



# **SME Policy**

## **EMA roundtable - London**

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SMEs – Unit H1 COSME Programme, SME Envoys (SME Policy)**



# European Commission SME policy

- *Small Business Act and Think Small First*
- *Refit and Better Regulation*
- *Single Market Strategy*
- *COSME*
- *Other initiatives*
- *DG GROW legislation in pharma/medical sector*



# The “Small Business Act”

- Adopted in June 2008
- Main objective: create a common framework for SME initiatives and implement the “Think Small First” principle
- 10 principles and a set of policy actions to implement them
- Exchange of good practices

# SBA Review and open consultation

- **Priority areas (2011):**
  - smart regulation
  - access to finance
  - access to markets
  - Entrepreneurship
  - Skills development (2015)
- **Enhanced governance**
  - SME envoys (MS) represent SMEs - acting as watchdogs for EU policy making and exchanging best practices in the network
- **SME assembly**
  - Includes SME representatives and associations

# SME Performance Review on the 10 principles

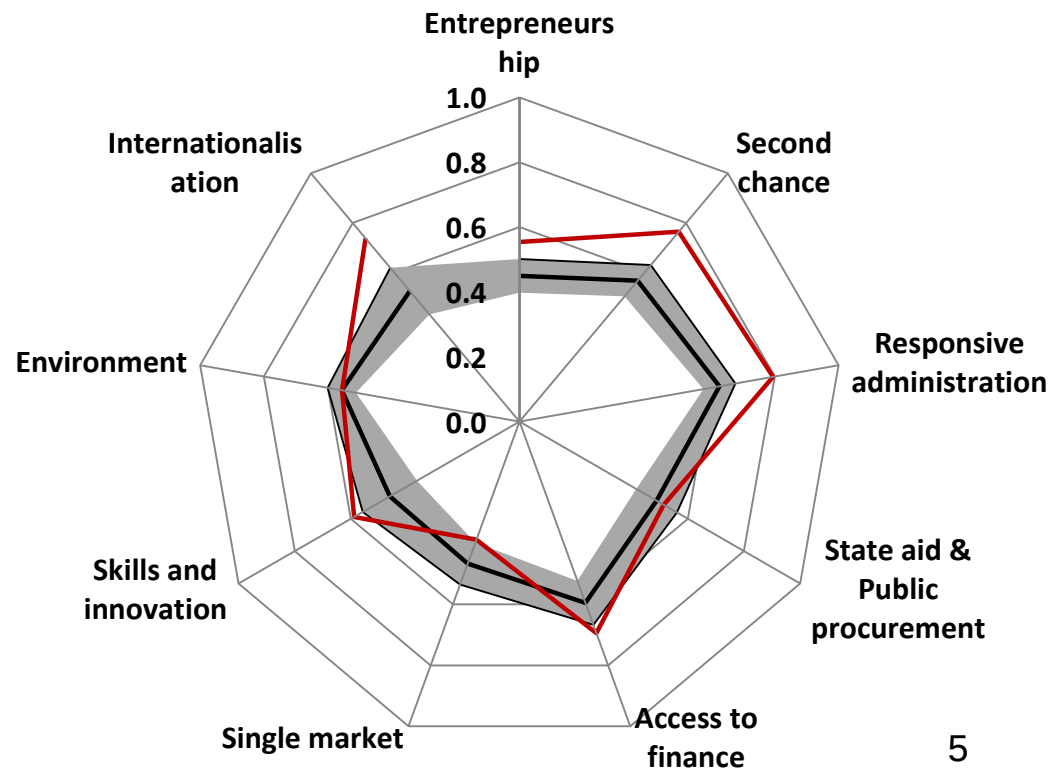
Annual Report – situation of  
SMEs in the entire EU

SBA country fact sheets –  
benchmark country  
performance vs EU average

Thematic studies:  
- subcontracting  
- labour market

□ EU average +/- 0,5 standard deviations

■ Finland



# Think Small First

Simplifying the regulatory and administrative environment for SMEs



## **1. Public administration responsive to SMEs' needs**

- e-government solutions
- 'only once' principle
- common commencement dates

## **2. Impact assessment for new legislation**

- exemptions for micro-enterprises
- SME Test

# Refit and Better Regulation

- not deregulation or amount of EU legislation, but better rules for better results
- provides a basis for timely and sound policy decisions, does not replace political decisions
- applies throughout the law-making cycle and builds on progress made with Impact Assessment and REFIT
- focuses on more transparency and stakeholder involvement throughout the legislative process

# Better regulation

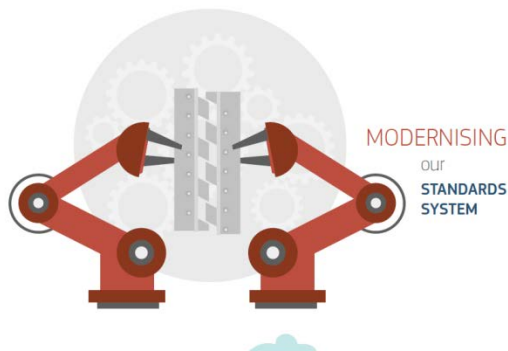


- a Communication on 'Better Regulation for Better Results – an EU Agenda'
- an Inter-Institutional Agreement on Better Regulation with the EP and the Council
- revised Better Regulation Guidelines and accompanying toolbox
- Regulatory Scrutiny Board
- REFIT Stakeholder Platform
- updated results on the REFIT scoreboard



European  
Commission

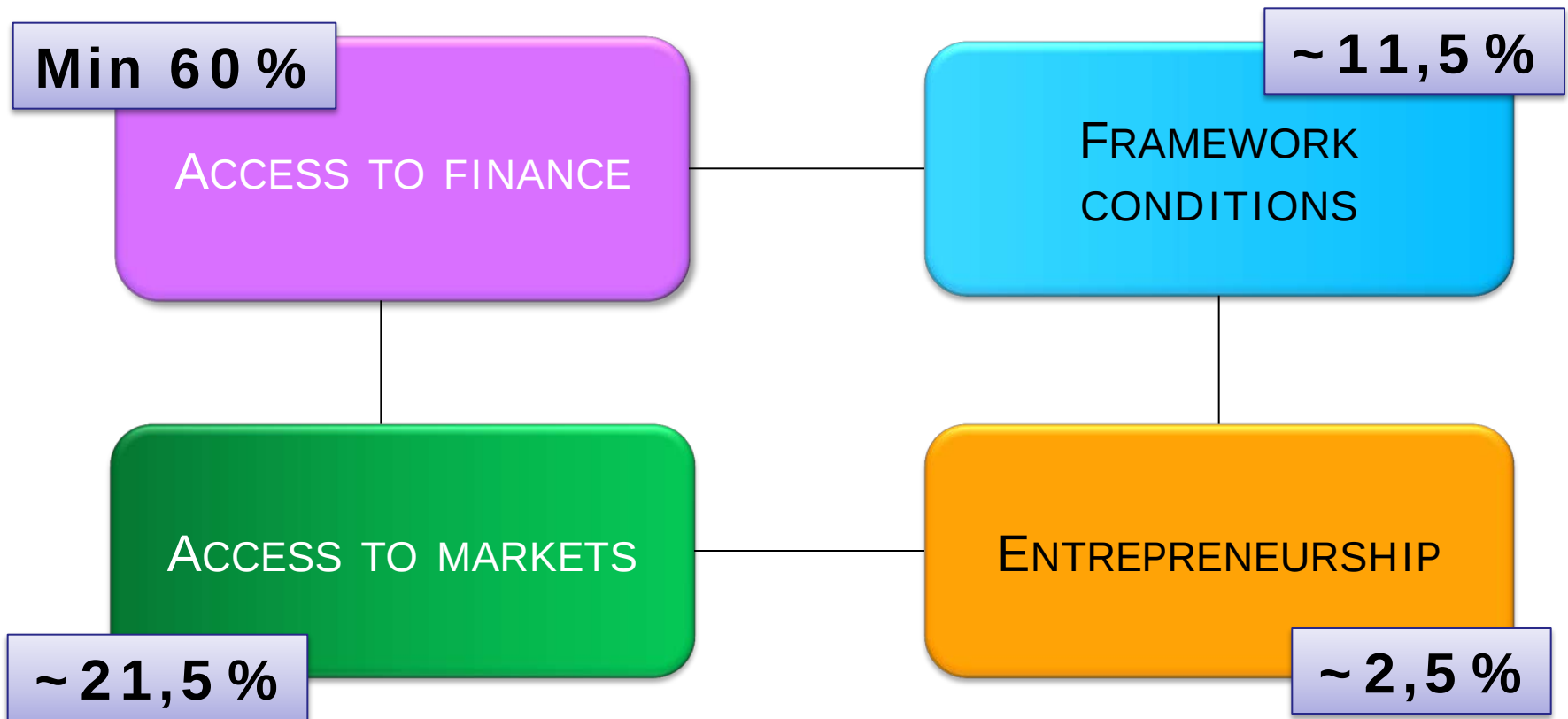
# Single Market Strategy key actions



# Programme for Competitiveness of Enterprises and SMEs (COSME)

- Strengthening the competitiveness and sustainability of European enterprises
- Encouraging entrepreneurship and promoting SMEs
- Main target audience: SMEs, Entrepreneurs, Business Support Organisations, regional and national Administrations
- Foreseen budget: € 2.3 billion from 2014 to 2020

# COSME specific objectives



# Objective 1 : Improving access to finance

- Equity instrument for SMEs' growth and R&I
  - o Equity Facility for R&I (H2020) – focus: early stage VC
  - o Equity Facility for Growth (COSME) – focus: growth-stage VC
  
- Debt instrument for SMEs' growth and R&I
  - o Loan Guarantee Facility (COSME)
    - o Guarantees for loans to SMEs
    - o Securitisation of SME debt finance portfolios
  - o SMEs & Small Midcaps R&I Loans Service (H2020)
    - o Guarantees for loans for R&I activities

See <http://access2eufinance.ec.europa.eu>



## Objective 2: Improving access to markets

- *Access to EU market and outside the EU*
- *Concrete services provided to SMEs*

### *Examples:*

- *Enterprise Europe Network*  
See <http://een.ec.europa.eu/>
- *On-line portals (e.g. Your Europe Business portal, SME internationalisation portal, IPR helpdesks)*
- *Awareness raising campaigns, trainings (ex. PSC action in WP 2016)*

### ***Objective 3: Improving framework conditions for businesses***

- *Reducing administrative burden, supporting smart regulation & SME policy*
- *Stimulate development of certain markets/sectors*

### ***Objective 4: Promoting entrepreneurship***

*Developing entrepreneurial skills and attitudes, especially among new entrepreneurs, young people and women, creating mentoring schemes, promoting social entrepreneurship*

## Other initiatives

### *The **Investment Plan**:*

- Mobilise investments of at least €315 billion in three years
- support investment in the real economy
- create an investment friendly environment

*The **Capital Markets Union**: break down barriers that block cross-border investments*

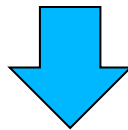
*Public consultation on the review of the European Venture Capital Funds (EuVECA)*

[http://ec.europa.eu/finance/consultations/2015/venture-capital-funds/index\\_en.htm](http://ec.europa.eu/finance/consultations/2015/venture-capital-funds/index_en.htm)

# Revision of the EU Medical Devices Legislation

## -State of play and next steps-

- **European Parliament** 1<sup>st</sup> reading vote: 2 April 2014
  - **Council:** Adoption of a general approach on 5 October 2015
  - 4 informal **trilogue meetings** took place



- Next trilogue meeting: 3 December 2015
  - Possible date for political agreement: early 2016

# Main issues under discussion during the trilogue

- pre-market control of high-risk medical devices
- reprocessing of single-use medical devices
- products without a medical purpose (aesthetic products)
- use of hazardous substances
- certain exemptions for in-house medical devices and IVDs
- counselling and informed consent in the case of genetic tests
- UDI (Unique Device Identifier)
- New EUDAMED database

# **"Pharmaceutical Industry: A Strategic Sector for the European Economy"**

## **Commission Staff Working Document of 26.06.2014**

- Main content of the Paper
  - ✓ Economic importance of the EU pharmaceutical industry, including SMEs.
  - ✓ Current and future major drivers and challenges in this sector.
  - ✓ Recent and ongoing activities to address these challenges.
- Paper presented to two Multi-stakeholders Workshops in Rome on 22.10.2014 and Riga on 15.04.2015
  - ✓ Participants: competent authorities pricing & reimbursement of pharmaceuticals, EU associations of patients, health professionals, consumers, insurers, hospitals, trade unions, industry including SMEs.
- Next steps:
  - ✓ In the ongoing reflection process, DG GROW will continue to involve SME's in any relevant multistakeholders meetings that may be organised in 2016.