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European collaboration between regulators and health technology assessment bodies

Joint work plan (2021-2023) between EMA and European HTA bodies facilitated through EUnetHTA21

Introduction

EMA and the previous European Network for Health Technology Assessment (EUnetHTA), which was established through consecutive Joint Actions of which the last one concluded in May 2021, started their collaboration in 2010 based on recommendations from the High-level Pharmaceutical Forum[1], with the aim to harness synergies between regulatory evaluation and health technology assessment (HTA) along the lifecycle of a medicine. A first EMA-EUnetHTA work plan was established for the years 2012-2015 and a report on the outcomes of this joint work published in April 2016. Subsequently, a second joint work plan for the years 2017-2021 was agreed and a report published in June 2021.

Following up on the achievements through such cooperation and the mutual trust and understanding developed through this joint technical work, EMA and EUnetHTA at their last bilateral during Joint Action 3 (minutes) agreed to establish a list of priority areas for future collaboration between regulators and HTA at European level to continue future collaborative work. The overall goal of such collaboration is to improve efficiency and quality of processes, whilst respecting the respective remits of different decision makers, and ensure mutual understanding and dialogue on evidence needs, to facilitate access to medicines for patients in the European Union.

Subsequent to the award of the "Service contract for the provision of joint Health Technology Assessment (HTA) work supporting the continuation of EU cooperation on HTA" to the EUnetHTA21 consortium, the European Commission has invited EMA and EUnetHTA21 to establish a joint work plan for delivering on the previously identified priorities. Deliverables on HTA side will either be actioned by EUnetHTA21 if related to their service contract delivery, or alternatively through individual HTA bodies from the consortium or beyond, who are from a European (EU/EEA) Member State and express interest to participate. In the latter situation, individual HTA bodies represent their own position and not the views of EUnetHTA21. In addition, all deliverables part of EUnetHTA21 will be subject to a public consultation, to which EMA is invited to participate.

EMA and the EUnetHTA21 secretariat will keep an oversight of all activities.

[1] http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pharmaceutical-forum/index_en.htm

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Areas for collaboration between EMA and HTA bodies

EMA and HTA bodies, facilitated through the previous EUnetHTA, have jointly identified several areas as focus of their European regulatory-HTA collaboration post-Joint Action. It is recognised that the implementation of the activities needs to be flexible, so that such collaborative work can transition into a legislative framework on European HTA cooperation, once adopted. Consequently, progress with the priority topics is complementary to technical work in relation to the plan for implementation of Regulation (EU) 2021/2282 and will be overseen in close cooperation with the European Commission. Four bilateral meetings are planned until September 2023, and each meeting will have a different theme to allow in-depth discussions on the items listed on the work plan.

Activities in each of the areas of collaboration

The following activities and expected outcomes have been identified.

As stated above, the activities that are related to the service contract delivery will be given high priority and will be actioned by EUnetHTA21. The other activities that do not fall within the remit of the consortium can be given high priority by the individual HTA bodies but will not be seen as part of the formal consortium duties and deliveries.

Activity	Expected outcomes	Actioned as part of EUnetHTA21 deliverables	Voluntary activity by individual HTA bodies
Joint scientific consultation (JSC) for robust evidence generation, including post-licensing/launch evidence generation			
Relaunch of a European procedure for Joint Scientific Consultation involving HTA bodies and EMA (previously known as parallel scientific advice / parallel consultation/Early Dialogue)	Establishment of a single process that reflects the needs of both regulators and HTABs	X	
	Regular review of work to allow transitioning into a process for "Parallel (EMA/HTA) Joint Scientific Consultation", in line with the requirements of Regulation (EU) 2021/2282 applicable from January 2025	X	
Optimise utilisation of registries for post-licensing/launch evidence generation to support decision making	Depending on products selected during JSC, provision of advice on requirements for data collection and analysis of disease registries in the context of development plans or for qualification of registries in disease areas of particular mutual interest.	X	
	Early engagement on evidence planning, including advice on (post licence evidence generation) PLEG collection, for products selected during JSC	X	

Activity	Expected outcomes	Actioned as part of EUnetHTA21 deliverables	Voluntary activity by individual HTA bodies
Exchange of information on the respective assessments of medicinal products by regulators and HTA bodies			
Foster opportunities for information exchange between regulatory assessors and HTA authors on identified products of mutual interest, including ATMPs	Proactive identification of relevant products that should be subject to discussion between regulators and HTAs. Arrange discussions between EMA and HTA bodies on ATMPs as suggested in the EC/EMAs action plan on ATMPs	X	
	Progress identification of PLEG requirements as a result of such product-specific discussions	X	
	Explore feasibility of earlier engagement between regulators and HTA bodies during the regulatory assessment, respecting remits. Assess feasibility and conduct a voluntary pilot for early engagement, evidence sharing, and managing uncertainties.	X	
	Initial drafting of rules for cooperation, in particular by exchange of information, with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products	X	
Generation of patient relevant data / information to support decision making			
Fostering development of methodologies in order to enable stronger reliance on patient relevant data in context of decision making	Contribute to EMA's initiative to establish an EU network of experts on PROs	X	
	Discussion and exchange in bilateral meeting, in parallel with respective guideline development (e.g. ICH Reflection Paper on Patient-Focused Drug Development and any follow-up action)		X

Activity	Expected outcomes	Actioned as part of EUnetHTA21 deliverables	Voluntary activity by individual HTA bodies
	Contribute to a workshop on patient experience data expected to take place in June 2022 (will serve as basis for further work / collaboration in area of patient data generation)		X
Methodologies for engagement of patients and healthcare professionals			
Deepen the mutual experience/exchange on the involvement of patients and healthcare professionals in activities with focus on challenges of mutual interest	Continue sharing respective practices and experiences related to compensation for expert participation, and guidance on how to incorporate and communicate expert input in the regulatory and HTA outputs	X	
Support to targeted consultations in the context of assessment activities	EMA and HTA to further exchange contacts for identification of experts for HTA and EMA activities, also acknowledging the risk of having the same experts. Enhance awareness and understanding by experts on the differences between HTA and regulatory through a process / information package to experts Follow-up on progress and facilitate further exchange through participation in the EMA PCWP/HCPWP and training sessions and EUnetHTA Stakeholder forums	X	
Horizon scanning and preparedness of HTA and regulatory systems			
Share horizon scanning activities and outcomes	Increased understanding of future challenges derived from innovative medicines	X	
Joint discussion of challenges stemming from high-impact innovative medicines that	Interaction and increased understanding of positions on data requirements and other preparatory measures for innovative products indicated for patient groups with high unmet need.		X

Activity	Expected outcomes	Actioned as part of EUnetHTA21 deliverables	Voluntary activity by individual HTA bodies
address an unmet medical need.			
Continuous optimisation of regulatory outputs as reference for down-stream decision making			
Further optimisation of the regulatory assessment report to facilitate uptake of regulatory consideration in the context of HTA	Regular experience reviews to update the assessment report guidance (e.g. feedback from product specific discussions), also to be complemented with information sessions / trainings		X
Continue sharing experience on labelling and EPARs information, e.g. regarding information on subpopulations	Share guidance on optimising information on subpopulations, e.g. in labelling and EPARs		X
Optimise the published information on orphan medicinal products	Obtain feedback from HTAs on the experience with the Orphan Medicines Assessment Report (OMAR) in order to continuously improve this output		X
Developing study methods and guidelines of real-world evidence, including for registries			
Collaborative work on registry methodologies	Multi-stakeholder discussions on the design, quality assurance and utilisation of disease registries Training on new guidance on registry-based studies (https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-registry-based-studies_en-0.pdf)		X
Collaborate on establishing evidentiary value of real-world	Collaborate on projects through the Horizon Europe Work programme 2021 – 2022 and		X

Activity	Expected outcomes	Actioned as part of EUnetHTA21 deliverables	Voluntary activity by individual HTA bodies
evidence	EU4Health.		
Supporting access to and analysis of real-world data	HTA representation in the advisory board of DARWIN EU	X	
	Explore use cases for HTA RWE and pilot them through DARWIN EU		X
Extrapolation / evidence transfer as a tool to support assessment in smaller populations			
Joint methodological work on the concept of extrapolation / evidence transfer to better understand each other's reasoning for accepting extrapolation	Consult a newly developed regulatory assessment template with HTA bodies		X
	Follow-up workshops to exchange of experiences of each other's remits and tasks.		X
Practices in the context of assessment work related to companion diagnostics			
Share practices and experiences with companion diagnostics	Multi-stakeholder discussions on the integrated assessment of companion diagnostics and/or other diagnostics for targeting therapeutics not directly related to use of specific therapeutics (e.g. genetic signatures), including operational issues around patient access to companion diagnostic tests		X