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

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Email from Jenny Goodare to Claire Cope
21 September 2015 18:24
How does society use evidence to judge risks and benefits of medicines?

Good afternoon,

I just wanted to get in touch regarding the consultation *How does society use evidence to judge risks and benefits of medicines?*.

I'm not sure that the issues we wish to raise fall very neatly within the assigned questions. It may be that it is not in scope, but I just thought I would raise alongside the questions in case it was useful.

Just to give a brief background, Breast Cancer Now is supporting Nick Thomas-Symonds MP's Off-patent Drugs Bill and has campaigned for several years on the challenges of making (clinically-proven) repurposed drugs routinely available to patients.

At present there is a clear market failure in the current regulatory pathway in the UK. This is caused by the lack of commercial incentive for a pharmaceutical company to license and drive adoption of a treatment, if it's shown to be effective in a new indication once the patent on a drug has lapsed. As a consequence, the treatment is usually not put forward for licensing or health technology assessment (HTA), and therefore NHS adoption is piecemeal and some patients are denied access, despite the treatment being low-cost.

We feel that regulatory processes in the UK need to evolve to ensure that off-patent drugs in new indications with sufficient evidence to be licensed and/or implemented in a clinical setting are able to be approved for routine commissioning, and that all relevant health professionals are fully informed about how to administer the treatment and are confident in doing so.

This market failure is currently a barrier to the uptake of new products that are both clinically- and costeffective.

With the repurposing of drugs becoming increasingly common, we feel that the UK has the opportunity to future-proof the drug approval and adoption system in the UK, and become the best place in the world to repurpose drugs.

Relevance to the AMS consultation
We feel that this issue cuts across the different themes of the consultation, and therefore might be something you wish to touch on. For instance, it highlights the limitations of the drug licensing system in the UK as being unable to clearly distinguish between safe and unsafe products - if some products are ineligible purely for commercial reasons. It's also an example of how conflicts of

interest impact on the perception of evidence, as commercial considerations, and not just safety and efficacy considerations, affect whether companies choose to pursue treatments to the licensing and adoption stage. Evidence supporting new treatments is also rarely communicated to health care professionals to support informed decision-making unless it is being driven by a company with a commercial interest.

This is problematic because the off-label or unlicensed status of a treatment can have a big impact on prescribing behaviour and how its safety is perceived by doctors, even when the treatment has the requisite evidence to be licensed for the new indication.

For instance, in a talk at an RCGP conference (I think in 2013), Dr Megumi Baba reported that in a survey with 80 respondents (46 paediatricians, 29 GPs and 5 foundation year doctors) to find out their interpretation of the phrase ‘not licensed for use in children’, 61% thought it meant ‘safety untested’, 58% thought ‘not to be marketed’ (correct answer) and 45% thought ‘efficacy untested’. 8 trainee doctors thought supplying unlicensed drugs was illegal and 7 thought it was illegal to prescribe. Only 58% of consultants and 46% of qualified GPs answered correctly.

I would be very happy to talk about the issue further or to talk you through the Bill and the wider nonlegislative work we have done in this area. I also attach a briefing in case this is useful.

Best wishes for a successful project,
Jenny