EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

The Director General

STAKEHOLDERS DIALOGUE ON THE PHARMACEUTICAL PACKAGE

Summary Report

- **Presence**

In total, 51 organisations and associations representing patients, healthcare professionals, industry and other relevant sectorial stakeholders were present.

- **Aim**

The aim of the workshop was to present the main changes in the proposed EU pharmaceutical revision published on 26 April 2023 and to have a balanced exchange with stakeholders.

- **Summary**

DG SANTE welcomed all stakeholders, thanked for their active involvement, and highlighted the importance of good collaboration between Member States, industry and regulators for patient's access to innovative medicines. Commission representative presented main changes in the revision of the EU pharmaceutical legislation per objective: access, availability, innovation, streamlining of procedures, environment risk assessment and antimicrobial resistance.

The feedback was in general positive. Patients' associations thanked the Commission for the proposals and for engaging patients in the European Medicines Agency's committees and in various consultations. They also appreciated the provisions on improving access to medicines and on the transparency of public funding. The importance of patients' involvement in the development of the scientific guidelines on unmet medical need and inclusion of quality of life criterion was mentioned. Industry recognised the amount of the work done, however expressed serious concerns regarding the modulation of incentives, various definitions, like unmet medical need, and provisions for access. They also highlighted the importance of SMEs growth in the EU and their impact on the development of medicines. Healthcare professionals welcomed the measures to improve access and earlier generics entry. Representative of researchers appreciated the provisions catering for innovation and incentives for academia. Other stakeholders raised

concerns about the transferrable vouchers and mentioned the importance of high quality evidence generation for marketing authorisation applications.

The Commission addressed the questions and closed the meeting by mentioning some points of conversion, namely the general acceptance of the need of this reform and its objectives. Improving access to medicines while striking the right balance with innovation was also a general point made by all participants who agreed to the need to continue the dialogue.