STATEMENT

Patients' safety must take precedence in EU coronavirus vaccination deals

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An effective vaccine will be the key to bringing the COVID-19 pandemic under control. Understandably, vaccine developers are under pressure to bring products to the market as quickly as possible, and authorities to approve them. While EPF appreciates the efforts made by industry and regulators to speed up the process, we stress that patient safety must be the highest priority. Regulatory 'shortcuts' must not lead to lowering the standards of safety or efficacy that should remain under the strict control of EMA.

Patients with chronic conditions are particularly at risk from serious illness and death from COVID-19. It is likely that they together with other vulnerable groups would be among the first to be offered – and wish to take up – a vaccine against coronavirus when it becomes available.

Patients need to be reassured that any new coronavirus vaccines will have been developed to the highest standards. In addition, their benefits and risks, but also possible limits on effectiveness (e.g. reducing the severity of disease vs. preventing infection) of any new vaccine must be clearly communicated, both publicly and to every patient to enable a meaningful shared decision.

While vaccines are generally very safe, as with any new medicinal product there is a risk of adverse effects; some rarer adverse effects are only seen once a product is being used at very large scale over time. Coronavirus vaccines will not only be new but will have been developed over an unprecedentedly short timeframe. They require an even greater level of vigilance and protection of patients' rights in case of adverse reactions.

EPF calls for reassurance from the European Commission that the EU Product Liability Directive will not be adapted and that its provisions will be applied to agreements with pharmaceutical companies developing coronavirus vaccines. It is not opportune, at this stage, to grant exemptions from civil liability and EU product liability regulation.

EPF President Marco Greco suggests that "as an important additional safety net, EPF would welcome the establishment of a mechanism such as an EU-level pooled fund that will ensure appropriate and swift compensation to patients in case of serious adverse effects."

Such a mechanism would require a transparent, inclusive governance structure that includes patient organisations. We suggest a formal dialogue between the Commission, EMA, Member States, industry representatives and EPF to explore this further.

As too many doubts and rumours are arising, Greco points out that "it would be helpful if the Commission and national authorities would urgently publish transparent information about the

conditions of contracts made with pharmaceutical companies, including their provisions regarding liability."

Transparency and trust in public authorities is vital to ensure the acceptance of the new coronavirus vaccine when it is available. We are concerned that a perceived lack of transparency may do massive damage to vaccine confidence and public trust in authorities, undermining public health and disease prevention efforts in the long term.

ABOUT EPF:

The European Patients' Forum (EPF) is an umbrella organisation of patient organisations across Europe and across disease-areas. Our 75 members include disease-specific patient groups active at EU level and national coalitions of patients. www.eu-patient.eu

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