EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

Comments from the European Medicines Agency for the public consultation on EDPB Guidelines 2/2020 on articles 46(2)(a) and 46(3)(b) of Regulation 2016/679

Dear European Data Protection Board,

Please find below the European Medicines Agency's comments for the public consultation on the draft *EDPB Guidelines 2/2020 on articles 46 (2) (a) and 46 (3) (b) of Regulation 2016/679 for transfers of personal data between EEA and non-EEA public authorities and bodies*, as follows:

I. Are these Guidelines applicable under Regulation (EU) 2018/1725 (EUDPR) as well? In the case of the 'EDPB Guidelines 4/2019 on Article 25 on Data Protection by Design and by Default' it is clearly stated that "*The interpretations provided herein equally apply to […] Article 27 of Regulation 2018/1725.*" However, in the present Guidelines no similar clarification is provided.

II. In case these Guidelines should equally apply under EUDPR, the recommendations on legally binding and enforceable instruments must take into account the limitations of Union institutions and bodies in entering into binding agreements with public authorities and bodies of third countries.

    It appears that paragraphs 60-64 of the draft Guidelines intend to address this issue with reference to 'self-executing administrative agreements', by which parties are obliged to commit themselves to certain data protection safeguards. The conditions set forth in these paragraphs (e.g. "the form of the instrument is not decisive as long as it is legally binding and enforceable", para. 64) cannot realistically be fulfilled by the Agencies. The European Commission has provided clear instructions that Agencies – with very limited exceptions - do not have a legal capacity to enter into legally binding agreements with public authorities of third countries. This underlying framework regarding the legal capacity of Union bodies in concluding legally binding and enforceable instruments must be assessed and taken into account by the EDPB before finalising these provisions in its Guidelines.

    Most importantly, it is unclear how the instrument explained in these paragraphs would be different than the one under Article 46(3)(b) GDPR, i.e. "*provisions to be inserted into administrative arrangements between public authorities or bodies which include enforceable and effective data subject rights*", especially in light of paragraph 63 of the draft Guidelines requiring prior consultation with a supervisory authority in case alternative redress mechanisms applied (instead of judicial route). The regulators' intention when adopting both

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Articles 46(2)(a) and 46(3)(b) could not be that, in practical terms, these instruments would overlap with each other.

III. In case these Guidelines should equally apply under EUDPR, clarification would be required in paragraph 26 that any derogations under Article 25 of the EUDPR may be provided not only by law, but also by internal rules of the EU institutions and bodies.

Thank you for the opportunity to provide comments on the draft Guidelines during this public consultation.