

# DII DRIVE INNOVATION INSIGHTS

1<sup>st</sup> ANNUAL FORUM  
GLOBAL PUBLIC AFFAIRS FORUM  
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## Building a global to country roadmap and ensuring impact at every level

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# Agenda

- I The operating environment – all politics is global?
- II Internal challenges to public affairs – all to be expected?
- III Some solutions – all simple?
  - IIIa Case study 1: Adapt global approach to local needs
  - IIIb Case study 2: Bridge Brussels and Member States



# Global trends disrupting Pharma

	Trend	Implications for Public Affairs
Global	<ul style="list-style-type: none"><li>❖ Increasing politicization</li></ul>	<ul style="list-style-type: none"><li>❖ Engage with policy, simplify narratives, ensure neutrality to technologies</li></ul>
	<ul style="list-style-type: none"><li>❖ Demand for transparency &amp; accountability from investors and patients</li></ul>	<ul style="list-style-type: none"><li>❖ Evidence-based input to counter public political statements</li><li>❖ Collaboration across whole value chain</li></ul>
	<ul style="list-style-type: none"><li>❖ Increased supervision, regulation and interconnectivity</li></ul>	<ul style="list-style-type: none"><li>❖ Strong global and local connection</li><li>❖ Connect global vision with day to day business</li><li>❖ Avoid fragmentation and spill over</li><li>❖ Leverage supra-national institutions</li></ul>
	<ul style="list-style-type: none"><li>❖ Technological disruption via AI and Data Analytics</li></ul>	<ul style="list-style-type: none"><li>❖ Segmentation of audiences for engagement</li><li>❖ Data analytics and AI-based tools as the future of PA campaign</li></ul>
	<ul style="list-style-type: none"><li>❖ Scientific breakthrough through big data</li></ul>	<ul style="list-style-type: none"><li>❖ Create understanding of gene- and cell-based therapies, facilitate promise of big data and digitalization</li></ul>
Sector specific	<ul style="list-style-type: none"><li>❖ Increasing pressure on healthcare spend</li></ul>	<ul style="list-style-type: none"><li>❖ Even more need to explain value and target customer needs</li></ul>

# Internal challenges to public affairs

## Challenges

- Vision & Strategy
- Structure & Alignment
- Systems & Network
- Resources

## Implications

- Prioritization
- Long/ short term
- Demonstrating value
- Senior sponsorship
- Alignment to business & other functions
- Global to country
- Planning
- Trade associations and alliances
- Cultural differences
- Talent
- Funding streams
- Agency support

# Case study: Patent challenge in South America (I)

## Context

- Cancer medicine was available at government negotiated price, one of the lowest globally
- Generic of the same compound covered around 2/3 of patients
- Government declared “public interest” and asked for massive price reduction

# Case study: Patent challenge in South America (II)

## Solutions

### Vision & Strategy

- What is the ultimate objective?

### Structure & Alignment

- Global guidance vs local interest
- Composition of Steering Committee

### Systems & Network

- Trade associations, long term alliances
- Media communication

### Resources

- Local team
- Headquarter Steering Committee
- Envoy negotiator
- Local and global intelligence

# Case study: Patent challenge in South America (III)

## Results and Learnings

- Once gone public, government had no flexibility to change position
- Changes achieved in local legislation that minimize risk of repetition
- No easy “cut and paste” by watching entities
- Early fix might have been favorable

# Case study: Pan-European relative efficacy assessment (I)

## Context

- New medicines are being assessed on scientific (quality, safety, efficacy) grounds by central body (EMA)
- EU member states determine price based on different set of scientific (relative efficacy) and economic (value assessment) parameters
- Time between EMA approval and local reimbursement last up to 3 years; duplicative and inconsistent approach
- EU launched legislative proposal on pan-European Relative Efficacy assessment
- Member states oppose mandatory nature

# Case study: Pan-European relative efficacy assessment (II)

## Solutions

### Vision & Strategy

- Prioritize objectives:
  - Scope: only REA, no cost elements
  - Mandatory assessment to avoid duplication
  - No delays of market authorization
  - Clear term sheet

### Structure & Alignment

- Driven through trade association presidency
- No immediate local benefit, however, requires massive engagement at country level
- Part of regional objectives

### Systems & Network

- Trade association lead
- Requires EU network of national associations -> local priorities
- Understand local concerns and local flexibilities: implementation into local law

### Resources

- Apply critical mass
- Limited agency support due to in-house expertise

# Case study: Pan-European relative efficacy assessment (III)

## Results and Learnings

- Current proposal risks rejection by majority of member states
- Consider concessions on mandatory nature, but not compromise on time-to-access
- Co-development with member states
- Strict separation between “clinical assessment” and “economic assessment” is not realistic

Final thoughts...

Never give up



Common sense  
prevails