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HEALTH AND FOOD SAFETY

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Dear Ms Cooke, *dear Emer*,

The safety of our vaccines has been a central priority under the common EU vaccine strategy. The continuous monitoring of authorised COVID-19 vaccines and the regulatory follow-up to any detected safety signal is of utmost importance.

This week, the European Medicines Agency found a possible link between the AstraZeneca vaccine and very rare cases of unusual blood clots with low blood platelets. While confirming that the overall benefit-risk of the vaccine remains positive, additional safety information has been included in the product information to inform about possible adverse effects.

I note that whilst most of the cases reported so far have occurred in women under 60 years of age within 2 weeks of vaccination, the evidence available at the time of the Agency recommendation did not allow to conclude on specific risk factors, such as age and gender at this stage. Stratified data on the rollout of the vaccines per age group and gender would be also needed from all Member States to complete the assessment.

The findings of the Agency are not only important for citizens and health professionals, they also inform national vaccination campaigns in their decisions on who to vaccinate with what vaccine. This was highlighted by the Ministers of Health at the *ad hoc* informal meeting organised by the Portuguese presidency on 7 April 2021.

Against this background and with the aim to provide more specific recommendations to the Member States to guide their vaccinations programs, I would like to **request the Agency on behalf of the Commission to carry out as a matter of great urgency a further analysis and stratification of data under Article 5(3) of Regulation (EC) 726/2004.**

This analysis should include vaccination data, and data on disease epidemiology including infection rates, hospitalisations, morbidity and mortality to better characterise the benefit and risk of the vaccine Vaxzevria in different age groups and/or gender as well as possible other risk factors that could be identified.

Emer Cooke
Executive Director
European Medicines Agency
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The Netherlands

To acquire the necessary data, the Agency should liaise with the European Centre for Disease Prevention and Control and the Joint Research Centre. We are also ready to support the Agency in the collection of the necessary vaccination and disease epidemiology data from the Member States, and I will send a letter to Ministers to help your efforts in this regard.

Moreover, the Agency is asked to provide, if possible, a recommendation on the administration of the second dose of the AstraZeneca vaccine on the basis of the available data.

The analysis under this procedure should be without prejudice to any other procedure that is deemed necessary to ensure that the marketing authorisation of the AstraZeneca vaccine is kept up to date with the current scientific knowledge.

The opinion and the process in which it is prepared should take account of the dynamic situation of the current pandemic and the evolution of the evidence base for the AstraZeneca vaccine. In order to support Member States, national medicines regulators and healthcare professionals, the results of this scientific assessment should be communicated to the Commission – possibly in an interim form - by 22 April 2021.

Yours sincerely,