

**Priority question for written answer P-001141/2023  
to the Commission**

Rule 138

**Ignazio Corrao** (Verts/ALE)

**Subject:** Congenital cataracts, more than 300 children in Italy denied the right to health.  
Pharmaceutical industry indifference and entry into force of Regulation (EU) 2017/745

Paediatric cataracts, congenital or acquired, are one of the main causes of preventable blindness in children, affecting some 200 000 children worldwide. In Italy, incidence in children is 0.4% of newborn infants, one in every 250.<sup>1</sup>

Refractive surgery using laser technology can correct only minor refractive defects and is not carried out on children. The more viable alternative, which is recommended by paediatric ophthalmologists, is the use of Silsoft® (elastofilcon A) lenses manufactured by the American firm Bausch & Lomb, the only company marketing them in Europe until 2021.

Their simplicity of use and safety, and the fact that they were fully reimbursable by the Regional Health System, made the Silsoft® lens the best choice for paediatric patients and families.<sup>2</sup>

Sales in Europe have been suspended because the characteristics of the product are not in conformity with the new requirements of Regulation (EU) 2017/745.

There are no other alternatives for the young patients who used to rely on elastofilcon A lenses.

Account should be taken of the derogations provided for by Regulation (EU) 2017/745, in particular for a possible authorisation for the device to be placed on the market.

In view of the above, I should like to ask the Commission the following:

1. Is it aware of this problem for children and their families, and what is its view of it?
2. What are the reasons why the device cannot be placed on the market in the EU?
3. Is it possible to obtain a derogation under Regulation (EU) 2017/745?

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<sup>1</sup> Around 300 children affected.

<sup>2</sup> Current cost of more than EUR 300, chargeable to the families.