

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
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Granting a marketing authorisation based on limited data is not a new concept. Under the current legislation¹, it is possible to grant a Conditional Marketing Authorisation² to a medicine addressing a seriously debilitating or life-threatening disease based on less comprehensive clinical data at the time of authorisation, to address an unmet medical need, provided that a positive benefit–risk balance of the product has been favourably demonstrated.

The new pharmaceutical Regulation³ proposed by the Commission and currently under negotiation proposes a Temporary Emergency Marketing Authorisation (TEMA) to ensure the swift availability of safe and efficacious medicinal products in the EU when they are directly related to an ongoing public health emergency. For the TEMA, the principle of an objective scientific assessment of the safety and efficacy of the medicine is maintained, based on the available knowledge, under the premise that the medicine’s benefits outweigh the risks in the context of the public health emergency.

Unlike the Member State’s temporary authorisation for the distribution of an unauthorised medicinal product in emergencies⁴, for the TEMA, as for any other marketing authorisation, the marketing authorisation holder bears the responsibility for marketing a medicine. The TEMA is not intended to affect the civil or criminal liability of the manufacturer or of the marketing authorisation holder pursuant to the applicable national law in Member States⁵.

¹ Article 14-a of Regulation (EC) 726/2004, OJ L 136, 30.4.2004.

² <https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/conditional-marketing-authorisation>.

³ Article 30 of the Commission proposal for a Regulation (COM(2023)193 final).

⁴ Article 5(2) of Directive 2001/83/EC, OJ L 311, 28.11.2001.

⁵ Idem, Article 23.