



Department
for Environment
Food & Rural Affairs

Evidence-based policy making while the evidence is patchy: pharmaceuticals in the aquatic environment.

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Outline

- How we got to current point in EU legislation
 - Where that leaves us (EU) for now
 - Policy considerations
 - Evidence needs / next steps
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- NB civil servants advise, ministers decide

Water Framework Directive

WFD – aim to achieve good status by 2015, may take until 2027 if exemption criteria met.

Annex X – priority substances, set by...

- Environmental Quality Standards Directive 2008/105/EC (EQSD) sets standards for 33 chemicals in surface waters;
- QA QC directive 2009/90/EC – the quality control measures for monitoring;
- Priority Substances Directive 2013/39/EU;
- Next review of EQSD expected 2017.

Key points of EU legislation on pharmaceuticals

- Veterinary medicines – authorisation dependent on Environmental Risk Assessment
- Human medicines – since 2006 environmental impact assessment required; authorisation cannot be withheld on basis of environmental concerns
- Watch list to gather evidence on E2, EE2 + DCF
- Waiting for EU Commission (DG SANCO) study on the risks posed by medicinal products in the environment.
- DGs ENV + SANCO then 2 years to develop a strategic approach to pollution of water by pharmaceutical substances.

Negotiation on revised 2013 Directive

- Commission proposal published Jan 2012 set EQS for 15 new priority substances,
- Included estradiol (naturally produced plus use in HRT), EE2 (contraceptive) and diclofenac (anti-inflammatory).
- Council and European Parliament Discussions Feb 2012 – Jan '13
- Trilogue negotiations Feb – April 2013
- Publication of revised Priority Substances Directive August (2013/39/EU)



The watch list

- Mechanism to gather information on the occurrence of emerging pollutants across the EU.
- Outcome of negotiations is that E2, EE2 and diclofenac will be on first watch list of 10 substances (rising to 14).
- Detail of process and content to be confirmed.
- First watch list due from Sept 2014.



Short term - Why was the proposal to set EQS for pharmaceuticals contentious?

- Commission's Impact Assessment – i.e. the socioeconomic evidence base underpinning the legislative proposals:
 - Costs (20bn euro / 20 yrs in UK); benefits “might improve fish stocks”
 - Lack of consideration of impacts of other options such as restriction
- “Fast tracking” of pharmaceuticals to prioritisation (non-comparability with other proposed priority substances)
- Environment policy “overriding” health policy

WFD – PiE lessons learned

- Concerns around harmful effects of certain pharmaceuticals in the environment.
- Prioritisation process under WFD to be refined to better incorporate pharmaceuticals
- Good quality impact assessment necessary for effective legislation (i.e. costs and benefits)
- Improve socio-economic evidence base.

- We are talking about medicines which are chemicals we use to improve our quality of life!

When is the time to act?

- Robust evidence needed – rarely “cutting edge”
- Consideration of impacts of possible policies eg environmental impact of 1000s more people if restrictions on contraceptive pill...
- Opportunity now to innovate -
 - eg less energy-intensive wastewater treatment.
 - new medicines
- More broadly, should the question be about “beneficial chemicals”, rather than individual as driven by an EQS?





Morris, CEFAS, 2013

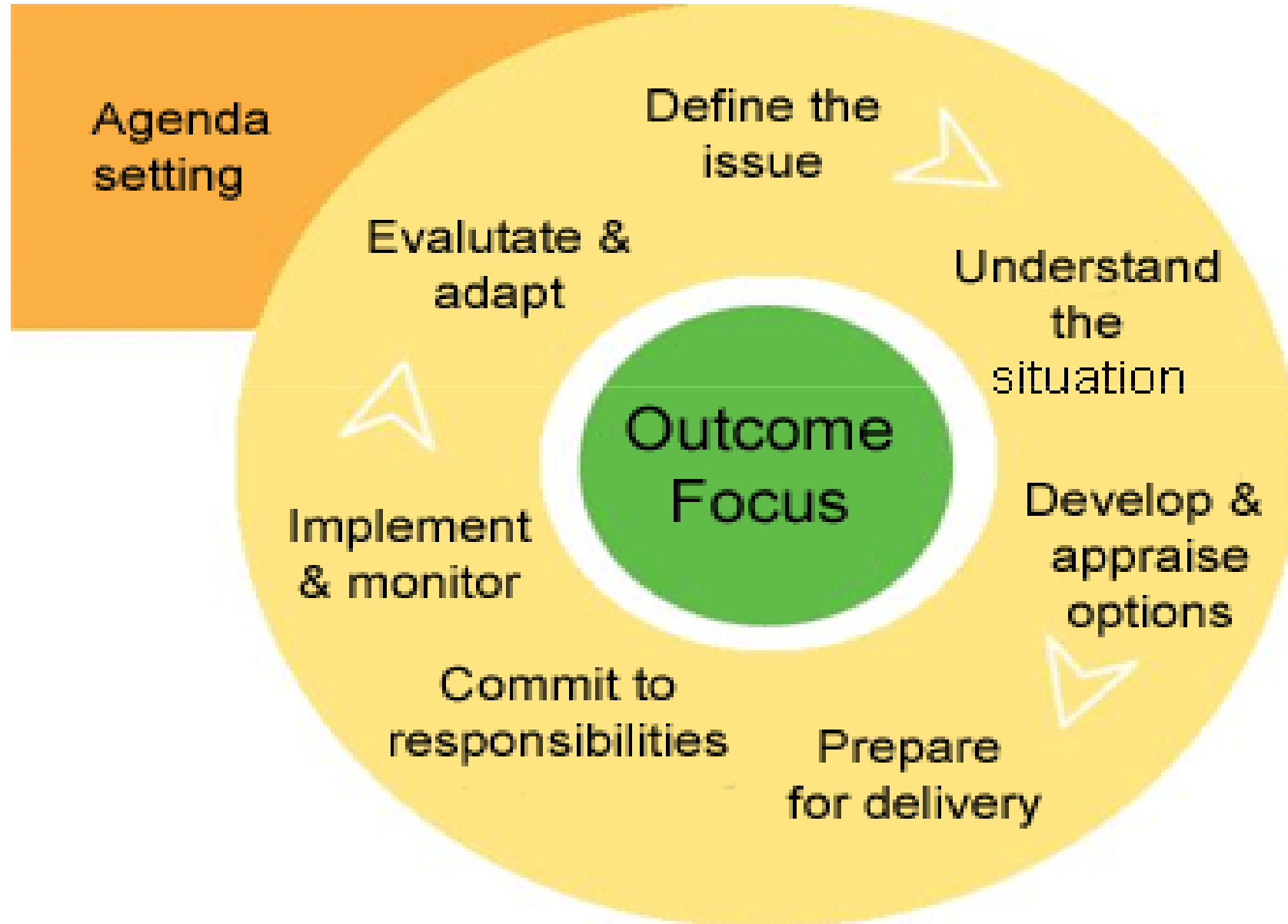
Summary of influences on policy makers – Dynamic!

What we are trying to achieve - the bottom line

- Improve environmental quality
 - Safe and sustainable water resources
 - Access to effective medicines
 - Affordable water and medicines
- **Looking to balance environmental protection with socioeconomic and public health needs**



Policy cycle



Evidence base

- UK Water Industry Research Chemicals Investigation programme – types and sources of chemicals in wastewater effluent
- EU FP7 projects eg PILLS, PHARMAS
- Independent review of government approach - House of Commons

Inquiry



House of Commons

Science and Technology
Committee

**Water quality: priority
substances**

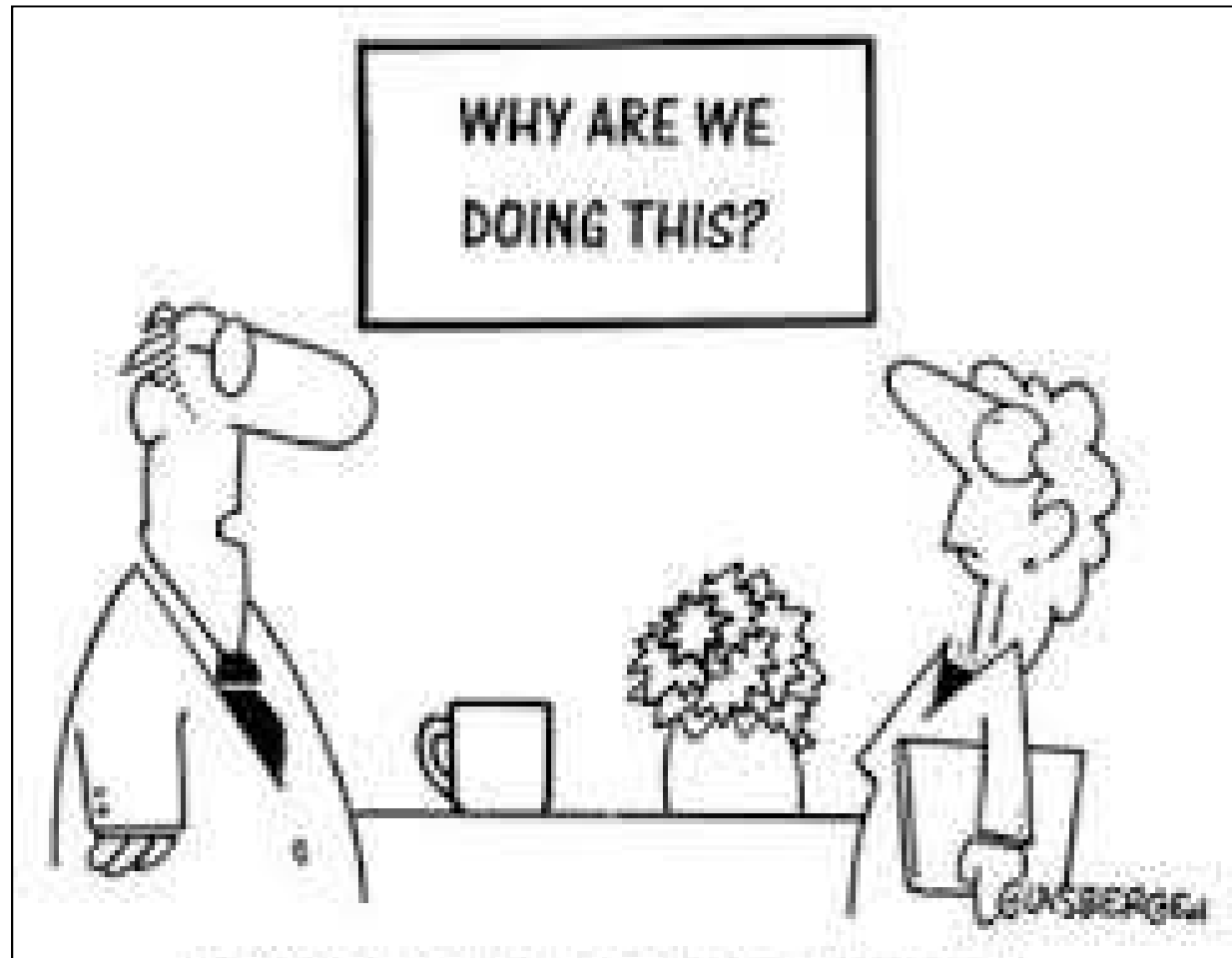
First Report of Session 2013–14

Evidence needs for policy

- Is there really an issue? - Impact of medicines on the aquatic environment eg population effects?
- Socioeconomic assessment framework
- Energy efficient, effective wastewater treatment for trace chemicals (not just pharmaceuticals)
- Environmental risk assessment of medicines and availability of alternatives
- Future pharmaceutical / metabolite loads reflecting demographic change
- Climate change impacts
- Mixtures

How we are developing the policy

- Developing socioeconomic assessment framework
- Engaging others in the debate – not just PiE experts!
- Developing our strategy around chemicals in water
- Looking ahead to possible EU legislation – Pharmaceuticals, Water Framework Directive



“If I had £20-30billion to spend on the UK environment, is meeting an EQS the most beneficial thing I could do?”