BIVDA
British In Vitro Diagnostics Association

British In Vitro Diagnostics Association
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HM Revenue and Customs
100 Parliament Street
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1st December 2021

Dear Sir/Madam,

Thank you for the opportunity to provide feedback on the technical consultation on Plastic Packaging Tax (General) Regulations 2021.

BIVDA represents approximately 200 organisations within the IVD industry including start-up companies, SMEs, UK developers and manufacturers as well as subsidiaries of the global IVD corporations. We also represent some distributors and other economic operators. Our response is therefore submitted on behalf of this membership and reflects the general views of companies within the IVD sector.

In vitro diagnostic medical devices (IVDs) are defined in the UK Medical Device Regulations 2002 (as amended) as a medical device which:

a) *is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination; and*
b) *is intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:*
    i. *concerning a physiological or pathological state*
    ii. *concerning a congenital abnormality*
    iii. *to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients, or*
    iv. *to monitor therapeutic measures*

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination.

This proposed legislation hugely affects the IVD sector. Plastics are used in packaging for a wide variety of IVD products, including cartridge assays, lateral flow tests, reagent storage, blood glucose monitors, and many others. The primary purpose of these products is to improve the lives of patients.

Please find our comments on this legislation below. These comments extend beyond the specific ongoing consultation.

Exemptions

BIVDA understands that an exemption for primary packaging for medicinal products was introduced in 2020 through the Finance Act, with further exemptions proposed within the secondary legislation set out earlier in 2021. These further exemptions are based on the support function of some medical devices, which may affect some of BIVDA's members within the IVD supply chain.

As an exemption already exists for medicinal products, it would be logical for an exemption to be implemented for the packaging of IVDs. The rationale for exemptions for both products are the same: plastic is essential within packaging of some products and plastic use in these situations is in the interest of patient safety.

The variety of IVDs on the market is vast, and there are circumstances where they overlap with other regulated products. For example, companion diagnostics. These products are diagnostic IVDs which are intended to provide information on a corresponding medicinal product such as eligibility for that product, or the likelihood of that patient suffering an adverse reaction. They are designed and developed in collaboration with the pharmaceutical manufacturer typically, and so span the UK Medical Device Regulations and the Human Medicines Regulations as it is important the device is validated for the medicinal product in question. Companion diagnostics utilise a number of reagents and calibrators (as well as other components) which currently require plastic packaging to ensure stability.

Where exemptions are introduced which could impact the IVD sector, we request these are made explicitly clear in whether they include packaging of IVDs (not just medical devices) within their scope. It should also be clear where overlaps may occur with specific products over multiple pieces of legislation, the requirements for where the product is exempt are specified.

Declarations

Within the proposed legislation it is implied that organisations are required to declare their plastic packaging information to HMRC, and then apply for an exemption. This would obviously be a particularly burdensome process for industry, especially in the case where there is an obvious exemption which would apply.

If this process could be amended to allow for organisations to not declare information in the situation where an obvious exemption applies, this would streamline the process and make it more manageable for organisations.

Where this is not amended, additional communication on this topic would be welcomed, as it is very likely that organisations are unaware of this requirement and are therefore not prepared to be compliant. This is particularly the case for suppliers elsewhere in the supply chain. Extended timelines to the deadlines on any penalties would be appreciated to ensure this is enforced fairly.

Virgin plastic

Virgin plastic is extensively used and required within the IVD sector. As a number of IVD products rely on chemical reactions to identify a result, it is crucial that there are no contaminants introduced to the process, which is possible from reprocessed plastics. Utilising virgin plastic in packaging ensures the accuracy of the result, and therefore any move to remove the use of virgin plastic would be strongly opposed by the IVD industry.

Considering the need for virgin plastic, it would also be disagreeable if any additional charges or taxes were introduced for this plastic specifically for the IVD sector.

Recycled plastic is often more expensive than virgin plastic due to commodity oil pricing and the means of levelling the price to account for these fluctuations should be considered by Government for those products where recycled plastic can be utilised. Consistency in pricing would ensure clear purchasing forecasts for companies such as those in the IVD sector reducing the financial burden. For IVDs there are further potential complexities for recycled plastic disposal due to contamination by reagents and other chemical substances. This is a particular and important issue to the sector, as information must be accurate and reproducible on potential reactions between recyclable plastic polymers and other substances which may lead to biohazardous waste. Companies should not be penalised for this toxic waste if insufficient advice is given on specific recyclable plastic content.

Composition of plastics

The IVD sector as a whole is working to become more environmentally friendly. This includes switching from single-use plastics to recyclable plastics where possible in secondary areas, where this switch would not have an impact on patient safety.

Plastic packaging is necessary to ensure stability, shelf life, transport requirements and sterility of products in the form of sterile barriers. ISO 11607: *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems* details that although recycled plastics are not prohibited within sterile barriers, the recycled material needs to be fully traceable, a requirement which is currently not always possible. This somewhat prevents manufacturers from utilising recyclable plastics in some circumstances. This standard is harmonised to the EU In Vitro Diagnostics Directive (98/79/EC), which is implemented in UK law through the UK Medical Device Regulations 2002 (as amended).

It is possible that safety risks may result from poor traceability (in the commercially available and viable mechanically recycled content), the difficulty of controlling materials and processes (loss of functional equivalency of materials leading to extensive revalidations needed for sterile products), and the requirement for reassessing the risk process relating to recycled packaging materials.

Complying with the proposed tax demands clear information on the composition and ingredients of the recyclable plastics used in packaging. Companies may not fully understand the composition of the materials and, along with patient safety as outlined before, this will take time to verify that the particular plastic used is acceptable. Maintaining a record of all suppliers of plastic components will be burdensome to organisations.

In addition, there are limitation subject to product requirements. This includes multi-material designs (MDMs) which rely on many complex or multi-material films and coatings specific to the device.

The IVD and Medical Device sector is committed to patient safety standards and upholding consistency in processing. Studies have raised uncertainty over the long-term usability of recyclable materials such as plastic, therefore companies need access to quality materials which do not bio-degrade rapidly or break up after use.

The Plastics Packaging Tax has the potential to disrupt quality and the strict regulation of IVDs.

We are grateful to be given the opportunity to comment on such proposed changes, and BIVDA is available to assist in activity and dialogue into any future changes within the landscape for IVDs in the UK. BIVDA remain at the disposal of HMRC should you require any clarification in relation to our consultation response.

Yours sincerely,

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