HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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HPRA Opening Statement

Thank you (Dr Holohan), and, good evening everyone.

I would like to provide you with a brief update in respect of the ongoing safety monitoring of the COVID-19 vaccines.

Safety monitoring is where we continue to check and verify that the vaccines in wide scale use in the population continue to be as safe and effective as possible. Safety monitoring of all medicines, including vaccines, is central to the remit of the HPRA. We do this by identifying and comparing new and emerging data – which comes from multiple sources – with what with we already know from large-scale clinical trials.

Safety is comprehensively monitored using four key components. These are:

1. Firstly, there is intensive analysis of reports of suspected side effects and suspected adverse events from patients and healthcare professionals: we have made a call to report – along with clear information on how to report. This has been provided to healthcare professionals and to everyone who is vaccinated. The HPRA also submits reports from Ireland to the EMA's safety committee, which assesses our data along with data from all other European countries.
2. Secondly, companies are obliged to submit monthly safety reports for analysis and to conduct additional post-approval safety studies as requested.
3. Thirdly, further independent studies by, for example, academic institutions, are being undertaken to evaluate additional considerations on the safety of vaccines when used in real life.
4. Finally, the HPRA is actively engaging, not just at a European level, but also internationally via global networks involving regulators from the US, Canada, the UK and the World Health Organisation. This ensures that we have access to the very latest global safety information.

Suspected Side Effects
Returning to the reports of suspected side effects, as said, we proactively call for all reports – including those that are expected and known to us from the clinical trial data, and included in the patient information leaflet. We do this to gather as much information as possible to:

- further inform what we already know about the safety profile and increase our knowledge of known side effects;
- but also, and most importantly, to act as an early warning system for the identification of previously unrecognised or rare side effects. Reports are a mechanism through which regulators are alerted of a possible cause-and-effect relationship that needs to be investigated.

I will now provide an update on the relatively small number of Irish reports of suspected side effects, we received in the initial weeks of rollout. In addition, from this Thursday, we intend to publish a regular update on our website of the number and nature of reports, we receive as the vaccination rollout continues.

Up to the 11th of January, the HPRA received a total of 81 reports of suspected side effects associated with the BioNTech Comirnaty® COVID-19 vaccine.

All reports were generally consistent with those typically observed with other vaccines and included events of a mild to moderate nature which resolved or were resolving at the time of reporting. Among those most frequently reported were abdominal pain, nausea, fatigue, joint pain and pains in the arms, some experience of dizziness, headache, itching and a rash – all consistent with the known and anticipated side effects as emerged during the clinical trials and clearly outlined for patients in the approved package leaflet.

While the relatively mild effects described are of course uncomfortable for those who experience them, they do pass quickly and generally do not require any medical treatment. I wish to thank all healthcare professionals and members of the public who have taken the time to make reports to the HPRA.

Internationally, there have been reports of anaphylaxis associated with the use of mRNA vaccines. Anaphylaxis is a known effect that can happen with vaccination, particularly for those with a history of serious allergic reaction. It is important to stress that this is very rare and, as is the case for all vaccines, vaccination centres are all well prepared for such events. Analphylaxis is typically seen with an incidence of about 1 in a million. It does seem that the incidence is higher with these vaccines and more in line with 1 in 100,000. This is something that remains under close review. To date, the HPRA has not yet received any confirmed reports of anaphylaxis. But, we can anticipate that as our vaccination numbers continue to increase we will receive reports of this nature.

Likewise, internationally reports of facial palsy have been received. A small number of cases were reported during the clinical trials and whether or not this is happening at a rate greater than would be expected in the non-vaccinated population, is not clear at this point. It is included as a possible rare side effect in the product information, and the expected incidence as such, is around 1 in 10,000. It is important to stress that this condition, should it occur, is usually temporary in nature. We can expect that we may receive some of these reports going forward. As always, when discussing potential side effects, we must remember, the risk they present is significantly outweighed by the health risks posed by the virus itself.

I also wish to refer to reports internationality of deaths after vaccination that have occurred among very frail, elderly patients, many of whom were also suffering from severe underlying conditions.

These reports are carefully evaluated as part of the close safety monitoring performed by regulatory authorities. But this does not mean that the fatality was caused by the vaccine. The EMA has confirmed that no deaths have been attributed to a COVID-19 vaccine to date.

While at this point, there are no similar cases reported in Ireland, it is likely the HPRA will receive similar reports where an individual, unfortunately passes, away shortly after receiving a vaccine. Sadly, we have to consider that fatalities will occur from natural causes or background illnesses, and will continue to do so over the course of any vaccination campaign. While such reports will be included in our data, I must stress again, that that does not mean that the loss of the individual was caused by the vaccine. For context, approximately 12,000 people unfortunately, die every day in the EU from various causes, of whom 83% are aged over 65 years.

Before I conclude, I would now like to highlight a number of important considerations with respect to the information coming through our reporting programme and the interpretation of this information. The receipt of reports is a very positive and important component of safety monitoring. However, it is vital that this information is not misconstrued or incorrectly interpreted to become misinformation.

The receipt of reports – and the frequency and numbers of reports received – is not and should not be reported or presented as a negative or unexpected development. It would be incorrect to use reporting numbers **in isolation** to draw conclusions as to the safety of the vaccines. The number of reports in isolation **does not** signal that the vaccines are unsafe.

I wish to stress that reports submitted are not confirmed side effects to the vaccine. They are "suspected" and therefore we **cannot** state categorically that the side effects reported were caused by the vaccine concerned. Reports often describe coincidental events which would have occurred even if vaccination had not taken place.

Reports of side effects in and of themselves are not sufficient to prove that a particular effect has been caused by the vaccine. They are compiled into a cumulative data set that undergoes extensive statistical and other analysis.

As the vaccination rollout continues, we anticipate the receipt of increasing numbers of reports of suspected side effects following the increased use of vaccines. Please be aware, that the number of reports received is not a basis for determining the frequency of a side effect or likelihood of a side effect occurring. Likewise, the number of reports should not be used in the context of comparing the safety profile between vaccines. Just because more reports are received for one vaccine, it does not mean it is any less safe. Reporting rates are influenced by many factors.

In closing, to highlight again, safety monitoring enables us to detect any new or changing side effects and to quickly share this information with healthcare professionals and the public as roll-out of the vaccines continue.

And my final comment is to stress that the ongoing monitoring of the COVID-19 vaccines worldwide has not to date identified any newly emerging safety concern. Close to 20 million doses of the Comirnaty and Moderna vaccines have now been administered globally at this point. The safety profile remains positive; the benefits continue to outweigh the known risks.

ENDS