Annex 2

ECDC reply to questions from [redacted] ECDC Management Board

1. The mandate of the ECDC to produce joint reports

ECDC's Founding Regulation provides a general mandate to collaborate with other Agencies, and it does not specify what the outputs/objectives of this collaboration could be (relevant excerpts are provided below). It is however clear that we should work with other Agencies within our remits. Furthermore, during the last years the EU Institutions have requested increased Agency collaboration. It should also be noted that this pandemic has shown its impact to the entire society, involving all sectors and therefore any response/guidance should not be developed in silos.

Excerpts from the ECDC Founding Regulation:

- Founding Regulation preamble (9) "As emerging health threats may have mental as well as physical health consequences, the Centre should in the fields within its mission gather and analyse data and information on emerging public health threats and developments for the purpose of protecting public health in the European Community by preparedness. It should assist and coordinate with Member States in developing and maintaining the capacity to react in a timely way. *In public health emergencies the Centre should operate in close collaboration with Commission services and other agencies, Member States and international organisations."*
- Art 3.1. "In order to enhance the capacity of the Community and the Member States to protect human health through the prevention and control of human disease, the mission of the Centre shall be to identify, assess and communicate current and emerging threats to human health from communicable diseases. In the case of other outbreaks of illness of unknown origin which may spread within or to the Community, the Centre shall act on its own initiative until the source of the outbreak is known. In the case of an outbreak which clearly is not caused by a communicable disease, the Centre shall act only in cooperation with the competent authority upon request from that authority. *In pursuing its mission the Centre shall take full account of the responsibilities of the Member States, the Commission and other Community agencies, and of the responsibilities of international organisations active within the field of public health, in order to ensure comprehensiveness, coherence and complementarity of action."*
- Art 9.1. "The Centre shall provide scientific and technical expertise to the Member States, the Commission and *other Community agencies* in the development, regular review and updating of preparedness plans, and *also in the development of intervention strategies in the fields within its mission."*

2. The standard operating procedure to prepare joint reports (and this one especially)

Prior to the current pandemic, ECDC has produced joint reports with a number of different EU Agencies, including in particular EFSA, EMA and EMCDDA. These reports follow different constructions, some being based largely on separate contributions by each Agency, and some produced as joint assessments. For the former type of joint output, ECDC follows its internal procedure for the production of scientific outputs for its sections or chapters, and similarly so does the partner Agency, while the combined elements, primarily the executive summary, are subject to the scientific output clearance process of both Agencies. An example of this type of joint report is the

regular series of The European Union Summary Reports on Antimicrobial Resistance in zoonotic and indicator bacteria from humans, animals and food, co-produced with EFSA (https://www.ecdc.europa.eu/en/publications/EU-summary-report-antimicrobial-resistance-zoonoses-2017-2018). On the other hand, for joint Rapid Outbreak Assessments, co-produced by ECDC and EFSA (e.g. https://www.ecdc.europa.eu/en/publications-data/salmonella-typhimurium-multi-country-outbreak-brazil-nuts), where there is not such a clear demarcation between the two Agencies' contributions, there is a joint SOP (see attached flowchart that summarises the process) that is followed by both Agencies.

For the recent EASA-ECDC document, the process followed was that each Agency followed its own internal process for review and clearance, with discussion between the drafting teams over any points of disagreement regarding the content, and then the resubmission to the respective internal review processes after changes were made to address the points of disagreement. This iterative process added to the time taken to develop the document, leaving very limited time for consultation with external stakeholders given the deadlines set for the publication date.

3. **The means of consultation between stakeholders relevant to the ECDC before publication of the joint reports (and in particular in this case, role of the AF and MSs as well as the commission)**

Consultations may be undertaken in writing, by sharing of a draft and seeking written feedback with the relevant National Focal Points and/or other relevant authorities (e.g. other experts involved in outbreak investigations that are the subject of a ROA, or bodies such as the European Commission), within a specified timescale, or through an audio-conference with that same audience. In addition, for scientific outputs that are categorised as Public Health Guidance or Expert Opinions, or for other guidance that contains substantial new conclusions on options for measures to be adopted, ECDC consults with the Advisory Forum, either through a scheduled meeting, or an ad hoc meeting, or through written procedure. In the case of the most recent EASA-ECDC report, this was seen more as an update to the existing joint report, and it was not considered that it contained a substantial amount of new conclusions on options for measures to be adopted.

4. **The ability to ensure the independence of the ECDC, especially when there may be conflicting interests between the different parties of the joint reports in question**

ECDC has Independence Policies for its own staff and for non-staff, both of which are published on the ECDC website. In the context of joint reports, while the Independence Policy for non-staff applies to members and alternates of the ECDC Management Board (MB) and Advisory Forum (AF), other individuals working on behalf of ECDC, including interims, as well as contractors and external experts participating in activities in which their evidence, expert opinion and advice may influence the scientific position of ECDC, regardless of their official job title or function, it does not cover staff that are subject to the provisions of the EU Staff Regulations and Conditions of Employment of Other Servants of the European Union. In preparing scientific guidance, both stand-alone and done in collaboration with other agencies, ECDC experts always analyse and take into account the best scientific evidence available at the time of writing and acknowledge any uncertainties. ECDC guidance usually outlines options for public health intervention based on underlying scientific evidence and often contains operational considerations to assist the users in prioritising/choosing an optimal option. In general, if ECDC considers that scientific independence cannot be assured in any collaborative work activity, it has the option, which it has exercised on occasion, not to engage with such joint activity. This decision may be taken after consultation with either the Advisory Forum or the Management Board, or both, such as was the case when ECDC was approached regarding undertaking joint work with the DRIVE consortium established in response to the IMI2 call on influenza vaccination effectiveness studies.