

Biopharmaceutical industry support EU regulators exceptional transparency measures and call other regulatory authorities to follow suit to help ensure confidence in the science and the decision-making

Geneva, 13 October 2020: IFPMA & EFPIA support European Medicines Agency's (EMA) initiative to implement exceptional transparency measures that are targeting regulatory activities for the assessment and approval of medicines and vaccines for COVID-19.¹ The biopharmaceutical industry represented by IFPMA and EFPIA encourage other national regulatory authorities to follow EMA's example.

The European Medicines Agency (EMA) announced several exceptional transparency measures² that are targeting regulatory activities for the assessment and approval of medicines and vaccines for COVID-19.³ These transparency measures are focused on accelerating the publication of key documents at this exceptional time, such as news announcements for rolling reviews and compassionate use opinions, as well as implementing shorter timeframes for publishing public assessment reports. The measures also include publication after marketing authorization of the complete version of the risk management plan and the clinical trial data used in support of the regulatory approval for the medicine and vaccine. Along with the implementation of the measures comes the added responsibility of providing the appropriate context around the availability of this additional data and information. It is paramount to ensure that safeguards are in place to preserve privacy of patients who volunteer in the biomedical research.

Thomas Cueni, Director General of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) says: *"As an industry, we recognize that there are important public health benefits associated with making clinical trial results more widely available and hope that such measures will help to broaden confidence in the science and the decision-making that is guiding the development of medicines and vaccines for COVID-19."*

Nathalie Moll, Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA) are of the same view: *"We believe that this initiative will better inform patients, health care professionals, researchers, media, policymakers, and the general public about ongoing regulatory processes and procedures. The EMA initiative of exceptional transparency measures will help to enhance trust and confidence in the evaluation and approval process that is critical during COVID-19."*

About IFPMA

[IFPMA](#) represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees discover, develop, and deliver medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

About EFPIA

The European Federation of Pharmaceutical Industries and Associations ([EFPIA](#)) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

¹ <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines-covid-19#exceptional-transparency-measures-section>

² EU regulators fully uphold transparency and independence standards for COVID-19 treatments and vaccines <https://www.ema.europa.eu/en/news/eu-regulators-fully-uphold-transparency-independence-standards-covid-19-treatments-vaccines>

³ <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines-covid-19#exceptional-transparency-measures-section>



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