



# ***The experience of biotech SMEs with Commission Regulation (EC) No 2049/2005 (SME Regulation)***

***European Medicines Agency roundtable with stakeholders  
on the 10-year anniversary of the SME Office***

***27 November 2015, London***

***Miriam Gargesi  
Director, Healthcare Biotechnology***



The European Association for Bioindustries

# We Represent 3 Industry Sectors



## INDUSTRIAL BIOTECH

Saves **33 million tonnes** of CO<sub>2</sub> emissions.

Equivalent to the energy use of 2.5 million homes per year



### Greener transport

thanks to biofuels, rubber tyres, bioplastic parts



### More effective detergents

allow to save up to 30% of the electricity used on laundry by washing at 30°C



### Materials



(including plastics) made from renewable resources instead of fossil fuels



## HEALTHCARE BIOTECH

**350 million patients**

already benefiting from treatment



Relieving **20 to 30 million** rare disease patients

**20% → 50%**  
(now) (2015)  
of all medicines



### Targeted treatments

for many diseases



Insulin, Factor VIII coagulant for haemophiliacs, antibodies for cancer, orphan medicinal products for rare diseases, vaccines, advanced therapies that repair organs, skin, bones and cartilage damage



## AGRICULTURAL BIOTECH

**18 million**

farmers globally on



**175 million** hectares



**Built-in protection** against insects

**Less fuel and CO<sub>2</sub>**



Equivalent to **7.8 million** less cars



**Reduced soil erosion**



**6% to 30%**



**more yield**

**Less toxins in food**

# Healthcare Biotech



EuropaBio represents 77 corporate/associate members/bio regions and 16 national biotechnology associations in turn representing over 1800 biotech SMEs developing medicines, vaccines and diagnostic tools using biotechnology in their development or manufacturing processes.



## HEALTHCARE BIOTECH

**350 million patients**  
already benefiting  
from treatment



Seeking to relieve  
**20 to 30 million**  
rare disease patients

**50%**

of all medicines will  
come from biotech in 2015



**Targeted treatments**  
for many diseases



Insulin, Factor VIII coagulant for haemophiliacs, antibodies for cancer, orphan medicinal products for rare diseases, vaccines, advanced therapies that repair organs, skin, bones and cartilage damage

# Healthcare Members

## Biopharmaceutical Companies



## Associate Members: Academia, Healthcare Industry Service Providers & Investors





# EuropaBio National Associations Council

- Cohesion of lobbying outreach throughout the Member States
- 16 National Biotech Associations across Europe representing over 1800 biotech SMEs:

|                                                            |                                                         |
|------------------------------------------------------------|---------------------------------------------------------|
| Belgium   <a href="#">Bio.be</a>                           | Denmark   <a href="#">Dansk Biotech</a>                 |
| Finland   <a href="#">FIB</a>                              | France   <a href="#">France Biotech</a>                 |
| Germany   <a href="#">BIO Deutschland</a>                  | Germany   <a href="#">DIB</a>                           |
| Ireland   <a href="#">IBIA</a>                             | Italy   <a href="#">Assobiotec</a>                      |
| Lithuania   <a href="#">Lithuanian Biotech Association</a> | The Netherlands   <a href="#">HollandBIO</a>            |
| Norway   <a href="#">Norwegian Bioindustry Association</a> | Spain   <a href="#">ASEBIO</a>                          |
| Sweden   <a href="#">SwedenBio</a>                         | Switzerland   <a href="#">Swiss Biotech Association</a> |
| Switzerland   <a href="#">scienceindustries</a>            | United Kingdom   <a href="#">BIA</a>                    |

# EuropaBio SME Platform

- A platform to propose and shape policies supporting the development of SMEs and facilitate access to finance.
- Members of the platform include CEOs of SMEs, National Biotech Associations, Venture Capitalists and private banks, European financial institutions, representatives from the EC, and other interested stakeholders.

***A word from the Chair of the SME Platform (Tom Saylor, CEO of Arecor)***

*“EuropaBio is actively working to improve access to financial resources and assure a policy climate which provides a sustainable pathway to creating value in Europe for biotech entrepreneurs and SMEs.”*

# Satisfaction with EMA's current SME program

- High level of satisfaction:
  - Fee incentives
  - Support of EMA staff during the process of product registration
  - Assistance with translation of the product information required for the granting of a MA

# Suggestions for the future

- Create more opportunities for providing SMEs with advice on administrative and procedural steps
- Introduce flexibility in the SME categorisation (2003/361/EC) to broaden the access to non-financial incentives
- Amplify the services of the EMA SME Office via National Biotech Associations
- Create SME offices at national level
- Enhance visibility for the SME initiative on the EMA website (e.g. separate tab)



# Any Questions?



Contact:

**Miriam Gargesi**

Director, Healthcare  
Biotechnology

Tel. +32 2 7391183

Email: [m.gargesi@europabio.org](mailto:m.gargesi@europabio.org)

**EuropaBio**

Avenue de l'armée 6

B-1040 Brussels

[www.europabio.org](http://www.europabio.org)