

Communicating adequately in an EU context

Session 2

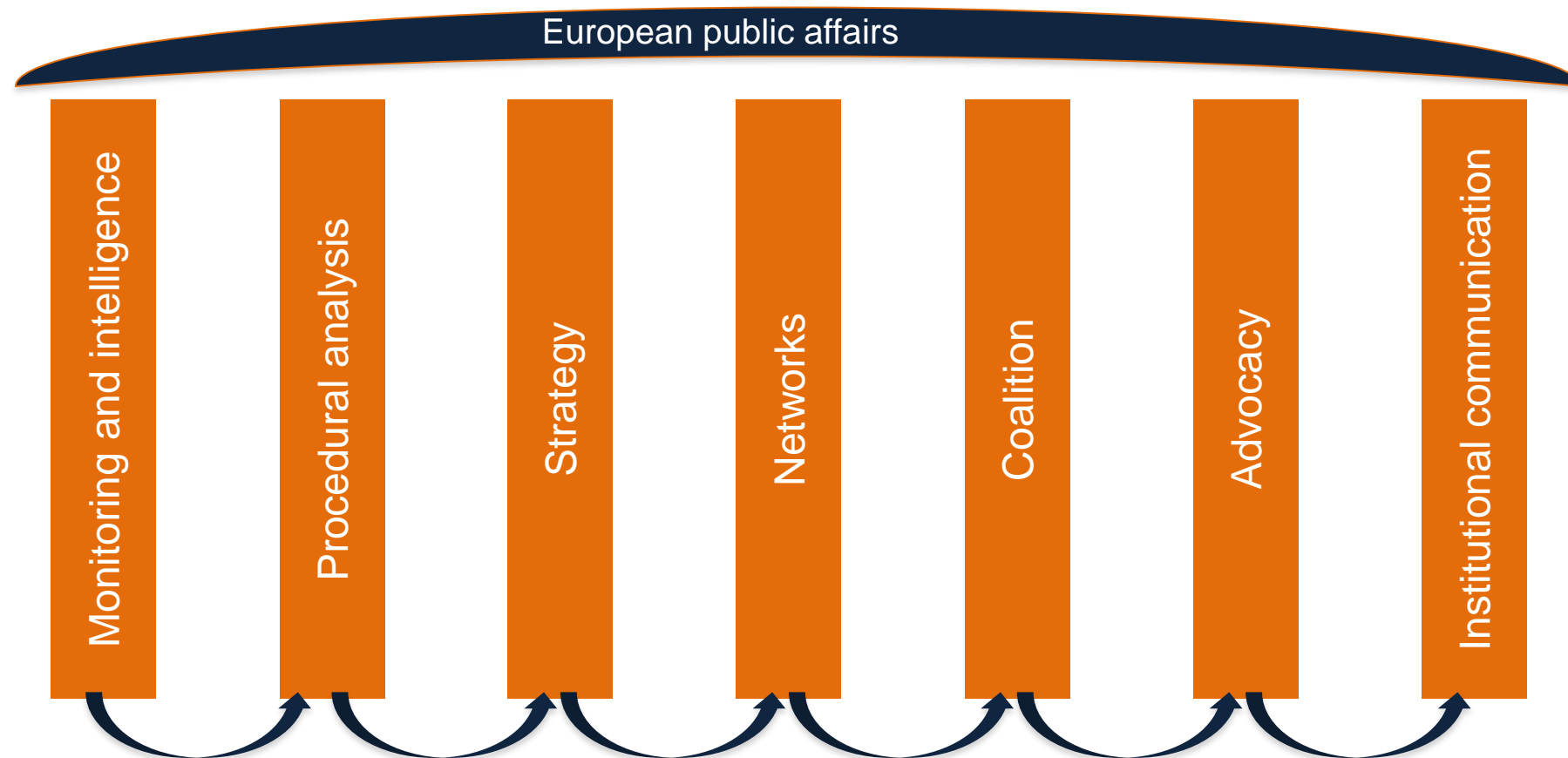
Vicky Marissen

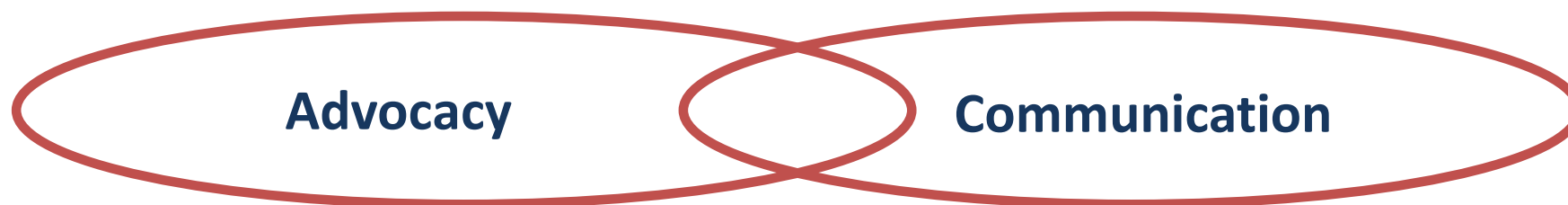
Brussels, 3 December 2018



Communication in an advocacy strategy







Fully integrated



Adequate communication: messages and tools



Position Paper to View paper



22 November 2016

IFPMA Position Paper on the Handling of Post-approval Changes to Marketing Authorizations

Introduction

Following the initial launch and throughout a drug product's commercial life, changes that might impact the product's quality and safety profile will inevitably occur. These changes may include modifications to raw materials, analytical methods, suppliers, manufacturing equipment, processes and sites and are a consequence of continual improvement, implementation of innovative technologies, efficiencies of production or increases in scale to improve the availability of drug products for patients. Variations, also known as post approval changes, are necessary in order to comply with evolving regulatory requirements.

After receiving market approval, drug products are used in a wider population that brings further knowledge to its safety profile. It is important that such information is reflected in the product labelling in a timely manner for the benefit and safety of patients and healthcare professionals. Thus post approval changes to the originally approved dossier are an essential part of a product's lifecycle. Therefore, it is important that new product knowledge is managed in a structured and planned way to enable continual improvement, to encourage innovation, state of control, and to ensure uninterrupted product availability for patients.

Many drug products are managed globally throughout the commercial part of their lifecycle. However as regulatory systems develop and evolve worldwide, the requirements to submit and review post approval changes and implement safety labelling updates are increasing. As a consequence there is a growing potential for divergence, increased complexity and less predictability across markets. The major challenges with managing variations globally include the variable or unpredictable timelines and submission requirements across National Regulatory Authorities (NRAs) for review and approval. This leads to different implementation dates for changes thus increasing the potential for compliance issues as well as contributing to the complexity due to the need to manage multiple variants of products/processes. International collaboration and cooperation towards regulatory convergence has been recognized as an appropriate regulatory mechanism which could address the NRAs' challenges with managing the associated increase in workload.

IFPMA believes that global regulatory convergence, such as work sharing between NRAs, as well as reliance on assessments by Stringent Regulatory Authorities¹ (SRAs), will provide a more efficient and predictable environment for the management of post approval changes to

¹ Stringent regulatory authority (SRA): a regulatory authority which is: (a) a member of the International Conference on Harmonization (ICH) (as specified on www.ich.org); or (b) an ICH observer, being the European Free Trade Association (EFTA), as represented by Swissmedic and Health Canada (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time). WHO Technical Report Series, No. 961, 2011, Annex 11

Position Paper to View paper



connecting government & business
society



Farmers and Protected Areas can be allies, working for common solutions. We must learn from the best practice available in effective partnerships, apply and adapt these models, develop tools to replicate and implement these successful approaches across the European Union.

A healthy environment and nature protection need farmers' engagement.

A change in agriculture and nature conservation towards a holistic and integrated vision is necessary.

EUROPARC seeks agricultural policies, which can be defined as:
Good for People, Good for Nature
because they ensure a good, secure supply of food, because they respect and protect the environment and natural resources, because they provide a fair income to the farmer.

EUROPARC Federation states:

- 1 Collectively, sustainable agriculture practices and Protected Area management can nurture resilient rural areas and create living landscapes.
- 2 Existing structures of Europe's Protected Area network are available to support working partnerships at local and regional levels.
- 3 Specific measures, programmes and funds are needed to support initiatives on partnership building among Protected Areas, farmers and consumers.
- 4 The new CAP should pay specific attention to farmers who are acting within or close to Protected Areas and Natura 2000 Sites, engaged in environment-friendly agriculture and working in partnership with Protected Areas authorities, in order to recognise their work and reward their efforts.
- 5 The role of the European Union is essential in maintaining a coherent policy on sustainable agriculture across all Member States, as well as in guaranteeing coherence with other European policies and the Natura 2000 network.

page 2/12

About EUROPARC



The EUROPARC Federation is the largest and most representative Protected Area network in Europe, comprising almost 40% of the Natura 2000 network. Nature and Regional Parks alone cover 8% of Europe's land.

Our members manage Europe's Protected Areas, covering almost every regional, national, European and international designation, such as National Parks, Nature and Regional Parks, Natura 2000 Sites, Biosphere Reserves, Ramsar Sites, Geoparks, World Heritage Sites.

Our membership reaches a constituency of about 25% of the European population touched by Protected Areas. With our Periurban Parks having 25 million visitors annually.

www.europarc.org/sustainable-agriculture

1 Collectively, sustainable agriculture practices and Protected Area management can nurture resilient rural areas and create living landscapes



The Challenge

Europe has a fragmented landscape, which is under increasing pressure from competing land use demands, challenging conditions for food production, climate change and insufficient management.

This context necessitates change and holds significant opportunities – change is not optional: how it is done, managed, resourced and prioritised is important.

New, better-integrated approaches and more innovative funding mechanisms are required.

While food and farmers' income should remain central issues, it is crucial to further consider the vital function of agriculture for environment, natural resources with genetic biodiversity, local as well as international economy and biosecurity.

The Opportunity

Europe's rural areas provide the life support system of our continent. They are the locus for management of our natural resources, in terms of agriculture and forestry, water management and nature conservation.

It is clear that the long-term viability of rural areas needs an integrated, visionary approach. Europe's Parks make a significant contribution to the sustainable development of rural areas and the viability of agriculture.

Having strong Parks means having strong rural areas.

Protected Areas are driving forces behind regional development. They stimulate tourism, economic diversification, job creation and sustainable food production, thus, strengthening rural communities.

Protected Areas and Natura 2000 Sites are more valuable than ever as repositories for nature, sanctuaries for human well-being and drivers of sustainable economic growth.

Working with farmers, Parks promote local markets and short marketing chains.

The Way Forward

Agriculture remains a vital activity for communities in and around European Protected Areas and Natura 2000 Sites. There can be effective partnership to develop more sustainable solutions for agriculture.

In Protected Areas, local-level solutions are being developed for global challenges, such as climate change and demographic change in rural areas.

Parks coordinate their development objectives in the region with a wide range of stakeholders, working to provide a structure that facilitates a commitment to the future-oriented development of the region from multiple interests.

Case Studies available
europarc.org/toolbox/sustainable-agriculture



Examples can be also found in the book **Living Landscapes**
www.europarc.org/book-living-landscapes

page 3/12

www.europarc.org/sustainable-agriculture

3 Specific measures, programmes and funds are needed to support initiatives on partnership building among Protected Areas, farmers and consumers



The Challenge

The coherence of priorities and objectives within the future CAP and other EU policies (see grey box), as well as with international environment and climate commitments, needs to be ensured. Measures under the CAP should hence strive for alignment, particularly with the Union's objective of transitioning towards

a green economy preserving ecosystem resilience. Society's concerns about human health and animal welfare also need to be taken into account. In many European Protected Areas, in order to protect landscapes, specific habitats & species, it is necessary to maintain or restore agricultural activities.

The EU Nature Directives, the 7th Environmental Action Programme, the European Strategy for Plastics in a Circular Economy, the Strategy on Air Pollution, the Aichi Biodiversity Targets under the convention on Biological Diversity (CBD), the Paris climate Agreement and the Sustainable Development Goals.

The Opportunity

A huge number of Protected Areas collaborate with farmers both to reduce any impact for the environment and to increase the added value of environment-friendly practices. Many Protected Areas, in rewarding of the value of the landscape and quality of the environment that Protected Area management brings, provide distinctive recognitions and certifications to producers and products of their territories.

Doing this, they trigger improvement of the production quality, foster the application of new promotion and marketing strategies and help raising consumers' awareness, thus enabling and supporting the market for local production and the viability of farming in and around the Protected Areas.

Culture and history are strongly connected with nature.

Most European Protected Areas protect both natural and cultural heritage, involving the agriculture sector and local communities in their activities.

In some cases, Protected Areas can be the repository of old domestic animal species and traditional crops. Doing that, they conserve the variety of genetic resources, traditional practices and the related immaterial cultural heritage.

The Way Forward

Working with farmers to safeguard traditional cultures in remote areas, as it is practised, for instance, in the Alpine Italian Adamello Regional Park, where a set of actions has been designed to help people slow down the landscape abandonment and to enhance the resilience of the communities.

Case Study Adamello Regional Park
europarc.org/landscapes/controlling-landscape-biodiversity-increasing-rural-communities

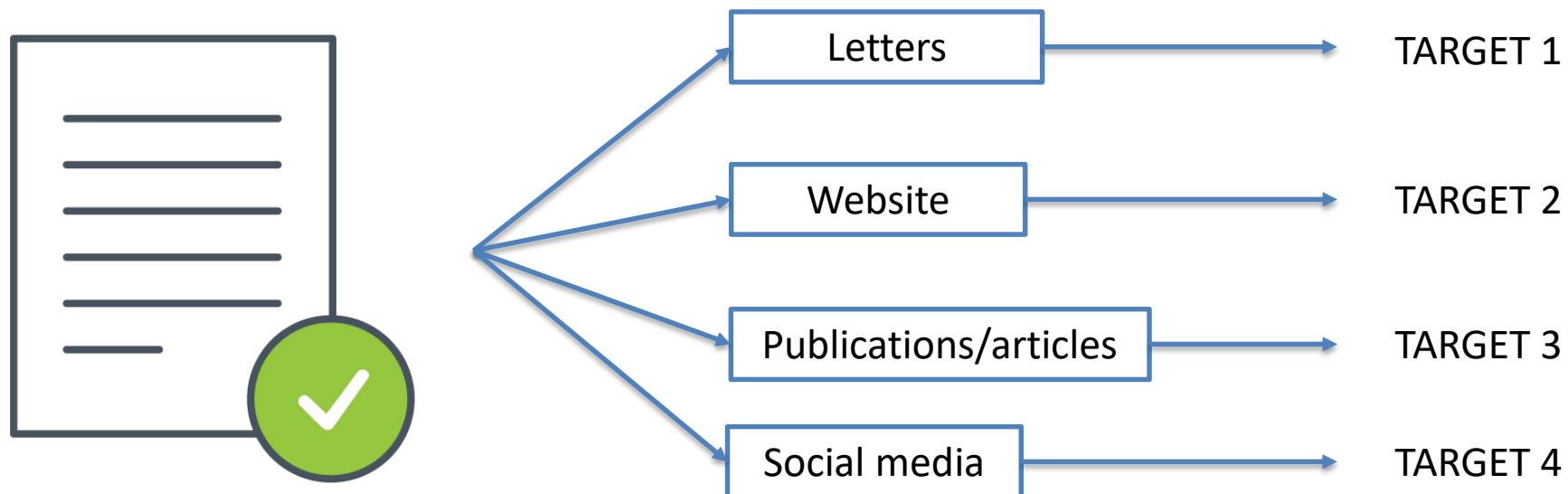
Farming close to urban areas is also of concern to Protected Areas. One successful initiative in this field can be found in the Collserola Regional Park in Spain, where forest expansion as a consequence of farm abandonment had resulted in the decline of some open space species. To counterbalance this, the Park is working with local farmers, supporting actions to recover farming activities.



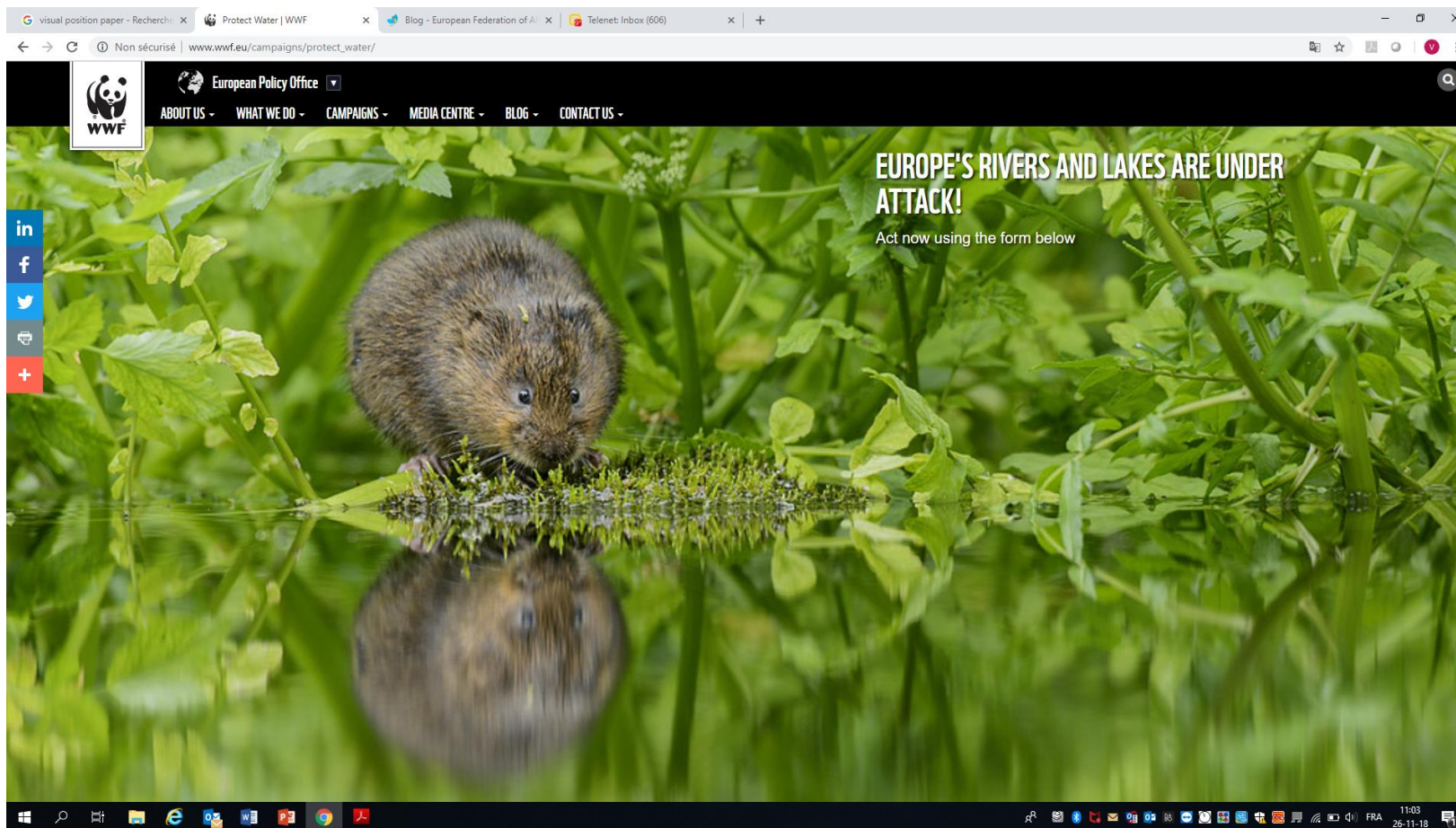
Case Study Collserola Regional Park
europarc.org/landscapes/controlling-landscape-biodiversity-increasing-rural-communities

page 5/12

www.europarc.org/sustainable-agriculture



Protect Water Campaign WWF



<https://youtu.be/QsSC8F7QSBY>

<https://youtu.be/nCRjqwhsN8M>

Presentation skills

Public speech and powerpoint presentation



Speeches: the content

'Begin with the end in mind'

The 3 Ts:

1. Tell them what you are going to tell them ...
 - *Present the general structure of your speech, and emphasize each key idea*
2. Tell them ...
 - *Two or three messages in a speech. Never more.*
3. Tell them what you have told them ...
 - *Signal that your speech is soon coming to an end*

STRONG VOICE

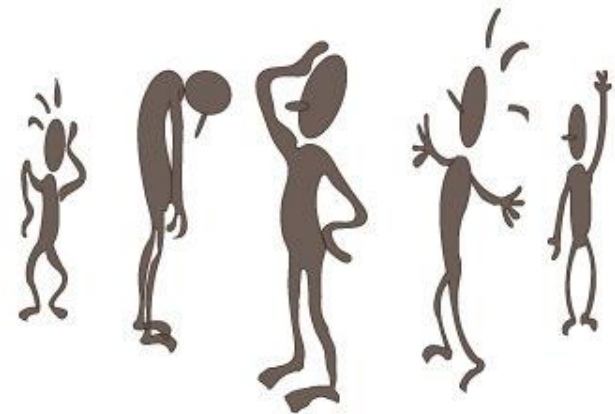
ARTICULATION

VOICE MODULATION

BREATHE

BODYLANGUAGE

NON-VERBAL COMMUNIIATION



SPEAKS LOUDLY

Speeches: body & soul

- **Wear something smart but comfortable**
- **Find out the dress code of the day (formal/informal)**
- **Room set-up: size and speakers position**
- **Use strong & open gestures and slow movements**
- **Use movement with a purpose**
- **Avoid distracting movements - i.e. jangling coins or flipping a pen**
- **Avoid 'velcro' arms!**
- **Your eyes are part of your body**

Powerpoint presentation

- Powerpoint supports the speaker, it is not a substitute!
- Powerpoint is a graphic programme, not a word processor!
- One graph/image says more than a hundred words
- No sentences, but key words in bullet points



Powerpoint presentation

- Number of slides in proportion to time
- ‘Guide’ the audience and do not read your slides
- Physical set-up between you, your powerpoint & the audience: do not turn to the screen
- Animations: use with caution
- Watch out for acronyms



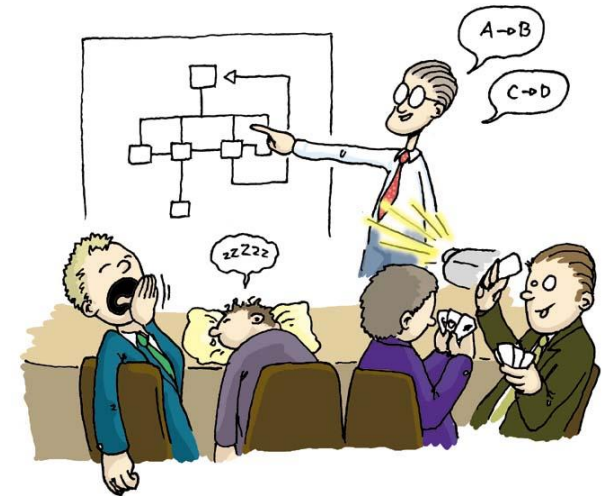
Stress management

- **Be well prepared**
- **Rehearsing**
- **Breathe**
- **Find a comfort point in the room**
- **Pausing is not a sin**



Managing questions & disturbances

- Anticipate questions in your preparation; know your audience
- Foresee Q&A time
- Short and to the point replies
- Stay calm, focused and credible



Social Media



Choosing Social Media



Scheduling and Frequency of Posting

	Frequency	Time of day	Day of the week
Twitter	5-10 times a day	9am-3pm	Thursday
Facebook	3 times a day	1-4pm	Wednesday and Sunday
LinkedIn	2 times a day	7-9 am and 5-6 pm	Tuesday and Thursday
Google+	3 times a day	9-10am	Wednesday
Instagram	As appropriate	As appropriate	Monday and Thursday
Pinterest	5-10 a week	9-11 am	Saturday

Do's and don'ts

- Plan ahead, earmark certain dates, but make sure you interact
- Number of posts is key, followers/contacts is even more important!
- Diversify your messages in accordance to the channel
- Monitor all your social media channels daily for comments (positive and negative ones) and respond effectively.
- Don't get involved in a negative spiral and be selective on what you get involved in.
- Links and hashtags a must, but used moderately.
- Visuals get the message across even better.



Working with press



Journalists and news



- In a rush
- Under pressure to produce, write
- Competition for attention
- They are not researchers
- You are the expert-not the victim!



- Anything new or unusual
- Criticism, controversy, rows
- Winners and losers/heroes and villains
- Interesting numbers/trends
- The future/forecasts/predictions

Remember:

You're not talking TO the journalist, you're talking THROUGH the journalist.

What journalists are looking for

- Interesting words - “Soundbites”
- No jargon
- Key facts, numbers
- Examples, case studies

George Robertson:

“Getting NATO members to agree on anything is like trying to carry frogs in a wheelbarrow.”



Fortis Invest:

“The failure of Lehman Brothers had the effect of a stone being thrown into a delicate spider’s web.”

Writing a good press release: content and structure

- Identify news “peg
- Who, what, why, where, when, how?
- Find catchy headline
- Think of picture opportunities
- Don’t forget contact details
- Max 1 page



- Para 1: State the news
- Para2: Explain the impact of the news
- Para 3: Quote from key player
- Para 4:Recent background relating to news being announced
- Para 5:General information on the organisation

TV and Radio Interviews

- Aim to sound positive, authoritative
- Energy x 5
- Never “No Comment” or “Off the Record”
- Avoid hypothetical questions
- Admit when you don’t know
- Don’t assume you’re off air immediately



The Magic Box

Key message(s)

- 1.
- 2.
- 3.
- ...

Key words and 'signposts'

- 1.
- 2.
- 3.
- ...

'No go' areas

- 1.
- 2.
- 3.
- ...

Questions

Additional info





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