Question for written answer E-002265/2019
to the Commission
Rule 130
Roberta Metsola (PPE)

Subject: Languages used on the packaging and instruction leaflets of medicinal products

Directive 2001/83/EC on the Community code relating to medicinal products for human use states that the labelling and package leaflets in medicinal products must appear in the official language or languages of the Member State where the product is placed on the market.

In spite of this, consumers in Member States with smaller markets frequently buy medicinal products in their home country that do not feature instructions or labelling in one of the official languages of their country.

How does the Commission ensure that the Member States' competent authorities enforce the Directive properly? What frameworks are in place for consumers to report instances where the provisions of the Directive have been violated?