

Structured Dialogue

Security of Medicines Supply – 2021

#SDmedicinesupply



Structured dialogue Working rules for the operational phase

- **Transparency**. All participants have equal access to all the information shared relating to the workstreams;
- **Inclusiveness**. All participants have the possibility to contribute actively to the work and express their views. The initiative is open to new participants able and willing to actively contribute to the objective of the structured dialogue.
- **Positive collaboration.** The participants work with positive values, including openmindedness, tolerance and respect. All views can be expressed and shall be listened to. The work of the structured dialogue will not permit disparagement practices nor will serve to develop strategies to cut-offs rivals' access to key inputs or customers.
- Active participation. All participants commit to provide inputs and contribute to the collective work within their remit and area of expertise. Participants endeavor to ensure their stable, continuous participation to the work.
- **Consensus.** The structured dialogue works by consensus, which entails collective discussions and negotiations among participants to identify the positions that gather the highest possible number of positive opinions and the lowest possible number of objections. In case of strong disagreements, the diverging positions should be reflected in the documents summarising the discussion.
- **Neutrality**. The structured dialogue is technology and product neutral. It shall not express preferences for specific technologies nor products.
- **Public health and patients' choice**. The structured dialogue shall be driven by public health consideration and shall not affect patients' choices or access to treatments and medicines.
- **Privacy**. The European Commission is committed to protect your personal data and to respect your privacy. The Commission collects and further processes personal data pursuant to <u>Regulation (EU) 2018/1725</u> of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data by

the Union institutions, bodies, offices and agencies and on the free movement of such data.

- **Knowledge sharing**. The structured dialogue aims at promoting and supporting sharing of data, knowledge, expertise and best practices along the pharmaceutical manufacturing value chains.
- **Common language**. The structured dialogue uses consistent terminology and definitions.
- Secretariat. The European Commission, DG SANTE, acts as a secretariat of the structured dialogue with a view to facilitate and support the work. The secretariat convenes the meetings of the working groups.
- **Competition compliance:** All persons involved in the Structured Dialogue initiative shall fully respect and enact all applicable laws and regulations, in particular EU and national competition rules. The structured dialogue shall not serve for discussions on investments in innovative treatments and medicines, their prices, their entering the market