548131 / 125818 +336%

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YIC status

France: one year later

- More than 1,000 SMEs have now adopted YIC status
- Including all biotech SMEs
- More than 6,500 researchers and managers in these SMEs are benefiting from YIC measures
- Average estimated cost saving: €10,000/employee/year
- Examples of companies moving to France:
 - Novexel (infectious diseases), spin-out Aventis Pharma
 - Initially planned to set up business in UK
 - However, due to YIC status venture established in France

SME-initiative at EPO

Reducing the costs

- *“As an alternative to the Community Patent...”*
- Patent costs are often early stage investments, long before revenues are generated to recuperate these investments
- Cost of patenting in EU is significantly higher than in US or Japan
- In 2005, Commission and EMEA (drug approval) installed new provisions for “SMEs” including fee reductions, payment deferrals, translation support, administrative support, etc.
- Industry asks for a similar initiative at EPO to reduce overall patent costs, allowing companies to re-invest savings in R&D such to reduce time-to-market of internal programs and increase productivity

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Examples of

PUSH measures

- European Investment Fund (EIF)
- “Phase III” Project (EIB)
- Institutional investors

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European Investment Fund (EIF)

Continuous dialogue

- EIF is fund-to-fund directly supporting venture capital community, thereby indirectly supporting biotech industry
- EIF also operates through mandates from Commission (e.g. CIP/MAP)
- Given the instrumental role of the EIF, the industry asks for a continuous dialogue to increase the understanding of the objectives, strategy, practices, interests and needs of each of all parties involved (i.e. EIF, VC-firms, Commission, etc.)

“Phase III” Project

Support late stage projects with public money

- Today, it’s almost “mission impossible” for biotechs to build a truly balanced pipeline, including phase III compounds
- Many companies are not able to grow further on global level and are becoming cheap targets for acquisitions by US and EU Big Pharma companies
- Explore ways where public financial instruments can be structured such to directly or indirectly support late stage product development
- Possible mandate for European Investment Bank (EIB)

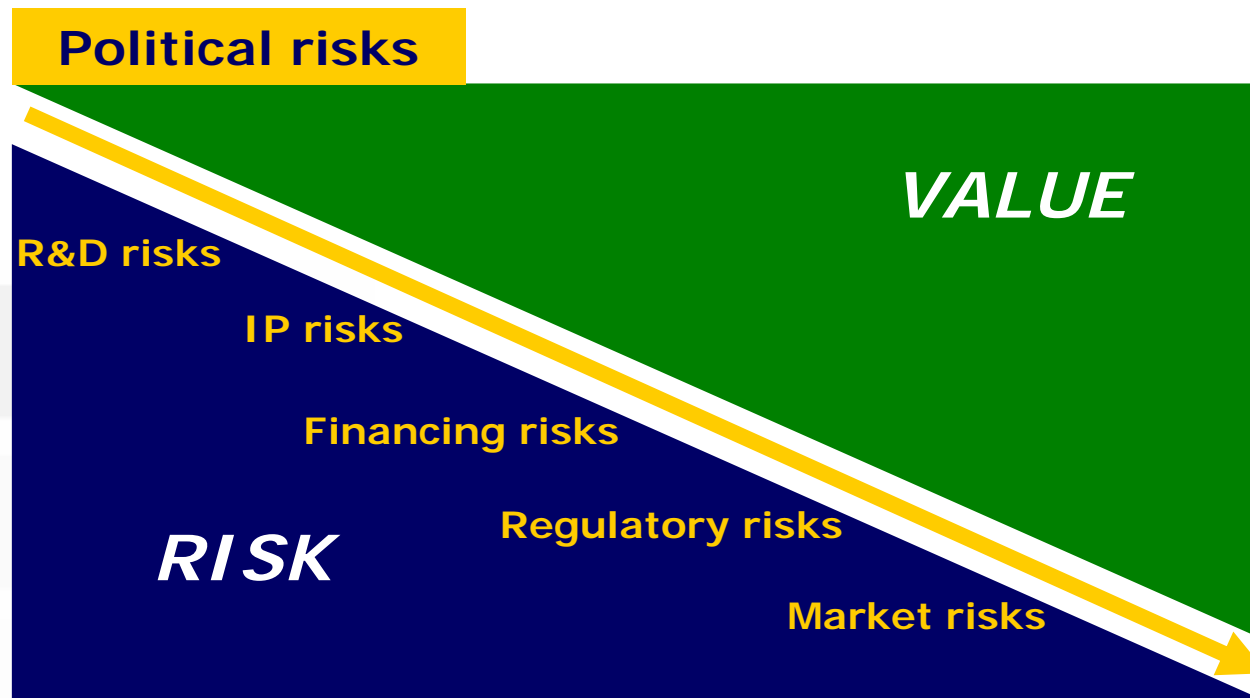
Institutional Investors

Increase spending in high-risk equity

- Clear correlation between status of institutional sector, and overall availability of (late stage) venture capital and of equity based trading activities in listed companies with high-risk profiles
- US sector far more developed than most part of Europe
- Fragmented regulation across Europe (“quantitative regulation” versus “prudent man”)
- Industry asks for measures to increase investments in high-risk equity to at least similar levels as in US, and for harmonization of regulatory framework across Europe

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Political risks



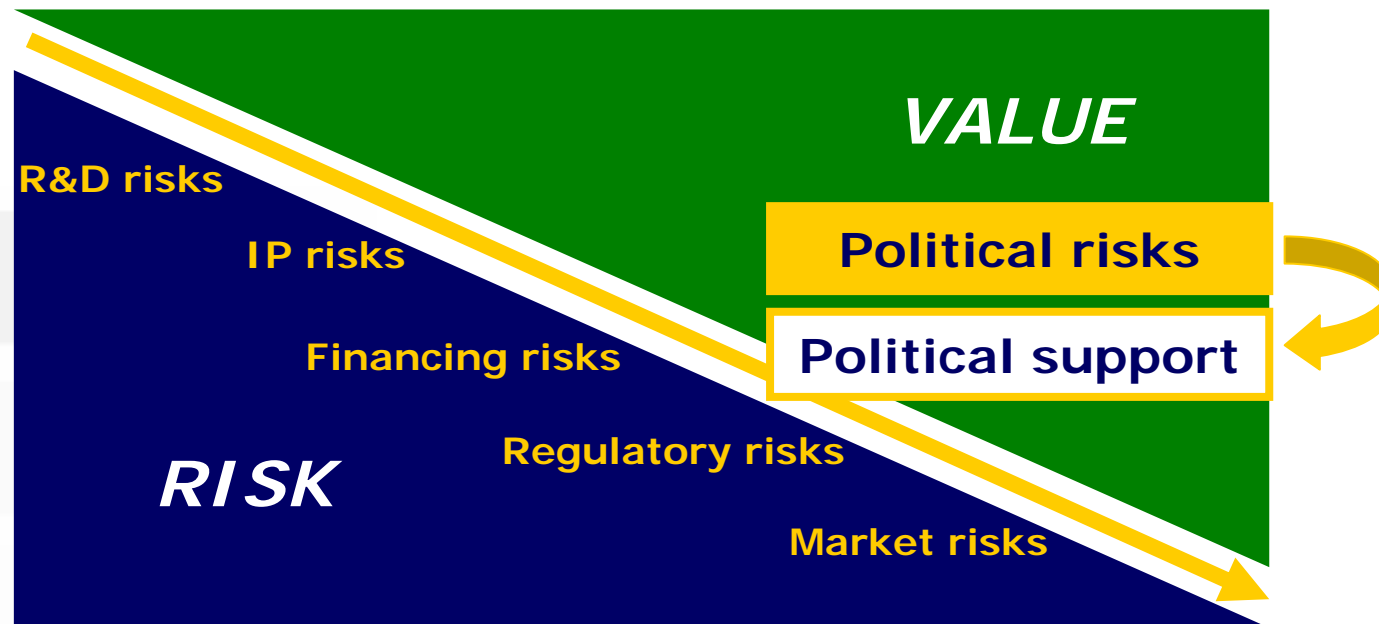
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TIME

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Turning political risks in political support



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The chicken and the egg



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Lisbon, we have a problem!

