Question for written answer E-000054/2021
to the Commission
Rule 138
Anna Zalewska (ECR)

Subject: Recommendation to change the procedure for administering the vaccine

Following the launch of the COVID-19 vaccination campaign in Europe, I note with concern the doubts raised by the medical community regarding information set out in a document issued by the European Medicines Agency summarising the characteristics of the medicinal product Comirnaty.

In practice, six doses of the vaccine can be obtained from each vial of the product. In line with the approved medical procedures, however, only five doses should be administered from each vial of the product.

At training sessions, representatives of the vaccine manufacturer Pfizer point out that the sixth dose is a spare one. So according to their recommendations, optimal use of all vials is not possible.

Some European countries are trying to solve this problem, for example by issuing special statements pointing out that it is possible to obtain and administer six doses from one vial. Unfortunately it seems as though a legal analysis is required to establish whether such statements make it possible to change the approved procedure set out in the product characteristics summary.

In the light of the foregoing:

1. Is the European Medicines Agency already working on an official change in this area?

2. When will a recommendation be issued to make it possible to change the procedures for administering the vaccine?

I would appreciate an immediate answer, and I would like that answer to be made public.