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Answer given by Mr Várhelyi
on behalf of the European Commission
(7.7.2025)

Under the Union pharmaceutical legislation, the granting of an EU marketing authorisation for a medicine is based on a scientific opinion of the European Medicine Agency concluding that, following a thorough assessment of the medicine quality, efficacy and safety, the benefit-risk balance for the medicine is positive. There are no current plans to propose a local production quota as a prerequisite for obtaining a marketing authorisation from the Commission.

The Commission fully agrees with the need to strengthen the manufacturing of medicines, in particular critical medicines, in the EU. This is why the Commission adopted a proposal for a Critical Medicines Act¹ on 11 March 2025. The proposed Act aims to support manufacturing and improve the availability of critical medicines in the EU. Key elements of the proposal include facilitating investments in EU's manufacturing capacity for critical medicines through the identification of strategic projects and using public procurement to encourage reliable supply chains of critical medicines. In case of high dependency on a single or a limited number of countries, procurers would also have to use procurement requirements that support the production of critical medicines in the EU in line with EU international commitments.

¹ COM(2025) 102 final.