Steve Reed
Secretary of State
DEFRA
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Copied to:

Mary Creagh, Minister for the Environment, DEFRA
Karin Smyth, Minister for Medicines, DHSC
Baroness Gillian Merron, Minister for Life Sciences Regulation, DHSC
Axel Heitmueller, Health Advisor, Prime Minister's Office
Isabel Abbs, Health Advisor, Prime Minister's Office
Varun Chandra, Business and Investment Adviser, Prime Minister's Office

Dear Secretary of State,

Extended Producer Responsibility (Packaging) Scheme:
Joint Letter from Healthcare Sector Industry Associations

As representatives of the medicines, medical devices, diagnostic and digital health technology sectors in the UK, we have significant concerns about the way the Extended Producer Responsibility for Packaging (pEPR) scheme will impact on the UK health system. We are committed to reducing the environmental impact of our products, but we need to work with Government do so in ways which recognise the highly specialist and tightly-regulated nature of our products and distribution channels. We do not believe the current pEPR scheme does this, and we urge the Government to pause the reporting and cost requirements of pEPR until a specialist packaging scheme has been developed for our sector.

Our concerns about pEPR as currently constituted are as follows:

- Medicines, devices, diagnostics and digital health products, including their packaging, are tightly regulated by bodies such as the MHRA. Changing packaging can only be done with permission from these authorities after they have considered evidence that the move will maintain the safety and efficacy of the product. Generating this evidence and obtaining approval is a lengthy and costly process. Should healthcare manufacturers look to reformulate their packaging to comply with the pEPR scheme, this could put additional pressure on regulatory bodies at a time of already strained capacity. For these reasons, in the short to medium term, the EPR scheme is unlikely to change much medical packaging: instead, it will simply act as an extra cost for health suppliers.

- Our members will have little alternative to passing on these increased costs to the NHS. The pEPR scheme will therefore transfer resources from the NHS to local authority waste processing operators, undermining the Government's drive to increase funding for the NHS.

- The EPR scheme requires producers to distinguish between packaging disposed of in homes and that disposed of in hospitals and other healthcare settings, which oversimplifies how products reach patients. Many of our products can be used in either setting. To identify where they have been disposed of requires a huge amount of information from the NHS organisations which have provided them to patients. The Government is seeking to reduce the amount of reporting front-line NHS organisations must do, not increase it, but this aspect of the scheme undermines this effort.

- DEFRA has recognised the aspect of the scheme addressing dual-use products is unworkable, but has insisted it must remain in place for the first year of the scheme's operation. The department has given our sector a very limited amount of time to propose a new methodology for this part of the scheme, get it consulted on and approved, get the scheme fees recalculated on the basis of the new system, and introduce new language into a draft Statutory Instrument. We do not believe it is possible to meaningfully achieve this task in the short amount of time we have been allocated and fear that such a rush fails to acknowledge the complexity of the sector. Our sector has been raising concerns over this policy for over a year, with little engagement from DEFRA.

- Some of the EPR scheme fees for next year have just been published (base fees and the 'red' surcharge); others (the 'green' discount) remain unknown. Not only does this level of uncertainty mean that companies cannot accurately undertake financial planning for the following year, it also runs counter to the Government's pledge to provide certainty for business to enable investment and economic growth.

- By imposing fees on packaging disposed of in households, but not on packaging disposed of in hospitals, the scheme penalises suppliers supporting the 10 Year Health Plan for England's drive to move care out of hospitals and into the community.

In short, this scheme will undermine the 10 Year Health Plan, NHS funding, NHS front-line organisations, the MHRA and economic growth. The healthcare sector should be exempt from the scheme in its current form.

Other environmental initiatives in our sector would have greater impact: for instance, moving to digital-first patient information for medicines and electronic Instructions for Use for medical devices and in-vitro diagnostics, with non-digital backup routes for those who cannot access electronic information. This would remove the need to provide paper leaflets in 3 billion medicine packs a year: producing these leaflets creates, at a conservative estimate, 18,000 tonnes of CO_2 equivalent. And with over 600,000 different medical devices registered on the UK market, the removal of paper Instructions for Use for them is considerable. This move would align with the 10 Year Health Plan's shift to digital, and also improve healthcare supply chain resilience, as problems with leaflets often stop production runs. We would welcome support from

DHSC and DEFRA for this initiative to reduce the environmental impact of packaging, as an alternative to pEPR.

In summary, we support the goal of reducing the environmental impact of healthcare packaging, but we need to do so in a practical, proportionate way, and the Government needs to work with our sector to design a scheme which reflects its complexity and regulation.

Signed,

- Mark Samuels, CEO, Medicines UK
- Michelle Riddalls OBE, CEO, PAGB – the Consumer Healthcare Association
- Peter Ellingworth, CEO, Association of British HealthTech Industries
- Sally Edgington, CEO, AXREM - Association of Healthcare Technology Providers, Imaging, Radiotherapy & Care
- William Lee, Head of Policy and Compliance, British Healthcare Trades Association
- Paul Fisher, Director of Policy and Programmes, BIVDA, British In-Vitro Diagnostics Association
- Martin Sawer, Executive Director, Healthcare Distribution Association
- Dr Andrew Tittershill, Secretary General, British Association of European Pharmaceutical Distributors