Question for written answer E-000956/2025
to the Commission
Rule 144
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Subject: Status of clear aligners in light of Regulation (EU) 2017/745

The regulation defines ‘custom-made device’ as a device that is specifically made in accordance with a written prescription from an authorised person and intended for the sole use of a particular patient to meet their individual conditions and needs.

In recent years, there has been a growth in the market for clear aligners that can be purchased directly online or without consulting a healthcare structure or professional. This is because they are not considered custom-made devices if they are manufactured in series production.

This is despite the fact that all aligners are expressly designed to be prescribed to individual patients based on a diagnosis of their specific dento-skeletal conditions by a healthcare professional.

This situation puts custom-made clear aligners at a competitive disadvantage as they cannot be placed directly on the market.

In view of the above, can the Commission answer the following:

1. Does it not consider that the possibility of placing non-custom-made clear aligners directly on the market puts prescribing dentists and manufacturers of custom-made clear aligners at a competitive disadvantage?

2. Bearing in mind that all clear aligners, regardless of the manufacturer, are intended for use by a single patient based on their specific anatomy and on a treatment plan that must be drawn up by a professional, does it not consider it appropriate to classify clear aligners as custom-made devices in the context of the revision of the regulation?

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