Question for written answer E-002755/2023
to the Commission
Rule 138
Gianna Gancia (ID)

Subject: Cancer medicine

Some 30 000 women in Italy suffer from Her2Low breast cancer, and the Italian Medicines Agency (AIFA) has approved the drug Enhertu (INN-trastuzumab deruxtecan) for the treatment of both Her2+ and Her2Low metastatic breast cancer.

Despite this, the reimbursement authorisation procedure has only been completed for patients suffering from Her2+, so those with Her2Low must wait until reimbursement is approved for their condition, expected to be February 2024 at the earliest.

AIFA has established and accepted the drug's efficacy for both types of cancer and Enhertu has shown promising results in the treatment of metastatic Her2 breast cancer, reducing the risk of disease aggravation or death.

Given the above:

1. Does the Commission know why two separate reimbursement authorisation procedures were needed for the same drug, with the same pharmaceutical companies, and for the same type of cancer?

2. What does it intend to do to ensure that all European patients have timely access to life-saving treatments, avoiding unnecessary and potentially dangerous delays?

3. Are there any mechanisms at European level to speed up reimbursement authorisation procedures for medicines, particularly when their efficacy has been clearly established and accepted by national agencies?

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