Benchmarking the Competitiveness of the Global Animal Health Industry 2011 Survey

A Report by BioBridge Ltd for IFAH-Europe

Supporting informed policy making in Europe

Purpose

The Global Benchmarking Survey 2011 report examines the interactions between industry and regulatory systems, particularly the impact of regulations on the animal health industry's ability to be competitive and innovative.

The outcome of this survey provides an invaluable wealth of information to support informed policy decisions in the continual search for best regulatory practice and opportunities for improvement.

This brochure provides an insight into the contents of the Global Benchmarking Survey 2011 report for Europe, which can be obtained from **www.ifaheurope.org**.

The source of the data

The 2011 Global Benchmarking report is the fourth in the series, based on a survey taking place every five years since 1996. The 2011 survey is the second to include Canada and Japan, in addition to Europe and USA. The data is based on 65 questionnaires and 72 in-depth interviews.

The European report analyses data from 16 European companies, and compares it with the other regions.

What issues are investigated

The Global Benchmarking Survey 2011 report for Europe examines the issues listed below. This brochure covers the top findings related to these issues.

1. What drives competitive success for animal health companies?
2. What is the impact of regulation on:
   - Innovation and on maintenance of existing products, including defensive R&D?
   - The time and direct costs of product development?
3. How do different regulatory procedures impact new and existing products?
4. How do the European regulatory procedures compare with best practices around the world?
5. What are the benefits of regulation?
6. How does regulation influence major business decisions in Europe?
7. Progress since the 2006 Benchmarking Survey Report
   - Progress since 2006
   - Lack of progress
   - "Wrong" progress
   - Hopes for the future

> *"On the positive side has been the variation regulation, which has helped us manage our portfolio."*

Key conclusions

1. Innovation is key to long-term competitive success
2. The key obstacle to innovation is the European regulatory environment
   - Insufficient data protection
   - Disproportionate costs of product maintenance
   - Lack of harmonisation and a single market
3. Centralised systems are more efficient and are greatly preferred
4. Europe's EMA[1] and the centralised procedure is the most respected regulatory set up of all regions
5. The key benefits of regulation are a stable business environment and quality of marketed products
6. Regulation has a major impact on business decisions
7. Good progress has been made since the 2006 survey:
   - New regulation on variations is very positive
   - There is hope for the future if based on a 1-1-1 Concept

However there is serious disquiet on the current evolution of the European regulatory environment and barriers to innovation:

- Persistent high cost of defensive R&D (highest of all regions)
- Increasing burden of pharmacovigilance
- Lack of harmonisation within Europe
- The politics of antibiotics create uncertainty – the need for security in the food supply is forgotten
- 2004 Directive strongly favours generics and disfavours line extensions

[1] European Medicines Agency

Overview of Issues and Top Findings

1 What drives competitive success for animal health companies?

SHORT-TERM DRIVERS

- Utilising existing products more profitably
- Providing new customer services
- Mergers and acquisitions (M&A) (of highest importance for European companies)
- Reducing production and distribution costs

LONG-TERM DRIVERS

- Developing new products
- Providing new customer services
- Entering new markets
- Increasing business efficiency (M&A, reducing operating costs)

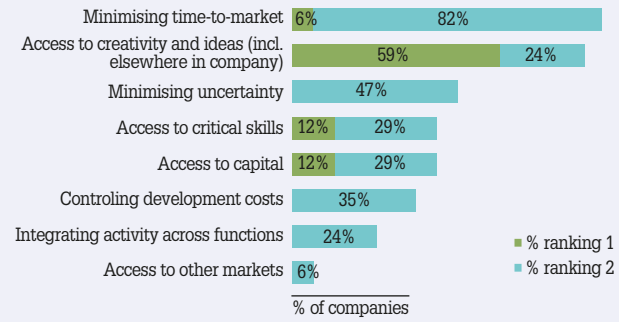
2 What is the impact of regulation?

IMPACT ON INNOVATION

Key factors to stimulate innovation

- Minimising time to market (of highest importance for European companies)
- Access to creativity and ideas
- Minimising uncertainty; predictable stable environment

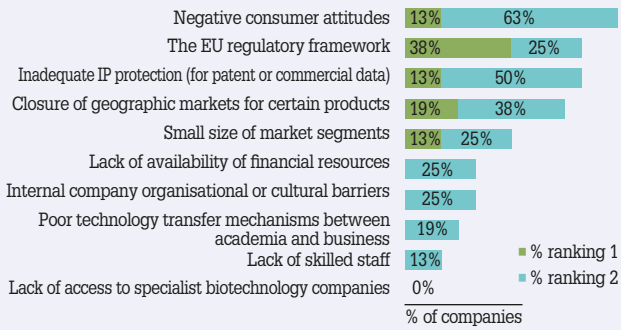
The most important factors for stimulating innovation in the animal health industry in Europe 2011



Key obstacles to innovation

- Regulatory environment in Europe (see background box)
- Negative consumer attitudes to new technologies (Europe highest of all regions)
- Inadequate data protection (of highest importance for European companies)
- Market closure for certain products (of highest importance for European companies)
- Small size of market segments
- Re-direction of resources into defensive R&D (Europe highest of all regions)
- Increased costs for product development
- Increased time for product development

Obstacles to innovation in Europe 2011



> *"Why invest millions of research dollars in antimicrobials when the regulatory (and commercial) outcome is so unpredictable."*

Background: the regulatory environment in Europe as a barrier to innovation

- Unnecessary administrative delays
- Lack of uniformity in regulatory assessment (a single Member State can de-rail a marketing authorisation procedure)
- Over-stringency (manufacturing, inspections, quality, driven by the human medicines sector)
- New focus on borderline products and medical devices
- Increasing demands for pharmacovigilance
- One-way barrier from EU to USA for biologicals

"The costs of defensive research have stayed the same and as a direct result there is less innovation and fewer new products in the pipeline."

IMPACT ON MAINTENANCE OF EXISTING PRODUCTS

Key obstacles in Europe

- Regulatory framework – by far most important obstacle
  - Disproportionate costs for product maintenance
  - Diversion of resources away from innovation
  - Removal of products from market
- Increased cost of production
- Increased competition: parallel imports and generics
- Increased concern about lack of data protection for new data
- Small size of animal health market segments

IMPACT ON DEFENSIVE R&D

- Significant proportion of budget spent on defensive R&D
- Diversion of resources away from innovation

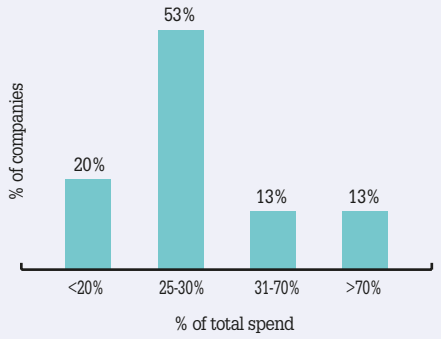
This is the single most important negative aspect of the EU regulatory framework with the average cost in Europe being 35% of total R&D budget:

- Broad range of expenditure (see figure): Majority (53%) in Europe spent 25-30% of total R&D budget on defensive R&D
- In other regions defensive R&D is 14-16% of total R&D budget
- Persistent EU problem, recurring in previous surveys

Reasons given for such investment in defensive R&D in Europe:

- Increase in product review activity at national level
- Deterioration in the regulatory environment
- Increased M&A activity

Mandatory defensive R&D in Europe 2011



IMPACT ON THE TIME AND DIRECT COSTS OF PRODUCT DEVELOPMENT

Product development period

- Large increase in time for new product development since 1991:
  - Increase of 7.5 years for food animal products
  - Increase of 4.3 years for companion animal products
  - Increase of 4 years for minor species
- Since 1991 costs have increased:
  - 229% for food animal products
  - 173% for companion animal products (highest rise in all regions)
  - 108% for minor species

Regulatory review period

- All products: the average review period is 1.6-1.8 years (ranges globally 1-2 years on average)
- Europe rates lowest of the regions for new products: 1.5 to 1.7 years (vs 2-3 years average globally)

Background: innovation and R&D

- New products are an R&D priority for all companies
- **64% of total R&D budget is spent in Europe** (Europe highest of all regions)
  - » Global multinationals: 53% spent in Europe
  - » Base cost of R&D has increased
  - » Local share of R&D has decreased
- Majority of R&D done in-house (Europe highest of all regions)
- Increasing portion contracted out (25% in 2001; 40% in 2011)

3 How do the different regulatory procedures impact new and existing products?

POSITIVE IMPACTS

- CP[2] very helpful for new products (of highest importance for European companies)
- CP very helpful for product maintenance (of highest importance for European companies)
- DCP[3] a good step forward but inefficient and resource-intensive

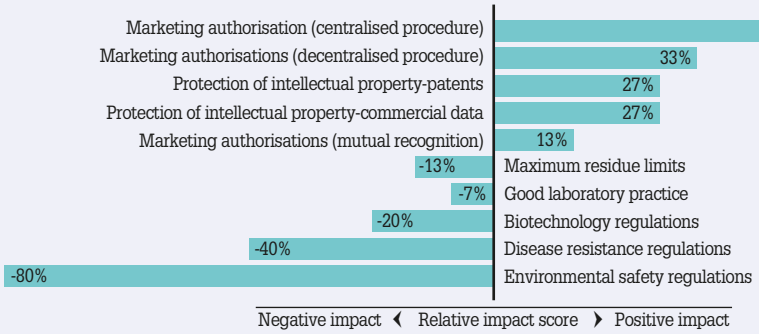
NEGATIVE IMPACTS

- Environmental safety requirements are severe
- Antibiotic resistance requirements are very unhelpful
- National packaging and labelling rules are burdensome
- National procedures for product maintenance are inefficient

TRENDS

- Positive view of CP increasing - but so is bureaucracy
- Negative view of ecotox consistently high
- Increased concern over data protection since 2004 Directive
- Increased concern about pharmacovigilance

Impacts of regulation on innovation in Europe 2011



4 How do the European regulatory procedures compare with best practices around the world?

Overall regulatory quality

- EMA/CVMP[4] score highest of all regions
- EU national agencies score 3rd lowest of all regions

New products

- EMA/CVMP score 2nd highest of all regions (Canada highest)

Maintenance of existing products

- EMA/CVMP score highest of all regions for predictability

Clarity of scientific assessment and international respect

- MRP[5]/DCP and national procedures score low

Importance of harmonisation

- Very important to harmonise within Europe
- VICH[6] consistently recognised as having high impact on harmonising test requirements for new products
- Acceptance of high-quality data from other regions – good achievement and high impact

5 What are the benefits of regulation?

- Stable business environment
- Quality and safety of marketed products
- Public reassurance
- Speed up time to market
- Protect innovation; confidence to invest
- Improve access to other geographic markets

Impact of political involvement on business

87.5% reported political involvement had impacted their business

- Creation of uncertainty
- Products removed without scientific evidence
- Preventing approval of products (which are approved in other markets)

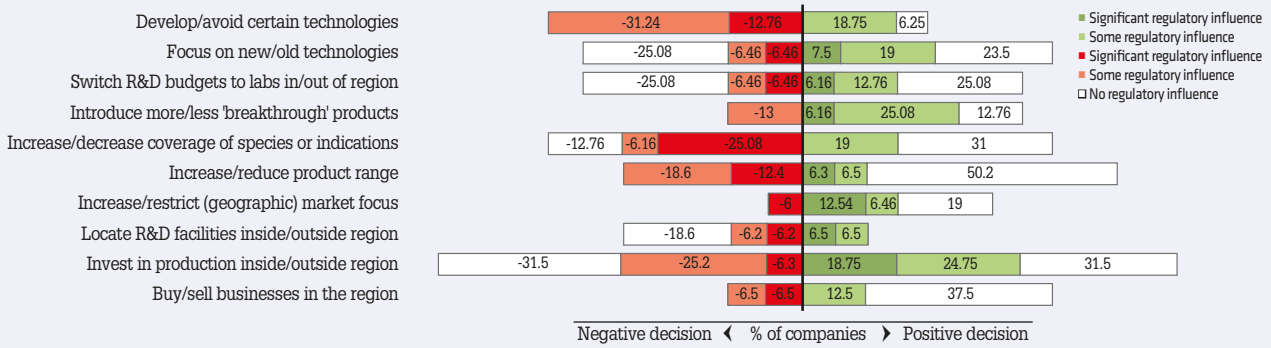
[2] Centralised Procedure | [3] Decentralised Procedure | [4] The EMA Committee for Medicinal Products for Veterinary Use | [5] Mutual Recognition Procedure
[6] International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

6 How does regulation influence major business decisions in Europe?

Regulation has a significant influence on:

- **All** decisions to avoid certain product technologies
- **All** decisions to decrease the product range in Europe
- The majority of decisions to invest in production both inside and outside Europe
- The majority of decisions to introduce more breakthrough products
- The majority of decisions to reduce coverage of species (highest of all regions)

Influence of regulations on major business decisions in Europe



7 Progress since the 2006 Benchmarking Survey Report

PROGRESS SINCE 2006

- Variations Regulation – single review of data
- Improved access to regulatory authorities for discussion
- Introduction of procedural efficiencies:
  - Time-tabling
  - Electronic submissions
  - Worksharing

"WRONG" PROGRESS

- Balance between innovation and generics
- Loss of data protection for line extensions, new indications / formulations
- Pharmacovigilance – next bureaucratic monster
- Increasingly stringent ecotox requirements
- Political involvement
- Wider public involvement in regulatory processes

LACK OF PROGRESS

- Failure to harmonise regulatory approaches
- Requirements for packaging and mock-ups
- Failure of mutual recognition - lack of confidence or respect in RMS[7] assessment
- Misuse of "serious risk" clause
- Failure of single market
- No reduction in administrative burden

HOPES FOR THE FUTURE

- Improved benefit:risk rather than zero risk approach
- Electronic submissions; single electronic portal
- European Commission Better Regulation initiative
- Acceptance of JECFA[8] evaluations
- Single market - full harmonisation and reduced administrative burden via the 1-1-1 concept

The full Europe report and further information including an overview presentation is available from the IFAH-Europe website: www.ifaheurope.org

[7] Reference Member States

[8] The Joint FAO/WHO Expert Committee on Food Additives

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