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Priority topics for European collaboration between regulators and health technology assessment bodies

Development of a 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 EUnetHTA 21 consortium, the European Commission has invited EMA and EUnetHTA 21 to establish a joint work plan for delivering on the previously identified priorities. Deliverables on HTA side will either be actioned by EUnetHTA 21 if related to their service contract delivery (see table of activities below), 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 EUnetHTA 21 that will be subject to a public consultation EMA is invited to participate.

Please see the EUnetHTA 21 joint work table for a detailed list of the EunetHTA 21 planned deliverables. For some deliverables, more specific interaction between EUnetHTA 21 and EMA is

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

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foreseen. It is suggested that this interaction takes place as part of the regular bi-annual bilateral meetings planned between EMA and EUnetHTA21. The planning needs to be a bit flexible to answer to the most urgent needs at the time of each meeting, but the plan is to cover the following topics:

- June 2022: horizon scanning (EMA and HTA objectives of HS, required outcomes)
- October 2022: ATMPs
- February 2023: PROs (with the possible addition of relevant aspects of RWE)
- September 2023: Joint Clinical Assessment (JCA) and Joint Scientific Consultation (JSC)

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

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 a future Regulation 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.

Update (March 2023): EMA and EUnetHTA21 agreed at their bilateral meeting in March 2023 to amend the joint work plan by replacing the activities related to "Practices in the context of assessment work related to companion diagnostics" with activities related to "Establish working practices in the context of the topic identification, selection and prioritisation (TISP) process for JCA on medical devices". This amendment was introduced to reflect in the work plan the priority activities from the consortium in view of the implementation of Regulation (EU) 2021/2282.

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	G-BA NoMA (Anja Schiel)	
	Regular review of work to allow transitioning into a process for "Parallel EMA/HTA Joint Scientific Consultation" under a Regulation on European HTA cooperation, once in force.	G-BA NoMA (Anja Schiel) INFARMED	
Optimise utilisation of registries	Depending on products selected during JSC, provision of advice on requirements for	G-BA	

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Activity	Expected outcomes	Actioned as part of EUnetHTA21 deliverables	Voluntary activity by individual HTA bodies
for post-licensing/launch evidence generation to support decision making	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.	NoMA (Anja Schiel)	
	Early engagement on evidence planning, including advice on (post licence evidence generation) PLEG collection, for products selected during JSC	G-BA NoMA (Anja Schiel)	
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	HAS/ZIN G-BA TLV	
	Progress identification of PLEG requirements as a result of such product-specific discussions	ZIN/HAS (D5.4) G-BA TLV	
	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.	ZIN/HAS (D5.4)	
	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	ZIN/HAS (D5.4)	

Activity	Expected outcomes	Actioned as part of EUnetHTA21 deliverables	Voluntary activity by individual HTA bodies
	assessments of medicinal products		
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	ZIN IQWiG G-BA	
	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)		HAS KCE (Irina)
	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)		NoMA (tbd) KCE (Irina) IQWiG (Beate)
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	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	D7.2 HOG, ZIN (Anne)/HAS (Maggie)/KCE (Irina) G-BA (Daniel	

Activity	Expected outcomes	Actioned as part of EUnetHTA21 deliverables	Voluntary activity by individual HTA bodies
challenges of mutual interest		Ritter)	
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	ZIN (Anne)/HAS (Maggie) G-BA (Daniel Ritter)	
Horizon scanning and preparedness of HTA and regulatory systems			
Share horizon scanning activities and outcomes	Increased understanding of future challenges derived from innovative medicines	ZIN (Marcus or Niels Speksnijder) NoMA (Anja Schiel) AIFA	
Joint discussion of challenges stemming from high-impact innovative medicines that address an unmet medical need.	Interaction and increased understanding of positions on data requirements and other preparatory measures for innovative products indicated for patient groups with high unmet need.		TLV KCE/RIZIV-INAMI
Continuous optimisation of regulatory outputs as reference for down-stream decision making			

Activity	Expected outcomes	Actioned as part of EUnetHTA21 deliverables	Voluntary activity by individual HTA bodies
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		TLV (tbc)
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		TLV
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)		G-BA HAS IQWiG
Collaborate on establishing evidentiary value of real-world evidence	Collaborate on projects through the Horizon Europe Work programme 2021 – 2022 and EU4Health.		HAS

Activity	Expected outcomes	Actioned as part of EUnetHTA21 deliverables	Voluntary activity by individual HTA bodies
Supporting access to and analysis of real-world data	HTA representation in the advisory board of DARWIN EU Explore use cases for HTA RWE and pilot them through DARWIN EU	TLV (Niklas Hedberg)	 HAS INFARMED
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		HAS
	Follow-up workshops to exchange of experiences of each other's remits and tasks.		TLV HAS
Establish working practices in the context of the topic identification, selection and prioritisation (TISP) process for JCA on medical devices			
Develop a process for engagement in the TISP process for JCA on medical devices	Supporting the preparation of the TISP process, particularly the clarification of interfaces with the EMA Secretariat of the expert panels including timing and sensitivity of information to be provided, in order to ensure the timely availability of the required information	X	
Support the exchange of information in the context of the TISP process for JCA on	Identification of information needed from the EMA Secretariat of the expert panels in the context of the TISP process	X	

Activity	Expected outcomes	Actioned as part of EUnetHTA21 deliverables	Voluntary activity by individual HTA bodies
medical devices			