

EN

P-001539/2025

Answer given by Mr Šefčovič
on behalf of the European Commission
(16.5.2025)

1. The exposure to United States (U.S.) tariffs should in principle be determined by the finished product's country of origin. As the relevant U.S. Presidential Memorandum and executive orders do not provide specific rules for determining the origin of goods, U.S. non-preferential rules of origin, outlined in U.S. Customs Regulations could be assumed to apply.

U.S. non-preferential rules of origin stipulate that: 'the country of origin is the country of manufacture, production, or growth of any article of foreign origin entering the United States. Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the country of origin'. Substantial transformation requires that a new and different article emerges, with 'distinctive name, character, or use'. This will not result from minor manufacturing or a combining process that leaves the identity of the article intact.

The origin of EU manufactured pharmaceuticals with Chinese active ingredients will therefore depend on whether U.S. Customs and Border Protection (CBP) deems the EU production a substantial transformation.

To get legal certainty, a ruling from CBP can be requested. In previous rulings, CBP has held that the simple processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. However, where this involves the combination of two or more active pharmaceutical ingredients (APIs), and the resulting combination offers additional medicinal benefits compared to taking each API alone, CBP has held that a substantial transformation occurred.

2. The same is true for other manufacturing sectors, such as automotive and technology.