



Council of the European Union
General Secretariat

**Interinstitutional files:
2018/0018(COD)**

Brussels, 05 April 2019

WK 4790/2019 INIT

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WORKING PAPER

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (HTA)
N° Cion doc.:	5844/18 PHARM 6 SAN 49 MI 61 COMPET 53 IA 43 CODEC 133 + ADD 1 + ADD 2 + ADD3 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

Delegations will find enclosed a short Presidency discussion paper on the tasks of the Coordination Group.

Presidency Paper on the Tasks of the Coordination Group

The Presidency proposes to discuss the tasks of the Coordination Group (CG) and its subgroups before proposing a discussion on the membership of the Coordination Group (CG).

During the discussion, please also keep in mind the sub-groups we've already defined (for joint clinical assessments, for joint scientific consultations, for the identification of emerging health technologies and for development of methodological and guidance documents) to see if they fit with the tasks we envisage for them and if there is a need to specify other sub-groups as well.

During the discussion so far on tasks, the Presidency has identified the following questions, that still need clarification:

1. Separation of operational (scientific) / strategic tasks

Are some of the tasks purely operational/scientific (for example: carrying out and approving Joint Scientific Consultations), while others more strategic (for example approval of the Annual Work Programme and Annual Report)? If yes, which belong to which category?

2. Level of decision for operational (scientific) / strategic tasks

Provided you see a difference between tasks as described above, do you see a different decision-making level - e.g. political for the strategic, and technical (HTA bodies) for the operational - for those two categories of tasks?