

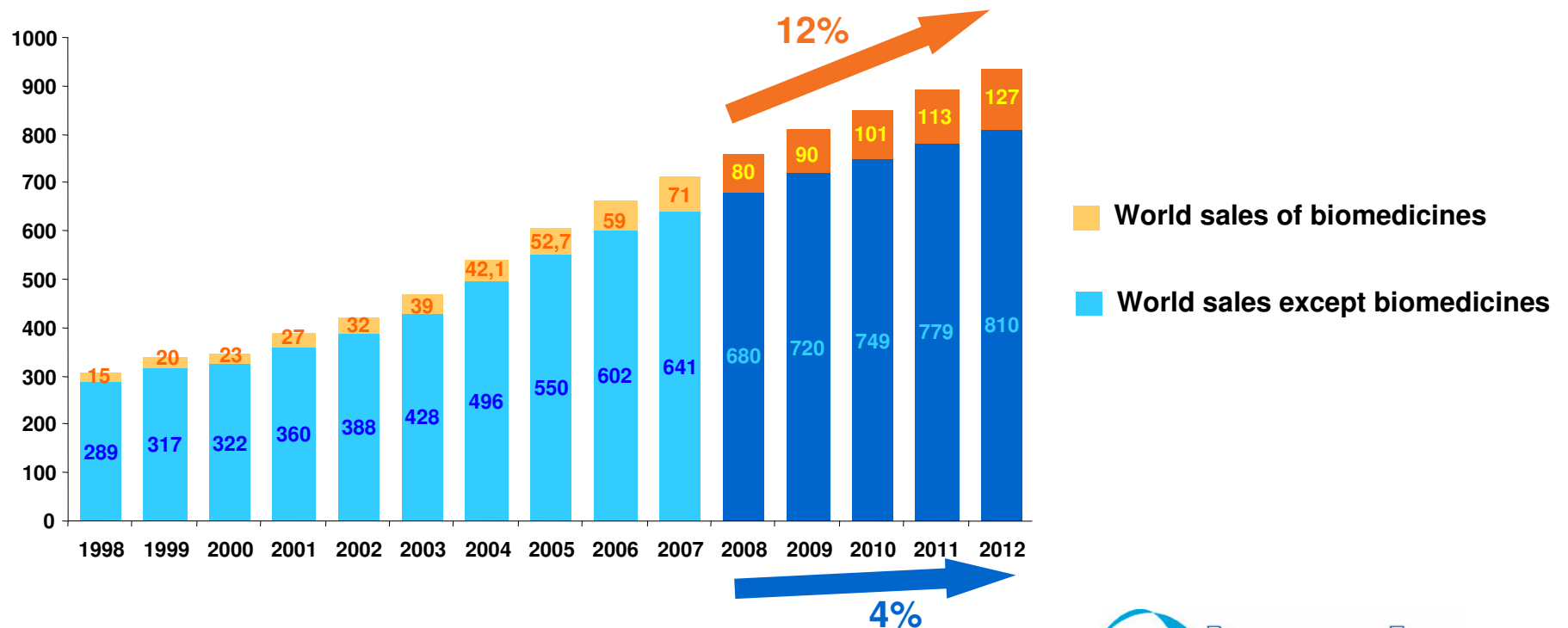
***Biomanufacturing 2008: a review of  
the state of the art in France and  
recommendations for improving  
the country's attractiveness***

*A national issue to support France  
in the world competition of  
medicine*

- **Weight of biomedicines in the pharmaceutical industry will increase from 10% to more than 15% between 2007 and 2012**

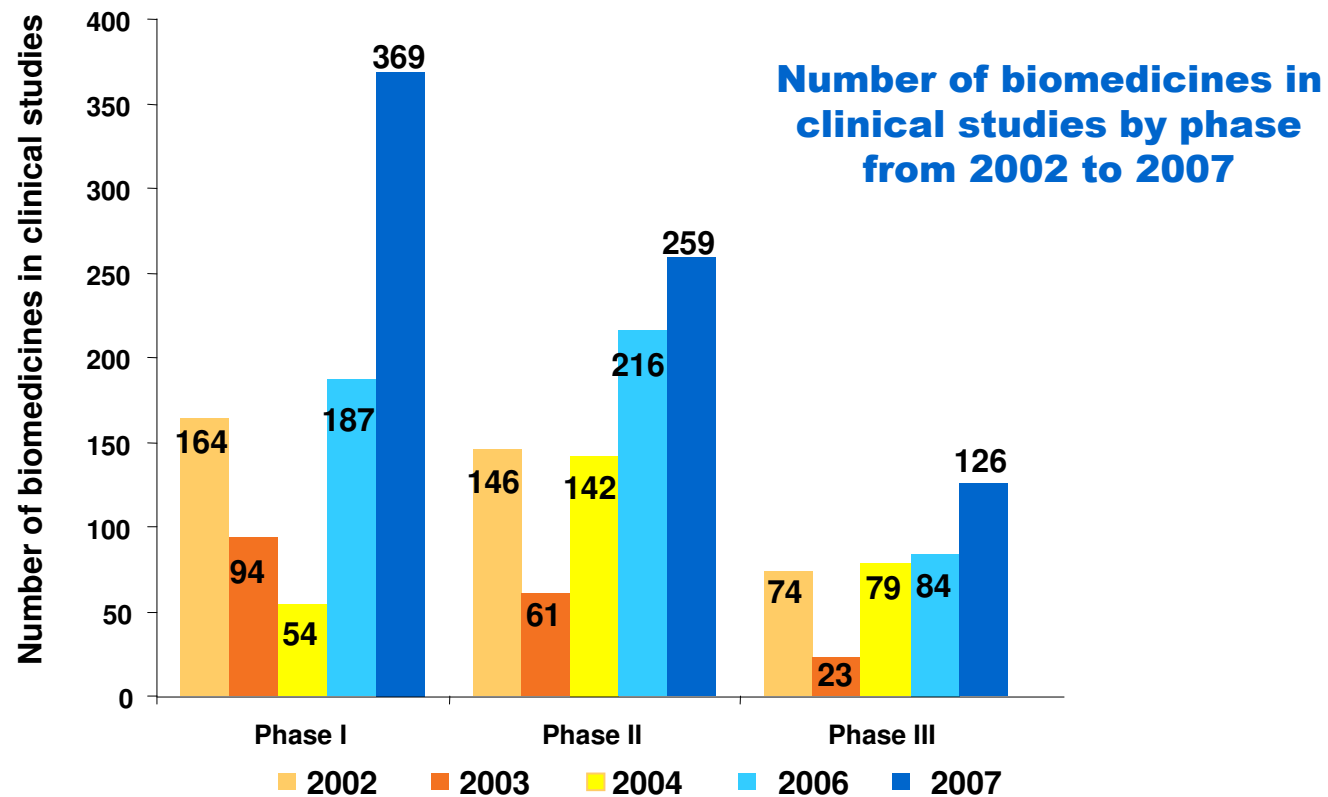
## Perspective of the biomedicine world market over the period 1994 -2007

World sales (Mds\$)



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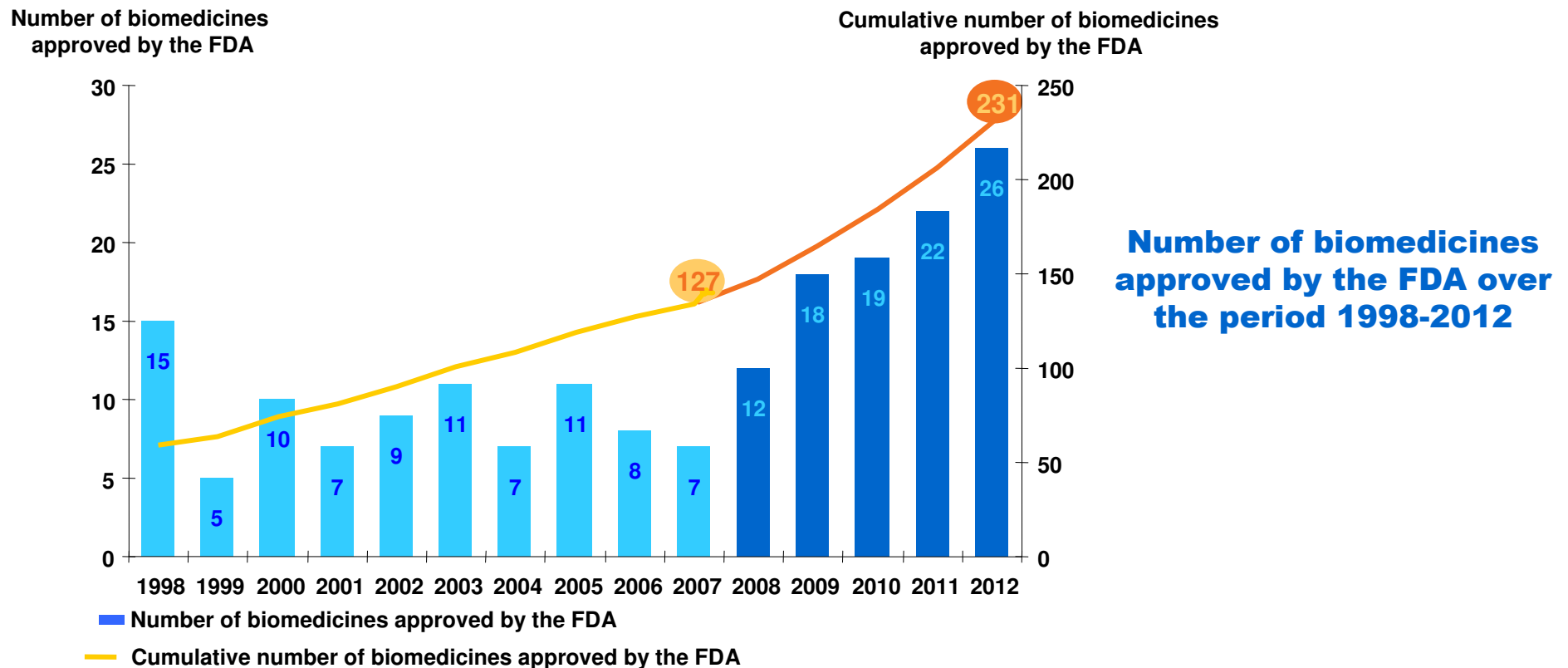
- **An important number of biomedicines in phase 1 clinical studies in 2007**



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# Trends in the launch of new biomedicines on the market and perspectives

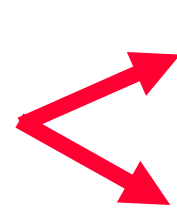
- **104 new biomedicines should be marketed before 2012**



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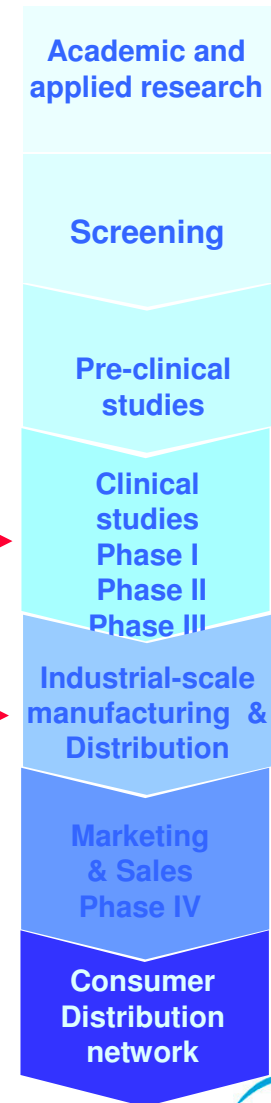
# The biopharmaceutical industry relies on 2 key stages of production

Important stages  
of  
biomanufacturing  
of the active  
pharmaceutical  
ingredients  
(« bulk »)



**Clinical-scale**  
biomanufacturing

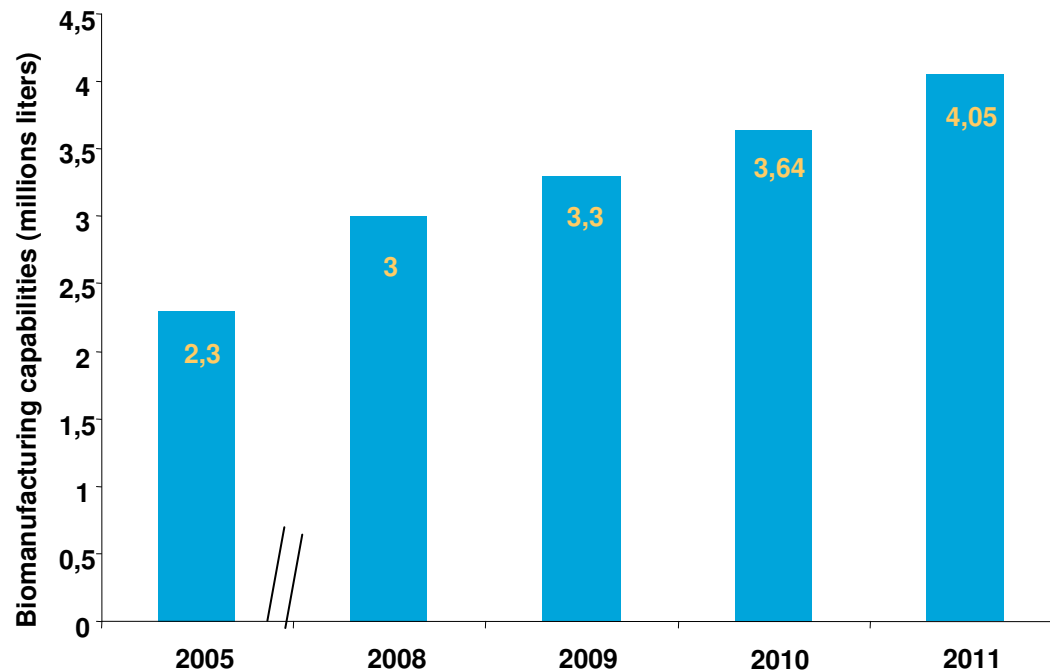
**Industrial-scale**  
biomanufacturing



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- **In 2008, the world total capacity reaches about 3 million liters**
- **Strong growth forecast in the biomedicine world market**

## Evolution of world biomanufacturing capabilities between 2005 and 2011



**Between 2008 and 2011, potential increase of 25% of the biomanufacturing capacities corresponding to :**

- *1 million additional liters,*
- *investments of 10 billions €*

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# World investments for openings of industrial-scale biomanufacturing units over 2009-2012

- **Similar amount of forecast investments on the 3 zones : North America, Asia and Europe**
- **But strong growth in the construction of new industrial-scale biomanufacturing units in Asia,**
- **Half of the forecast units will be built in Singapore**



**Investments by  
geographical  
zone (Billions €)**

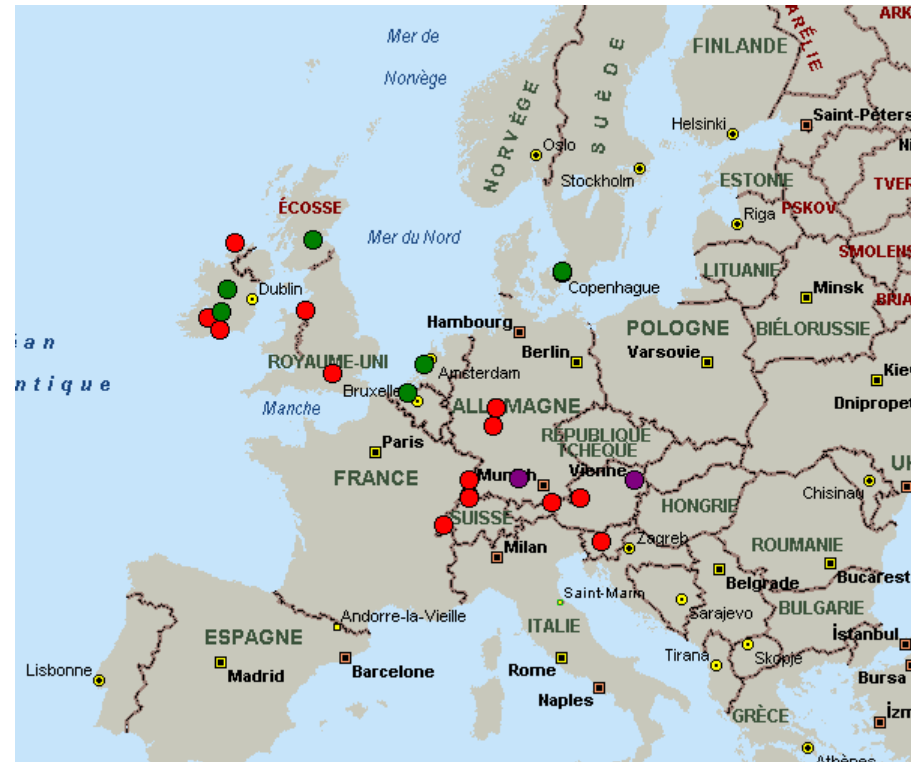
■ Construction  
■ Extension

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**Industrial-scale biomanufacturing units set up preferentially in the countries which possess a powerful biotechnology R&D sector and a developed clinical-scale biomanufacturing with capabilities from pre-clinical-scale to phase III clinical scale biomanufacturing**



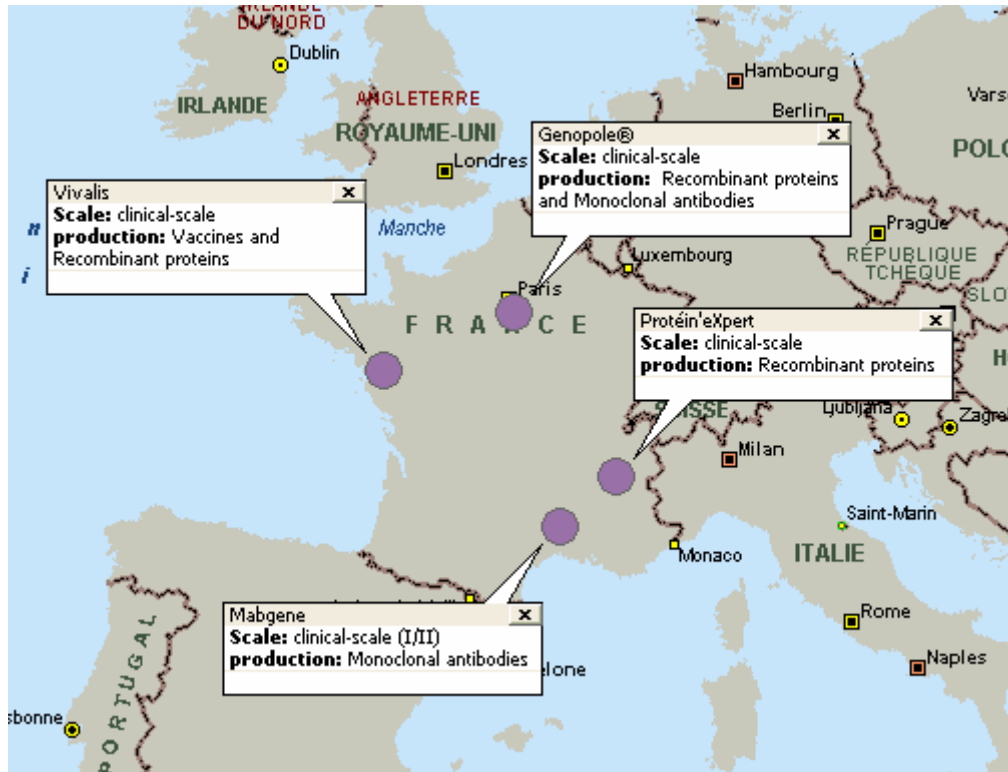
**Cartography of clinical-scale biomanufacturing units in Europe in 2008**



**Cartography of industrial-scale biomanufacturing units in Europe since 2003**

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# Clinical-scale biomanufacturing in France



Only three GMP sites of biomanufacturing with limited capabilities in France, corresponding to a total of 500 l of batch culture in bioreactor

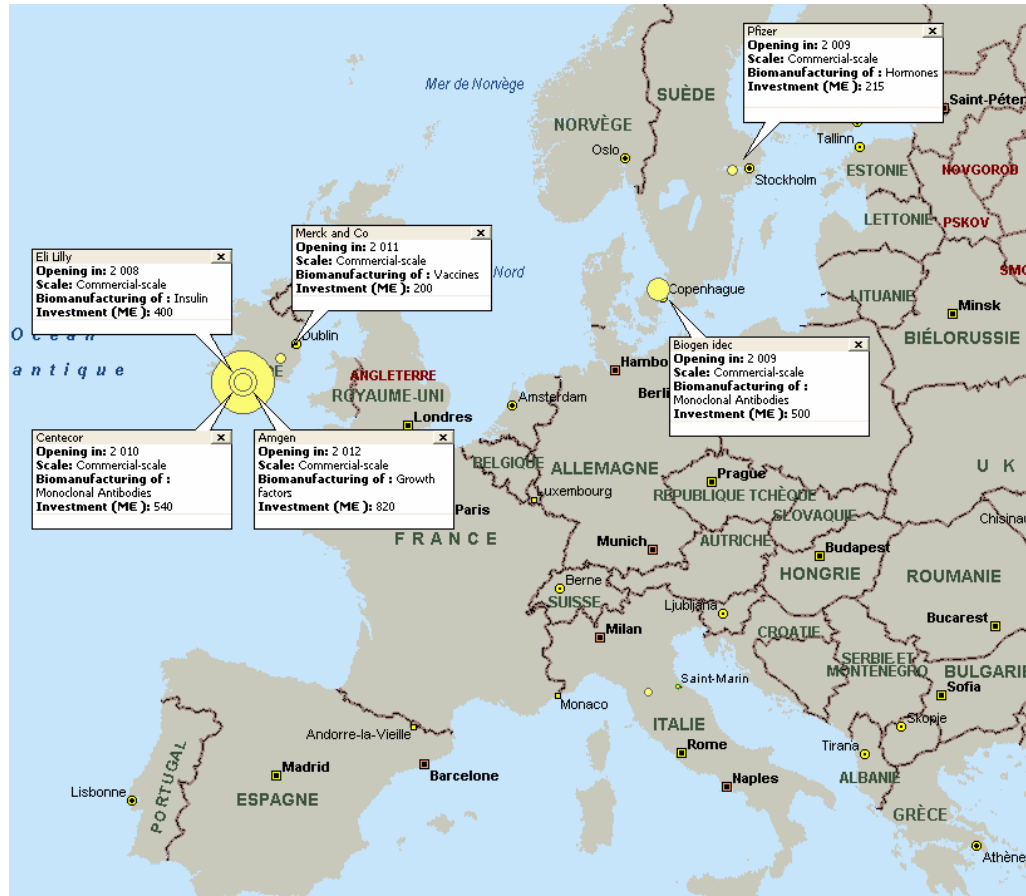
➤ Impossibility for a company to subcontract, on the same site, the biomanufacturing of the preclinical-scale up to the phase III clinical-scale

➤ Many companies prefer to produce straightaway in another european country

The opening of the biomanufacturing center of Evry will fulfill this deficiency from 2009. Foreseen capacity of 1500 liters

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# New industrial-scale biomanufacturing units in Europe



In Europe, seven new units under construction

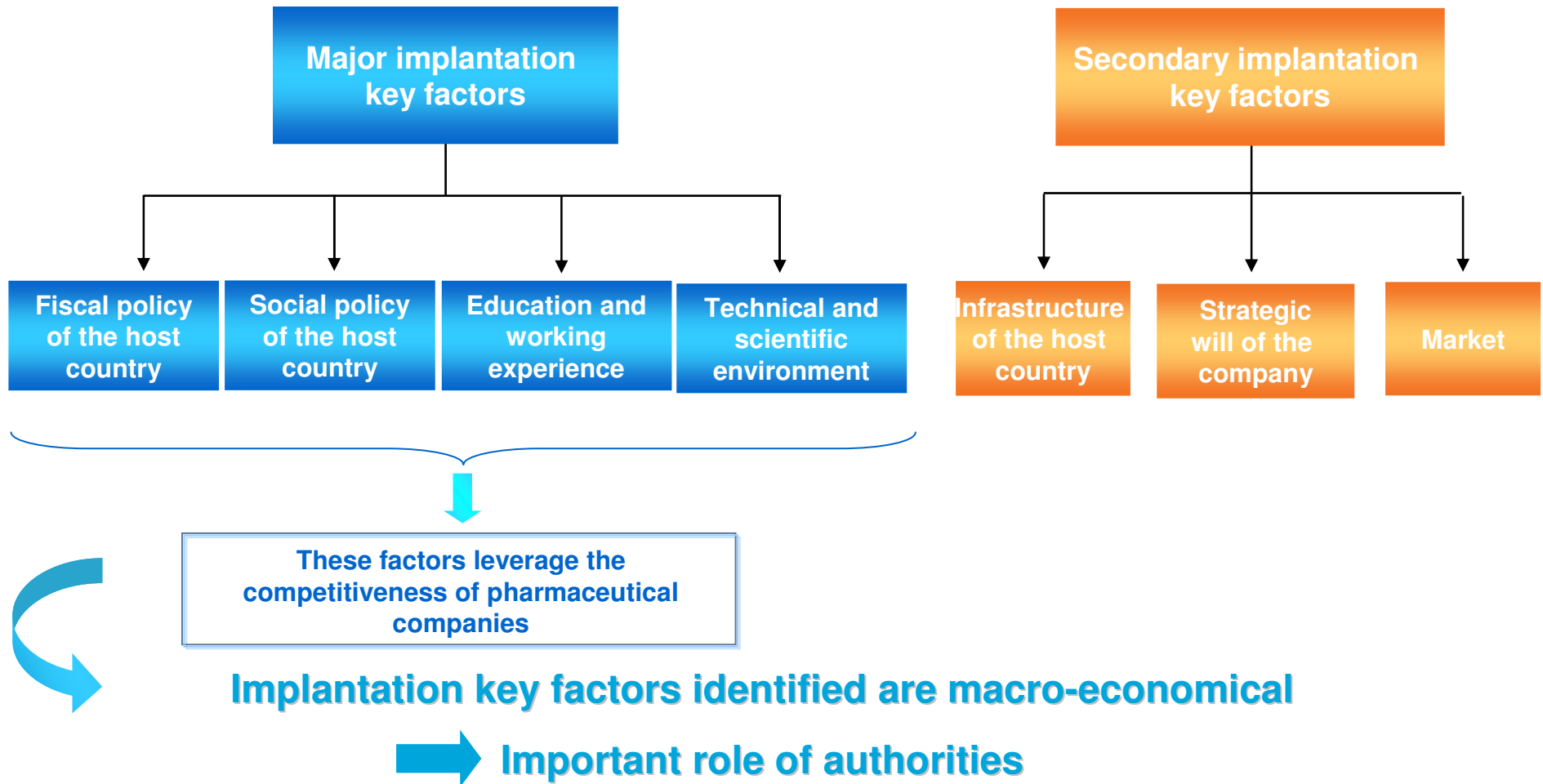
No project in France,  
until 2011

- 4 in Ireland : Eli Lilly (2008), Centecor(2011), Merck (2011), Amgen (2012)
- Pfizer in Sweden
- Biogen in Denmark
- Eli Lilly in Italy (2009)

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# How to attract in France the forthcoming investments in industrial-scale biomanufacturing?

# Implantation key factors for the industry stakeholders



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# Recommendations for reinforcing France's attractiveness

*Christian Lajoux*  
*Président of Entreprises  
du Médicament*

***It's necessary to assure the sanitary independence of France by protecting biological molecules from Research to industrial-scale Biomanufacturing***

- 1. To protect clinical-scale biomanufacturing in France**
- 2. To promote the creation of new industrial-scale biomanufacturing units in France**
- 3. To support a national public / private partnership research on bioprocess**
- 4. To develop education and specific competencies**

***It's necessary to assure the sanitary independence of France by protecting biological molecules from Research to industrial-scale Biomanufacturing***

**1. To protect clinical-scale biomanufacturing in France**

***Create a fund to support clinical-scale biomanufacturing and to promote the continuity of preclinical-scale to preindustrial-scale in the respect of a continuous process, avoiding the risk and the cost of a technological transfer***

***It's necessary to assure the sanitary independence of France by protecting biological molecules from Research to industrial-scale Biomanufacturing***

**2. To promote the creation of new industrial-scale biomanufacturing units in France**

***To set up fiscal incentive to facilitate new implantations :***

***By the creation of “free industrial zones“ particularly in health clusters***

***By access to the “credit impôt-recherche” for firms having a research program on bioprocess.***

***To allow companies, who wish to subcontract biomanufacturing, to produce the biomedicine in France, by supporting common platforms***

***It's necessary to assure the sanitary independence of France by protecting biological molecules from Research to industrial-scale Biomanufacturing***

**3. To support a national public / private partnership research on bioprocess**

***In close collaborations with the major suppliers and the french pharmaceutical companies :***

- ***New cell line development,***
- ***Optimization of the biomanufacturing phase, in order to decrease the biomedicine cost,***

***It's necessary to assure the sanitary independence of France by protecting biological molecules from Research to industrial-scale Biomanufacturing***

**4. To develop education and specific competencies**

- ***To offer actionable competencies to industrial actors .:***
  - **To provide formation organisms with “GMP like” pilots, allowing them to acquire hands-on experiences**
  
- ***To integrate additional programs into education :***
  - **Authorize other persons than the pharmacists to supervize batch delivery (in compliance with appendix 16 of EU GMP and articles 48 - 53 of the 2001 / 83 / CE directive)**

Find the study Biomanufacturing 2008 on  
Web :

[www.leem.org/espace biotech](http://www.leem.org/espace_biotech)

[www.leem-recherche.org](http://www.leem-recherche.org)

[www.genopole.fr](http://www.genopole.fr)