

(English version)

**Priority question for written answer P-000624/25
to the Commission
Christine Anderson (ESN)
(11 February 2025)**

Subject: Why did the Pfizer/BionTech agreement waive serialisation?

The unredacted Advance Purchase Agreement (APA) for the development, production, priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member States has now been published online ⁽¹⁾.

I quote from Annex I (Vaccine Order Form), Article I(4), page 49: 'Further, to the extent applicable, the Participating Member State acknowledges that the Vaccine shall not be serialized'.

The term 'serialise' typically refers to the process of uniquely identifying each vaccine dose or package with a distinct identifier, such as a serial number, barcode or QR code.

By waiving the serialisation of the vaccine, the APA, as negotiated by the Commission, has made it impossible to uniquely identify each dose and track it from production to delivery and eventual administration.

1. What is the reason for this, other than to create obstacles to being able to hold Pfizer liable in the event of sub-standard vaccines?
2. How is this compliant with the Falsified Medicines Directive ⁽²⁾, which mandates the serialisation of medicinal products?
3. Did the Commission not see how not serialising the vaccine would create difficulties for tracking, tracing and monitoring vaccine distribution and administration, managing inventory levels, gathering and sharing information, ensuring accountability, and recalling the product, especially in the light of the fact that this was a largely untested product that was destined to be administered to hundreds of millions of EU citizens?

Submitted: 11.2.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(6 April 2025)**

The COVID-19 pandemic was an unprecedented public health crisis which required facilitation of the development, authorisation and deployment of COVID-19 vaccines and treatments.

It was in this context that vaccine manufacturers requested a temporary derogation from serialisation requirements on the outer packaging of their vaccines to ensure continuous supply of the vaccine in the critical stage of the pandemic.

The derogation was granted, upon consultation with Member States under clearly specified conditions, including the obligation to report immediately any relevant incidents to ensure accountability and reconciliation of distributed products.

The derogation was granted on the basis on Article 63(3) of Directive 2001/83/EC ⁽¹⁾ without prejudice to the manufacturer's liability.

It should be also pointed out that the continuous monitoring of the quality, safety and efficacy of medicines was organised independently and not impacted by waiving the serialisation requirement.

Each batch was tested prior to its release by Official Medicines Control Laboratories of the Member States. Moreover, in the EU, a robust pharmacovigilance system is in place to collect and assess potential adverse drug reactions (ADRs).

EudraVigilance, the European database managed by the European Medicines Agency, compiles all ADR reports. Moreover, healthcare professionals were required to report ADRs for each patient following COVID-19 vaccination.

¹ https://archive.org/details/contract_03.

² Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, OJ L 174, 1.7.2011, p. 74, ELI: <http://data.europa.eu/eli/dir/2011/62/oj>.

⁽¹⁾ <http://data.europa.eu/eli/dir/2001/83/oj>