



RECOMMENDATION  
& DISCUSSION

# BIOTECHNOLOGY IN THE NEW EU MEMBER STATES: AN EMERGING SECTOR

## Development of recommendations

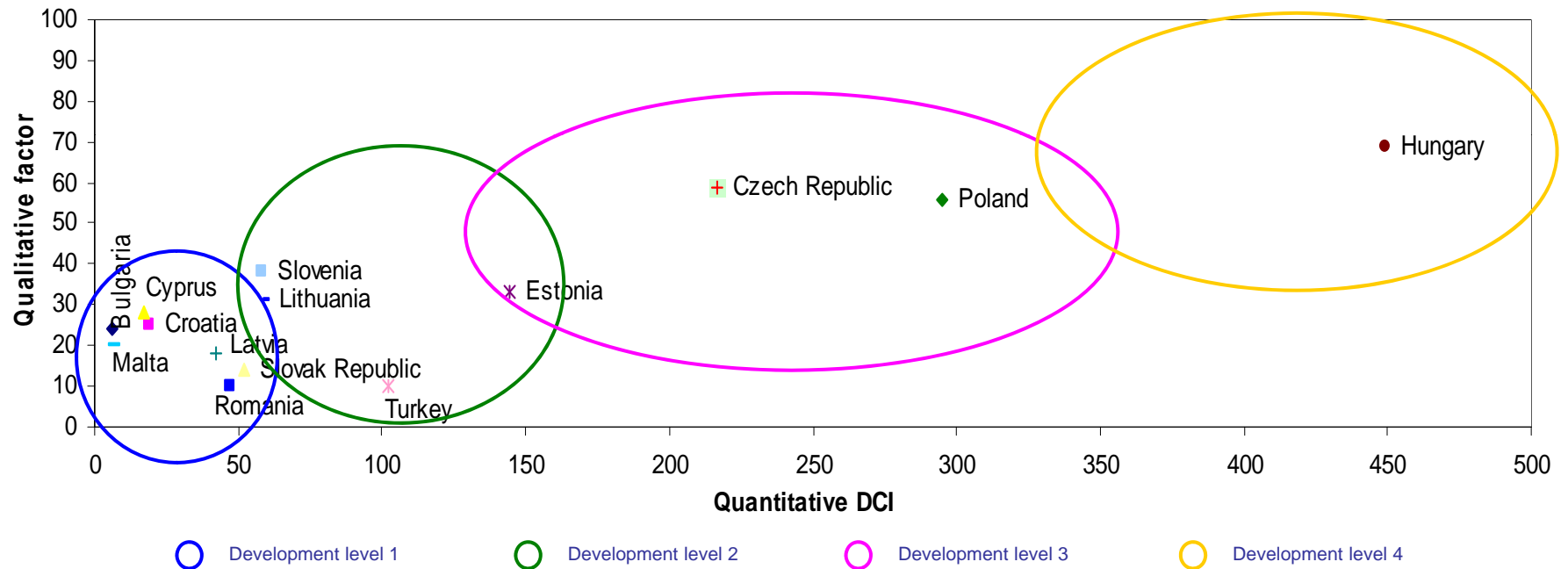
- Draft recommendations based on
  - EuropaBio experience of SMEs at European level
  - discussions with national partners, and other stakeholders in the 14 new EU Member States
  - feedback/ interviews of biotech companies
  - existing studies, literature
- Discussions at 3 workshops: Hungary, Lithuania and Czech Republic
- Final presentation in Brussels

# Structure of recommendations

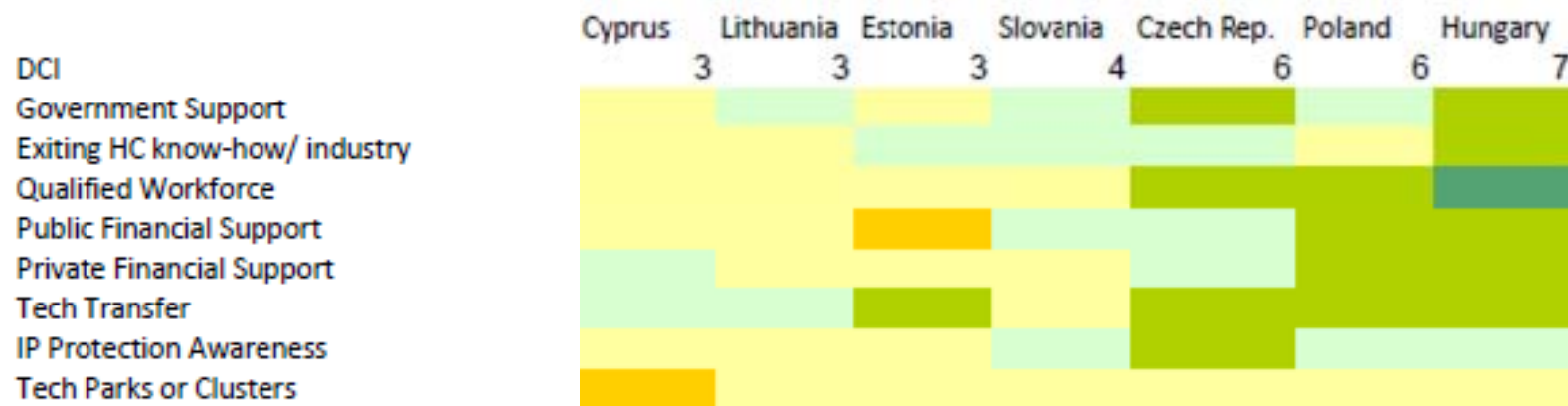
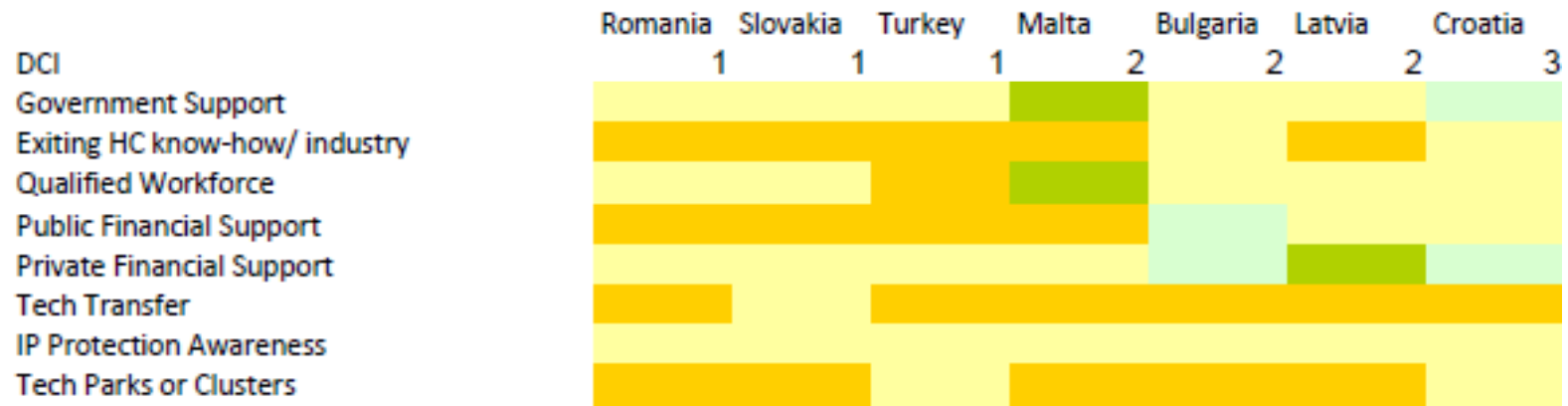
- Countries studied face very diverse situations (historical, economic) and status of biotech development
  - Four level of developments
- No 'one-size-fit-all' recommendations
- No magic wand to develop the biotech sector
- Four key aspects are covered:
  - Skills and knowledge development
  - Funding (availability, awareness and access)
  - SME/Innovation support infrastructure
  - IP and technology transfer

# Development levels - DCI

## Development Capacity Index



# Qualitative factor



# Skills & Knowledge development –

Some key recommendations

- Strong political commitment for biotech R&D&I
- Dedicated biotech R&D plans, not just high-tech or innovation
- Management skills programmes for entrepreneurs
- Reintegration programme after training/ experience abroad
- Promote international cooperation (e.g. FP7)
- Foster cooperation between industry & academia (joint projects, training etc)

# Funding availability, awareness, access –

## Some key recommendations

- Use EU State Aid rules for SME financing (R&D&I exemption, support access to finance)
- Encourage private (FDI, banks, VCs) investment to SMEs (e.g. EIB co-investment with VCs or guarantee of bank loan)
- National coordination service or info point to provide info and advice on the different national and EU funding
- Improve access of SME to
  - National programmes (e.g. web-based application, timing of evaluation and payments)
  - EU FP7 (cut red tape, delay of payment; SME specific calls)

# SME & Innovation Support structure –

Some key recommendations

- Promote the implementation of the Small Business Act and adoption of the YIC status
- Encourage the creation of biotech/ life science technology parks, incubators
- Create healthcare biotech clusters to generate critical mass and visibility at EU/international level
- Create ‘one-stop shop’ to provide info for SME on legislation, administrative support, funding or incentives opportunities
- Promote existing EU advice structure (e.g. EMEA SME office)

# Intellectual Property and Tech transfer –

## Some key recommendations

- Establishment of a legal framework for IP
- Implement EU IPR strategy (2008)
- Communicate about Europe-wide source of help (e.g. InnovAccess)
- Ensure national legislation makes patenting accessible (costs, administration, ownership)
- Promote benefits of patent and IPR
- Create tech transfer offices linked with major universities

## Implementation - What next?

- European actions
  - EuropaBio SME platform
  - Brussels Day (1-2 Dec 09): 'Meet the MEPs and Commission'
- National action through the Hungarian Biotech Association

# Access to finance: a call for action



## SME Platform

### Access to Finance: A Call for Action

27 May 2009

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## The Financial Crisis and Biotech SMEs: Time for Action

Small and Medium-sized Enterprises (SMEs) are a pipeline to create innovative and sustainable biotech products and processes. Cutting the pipeline of this strategic industry will have repercussions – both the EU and industry will suffer if we do not find a way to secure investment in biotech innovation, a sector which could lead the economic recovery.

#### Why should we worry about SMEs?

- In the EU, SMEs comprise approximately 99% of all firms and employ about 75 million people. In many sectors, SMEs are also responsible for driving innovation and competition. Globally, SMEs account for 40% to 50% of GDP.
- Biotech SMEs are knowledge-based enterprises and provide the jobs that will help the EU achieve its goal of becoming a knowledge-based economy.

#### How hard are Biotech SMEs hit by the financial crisis?

- According to recent figures published, around 20% of Europe's biotech companies, the overwhelming majority of which are SMEs, could be gone within the next year if no immediate action is taken.

#### Why is there such a big impact on biotech SMEs?

- The EU is working hard to develop policy tools to assist SMEs through the financial crisis, but those that have emerged or been announced so far are poorly suited to deal with the specific situation for biotech SMEs or are not being implemented effectively at national level.



- Young, innovative biotech SMEs are often pre-profit for many years due to the high levels of investment for R&D and product trials needed to develop a biotech product. This means that biotech SMEs need significant levels of funding to develop a product before commercialization. Even before the financial crisis, funding a new product often proved insufficient. This situation has now been further aggravated.
- Most biotech SMEs are funded by capital, rather than by cash flow. This means that when sources of capital dry up, as has happened in this current crisis, day to day funding for the biotech company concerned also vanishes.

More than 1 in 4 of small biotech firms have less than 6 months cash in hand, and 45% of the publicly traded biotech SMEs have less than 1 year's cash available. These firms rely on private equity sources for continuous growth funding, but the current financial crisis has made access to capital very difficult.

VCs are one of the primary sources for risk investments in biotech start-ups, but the VC investment is declining, by almost 57% in 2008 compared to 2007. All forms of investment (including VC) raised by biotech firms decreased by 54% for the first nine months of 2008, compared to the previous year.

#### The healthcare sector as an example...

For the last 5 years, larger biopharmaceutical companies have tended to place greater reliance on external R&D, mostly performed by emerging SMEs. These externally-initiated programmes now represent as much as 30% to 50% of the pipeline for many major companies. If these SMEs do not survive then the R&D and potentially life saving treatments will either disappear or be significantly delayed, resulting in fewer innovative treatments to further develop, and finally to fewer treatments for patients in dire need.



# Overview of the recommendations

- Make the EU funding instruments more accessible to biotech SMEs
- The European institutions such as the EIB should develop a short term investment vehicle to increase risk capital for VCs (in time of crisis)
- Make maximum use of the European State Aid rules in these difficult times
- Develop measures and opportunities to capture the value of research within Europe
- Make the EU Framework Programme for Research more attractive for (biotech) SMEs