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Is this input submitted as an organisational or individual response? Individual
Are you happy for your response to be published by the Academy? Yes

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1. The overarching aim of the workstream is to better understand how society uses evidence to judge the risks and benefits of medicinal products. In your view, what are the key factors underpinning this process that the Academy should consider?

The sad reality is that significant amounts of evidence of how culture and systems science influences decision making about evidence has not been acted upon systematically. This was first highlighted in the seminal book To Err is Human by the Institute of Medicine. There was a response to this from the US National Patient Safety Foundation who convened a multi-stakeholder conference and produced a draft report which I attach. Unfortunately no such meeting has happened since and certainly the recommendations in the report have not been acted upon systematically. Yes, there has been patchy and partial adoption but not systems –wide.
Why is this? The reason is simple Society as a whole does not have agreed Guiding Safety Principles for safe use of medicines and I attach my peer reviewed argument for this (Guiding Principles for Pharmaceutical safety Culture Current Drug Safety 2007; 2: 135-139)
This was followed by two further editorials discussing further system weaknesses with recommendations for actions which I attach (Restoring Public Confidence and Trust Based on a Systematic Approach to Safety Monitor April 2011; What Can Be Done to Improve Confidence in the Safety of the System for Pharmaceutical Products? Current Drug Safety, 2013, Vol. 8, No. 1).

A systems wide analysis of medicine safety in the UK has never been performed. To illustrate my point see the paper by (Vicki Lewis et al. Current Drug Safety, 2013, 8 Defining the Pharmaceutical System to Support Proactive Drug Safety) as she analyses the US pharmaceutical system much of which can apply to the UK although names and details differ.
Similarly, the attached article by Leveson et al. (Journal of Healthcare Engineering Vol. 3 · No. 3 · 2012) is another attempt to define the US system. Pharmaceutical safety. To my knowledge, these are the only 2 published systems assessment of safe use of medicines.

5. Please highlight any broadly applicable principles that should govern the presentation, interpretation and weighting of evidence about medicinal products.

Please find attached my published article entitled Guiding Principles for Pharmaceutical safety (Culture Current Drug Safety 2007; 2: 135-139)

7. Please outline any past, current or planned initiatives to examine how patients, citizens and healthcare professionals (and those who seek to inform them) evaluate scientific evidence about medicinal products.

The Academy may like to know that a dedicated pharmaceutical human factors group has been set up within the Chartered Institute Ergonomics and Human Factors http://www.ergonomics.org.uk/ This will be a novel stakeholder group where all involved across the system for medicines can come together to seek systems solutions for safe use of medicines. I chair this group and would be happy to liaise with Academy

8. What are the most effective ways of communicating evidence to various stakeholders and engaging with them about such evidence?

Much has been published about optimal ways of communicating evidence and this was assessed in a special edition of Drug Safety within which is the article Risk Communication and the Pharmaceutical Industry: What is the Reality? Drug Saf 2012; 35 (11): 1027-1040 which I attach. There is a subsequent follow up-article to this entitled The Future of Risk Communication and the Role of the Pharmaceutical Industry by Sweta Chakraborty and Frederic Bouder (who are independent academics).

Attached Documents:

- Chakraborty S & Bouder F (2013). *The Future of Risk Communication and the Role of the Pharmaceutical Industry*. Current Drug Safety **8(1)**.
- Dye KMC (1999). *Developing a Consensus on the Accountability and Responsibility for the Safe Use of Pharmaceuticals: a Preliminary White Paper*.
- Edwards B (2007). *Safety Ethics as Central to the Management of Benefit and Risk*. Monitor, 23-27.
- Edwards B & Chakraborty S (2012). *Risk Communication and the Pharmaceutical Industry: What is the Reality?* Drug Safety **35(11)**, 1027-1040.
- Edwards BD & Krokstad TH (2011). *Restoring Public Confidence and Trust Based on a Systematic Approach to Safety*. Monitor, 47-50.
- Edwards B, *et al*. (2007). *Guiding Principles of Safety as a Basis for Developing a Pharmaceutical Safety Culture*. Current Drug Safety **2(2)**, 135-139.
- Edwards BD, Whalen MD & Powell SM (2013). *What Can Be Done to Improve Confidence in the Safety of the System for Pharmaceutical Products?* Current Drug Safety **8(1)**.
- Leveson N, *et al*. (2012). *Applying System Engineering to Pharmaceutical Safety*. Journal of Healthcare Engineering **3(3)**, 391-414.
- Lewis VR, Hernandez A & Meadors M (2013). *Defining the Pharmaceutical System to Support Proactive Drug Safety*. Current Drug Safety **8(1)**.