

K. The Parties recognise that the accelerated timelines to develop, produce, sell and supply the *Product* means that the *contractor* under no circumstance can warrant, or assume any liability, at the time of entry into force of this *APA* that the *Product* will be ultimately available or will produce the desired results, i.e. shows sufficient efficacy to prevent a *COVID-19* infection, or be without unacceptable side effects. The Participating Member States are willing to share those risks, which includes an obligation of the Participating Member States to indemnify the contractor and its CMOs in case of liability incurred, settlements paid and certain costs relating to

² Such agreement is based on Article 4(5)(b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union, OJ L 70, 16.3.2016, p.1, as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 **Text** peak, OJ L 117, 15.4.2020, p. 3. The agreement was approved Decision C(2020) 4192 final of 18 June 2020 (see Annex III to this *APA*).

Sensitive*

RELEASABLE TO: Need to know basis

Epidemic peak is a NO GO for vaccination –
States had to ACCEPT the risks - it is THEUR
sole responsibility

third party claims with respect to those risks under the conditions set out in this *APA*. The Commission and Participating Member States acknowledge that the use of *Products* will happen under epidemic conditions requiring such use, and that the administration of the *Product* will therefore be conducted under the sole responsibility of the Participating Member States.