

PAGB briefing on Extended Producer Responsibility for packaging requirements

PAGB, the consumer healthcare association, represents the manufacturers of branded over-the-counter (OTC) medicines, self-care medical devices and food supplements in the UK.

About this briefing

This briefing provides an overview of the Extended Producer Responsibility for Packaging (pEPR) scheme as set out by the Department for Environment, Farming and Rural Affairs (DEFRA), and how it relates to the OTC sector.

It also outlines PAGB's concerns regarding the scheme, the impact it will have on our members and what we are doing to try and mitigate the consequences of the scheme.

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What is Extended Producer Responsibility for Packaging?

Extended Producer Responsibility for Packaging (pEPR) is a project within the UK Government's wider collection and packaging reforms which requires packaging producers to take responsibility for the environmental impact of the packaging they place on the UK market. This includes reporting packaging data, paying fees, and ensuring packaging is recyclable.

What is packaging?

According to <u>DEFRA</u>, packaging is 'any material that is used to cover or protect goods that are supplied. It makes handling and delivering goods easier and safer'. It also states that packaging can 'make good looks appealing for sale and may display a company's logo or brand'.

Who is responsible for regulating the scheme?

<u>PackUK</u> is the scheme administrator for pEPR. It was launched by DEFRA on behalf of the four UK nations. PackUK's primary role is to shift the cost of managing household packaging waste from taxpayers and local authorities to producers or packaging. It will collect fees from obligated producers and distribute these funds to local authorities to support improvements in packaging waste collection and recycling.

What are the aims of the scheme?

The scheme, which came into effect on 1 January 2025, will secure local authority funding for the improved management of discarded packaging materials. The aim is to drive improvements in the quality and quantity of recycled materials, investment in domestic reprocessing facilities, economic growth and new jobs across the UK.

In terms of the environment, the pEPR scheme aims to:

- Encourage the use of environmentally sustainable packaging
- Reduce the amount of packaging becoming waste and increase the reuse of packaging

• Reduce the amount of packaging material placed on the market

Who does the scheme apply to?

The regulations will apply to all obligated UK organisations that import or supply packaging. Companies must collect and report packaging data for a given year if all the following apply:

- The organisation is an individual business, subsidiary or group (but not a charity)
- The organisation has an annual turnover of £1 million or more, based on most recent annual accounts up to 7 April each year
- The organisation was responsible for importing or supplying more than 25 tonnes of packaging to the UK market in the previous calendar year
- The organisation carries out any of the packaging activities

What to do if you are a 'small producer'?

A small producer is an organisation that either:

- has an annual turnover of more than £1 million and up to £2 million and supplies more than 25 tonnes of packaging in the UK
- has an annual turnover of more than £1 million and supplies more than 25 tonnes and no more than 50 tonnes of packaging in the UK

Small producers must keep records about:

- Packaging activities
- The 'class' of any packaging
- The packaging material
- The weight of each packaging material

What packaging is in scope of the scheme?

Currently only household packaging waste is subject to pEPR fees by obligated producers. All types of household packaging, with the exception of drinks containers, are covered by the scheme. This includes packaging waste that ends up in households and workplaces; packaging used to protect goods when they are being transported; and packaging used in restaurants such as takeaway food containers.

All producers must report their tonnages of packaging placed on the market on the <u>Report Packaging Data online portal</u>.

What is classed as household waste?

According to the Producer Responsibility Obligations (Packaging and Packaging Waste) Regulations 2024, primary packaging and shipment packaging must be classed as household waste unless it meets specific conditions. This would include blister packs, pill bottles, performance information leaflets etc.

What is the Recyclability Assessment Methodology (RAM)?

The RAM is a framework which is used to assess the recyclability of household packaging and inform EPR fees. It evaluates packaging based on its ability to be collected, sorted and reprocessed into new materials using a Red, Amber, Green (RAG) system to categorise recyclability. The aim of the RAM is to help producers understand the environmental impact of their packaging and how they could adjust their designs to improve recyclability.

As of 1 January 2025, liable producers who supply household packaging must assess the recyclability of that packaging and report the results to PackUK. To do this, producers must assess packaging they supply using the RAM. The most <u>recent methodology</u> was published on 28 April 2025.

How does the RAM work?

The RAM requires producers to input data about their household packaging, including material composition, contaminants and collection, sorting and reprocessing capabilities. The methodology analyses data to determine if the packaging can be effectively recycled and transformed into new products.

There are 8 material categories in the RAM. Each unit of packaging or component should be assessed under <u>one of these categories</u>.

Material	Rate (in £ per tonne)
Aluminium	266
Fibre-based composite	461
Glass	192
Paper and card	196
Plastic	423
Steel	259
Wood	280
Other	259

<u>Large producers</u> will be required to submit data every 6 months whilst a <u>small producer</u> will only have to supply data once a year.

The RAM then assigns a RAG rating to each packaging component which will directly influence the fees producers pay under the scheme.

How do modulated fees work?

Using the RAM, producers will be able to assess the recyclability of different packaging materials. Modulated fees will then be adjusted based on the recyclability of those packaging materials. Producers will pay higher fees for packaging that is difficult to recycle and lower fees for packaging that is easily recyclable, as set out in the RAG scale:

• Red packaging has specifications that make it difficult to recycle at scale

- Amber packaging may experience challenges during collection and sortation, requires specialist infrastructure for reprocessing, the efficiency and output quality of reprocessing is affected, or there is some secondary material loss
- Green packaging is widely recyclable in the current UK infrastructure

Earlier this year, PackUK published a <u>policy paper</u> on modulated disposal fees for pEPR. It states that modulation will begin from year 2 of the scheme, with the first modulated fees 'applying to disposal fee calculations for the 2026 to 2027 financial year (calculated using data relating to packaging supplied in 2025)'.

The policy paper should be read alongside the <u>guidance on base fees</u>. In the future, base fees will be published with modulated fees following the submission of packaging data by obligated producers.

From 2026, the base fee provided for each material 'will be calculated using a household packaging waste tonnage fee and be reflective of an Amber rating'. For materials classed as Red under the recyclability assessment methodology, the <u>modulation factors</u> can be found below.

Table 1: Modulation factors per year

Assessment Year	Factor
2026 to 2027	1.2
2027 to 2028	1.6
2028 to 2029	2.0

Materials that are exempt from a recyclability assessment include:

- Reused packaging, unless it has been imported into the United Kingdom
- Any packaging exported from the United Kingdom by the producer
- Drinks containers made of polyethylene terephthalate (PET) plastic, steel or aluminium
- Drinks containers for which a deposit is payable and is within scope of a DRS which is in operation
- Non-household packaging

How does the scheme apply to OTC medicine manufacturers?

According to PackUK, medical packaging is **not** exempt from fee modulation and obligated producers must therefore comply with the EPR scheme and assess the recyclability of its packaging via the RAM.

However, PackUK does recognise that <u>medical packaging</u> occupies a 'special place in the packaging landscape and is subject to a different approach to regulation to other types of packaging'. As a result of this, medical packaging will be treated differently to other packaging in that 'where medical packaging is assessed to be Red and the producer

determines that the packaging is Red by virtue of regulatory requirement, then it can be reported as Amber'.

What if your product is subject to dual-branding regulations?

According to the <u>Packaging Waste Regulations</u>, where two brands appear on a product, the first company to supply the packaging filled is the brand owner (<u>see regulation 16</u>, paragraph 3). A brand is defined in the regulations as 'a brand name, trade mark or other distinctive mark;' (see Regulation 2).

This means if your company name appears on the packaging, and you are the first company to sell the packaging with the product in it, you will be considered the brand owner and responsible for reporting it. The Environment Agency have confirmed that this is the case even in instances where legislation requires you to display your company name.

What are PAGB's concerns regarding the scheme?

- Although medicine manufacturers are working hard to mitigate the environmental impact of their products through a number of initiatives, many cannot easily reformulate their packaging, particularly product sensitive packaging such as blister packs, to be more recyclable due to a lack of feasible alternatives that would be appropriate for medicines.
- 2. Medical packaging for medicines, devices, and diagnostic products must follow strict rules set by the Medicines and Healthcare products Regulatory Agency (MHRA) to ensure safety and legal compliance. Any changes, such as the use of more recyclable materials, require official approval, which involves both time and financial investment. 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. So, while the new packaging rules under the EPR scheme may increase costs for healthcare suppliers, they're unlikely to lead to major packaging changes in the short term.
- 3. 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. The current proposals means that EPR will be payable for "household" products but not for those defined as non-household e.g. those provided in hospital or other healthcare settings. Given many of the products provided in hospitals and other healthcare settings may also end up in household waste, we remain concerned that the burden of reporting and financial pressure will be placed on our members compared to other medicine manufacturers purely due to the arbitrary distinction.
- 4. PackUK has <u>recognised</u> the aspect of the scheme addressing dual-use products (packaging which can be discarded by both consumers and businesses) 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 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.

- 5. 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.
- 6. 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.
- 7. We remain concerned by the lack of effective communication around the Environment Agency's clarification of dual-branding for medical packaging. This may have resulted in under/over-reporting of packaging data which risks undermining the efficacy of the EPR scheme.

PAGB has been working cross functionally with other trade associations, led by Medicines UK, to raise these concerns with DEFRA. As part of this work a joint letter between the trade associations has been sent 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

Within the letter we also highlight the work that is already being done by members to mitigate the environmental impact of their packaging. This include shifting 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.

The development of these electronic alternatives would remove the need to provide paper leaflets in 3 billion medicine packs a year which in turn would reduce approximately 18,000 tonnes of CO2 equivalent. And with over 600,000 different medical devices registered on the UK market, the removal of paper "Instructions for Use" would be considerable.

This move would also 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.

What is PAGB doing to mitigate the impact?

In July 2025, PAGB hosted a bespoke round table bringing together members of the Environment and Sustainability Working Group to discuss the issues around EPR and to understand the impact this is having on their organisations. It was a very constructive conversation and from this, we have relayed member concerns to DEFRA colleagues in various stakeholder meetings.

Earlier this month, PAGB also signed a joint letter alongside fellow trade associations highlighting common concerns as outlined above. Within the joint letter we urged the

Government to pause the reporting and cost requirements of pEPR until a specialist packaging scheme has been developed for our sector.

Next steps

PAGB continues to liaise with DEFRA and relevant colleagues to raise the concerns around EPR and the lack of effective communication on the complexities of the scheme. As part of this, we are navigating specific issues that members face, around the issue of dual-branding and the distinction between household and non-household waste.

In July 2025, PackUK and the Environment Agency convened a round table with trade associations representing medicine manufacturers to determine the appropriate methodology for defining household versus non-household waste. During this meeting, PAGB highlighted concerns about OTC medical packaging being subject to the EPR scheme as it currently stands and the unfairness of implementing an arbitrary distinction across the sector.

We have also been working with colleagues at DEFRA to gain clarity on the issue of dualbranding to ensure this is effectively communicated to members to mitigate the risk of inaccurate reporting across the OTC sector.

Although we are working hard to highlight the challenges associated with the scheme for medical packaging, given the tight timelines for implementation, we remain concerned that the window for influence is small and the implementation of the scheme is likely to proceed in its current form.

Contact information

If you have any questions about this briefing, please contact Hannah Hayes, Policy and Public Affairs Manager, at Hannah. Hayes@pagb.co.uk or on 07596 882900.

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