

EN
E-000601/2025
Answer given by Mr Várhelyi
on behalf of the European Commission
(8.4.2025)

For marketing authorisations authorised at centralised level, granted by the Commission, the product information for each medicinal product details the name and address of both manufacturer(s) of the active ingredient substance and manufacturer(s) responsible for batch release. This information is publicly available in the Union Register for medicinal products¹.

In view of further increasing the transparency of the supply chain of medicinal products, the proposal for a reform of the EU pharmaceutical legislation, currently being negotiated by the co-legislators, includes a dedicated provision aiming at reinforcing the traceability of any substance that is used, intended or expected to be present in a medicinal product at all stages of manufacturing and distribution, and identify any natural or legal person from whom these substances have been supplied².

¹ Union Register of medicinal products https://ec.europa.eu/health/documents/community-register/html/index_en.htm

² Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, COM/2023/192 final, Recital 89 and Article 58.