Andrew Miller MP  
Chair,  
Science and Technology Committee (Commons),  
House of Commons,  
London SW1A 0AA

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From Dan Rogerson  
Parliamentary Under Secretary of State for Water, Forestry, Rural Affairs and Resource Management

Dear Andrew

Further to the Government response to the Committee’s 2013 Inquiry into Priority Substances, I am writing to update the Committee on progress with development of the evidence base on pharmaceuticals in the environment.

Background

The Priority Substances Directive 2013/39/EU was published in August last year, with a transposition deadline of September 2015. The “three pharmaceuticals” (ethinyl estradiol (“EE2”), estradiol and diclofenac) will be on a watch list to gather information on emerging pollutants across the EU. Although that list may be published from September 2014, we are still waiting on further detail about the proposed process etc. from the European Commission.

The 2013 Directive requires the European Commission to develop a strategic approach to pollution of water by pharmaceutical substances, as far as possible within two years, and may include proposals enabling the environmental impacts of medicines to be taken into account more effectively in the procedure for placing medicinal products on the market. By September 2017, the Commission should propose measures to address the possible environmental impacts of pharmaceutical substances with a view to reducing discharges, emissions and losses of such substances into the aquatic environment, taking into account public health needs and the cost-effectiveness of the measures proposed. The European Commission have recently conducted a workshop to develop their strategic approach.
Widening the debate

Over the last year, my officials have expanded the cross-government Pharmaceuticals in the Environment (PiE) network. In particular, introducing external experts has increased the perspective available to the group. This has helped to broaden the debate on PiE across the UK. Defra recently led a workshop across sectors affected by the issues, stimulating debate and helping us to better understand the risks, for instance, by bringing in experts on patient perspectives.

The workshop was well-received, particularly by those who had not previously been engaged in the PiE discussion. Summarising the outputs, there was agreement that the evidence base needed improving in a number of areas, including ecotoxicological data; quality of research; and access to data (e.g. those owned by pharmaceutical companies). Participants also considered that there was a need to improve the impact assessment of reducing pharmaceuticals in the environment, to take account of human health and societal impacts and to quantify the benefits of such action. They felt the UK should promote its expertise with the EU Commission and that further work is required to identify what degree of effect to aquatic life is unacceptable (e.g. individual or population?). Given the evidence currently available, there was a call from participants for government to be more robust about the actual level of risk, with the question remaining as to whether pharmaceuticals in the environment really are a problem.

We will be using the outputs to inform our further work in this area, in the context of broader work to look at challenges of chemical micro-pollutants in water.

Research activities

My Department is funding a project with the Centre for Ecology and Hydrology “Intelligent ecotoxicology of chemicals and substances in UK rivers- development of a systems based approach”. The study considers pharmaceuticals alongside a number of other pollutants subject to chronic discharge from the human population and is expected to report at the end of 2015. It is reviewing the information we have available now to examine how chemicals could be ranked with current knowledge. Preliminary results suggest that it would appear that the historic focus by environmental scientists and regulators on metals has been justified. There is little evidence of pharmaceuticals having a significant effect on aquatic wildlife, with the exception of EE2 which appears to pose a risk to fish. What has been highlighted by the study however, is that to date only a small proportion of pharmaceuticals have been studied.

With steering group including members from the Department of Health, my Department has also funded a “Review of socioeconomic impacts of pharmaceuticals in the water environment”. The final project report is expected shortly. Its outputs should include a literature review, scoping of possible impacts (costs and benefits), a gap analysis and approaches to addressing any valuation gaps.
Reports of Defra’s Research and Development activity are made available through the website http://randd.defra.gov.uk/

A number of relevant other initiatives are under way. In particular, UK Water Industry Research recently undertook the collaborative project, a “Risk based prioritisation of pharmaceuticals”, the outputs of which will be used to inform further work on characterisation of chemicals in wastewater. The pharmaceutical industry is developing its approach to PIE and has launched a call under its Innovative Medicines Initiative “Ecorisk” to develop a methodology for the prediction of the potential environmental risk of pharmaceutical substances http://www.imi.europa.eu/content/11th-call-2013-8.

I consider the issues highlighted by pharmaceuticals in the environment as significant and intend to undertake further work to develop our understanding.

DAN ROGERSON MP