2/2/2024

JOHNSON AND JOHNSON – PPWR POSITION FOR THE TRILOGUES

HARMONISATION

209 – We support the **European Commission's proposal** for a definition of contact sensitive packaging, as it is the most aligned with our sectorial legislation, allowing for clarity of application.

239 - We support the **EP's proposal** to delete article 4(5) that would allow Member States to provide for further labelling requirements. In recent years, the industry has witnessed an increase in disparate national labelling and sustainability requirements that have resulted in internal market barriers. Safeguards are needed to ensure the proportionality and non-discriminatory nature of any requirement introduced by a Member State to avoid single market disruptions and create better harmonisation across the EU.

243a – **We do not support this amendment** to be included in the final text as, as any attempt to restrict the manufacturing, placing on the market, and use of specific substances, such as on per-and polyfluorinated alkyl substances (PFAS) in packaging are already governed under the EU's horizontal REACH Regulation and should not be duplicated.

RECYCLABILITY REQUIREMENTS

34 – We welcome the **Council's proposed** amendment to Recital 24 clarifying that the exemption from the recyclability requirements set forth in Article 6 do not apply to the outer packaging of medicinal products. We recommend extending the same clarification to the outer packaging of medical devices.

282 – We support the **Council's proposal** to remove the time limit on the derogation for immediate and outer medicines packaging and contact sensitive packaging for medical devices and IVDs. Recycling the packaging of medicines and medical technologies is highly complex and involves entire healthcare system changes. Achieving recycling at scale requires time to allow for enough data to be collected, the implementation of workable ecosystem solutions for the safe and innovative waste management and recycling of medical technologies packaging that ensures that health hazards are eliminated, and no adverse community health impacts arise.

284 & 285 - We support the **EP's proposal** to extend the derogation to all contact sensitive packaging of medical devices and IVDs, and not just plastic. These materials are subject to the same regulatory requirements and therefore should receive the same attention when it comes to derogation.

285a - We support the **Council's proposal** to extend the derogation to outer packaging for medicines. As above, these materials are also subject to sector specific regulatory requirements.

285e – We support the **EP's proposal** to allow the Commission to assess the need to extend the derogation based on available scientific guidelines of the relevant regulatory authorities, the state of scientific and technical progress, and the availability and prices of recyclable materials, and in consultation with relevant stakeholders.

RECYCLED CONTENT

299 – We welcome the **EP's proposal** to extend the exemption to contact sensitive plastic packaging of devices exclusively destined for research use and investigational devices.

301d – We would support the **EP's proposal** to exempt packaging of supplies, components, and immediate packaging components for the manufacturing of medicinal products. We would welcome

the exemption to be extended for medical devices (Regulation (EU) 2017/745), given the stringent needs for this part of the healthcare sector.

TRANSPORT PACKAGING AND EMPTY SPACE RATIOS

79 – We support the **Council's proposal** in the recitals for cardboard boxes to exempted from the obligation to meet the transport packaging re-use targets. Particularly in the healthcare sector, recycling the packaging of medical technologies is highly complex and most of the time is not possible (i.e. healthcare packaging often becomes contaminated with hazardous chemicals, biological agents or bodily fluids and needs to be incinerated).

421 – We would support the **Council's proposal** to have a methodology for calculating empty space ratios that considers, amongst other factors, the minimum transport packaging sizing abiding by international labelling standards.

370a – We support the **EP's proposal** to exempt custom-made transport packaging for configurable medical devices and medical systems that are to be used in industrial and healthcare environments, due to the specificities and needs of the sector. Nonetheless, this proposal would be more suitable to be included in Article 2, rather in Article 13, just for consistency and readability of the text.

464, 467, 470, 473 – We support the **EP's proposal** to limit the scope of reuse targets to transport packaging used "within the territory of the Union".

477 – We support the **Council's proposal** to remove targets for the use of transport packaging between sites.

485b and 486 – We would support the **EP's proposal** for economic operators to be exempt from Article 26 reuse targets if a third party-certified LCA proves reuse is not the option that delivers the best overall environmental outcome for single-use packaging (in line with Directive 2008/98/EC, Article 4).

486a – We support the **Council's proposal** to allow economic operators form pools for the purpose of meeting their obligations but would recommend extending this possibility to all transport packaging obligations.

Furthermore, we would like to request the following amendments:

- We would request a full exemption of the empty space ratio requirements for transport packaging for clinical trials to ensure product safety and quality **(**Amendment 1*).**

Proposal for a Regulation **Article 21 – paragraph 3 – point a (new)**	
Text proposed by the Commission	*Amendment*
(a) **new**	**(a) Transport packaging for products intended for clinical trials shall be exempted from the obligation laid down in paragraph 1.**
Justification	
In clinical trials, some products require cold-chain shipping, advanced tracking, or extra packing materials to protect them from damage. Given the importance to safeguard the	

quality of the product being transported, it is not possible to ensure that the empty space ratio will be achieved. ***We would welcome a full exemption of the empty space ratio requirements for transport packaging for clinical trials, as not providing such exemption could lead to a hard stop on the research of medicines in the EU.***

- We would request an exemption from empty ratio targets when using minimum-sized GS1-compliant transport packaging with no smaller alternative **(**Amendment 2).***

Proposal for a Regulation **Article 21 – paragraph 3 – point b (new)**	
Text proposed by the Commission	*Amendment*
(b) **new**	**(b) Transport packaging abiding by GS1 standards[1] and shipped individually for medical purposes shall be exempted from the obligation laid down in paragraph 1.**
Justification	
When it comes to commercial products, hospitals and pharmacies make one-unit orders for patients, rather than in bulk, due to urgency or other reasons deemed by the healthcare practitioners. ***Minimum sized orders as a measure already exist to reduce empty space, but our sector works with life-threatening emergencies, which require exemptions to the rule.*** *If our products are small in size (i.e. sutures) and have to be shipped individually due to a medical need (i.e. urgent surgery), we would use the smallest transport packaging available and not fulfill the empty space ratio, which would create issues due to non-compliance.* ***Not providing such exemption to the healthcare sector would lead to shortages of medicines and medical devices, given the impossibility to make the products arrive to hospitals and patients, risking patients' safety.*** *As a result, even if the Marketing Authorisation Holders make the effort to minimise the packaging by using the minimum transport packaging available in the market, GS1 standards, which are internationally recognized standards establishing labelling size requirements, dictate the minimum size a package must have in order to comply.* *These two factors (one-unit orders and minimum transport requirements) would make healthcare transport non-compliant with the empty space ratio target proposed in the regulation.*	

LABELLING

345 - We support the **EP's proposal** to, firstly, link the implementation of the provisions to the adoption of secondary legislation and the facilitation of readability across the EU of the labels by basing it on pictograms. This would facilitate harmonization across member states.

[1] https://www.gs1.org/standards/gs1-logistic-label-guideline/1-3#4-How-to-include-trade-item-information+4-5-Trade-item-measures

354a – We would support the **EP's proposal** with the caveat that the difference between manufactured and imported is considered when implementing labelling requirements **(**Amendment 3*)***.

Proposal for a Regulation **Article 11 – paragraph 8 – point a (new)**	
Text proposed by the European Parliament	*Amendment*
(a) Packaging as referred to in paragraphs 1, 2 and 3, that is manufactured or imported before the deadlines referred in those paragraphs, may be marketed until 36 months after the date of entry into force of the labelling requirements laid down in paragraphs 1, 2 and 3.	(a) Packaging as referred to in paragraphs 1, 2 and 3, that is manufactured ~~**or**~~ ~~**imported**~~ before the deadlines referred in those paragraphs, may be marketed until 36 months after the date of entry into force of the labelling requirements laid down in paragraphs 1, 2 and 3.
Justification	
Due to the international nature of businesses, packaging for products may be manufactured outside of the EU and later imported for use. It is important to note that once the labelling rules come into effect, any newly manufactured packaging must comply with these regulations. *However, a significant concern arises with packaging that was manufactured and imported before the entry into force of these rules. Ideally, this existing packaging should be allowed to be stored and used until the end of its lifecycle. Disposing of large quantities of packaging prematurely would defeat the purpose of PPWR.*	

354b – We support the **Council's proposal** to restrict labelling requirements for the healthcare sector when it could conflict with labelling requirements laid down by sectorial legislation. Furthermore, we would request that labelling requirements outside of those required by sectorial legislation to medicine products and medical devices shall be made available digitally to ensure readability **(**Amendment 4*)***.

Proposal for a Regulation **Article 11 – paragraph 8 – point b (new)**	
Text proposed by the Council	*Amendment*
(b) This Article shall not apply to the immediate and outer packaging as defined in Directive 2001/83/EC and in Regulation (EU) 2019/6, in Regulation (EU) 2017/745 and in Regulation (EU) 2017/746, if there is no space on the packaging due to other labelling requirements as defined in the legislation mentioned above, or if the labelling of the packaging could jeopardise the safe use of medicinal products for human use and veterinary medicinal products.	(b) This Article shall not apply to the immediate and outer packaging as defined in Directive 2001/83/EC and in Regulation (EU) 2019/6, in Regulation (EU) 2017/745 and in Regulation (EU) 2017/746, if there is no space on the packaging due to other labelling requirements as defined in the legislation mentioned above, or if the labelling of the packaging could jeopardise the safe use of medicinal products for human use and veterinary medicinal products. **In order to facilitate the application of the labelling requirements, such products**

	shall have the possibility to fulfill the requirements through a standardized data carrier or a QR code.
Justification	
Medical devices and medicinal products are subject to stringent regulations, requiring essential information to be present on their packaging. It is crucial that patients can easily read and access this information. However, excessive labelling can overwhelm patients and deter them from reviewing important instructions. *To address this issue, utilizing a digital carrier or QR code for storing and accessing this information would be a practical solution. By implementing a digital carrier for healthcare products, we can ensure the necessary information is readily available without overwhelming the packaging.*	