



Improving patient access to new health interventions: introduction of HTA for medical devices in Ukraine according to the roadmap

HTA29

Abstract ID: 137550

Piniashko O.¹, Khmelovska M.¹, Serediuk V.¹, Oleshchuk O.², Romanenko I.¹, Malyshevska Yu.¹, Lobas M., Babenko M.¹

¹State Expert Centre of the Ministry of Health of Ukraine, Kyiv, Ukraine

²Ternopil National Medical University, Ternopil, Ukraine

OBJECTIVES: One of the goals of HTA roadmap in Ukraine according to the Decree of Cabinet of Ministers of Ukraine №1300 “On the approval of the state health technology assessment procedure” dated on 23 December, 2020 with amendments was to develop the HTA Guideline for medical devices (MDs). The study aims to provide a review of the perspectives of introduction of HTA for MDs in Ukraine in 2024.

METHODS: Comprehensive review of current legislation towards introduction of HTA for MDs in Ukraine and the development of HTA Guideline for MDs was conducted.

RESULTS: In 2023 the first HTA Guideline for medicines was revised according to the knowledge transfer and capability building programme on institutionalisation and governance of HTA Ukraine with NICE International and amendments were approved by the Order of MoH №1741 on 6 October 2023. The first project of HTA Guideline for MDs was developed to cover the continued recommendations and particularities of HTA for MDs and will provide stakeholders with updated methodological recommendations for planning and conducting HTA for the company submissions of the MDs, development of conclusions and recommendations by Ukrainian authorized institution on HTA (temporarily HTA Department). The provisions of the HTA Guideline for MDs reflect harmonized international recommendations and approaches to HTA (EUnetHTA, NICE, ICER, AOTMiT and others), in particular, the stages of HTA, comparative clinical effectiveness, pharmacoeconomic analysis for the devices that are associated with high risks (class IIb and III, according to European regulatory framework). The authors plan to conduct several rounds of public discussion and consultations with stakeholders before MoH approval.

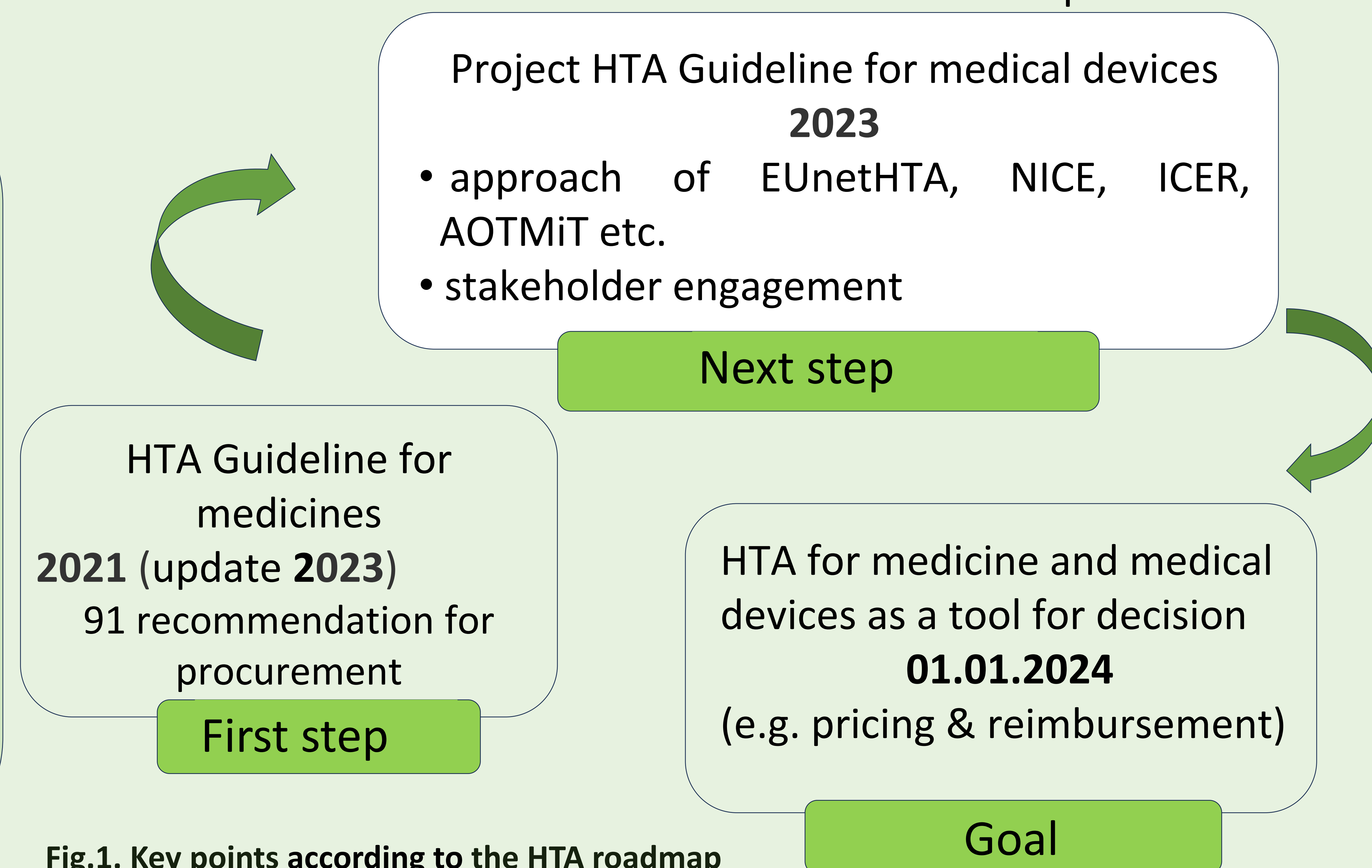


Fig.1. Key points according to the HTA roadmap

CONCLUSIONS: Introduction of HTA for MDs with implementation of first HTA guideline for MDs is an important stage in the evolvement of HTA process in Ukraine for the improvement of patient access to new medical technologies and conducting HTA in a systematic way according to the best international practice.