
Innovative strategies for 'Medical Device'

Lobbying in Brussels:

Gaining company specific competitive advantages

CONSULTANCY REPORT SPECIFICATION

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1. Changes in the Brussels lobbying environment

Why the study?

A number of changes are taking place in Brussels that are altering the decision making landscape irrevocably:

- **EU Constitution** - With several risky referenda taking place between 20 February in Spain and the end of next year, the ratification of the EU constitution is a 'moment of truth' for the European Union. The big question, which is being conspicuously avoided by EU leaders, is what will happen if several member states reject the constitution?
- **Enlargement, integration and next wave** - May 2004 saw the admission of 10 new Member States expanding the EU to 25. What has been the impact the decision making? What new alliances are being formed? How will the next wave of Bulgaria, Romania, Croatia and, eventually, Turkey affect the Brussels processes?
- **New Commission initiatives** - the new President of the Commission, José Manuel Barroso, is mindful of the urgent challenges his Commission face. Without successful measures to re-invigorate economic prosperity, disenchantment and antipathy towards Brussels will become rampant. Much hope is being pinned on the so called 'knowledge economy'.
- **"Voice of the people"** - More and more, Brussels law-making institutions recognise the need to engage and listen to the EU 'man-in-the-street.' "Dialogue must reach beyond the Brussels-based political debate into a full-blown European Public Space This will help to generate a sense of European identity, particularly amongst young people." (Strategic Objectives 2005-2009, 26.1.2005 COM 12)
- **Patient NGOs in ascendency** - For national governments, health often features as the No.1 or No.2 issue in election manifestos. No surprise therefore, that EU NGOs representing patient interests, for many years in the wilderness, are breaking into power sharing, threatening the cosy position held by industry.
- **Parliamentary power** - the European Parliament is increasingly flexing its muscles. Last October, for the first time in the history of the European Union, a Commission was unable to take up office as planned. President Barroso had to postpone putting forward his commission for approval by the European parliament due to objections, and had to make changes. Parliament is especially sensitive to vote winning patient issues (e.g. STOA workshop on organ transplantation 2004).

2. Medical Device lobbying

issues for industry

There are at least six key issues facing Medical Device companies that have spurred us to prepare this report:

- i) **Making intra-Commission connections** – Health policy in Brussels is spread around different DGs: DG Enterprise – Medical Devices; DG Health & Consumer Protection - public health; DG Information Society – eHealth; and others. Few companies seem to understand the lobbying leverage possible by making the connections work for you.
- ii) **Company specificity** – Trade associations such as Eucomed serve a vital function. But they have to work by consensus at the speed of lowest common denominator. Pharma companies understand the need for own company initiatives to protect and enhance their competitive positions.
- iii) **EU Parliament a mystery** – Med. Dev. companies lack understanding of when or how to involve parliamentary lobbying in Brussels. Bad lobby experiences abound. Yet health issues are drawing an increasing attention from MEPs.
- iv) **New technology blurs boundaries** – The pace of technological change is accelerating: biologicals, medicine containing devices and nanotechnology bring ever more radical solutions. The legislative framework is finding it hard to keep up. How many companies address this at phase 1 development stage? Yet Brussels, in other sectors, is littered with new technology launch-delay disappointments.
- v) **Working with NGOs** – Industry partnerships with NGOs can be very powerful in Brussels lobbying. Many Med. Dev. companies have little contact, if any. Few know how to approach NGOs and are fearful of being misunderstood, or worse, of lobby argument corruption.
- vi) **Presentation style** – Technical companies are often not adept at simplifying and presenting their arguments to non-technical bureaucrats in the Brussels corridors. Marketing departments have PR skills but these are seldom put to use. *"Consultancies with integrated skills and a particular expertise in PR will see continued demand for their services."* - Philip A. Springuel, Senior Public Affairs Manager, EurActiv, Brussels.

3. Objectives of the study

- a) To increase awareness and develop knowledge across different departments within companies of the rapidly evolving decision landscape in Brussels;
- b) To identify the profitable areas in which company specific action will most likely achieve lobbying success and other areas where intra-industry and extra-industry partnerships are more appropriate;
- c) To shape a more pro-active Public Affairs and Corporate Communications strategy and to advise on the most suitable internal restructuring to achieve success;

And ultimately...

- d) To become more effective in defending your products, your production processes, your market position and your **shareholder value** against threats from restrictive legislation.

4. Who the report is for

JOB RESPONSIBILITY	CEOs Principals Corporate communication	Government & Public Affairs Product managers Permanent representatives
REPRESENTATION IN BRUSSELS	Those who do not have their own office in Brussels and work only through their trade association and/or national government	Those with their own company permanent representative in the Brussels scene.
LOCATION	EU-based US global companies Japanese global companies	Exporters into EU from – USA Far East Australasia
BUSINESS TYPE	Active implantable devices Non-active implantable devices Biotechnological products Dental Ophthalmic	Anaesthetic/respiratory equipment Electromedical equipment Diagnostics Surgical instruments Medical disposables

5. Scope of the report

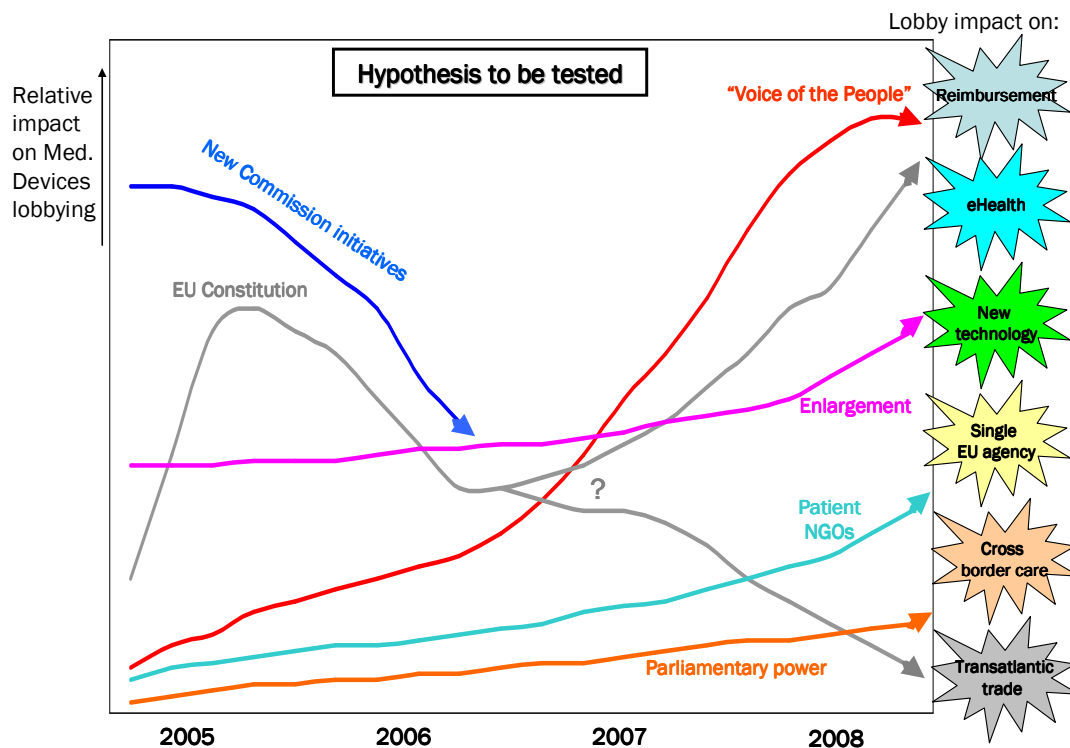
- EU Directives - Categories
 - Active Implantable Medical Devices: Directive 90/385/EEC
 - Medical Devices Directive (MDD): Directive 93/42/EEC
 - In Vitro Diagnostic Directive (IVDD): Directive 98/79/EC
- Relationships with
 - Directorates of the Commission
 - European Parliament
 - COREPER (Comité des Représentations Permanentes)
 - European Agencies (eg. JRC, OSHA, EEA, CEN)
 - NGOs
- Location
 - Only for Brussels
 - Integrated and co-ordinated national actions will be covered in principle but not in terms of specific country variations
- Relationships with Trade Associations (Eucomed and others)
- Time horizon:
 - 2005 to 2008

6. How will you use the report?

- To provide a basis for reviewing overall **lobbying strategy** leading to changes in the way in which the company engages the process.
- To **stimulate actions** to get closer and communicate effectively with EU Institutions, and Agencies – both directly and via your trade associations or national government.
- To establish a programme of interactive **surveillance** of **all** company communications with EU and national government to maximise synergy and minimise alienation risk.

- To identify areas where your company has a **competitive differential** in its work in Brussels and has an interest to establish its own contacts and communication campaign.
- To consider different, and more effective, options for **structuring the Government Affairs** activity within your company.
- To consider the impact of general public company **PR campaigns** in the context of knock-on effect into patient NGO lobbying.
- To identify the needs for **training** throughout the company on lobbying and relationships with EU Institutions, Agencies, Competent Authorities and NGOs.

7. Forces for change



8. Draft report contents

Expected ~100 pages including graphics and annexes

8.1 Changes in the Brussels lobbying environment

Trends in real politics – the practice rather than the theory

Impact of

- ⇒ New Commission initiatives
- ⇒ EU Constitution
- ⇒ Enlargement, integration and next wave of enlargement
- ⇒ “Voice of the people”
- ⇒ Parliamentary power increase
- ⇒ Patient NGOs in ascendancy

8.2 Motivation ‘maps’

- *What drives the individuals to whom you wish to bring lobbying arguments?*
 - *Do the target lobby institutions and organisations have ‘corporate’ positions and styles that can be mapped, just like brand mapping?*
 - *How should your messages be moderated and moulded to be better in tune with these maps?*
- ⇒ Directorates of the Commission
 - DG Enterprise;
 - DG Health & Consumer Protection;
 - DG Information Society
 - ⇒ European Parliament
 - ⇒ European Agencies (eg. JRC, OSHA, EEA, CEN)
 - ⇒ Member State national Ministries (not differentiated by country)
 - ⇒ Patient NGOs

- ⇒ 'Professional' representation bodies, e.g. (CPME)
- ⇒ Industry trade associations

8.3 Industry issues

Application of motivational maps to a range of characteristic industry issues – with an emphasis on future dimensions rather than past

- ⇒ Reimbursement
- ⇒ Electronic labelling and related issues
- ⇒ Single European Medical Devices agency
- ⇒ Cross Border care
- ⇒ eHealth
- ⇒ New technology
 - especially Human tissues
 - nanotechnology
 - pharma borderline cases
- ⇒ Trade – e.g. Transatlantic Market by 2015?

8.4 Case study

Case study to draw out lessons about own company activity and impact:

- *relationships with the EU Institutions*
 - *relationships with trade associations*
 - *relationships with Member State governments*
 - *reasons for successes and failures*
- ⇒ 10 year review of Medical Devices Directive (93/42/EEC)
- e.g. – Upclassification, IIb to III hip and knee implants

Rationale for choosing: Good example of the interface of technical arguments and scientific risk assessment with pure politics. Required direct company action.

8.5 Strategic implications

Differentiated conclusions where appropriate for

- *Non-active implant manufacturers*
- *Active implant manufacturers*
- *Non-implant equipment manufacturers*
- *Diagnostics*
- *New technology- biological, nanotechnology, and the like*

Innovative changes to lobbying strategy, INCLUDING:

- ⇒ actions to get closer and communicate effectively with EU Institutions, and Agencies
- ⇒ interactive surveillance programmes of all company communications
- ⇒ competitive differential impact in campaigns
- ⇒ options for structuring the Public / Government Affairs activity within your company
- ⇒ company general public PR campaigns in the context of patient NGO lobbying
- ⇒ needs for training on lobbying and relationships with EU Institutions, Agencies, Competent Authorities and NGOs

9. Research method and resources

9.1 Method

a) Desk Research

- published material
- annual reports
- position papers
- work programmes
- conference papers

b) Interviews with

Commission Officials	Journalists
MEPs / Secretariat	Trade Associations
Professional representation	Exports
NGOs	

c) Brainstorming sessions

- strategic implications

10. References: our heritage

TG2 is a public affairs and marketing communication consultancy that specialises in the health (medical devices) sector.

10.1 Our mission statement

As a European public affairs and marketing communication consultancy specialising in healthcare: *“to deliver business enhancing services to our customers of unbeatable value for money”*

10.2 Previous multi-client projects: Brussels politics

author or co-author: Tony Houghton

- ◆ [European Parliament and industry to 2010: new tactics to improve lobbying of Parliament](#) , June 2001
- ◆ [NGOs & Consumer Organisations: strategies for industry to establish constructive communication](#), February 2001

- ◆ The commercial impact of EU Enlargement to include East & Central Europe, Sept 1997
- ◆ Product registration politics: EU Member State attitudes and company manoeuvres for operational decisions, March 1995.

10.3 Examples: recent and company specific projects

- Report: "Regulatory framework for data protection affecting eHealth websites Europe."
- Report: "Advertising, promotion & internet for medical devices: Codes & regulatory framework in the EU."
- Retainer: developing concept and executing start up, first six months "Management Brief," an internal company monthly publication concerning EU regulatory issues affecting Medical Device company's business.
- Training: running training workshops for Europe marketing teams on regulatory procedures for websites and communication.

10.4 Our heritage

- Roots go back to 1985
 - Reputation – incessantly creative
 - Calling – to be exciting to work with
 - Head office in UK
 - Other European resources:
 - Brussels
 - and strategic partnerships
 - North America: partnership with US agency – healthcare specialism
 - consultancy supplying
 - advertising
 - marketing communication and promotion
 - web & design

Why TG2? All this is for your benefit, so that the grace that is reaching more and more people may cause thanksgiving to overflow to the glory of God. 2 Corinthians 4:15

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