First EMA-EUnetHTA Parallel Consultation for Vaccines

Is the EU Early Consultation Procedure Adapted to Vaccine?

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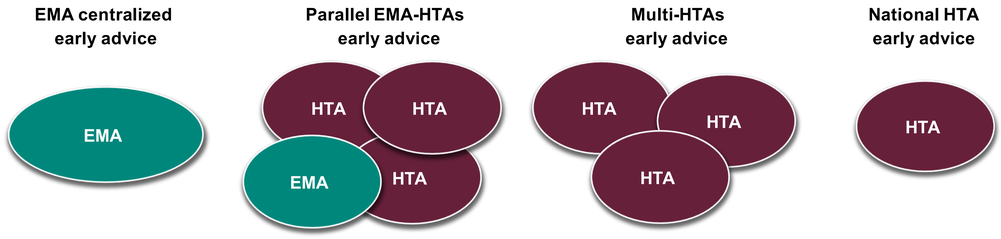
VARIOUS PROCEDURES FOR AN EARLY ADVICE AT EU LEVEL



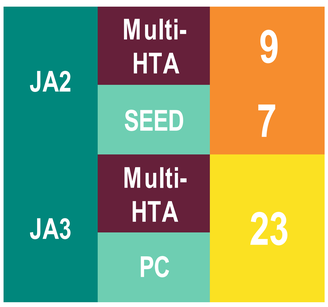
At a national level, there are no or very few possibilities of early advice for vaccines because most of the NITAGs do not have formal processes and have limited time during their horizon scanning meetings. There are few countries where HTA bodies are involved in vaccines HTA assessment/early consultation. The objective of this first vaccines EMA pilot was to test the feasibility of the procedure for vaccine involving NiTAGs despite their specific infrastructure and their lack of experience in early advice

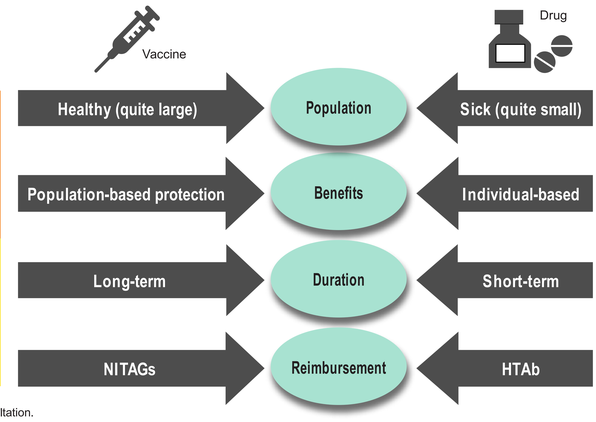
All Therapeutic Area Represented Except Vaccines

During Joint Action (JA) 2 and 3, 39 early consultation procedures were performed either by multi-HTA procedure or by an EMA-HTA procedure (SEED or PC)

TA: Therapeutic Area

- Immunology
- Infectious disease
- Metabolic disease
- Neurology
- Oncology, onco-hematology
- Ophthalmology
- Orphan disease
- …….





JA: Joint Action / SEED: Shaping European Early Dialogues for health technologies project / PC: Parallel Consultation.
https://www.eunethta.eu/wp-content/uploads/2019/04/EUnetHTA-2019-Assemby-Forum-Welcome-Guide.pdf

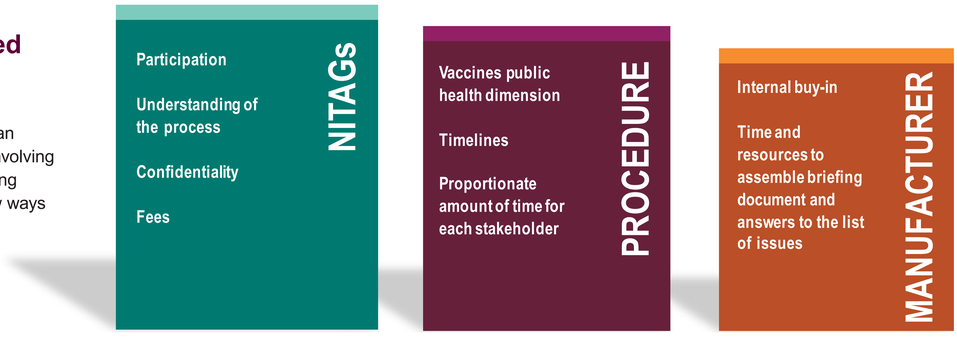
Pilot the Practice of Early Consultation Procedure for a Novel Vaccine

10 countries were listed on the Letter of Intent (LOI) with the demand of involvement of their respective National Immunization Technical Advisory Group (NITAGs) if appropriate.

10	11	7	6
NITAGs proposed at LOI by MSD	HTABs/NITAGs expressed interest and received the Briefing Package	HTABs and NITAGs attended the meeting	HTABs and NITAGs provided written feedback

1 The Expected Challenges

A pilot parallel consultation can anticipate challenges when involving new entities (NITAGs), adapting processes, and requiring new ways of working internally.



2 The Learnings

This EMA EUnetHTA Parallel Consultation Involving NITAGs Was a First for the Vaccines Industry

Need for developing a more robust framework allowing interaction between Regulators, HTABs and NITAGs, critical to facilitate end-users' access to important new vaccines and hence for the overall benefit of Public Health.

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