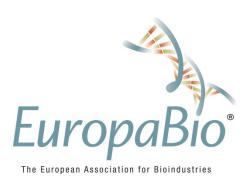


The experience of biotech SMEs with Commission Regulation (EC) No 2049/2005 (SME Regulation)

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

27 November 2015, London

Miriam Gargesi Director, Healthcare Biotechnology





We Represent 3 Industry Sectors



INDUSTRIAL BIOTECH

Spares 33 million tonnes

of CO2 emissions. Equivalent to the energy use of 2.5 million homes per year



Greener transport

thanks to biofuels, rubber tyres, bioplastic parts



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% of all medicines



Targeted teatments

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











30%



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 Bio.be	Denmark Dansk Biotech
Finland FIB	France France Biotech
Germany BIO Deutschland	Germany DIB
Ireland IBIA	Italy Assobiotec
Lithuania Lithuanian Biotech Association	The Netherlands HollandBIO
Norway Norwegian Bioindustry Association	Spain ASEBIO
Sweden SwedenBio	Switzerland Swiss Biotech Association
Switzerland scienceindustries	United Kingdom BIA



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?



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