

**Health-related activities
of the German Council Presidency II/2020**

Ortwin Schulte

Head of Health Unit at German PermRep to EU

Overarching Pres Priorities in EU Health Policy

- managing the COVID-19-crisis
- creating more resilient health systems
- returning to interinstitutional best practices in the EU
- covering health priorities not directly linked to the crisis

main fora for policy making

from October 2020	Special European Council meetings on COVID-19 (VC, starting 29 October)
September and October 2020	three special meetings of EU health ministers on COVID-19 and WHO reform (VC)
2 December 2020	Formal EU Health Ministers Council
whole Presidency	around 20 meetings of CWP Health and Pharma and 20 meetings of IPCR crisis management

Council files already achieved or on track

- **EU regulation on GMO procedures for COVID-19-vaccines development**
finalization in July 2020 – clarifies some open questions and safeguards vaccine development processes
- **new EU health program EU4health for 2021-2027**
general alignment of Council for trilogue with EP agreed on 21 October 2020 – main points: governance, priority areas and financial volume
- **Council recommendation on COVID-19-coordination**
agreed in written procedure in October 2020 – main points: classification of risk areas, recommendations for cross-border movement of persons in EU, list of essential travel purposes
- **Council conclusions on WHO strengthening** (planned November 2020)
political agreement on EU priorities for WHO strengthening – main points: pandemic response, new structures, better cooperation
- **[Vaccines advance purchase agreements]** – cooperation COM/member states

Council files still to be negotiated

- **Council Conclusions on lessons-learned from COVID-19**
main areas: pandemic preparedness, pharmaceutical shortages, European Health Data Space, implications for health systems, global health
- **(poss.): New Council Recommendations on COVID-19-coordination**
likely topics: quarantine and testing, vaccination, coordination of national measures
- **proposal for a EU-HTA regulation**
continuation of negotiations since January 2018
- **proposal for new mandates for ECDC and EMA**
COM proposal expected for mid-November

EU-HTA: core problems negotiated in the Council

- **binding nature of EU-HTA assessments**
flexibility for implementation in national health systems; suitability of an escape clause vs. stronger reference to national health competence
- **challenging of EU-HTA assessments at courts**
defining the EU-HTA assessment as preparatory act or as an administrative decision; opening a possibility to challenge the EU decision at European Courts; risk of overshadowing national court procedures
- **decision-making processes in the member states coordination Group**
possibility of votes on scientific questions vs. consensus principle in science; introduction of simple majority, two-thirds majority or qualified majority with reference to the population size of member states
- **scope of the EU-HTA regulation**
pharmaceuticals: covering all products authorized by EMA vs. selection of about 10 products a year; medical devices: selection criteria taking into account differences in market authorization

EU-HTA: next steps and timelines

- **November 2020**
compromise proposal of DEU Presidency
- **November /December 2020**
Council Working Party Pharma discusses the compromise
- **2 December 2020**
HTA progress report at EPSCO Health Ministers Council
- **follow-up procedure I/2021 to be defined by Portuguese Presidency**