



**Wednesday, 17 January 2024 at 13.00 hrs**

**Restaurant des Députés Louise Weiss / Salon Privé**

**Building Louise Weiss / European Parliament Strasbourg**

It is with great pleasure that the Kangaroo Group invites you to its

**1<sup>st</sup> STRASBOURG LUNCH DEBATE**

**Unlocking the Value of Platform Technologies for  
Public Health in Europe  
Future proofing the EU regulatory framework**

*BioNTech and Moderna are leading pharmaceutical and biotechnology companies in mRNA Platform Technology. Both companies recognise the importance of the overall objectives of the European Commission's proposal for a reform of the EU General Pharmaceutical Legislation (GPL), creating an innovative and competitive EU healthcare ecosystem at a global level, investing in R&D, increasing equal access to and availability of innovative medicines to patients across the EU.*

*As demonstrated during the Covid-19 pandemic, mRNA is an agile and flexible platform technology, enabling faster provision of vaccines and treatments to patients. mRNA-based products for disease prevention or treatment are under development for cancer, rare diseases, HIV, malaria, mpox and priority pathogens as well as other life threatening conditions.*

*In this context, it is important that the GPL provides a clear and broad scope for the definition of Platform Technologies, as well as a clear demarcation between Gene Therapies Medicinal Products that alter human genomes, and those that do not (e.g. mRNA).*

*The establishment of a legal basis for a 'Platform Technology Master File' and the development of accompanying scientific guidance by the European Medicines Agency is needed to ensure global regulatory alignment, enable and strengthen the development of platform technologies in Europe and to realise their public health potential.*

**Welcome and Chair:**

Michael GAHLER MEP, President of the Kangaroo Group

**Introduction:**

**Dr. Maren** VON FRITSCHEN, Head Regulatory Policy EU, Moderna

Dr. Constanze BLUME, Senior Vice President Global Regulatory Affairs, BioNTech

**Statements:**

Pernille WEISS MEP, EPP/Denmark, Member of the Committee on the Environment, Public Health and Food Safety

Peter LIESE MEP, EPP/Germany, Member of the Committee on the Environment, Public Health and Food Safety

Tomislav SOKOL MEP, EPP/Croatia, Vice-Chair of the Committee on the Internal Market and Consumer Protection

István UJHELYI MEP, S&D/Hungary, Member of the Committee on the Environment, Public Health and Food Safety

**Q&A-Session/Discussion**