

OP48 Interactions Between Regulatory, Health Technology Assessment And Companies: Multi-Stakeholder Survey On The Current Experiences And Future Landscape Evolvement

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Introduction. The interactions between regulators, health technology assessment (HTA), and companies play a significant role in the process of getting medicine to patients. These have evolved at a product level as well as at a policy and cross-jurisdictional level; however, it is important these activities are adding value for stakeholders involved. A survey conducted in March 2021 assessed the current interactions from multi-stakeholders, and their perceptions on the added value these interactions bring to better decision-making.

Methods. Three separate questionnaires containing nine questions were developed to assess the perceptions from pharmaceutical companies, regulators, and HTA agencies. The three questionnaires contained analogous questions where appropriate. The company questionnaire was sent to senior management at 19 international pharmaceutical companies, the agency survey was sent to 32 agencies (17 regulatory agencies and 15 HTA agencies) in Australia, Canada, Europe, and Asia.

Results. Seven regulators, seven HTA agencies, and nine companies responded to the survey. All regulators and HTAs indicated they have interactions with their peer agencies, as well as between regulators and HTA. The top areas of interactions for regulators were formal work-sharing between regulators during review (86% response) and regulatory strengthening (86%), whilst for HTAs, interactions between HTA on methodology/framework (83%) and HTA capacity building (67%). Regulatory-HTA interactions were seen to have fewer practical benefits, which may suggest areas for improvement. Both companies and agencies believed an effective engagement model should support evidence generation; agencies also viewed an aligned process and improved decision-making as important. Respondents believed that an ideal ecosystem for interactions should facilitate separate remits for stakeholders, converged requirements, aligned process and increased transparency and trust.

Conclusions. This survey provided a snapshot of the current landscape interactions between stakeholders during the life cycle of new medicines, identified the areas where value is added and improvement are needed. Suggested building blocks to improve future interactions included early scientific advice, alignment of evidence requirements, and a collaborative approach among all stakeholders.

OP49 A Systematic Review Of The Activities Of Early Advice, Early Dialogue, Scientific Advice By HTA Doers

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Introduction. There is a range of activities that health technology assessment (HTA) doers have started to improve the process of generation of required evidence for new technologies, and the alignment of regulatory and reimbursement processes that retard the access to patients to them. Different organizations call those processes early advice, early dialogue, or scientific advice to those activities.

Methods. We performed a systematic review of the activities named scientific advice (SA), early advice (EA) and early dialogue (ED). Major databases and HTA organizations were explored. The protocol and search strategy were published in PROSPERO. The selection of final articles and documents was done in pairs, and when discrepancies were found a third person resolved with the consensus of the others. A matrix was used to define the commonalities and differences of the described processes.

Results. We initially retrieved 949 documents, after the analysis of duplications and the full text reading of the selected ones, we finally selected 39 documents and described: the type of technologies, the process, the stakeholders, the duration, the costs, and the impact. Big HTA agencies such as the Canadian Agency for Drugs and Technologies in Health (CADTH) or the National Institute for Health and Care Excellence (NICE) included EA or SA among their portfolio of activities as well as networks (European Network for HTA (EUnetHTA) or smaller agencies such as HTA Wales or Basque Office for HTA (Osteba) among others. The type of activity, the process, duration, purpose and costs differ among HTA doers.

Conclusions. There is a need to define what we meant when we are talking about SA, ED, and EA. In fact, regulators used the same processes with different purposes. Our systematic review and the lessons learnt from the European-funded SAFENMEDTECH project will propose a detailed framework that can be useful to better understanding the needs of each of the involved parties and how to make the processes involved more efficient.