The Consumer Healthcare Association

HM Revenue and Customs

Plastic Packaging Tax

Submission from PAGB, the consumer healthcare association.
19 August 2020

PAGB, the consumer healthcare association, is the UK trade association which represents the manufacturers of branded over-the-counter (OTC) medicines, self care medical devices and food supplements. PAGB represents 42 manufacturers, a full list of our member companies is available on our website at https://www.pagb.co.uk/about-us/our-members/.

PAGB is not an obligated packaging producer under Producer Responsibility (Packaging Waste) Regulations in the UK and is not a business that manufactures or imports plastic packaging.

We do not require our response to be confidential.

PAGB welcomes the opportunity to respond to this consultation on the proposed plastic packaging tax, which from April 2022 will apply to plastic packaging manufactured in or imported into the UK containing less than 30% recycled plastic. In responding to this consultation, we have restricted our comments to the areas of most relevance to the consumer healthcare industry and where we feel we can most contribute to the debate.

Overall, we welcome the Government's acknowledgement of the safety concerns related to use of recycled content in the immediate packaging of medicines and therefore fully support the introduction of the narrow exemption being considered for medicinal packaging. The same safety concerns exist for substance-based, sterile, and invasive self care medical devices and we urge the Government to also exempt product-contact packaging for these medical devices. These categories of devices are clearly defined in EU regulations. In addition, the Medicines and Healthcare products Regulatory Agency (MHRA) will hold a list of all medical device products as a result of the Medicines and Medical Devices Bill, making such an exemption feasible for HMRC to administer.

Impact of COVID-19

We are grateful to HMRC for extending the deadline on this consultation to 20 August. We hope this will allow experts from relevant Government departments/agencies whose input is critical to these proposals, such as the Department of Health and Social Care (DHSC) and MHRA, to dedicate the necessary time to provide meaningful feedback on the proposals.

COVID-19 has caused disruption to normal supply chains / production and challenges to ongoing supply of products to consumers. Sourcing materials may be difficult, and all focus is currently on ensuring supply of vital medicines and consumer healthcare products, many

of which are needed now more than ever to help people manage their own health as access to usual healthcare provision is limited. Given the current situation, and the limitations in supply, an additional requirement for the industry to develop, and gain approval for, new packaging for medicines and self care medical devices at this time would provide an additional burden to the already strained situation. The magnitude of the impact on supply chains is also highlighted by the pragmatic approach MHRA has taken in response to COVID-19, MHRA is working closely with DHSC and other healthcare partners and stakeholders to rapidly develop a package of 'flexibilities' to regulatory guidance, in order to support the medicines supply chain and wider healthcare response to the COVID-19 outbreak in the UK. While this pandemic will (hopefully) pass before April 2022, when the plastics tax is due to come into force, the knock-on effect on businesses will still be felt for some time after.

Q1. Do you agree with the revised definition of plastic, which removes the 'main structural component' test and limits the exclusion to 'cellulose-based' polymers? Please outline your reasoning.

PAGB has no comment in response to this question.

Q2. Do you agree that packaging-type products that do not fulfil a packaging function until they are used by the end consumer should be included in the tax unless they are for longer term storage? Please outline your reasoning.

PAGB has no comment in response to this question.

Q3. Do you have any observations on the Government's proposed approach to exclude plastic packaging used to facilitate the transport of imported goods?

PAGB is supportive of the Government's proposed approach to exclude packaging used to facilitate the transport of imported goods. A number of important self care medicines and medical devices are manufactured outside of the UK and imported on pallets for use in this country. Exempting packaging which facilitates this import, such as pallets, crates, and pallet wrap, will help ensure UK citizens' access to these important products is not affected.

Q4. Do you think it is feasible to provide evidence that packaging has been commissioned for use as immediate packaging for licensed human medicines at the time the tax is chargeable? If not, please explain why.

Medicines

PAGB welcomes the Government's consideration of an exemption for medical packaging covering all human medicines licensed to be placed on the UK market under the Human Medicines Regulations 2012, given the strict regulatory and safety requirements for medical

packaging make the inclusion of recycled plastic extremely complex. As the regulatory requirements and safety concerns are greatest for the packaging in direct contact with the medicine, the proposal of the exemption to be limited to 'immediate packaging' of both prescription and over the counter medicines is reasonable.

The ability of plastic packaging to fulfil the technical functions that are necessary for medicines makes it an ideal packaging material:

- To ensure the product specification is maintained throughout its shelf life
- To maintain sterility and prevent potential contamination or degradation
- To prevent tampering and protect children from accidental exposure
- To support compliance and unit pack dispensing
- To offer additional safeguards to prevent or identify counterfeit products.

Medicines are subject to statutory requirements with regard to the nature of the immediate (primary) packaging (the container or other forms of packaging immediately in contact with the medicinal product). These requirements are intended to ensure the safety of any material that is in contact with the medicines as well as to ensure that the stability of the product is maintained.

The material/s used in immediate packaging and the standards they need to routinely meet, must be specified in the Product Marketing Authorisation to ensure the absence of toxic materials. The amount of data that is required to support the use of a specific material is extensive and costly to generate. The variability in content of recycled materials means that batch to batch quality cannot be guaranteed and therefore the provision of safeguards that packaging for medicines must carry cannot be assured.
There are specific requirements for the materials that can be used in the packaging for medicines. Standards for the materials used in packaging for medicines are currently set under the framework for food contact materials which ensures that chemicals in packaging will not transfer onto any product they may come into contact with. These are set out in Regulation 1935/2004[1] on materials and articles intended to come into contact with food as well as Regulation 10/2011[2] and Regulation 1282/2011[3] on plastic materials and articles intended to come into contact with food. In addition, there are restrictions to the use of recycled material in any food contact material which are set out in Regulation 282/2008 on recycled plastic materials and articles intended to come into contact with food[4]. The requirements for the use of recycled plastic in any food contact material must have been obtained from processes evaluated as safe by EFSA and, although multiple dossiers have been submitted, very few processes have been agreed as safe and very few plastic polymers are available for use.

An exemption from the tax for medicines would be based on the provision of evidence, at the time the tax would be chargeable, to ensure the packaging has been commissioned for use as immediate packaging for licensed human medicines. Due to the Good Manufacturing

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R1935-20090807&from=EN
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0010&from=EN
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1282&from=EN
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0282&from=EN

Practice (GMP) requirements that manufacturers of human licensed medicines must adhere to, all materials, including immediate packaging is fully traceable.

Depending on the supply chain a company has in place, we believe there are likely to be two scenarios for the taxable person:

- The manufacturer – where there is no manufacturing or packaging supply chain in the UK and finished products are imported for UK patients; or the manufacturer has a manufacturing facility in the UK and brings in packaging direct to its facility
- The packaging supplier – who is based in the UK and supplies packaging to a UK manufacturing facility.

Feedback from our members suggests that many of the self care medicines supplied to UK patients are brought into the UK as finished goods. As such, the exemption for the majority of medicines immediate packaging will be claimed by the manufacturer who will have all of the necessary information to evidence a medicines exemption.

When the packaging supplier is the taxable person, the manufacturer will need to provide the necessary information to the packaging supplier to evidence the exemption. We understand the packaging supplier will need to hold this information in their business records and produce it if requested. We believe that this is possible, given that the manufacturers have full traceability of the packaging material usage.

PAGB is willing to collaborate with HMRC and other government agencies to further refine the exact mechanism and to ensure that this can be achieved efficiently.

Medical devices

Medical devices placed onto the market in the UK must currently meet the requirements set out in the EU Medical Device Directive 1993 (Council Directive 93/42/EEC[5], MDD), transposed into UK law in the Medical Devices Regulations 2002 (also in UK law) and going forward the retained Medical Devices Regulation 2017 (Regulation (EU) 2017/745[6], MDR).

The MDR requires that medical devices be designed, manufactured, and packaged in such a way that they can:

- Achieve their intended medical purpose
- Maintain their performance and characteristics during their intended use and will not be adversely affected during transport and storage up to its shelf life
- Minimise the risk posed by contaminants and residue
- Where applicable, maintain sterility and prevent potential contamination or degradation

PAGB acknowledges the fact that medical devices can vary significantly and could cover a wide range of products from replacement hip and knee joints to blood-testing monitors and eye drops. We accept that exempting the packaging for all medical devices would be too

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31993L0042
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

wide reaching and, in some cases, could potentially exempt packaging that can safely include recycled content, with no or minimal additional burden.

However, we would specifically like to draw your attention to three specific groups of medical device products, namely substance-based, sterile, and invasive self care medical devices. The technical packaging requirements of these three groups of medical devices closely resemble those required for medicines. In the case of substance-based medical devices, these products are available in the same pharmaceutical forms as medicines (such as creams, tablets, solutions, drops, sachets etc) and bear a CE mark. The main factors that determine whether a product is a medicine or substance-based medical device are the stated intended purpose of the product and its mode of action.

For these three specific groups of medical device products (please refer to Table 1 below) the requirements for the immediate packaging closely resemble those for medicines and need to ensure the safety and stability of the product, with the same challenges in using recycled content.

Table 1: Proposed medical devices type to be exempt, together with their definition, their reference to legislation and examples

Medical Device types to be exempt	Definition	Reference to legislation/standards	Examples of products	Examples of immediate packaging
Substance-based medical devices	Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body	Regulation (EU) 2017/745[6] (MDR): Annex I, Chapter II, 12.2 Regulation (EU) 2017/745[6] (MDR): Rule 21 ISO 10993: Biological Evaluation of Medical Devices (biocompatibility)	Creams, eye drops, caps, tablets etc	Immediate packaging could consist of bottles, tubes, caps etc
Sterile products		ISO 11607: Packaging for terminally sterilized medical devices Sterile Devices are also labelled as 'sterile' on the pack with a symbol which would be easily identified	Sterile eye drops etc	Immediate packaging could consist of bottles, caps, tubes etc
Invasive devices	Any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body	Regulation (EU) 2017/745[6] (MDR): Article 2 (6) Regulation (EU) 2017/745[6] (MDR): Rules 5, 6, 7, 8	Condoms, lubricants	Sachets, tubes, caps etc

To comply with the MDD and MDR, substance-based medical devices need to take into account the standards already established for this type of product, such as contact with food requirements, and Ph Eur. specifications. The testing requirements for substance-based medical devices also involve extensive biocompatibility, migration, and stability testing to ensure the safety and effectiveness of the packaged medical device during its shelf life, especially for packaging in immediate contact with the device. Biocompatibility standard (ISO 10993 that could require chemical characterisation, product/pack interaction testing, testing on aged product) and sterile standard (ISO 11607) should also be followed where appropriate. Packaging is produced to an approved specification and is subject to the normal annual audit process. Child-resistant opening is a further key requirement for packaging and use of recycled material could affect performance against this requirement.

For both medicines and medical devices (Class IIa and above), changes to product contact packaging would need regulatory approval. Any new packaging material for medical devices, would need to be tested, validated, and then approved by a Notified Body. PAGB broadly supports the Government's suggested approach to defining recycled content for the purposes of the tax. However, while the inclusion of chemically recycled plastic and other innovative recycling processes is to be welcomed, these are not yet widely available and therefore cannot be relied upon to provide a source of recycled material.

From a quality point of view, products using 30% recycled plastic are weaker and have a higher contamination risk. Furthermore, the mechanical or chemical behaviour of the plastic material is impacted by the manufacturing and cleaning steps. This has to be considered for both medicinal products and medical devices which are in direct contact with humans. Last but not least, any recycling provisions should be discussed with other relevant government departments and agencies, including the MHRA, to ensure that they are achievable within the regulatory framework and maintain public health and safety. Any measures introduced should not increase the risk to public health.

In summary, the lack of precedent, lack of material for testing and lack of formal authorisation that materials are safe to use, combined with the extensive testing requirements, means that – as for medicines – it would not be appropriate to incentivise the use (and penalise lack of use) of recycled content in the immediate packaging for substance-based, sterile, and invasive self care medical devices.

We, therefore, ask HMRC to exempt these types of medical device (substance-based, sterile, and invasive self care medical devices) from the taxation, under the same conditions as medicines. Providing an exemption for these medical devices, given they have similar regulatory constraints and safety requirements as medicines, would ensure the continued quality, safety, stability, sterility, and availability of these important products. In addition, this will ensure that the highest safety standards are maintained for the vulnerable population using these products.

Similar to medicines, an exemption from the tax for medical devices would be based on the provision of evidence, at the time the tax would be chargeable, to ensure the packaging has been commissioned for use as immediate packaging for medical devices. Due to the Quality

Management System ISO 13485 requirements that manufacturers of medical devices have to adhere to, all materials, including packaging in contact with the medical device, are fully traceable.

Depending on the supply chain a company has in place, we believe there are likely to be two scenarios for the taxable person:

- The manufacturer – there is no manufacturing or packaging supply chain in the UK and finished products are imported for UK patients; or the manufacturer has a manufacturing facility in the UK and brings in packaging direct to its facility
- The packaging supplier – who is based in the UK and supplies packaging to a UK manufacturing facility

Feedback from our member companies suggests that many of the self care medical devices supplied to UK patients are brought into the UK as finished goods. As such, the exemption for the majority of packaging in contact with the medical device will be claimed by the manufacturer who will have all of the necessary information to evidence a medical device exemption.
When the packaging supplier is the taxable person, the manufacturer will need to provide the necessary information to the packaging supplier to evidence the exemption. We understand the packaging supplier will need to hold this information in their business records and produce it if requested. We believe that this is possible, given that the manufacturers have full traceability of the packaging material usage.

PAGB is willing to collaborate with HMRC, and other government agencies, in order to define the exact mechanism and to ensure that this can be achieved efficiently, including developing a clear definition of packaging for medical devices eligible for exemption.

List of medical devices to enable the administration of an exemption:

The consultation document (point 3.2.1) states that "*there is no clear list held by a regulator or other relevant body of all devices approved to be used in the UK which HMRC officers could reference as part of their assurance work*", however, this is factually incorrect. MHRA is the regulatory authority responsible for both medicines and medical devices in the UK. Currently, as part of the UK Medical Device Regulations, MHRA has a register of Class I medical devices in the UK. Under the Medicines and Medical Devices Bill, a comprehensive register of all medical devices will be developed, collecting appropriate levels of information about the medical devices available on the UK market. According to the Bill, this register would support the MHRA's critical market surveillance and oversight functions to ensure the ongoing safety of medical devices once they reach the market. In addition, following discussions with MHRA's Medical Devices Team, we were informed of the inclusion of a Medical Devices registry in the updated EU Exit SI. This document will be published later this year with the aim to become legally binding by 1 January 2021. This will therefore enable HMRC to identify medical devices and provide the assurance needed to offer an exemption from the plastics tax to these products.

Q5. Would the proposed exemption cause any market distortion or other unintended consequences? If yes, please provide more details.

Not providing an exemption for medicines and substance-based, sterile, and invasive self care medical devices could have unintended consequences for self care and demand on NHS services, and for the availability of these products for people who rely on them to manage their health conditions.

A central aim of self care is reducing unnecessary demand on the NHS. Any impact on the production or availability of OTC medicines and substance-based, sterile, and invasive self care medical devices could negatively impact some of the most disadvantaged members of society by reducing their access to self care products. This will in turn increase the burden on the NHS when GP services are accessed for conditions that could well have been managed with self care and the support of a pharmacist.

The length of time it would take to test a new material, create a dossier of information in relation to its stability and safety and submit it to the MHRA would be a significant regulatory burden. In some cases, smaller manufacturers may be unable to absorb the additional costs that would be incurred if exemptions for medicines and self care medical devices were not granted. This could result in products being withdrawn from the UK market, significantly disadvantaging people who rely on those products to manage their health and wellbeing.

<u>Implications of new medical device regulations:</u>

The medical device regulations are changing in the UK. The initial implementation day was 26 May 2020, but this has now been postponed for a year due to the COVID-19 crisis. This extension was given to allow manufacturers to focus on the production of critical medical devices and avoiding shortages or delays potentially caused by notified bodies, thereby saving lives. During the transition period for MDR, devices can be placed on the market under the current EU Directives (MDD) or the new Regulations (MDR). For products already under MDD, any significant change such as to packaging and re-assessing biocompatibility and stability could trigger immediate MDR compliance including product re-certification by a Notified Body. However, Notified Body certification capacity under the new Regulation is currently limited, and therefore, a bottleneck in the authorisation process will be created. This could create a significant limitation in the supply of medical devices to patients and the public, because of the need for the involvement of a Notified Body. In addition to impacting consumer access to medical devices, it could potentially disadvantage the UK industry compared to the rest of the EU market.

Q6. Do you agree the proposed charging conditions will ensure that the UK manufacturer of plastic packaging is liable for the tax? If not, please explain why.

PAGB has no comment in response to this question.

Q7. Do you foresee any issues for specific packaging components due to the proposed approach of disregarding further ancillary processes for the purposes of the tax? Please explain what these issues are.

PAGB has no comment in response to this question.

Q8. Do you have any observations on the proposed treatment of imports of plastic packaging, particularly linking the tax point to "first commercial exploitation" i.e. when it is controlled, moved, stored, is subject to an agreement to sell, or otherwise used in the UK in the course or furtherance of business?

PAGB has no comment in response to this question.

Q9. Do you agree the "consignee" on import documentation is likely to be the taxable person for imports of plastic packaging? In what scenarios might someone else be the person on whose behalf the plastic packaging is commercially exploited?

PAGB has no comment in response to this question.

Q10. Do you agree that packaging that is damaged after the tax has become due should not be relieved? If not, please explain why you think this packaging should be relieved.

PAGB has no comment in response to this question.

Q11. Do you foresee any difficulty or added costs with the proposal for the taxable person to incorporate the amount of Plastic Packaging Tax onto the sales invoice, and if so, could this information be provided to customers in any other way?

PAGB has no comment in response to this question.

Q12. Are the proposals for joint and several liability reasonable? If not, please say why?

PAGB has no comment in response to this question.

Q13. Do you envisage any problems with extending joint and several liability to online marketplaces and fulfilment house operators who knew, or had reasonable grounds to suspect that the tax had not been accounted for on sales made through their platform?

PAGB has no comment in response to this question.

Q14. Will extending joint and several liability to third-party fulfilment house operators and online marketplaces be sufficient to deter overseas sellers from non-compliance with the tax? If not, what other steps should HMRC consider?

PAGB has no comment in response to this question.

Q15. Do you agree with the proposed guidance and tools to help business determine if they are above or below the de minimis? What other help could the government provide?

PAGB has no comment in response to this question.

Q16. Do you agree with the approach to record keeping for businesses below de minimis? If you disagree, please suggest what alternative approaches would be more appropriate and why.

PAGB has no comment in response to this question.

Q17. Do you agree with the proposed forward and backward look test to apply the 10 tonne threshold? If you disagree, please suggest what would be more suitable and provide evidence to support your view.

PAGB has no comment in response to this question.

Q18. Do you agree with the government's proposal to restrict calculations of recycled plastic content to approved methods? If not, please explain why. What methods other than the proposed mass balance approach should be considered?

PAGB has no comment in response to this question.

Q19. Where businesses are importing plastic packaging with at least 30% recycled content, will it be feasible for them to obtain the mass balance evidence from overseas manufacturers? What other ways could importers demonstrate the proportion of recycled plastic?

PAGB has no comment in response to this question.

Q20. Do you agree with the government's proposed method for calculating the weight of the packaging? If not, please explain why and how you would calculate it.

PAGB has no comment in response to this question.

Q21. Are the types of evidence within the government's list appropriate for proving recycled plastic content and the other information required by HMRC? Are there any additional sources of evidence which could be used? If so, please provide details.

PAGB has no comment in response to this question.

Q22. What further due diligence could businesses reasonably conduct to ensure their products meet the relevant specifications for tonnage and recycled plastic?

PAGB has no comment in response to this question.

Q23. Are there any observations or issues you can see with the government's proposals to provide relief for exported plastic packaging through direct exports, REPs and tax credits? Please provide details of any alternative methods of relieving exports you would recommend.

PAGB has no comment in response to this question.

Q24. Do you agree with the proposed information requirements to evidence the proposed export reliefs? If not, please explain how you could evidence the export.

PAGB has no comment in response to this question.

Q25. Do you agree with the proposal not to relieve transport packaging used on exports? If not, do you have any suggestions on how transport packaging could be offered relief?

PAGB has no comment in response to this question.

Q26. Do you consider these registration requirements to be appropriate? If not, please specify why.

PAGB has no comment in response to this question.

Q27. Do you agree that the group eligibility criteria are appropriate? If not, please specify why.

PAGB has no comment in response to this question.

Q28. In your view, are businesses eligible to form a group likely to make use of this facility? If so, please estimate the value of savings that may be offered by registering and reporting as a group.

PAGB has no comment in response to this question.

Q29. Do you agree that these deregistration requirements are appropriate? If not, please specify why.

PAGB has no comment in response to this question.

Q30. In your view, will the reporting requirements be straightforward to comply with? If not, please provide details of any issues you expect.

PAGB has no comment in response to this question.

Q31. Do you intend to use a third-party agent to help meet your obligations for the tax or are you an agent expecting to provide this service? Would you expect their responsibilities to include filing your returns?

PAGB has no comment in response to this question.

Q32. Please provide details of the expected costs to your business of registering for the tax, and any expected one-off and on-going costs of completing, filing and paying the return, excluding any expected tax liability.

PAGB has no comment in response to this question.

Q33. Do you consider that HMRC's approach to powers and penalties is appropriate? If not, please specify why.

PAGB has no comment in response to this question.

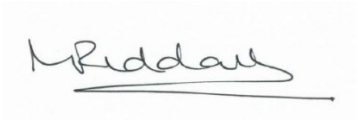
Q34. Unless already covered in your responses to other questions within this document or the previous consultation, please tell us about the plastic packaging

manufactured or imported by your business and how you think your business would be impacted by the tax, including additional administrative burdens?

PAGB has no comment in response to this question.

Q35. Do you have any comments on the assessment of equality and other impacts in the Tax Impact Assessment?

PAGB has no comment in response to this question.



Michelle Riddalls
Chief Executive Officer
19 August 2020

For more information about PAGB, the consumer healthcare association, please visit:
https://www.pagb.co.uk/about-us/

Contact details:
Christina Gkouva
Senior Regulatory Affairs Executive
Christina.Gkouva@pagb.co.uk
020 7421 9313