INCEPTION IMPACT ASSESSMENT			
TITLE OF THE INITIATIVE	Strengthening of the EU cooperation on Health Technology Assessment (HTA)		
LEAD DG – RESPONSIBLE UNIT – AP NUMBER	SANTE.B4	**DATE OF ROADMAP**	14/09/2016
LIKELY TYPE OF INITIATIVE	Legislative or non-legislative Initiative		
INDICATIVE PLANNING	*Q4 2017*		
ADDITIONAL INFORMATION			
This Inception Impact Assessment is provided for information purposes only and can be subject to change. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.			

A. Context, Subsidiarity Check and Objectives

Context

In the EU total (public and private) **health care expenditure amounts to around EUR 1 300 billion** per annum[1] (including EUR 220 billion for pharmaceuticals[2] and EUR 100 billion for medical devices[3]). Health care expenditure thus accounts on average for about 10% of the EU GDP.[4] The expenditure is likely to increase in the coming years, considering *inter alia* Europe's ageing population, the increase of chronic diseases, and complex new technologies.[5] [6] At the same time, Member States are increasingly confronted with budgetary constraints. These developments will require Member States to further improve the efficiency of health budgets – focusing on effective technologies whilst maintaining a stimulus for innovation.[7]

Definition

Health technology refers to a medicinal product, a medical device or medical and surgical/radiation procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare. [8] **9**

1 Eurostat, expenditure of providers of health care using data from 2012 or latest data entry for all Member States available. The figure is complemented by WHO Health data for the following countries: IE, IT, MT and UK (ECB annual exchange rate).

2 Eurostat data. In. DG GROW SWP. 2014. Pharmaceutical Industry: A Strategic Sector for the European Economy.

3 Communication on Safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals. COM(2012) 540 final. World Bank, EDMA, Espicom and Eucomed calculations.

4 European Commission. European Semester Thematic Fiche: Health and Health systems, 2015.

5 DG ECFIN. The 2015 Ageing report, 2015.

6 OECD. 2015. Pharmaceutical expenditure and policies: past trends and future challenges.

7 DG ECFIN. Cost-containment policies in public pharmaceutical spending in the EU, 2012.

8 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross border healthcare Article 3

In the EU, health technology assessment (HTA) is defined as *"a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value"*.[10] HTA covers different aspects (referred to as "domains") (see Fig. 1), but does not include pricing and reimbursement decisions, which is a national level prerogative. Two types of assessments can be identified: the Rapid **Relative Effectiveness Assessment (REA)** covers the clinical domains and measures the *medical/therapeutic added value* of a technology; the **Full HTA Assessment** also includes other domains (*cost-effectiveness, budget impact, ethical, and legal considerations as well as impact on patients and the organisation of health care systems*). Full HTA assessments are more linked to the national/regional context than clinical assessments (REA).

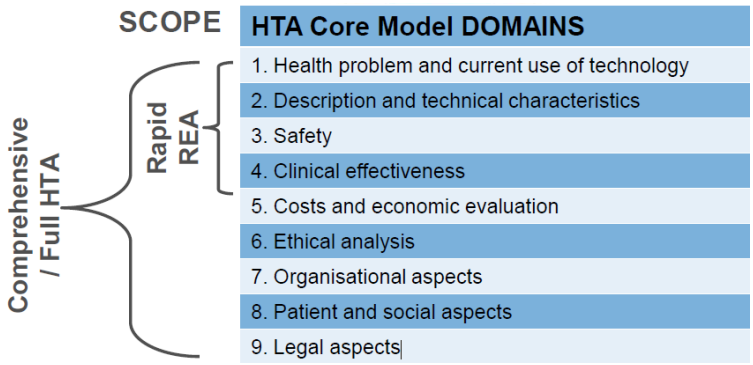

Figure 1. HTA Core Model domains as developed by the EUnetHTA JA

Main objectives of Health Technology Assessment

Health Technology Assessment (HTA) is a key tool for Member States to ensure the accessibility, quality and sustainability of health care. **HTA assesses the added value of a given health technology over and above existing ones**. In other words, it establishes the relative effectiveness of the new technology, compared to the existing ones. Therefore HTA helps Member States to allocate national resources to effective health interventions.

Whilst no comprehensive analysis of the impact of HTA on resources has been concluded thus far, some individual studies offer a certain level of insight. A recent study for the UK,[11] focusing on 10 health technology assessments, for instance, reached the conclusion that a potential benefit[12] of approximately £ 3.0 billion/year could be achieved, if the recommendations from HTA reports were followed. Similar studies exist also for other Member States, which demonstrate the potential of HTA.[13,14] [15]

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9 For ease of reading, the document will refer to pharmaceuticals instead of medicinal products. (cf. Directive 2011/24/EU, Article 4).

10 EUnetHTA Joint Action definition.

11 Guthrie S, Hafner M, Bienkowska-Gibbs T and Wooding S, Returns on research funded under the NIHR. Health Technology Assessment (HTA) Programme: Economic analysis and case studies. RAND Report RR-666-DH, 2015.

12 The benefits include actual cost savings and the monetised value of life years gained.

13 Ognyanova, D, Zentner, A, and Busse, R. Pharmaceutical reform 2010 in Germany: striking a balance between innovation and affordability. Eurohealth (Lond). 2011; 17: 11–13

The need for a tool that assesses the added value of technologies is also underlined by the market entry of new and expensive technologies with limited or no added value. Two recent studies suggest that many new technologies appear to have no or minor added value (FR over 80%[16], DE 67%[17]). Despite the fact that some products do not bring (significant) added therapeutic value, if reimbursed, they would still put pressure on national health budgets.[18]

HTA is therefore a tool that can contribute to the **sustainability of national health systems**. At the same time, it creates/maintains an **incentive for innovation** by rewarding technologies with high added value. In conclusion, HTA allows for an evidence based policy contributing to the sustainability, resilience and accessibility of national health systems, whilst encouraging industry to address unmet needs of patients.

STATE OF PLAY OF HTA COOPERATION

In EU, comprehensive legal frameworks regulate the conditions under which new pharmaceuticals and medical devices can be placed on the market, yet the market access paths are different.
For the authorisation and supervision of pharmaceuticals, Directive 2001/83 on the Community code relating to medicinal products for human use[19] and Regulation 726/2004 establishing a European Medicines Agency[20] contain the main legal provisions. After market authorisation, in accordance with national legislation, pharmaceuticals usually undergo a process of assessment of their clinical and economic value, which is often taken into account when establishing their pricing and reimbursement level. Even though pricing and reimbursement are national competence, the Transparency Directive defines procedural requirements to ensure the transparency of these two processes.[21] Nonetheless, pricing and reimbursement is a national competence and will not be affected by the current initiative.

As regards medical devices, in vitro diagnostics and active implantable devices, individual directives lay down harmonised standards that need to be met in order to receive the CE marking and to market a product.[22] After CE marking, HTA is conducted at national level only in some countries. Public procurement (instead of a central decision on reimbursement) is frequently the

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14 Schumacher I, Zechmeister I: Assessing the impact of health technology assessment on the Austrian healthcare system. Int J Technol Assess Health Care 2013, 29:84–91.

15 Extrapolating the efficiencies in the UK study, based on the fact that some Member States with advanced HTA systems carry out up to 60 assessments of health technologies per year, the cumulative benefits of up to £18 billion/year could be reached. However, it is not possible to verify at this stage whether the sample of technologies is representative. It should also be noted that the benefits include actual savings and monetised health and other benefits.

16 The percentage of classes III+IV+V. Haute Autorité de santé Rapport d'activité 2014. p. 82

17 The percentages of drugs classified as of minor and no added benefit. Situational Analyses on Health Technology Assessment. IMS Health. January 2015.

18 In real life, some technologies with lower added value will still need to be reimbursed, for instance if there is unmet medical need.

19 Directive 2001/83/EC OF the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

20 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

21 Council Directive 89/105/EEC

22 Directive 90/385/EEC regarding active implantable medical devices (AIMD); Directive 93/42/EEC regarding medical devices (MDD); Directive 98/79/EC regarding in vitro diagnostic medical devices (IVDD). These medical devices directives are being reviewed. The regulatory requirements cover in particular the safety as well as the efficacy/performance of the individual products, but not explicitly the relative efficacy of the new products vis a vis existing treatments, and not at all their added value from an economic perspective.

final step of the market access path.

Member States recognised the importance/ relevance of a well-functioning HTA framework for their national health systems.[23] In the last 20 years, most Member States have started to introduce HTA systems at national or regional level. Other Member States are only at the initial phases of establishing HTA systems and/or have dedicated limited resources to HTA. All HTA bodies, even well-established and large agencies, acknowledge the challenge of meeting the growing demand for HTAs, both in relation to resources and specialised expertise.

To support cooperation among Member States, the HTA Network was set up in 2013. It works on strategy and policy aspects, as it involves representatives of health ministries or competent authorities responsible for HTA. While in accordance with Article 15 of the Cross-border Healthcare Directive 2011/24/EU participation in the HTA Network is voluntary for the Member States, all of them have applied for membership, demonstrating their interest in and commitment to the cooperation.

Well before the HTA Network was set up, Member States and the European Commission had already made substantial investments in the cooperation. After an initial focus on studies and projects,[24] including research projects,[25] the support shifted to Joint Actions (EUnetHTA JA).[26] So far two Joint Actions were co-funded through the EU Health Programme: EUnetHTA 1 ran from 2010-2012 (budget EUR 6 million), EUnetHTA 2 ran from 2012-2015 (budget EUR 9.5 million). A **third Joint Action – EUnetHTA 3, running from 2016 until 2020** – has been launched (budget EUR 20 million) on the 1st June 2016. The Joint Actions are open to national and regional HTA bodies (who carry out health technology assessments) of all Member States, Norway and Switzerland. Also industry and other stakeholders are involved. Overall participation in the Joint Actions was/is very high and the latest Joint Action 3 has more than 70 members and observers.

The primary objective of the Joint Actions is on scientific and technical cooperation. The Joint Actions focus on **developing common methodologies, on piloting joint REA and Full HTA reports**, and on developing and maintaining common IT tools. These activities in which HTA bodies work together in order to prepare shared products or agreed outcomes are referred to as joint work.[27] Fostering cooperation on technical and scientific issues also has the important advantage of building HTA capacity.

Important outputs of the joint work include the so called Core Model® as a framework for HTA assessments. The cooperation also lead to the production of about 20 joint reports, including REA

[23] e.g. Council conclusions on innovation for the benefit of patients (2014/C 438/06) .

[24] EUR-ASSES 1994-1997; ECHTA/ECHAI 1999- 2001; EUnetHTA 2006-2008.

[25] Co funded via the 7th Framework Research Programme: AdHopHTA; INTEGRATE-HTA; MedtechHTA; Advance HTA

[26] The Joint Action EUnetHTA is co-funded through the EU Health Programme. Its scope is scientific and technical: EUnetHTA develops common methodologies, pilot joint early dialogues, Joint REA and Full HTA reports. It develops and maintains common IT tools. EUnetHTA is a voluntary, time-limited initiative with a defined work plan. The third EUnetHTA Joint Action (2016-2020) will include 75 partners from 27 Member States (i.e. national and regional bodies active in HTA) and Norway. Luxemburg will also participate as collaborating party.

[27] In addition to developing methodologies, tools and joint health technology assessments (focusing only on the clinical elements or also on the non-clinical ones), joint work also includes literature reviews, structured information for rapid or full HTAs, early dialogues or scientific advice on R&D planning and study design. Joint Work aims at supporting Member States in providing objective, reliable, timely, transparent, comparable and transferable information and enables an effective exchange of this information.

(focusing on the clinical/therapeutic added value) and Full HTA (including assessment of economic and organisational aspects). The cooperation also facilitated over 20 early dialogues[28] between technology developers and HTA bodies, which help industry to design the studies in terms of regulatory and HTA requirements. Further progress is expected under the Joint Action 3, which foresees 80 joint reports and 35 early dialogues. [29] Increased uptake of the joint work at national level is also a declared aim of the Joint Action. In addition, Joint Action 3 will also perform a revision of current guidelines, models, methodologies and other tools, as well as the development of new ones, with the aim of facilitating HTA collaboration at EU level beyond the end of the project in 2020.

A key characteristic of the current cooperation is that **participation and uptake of work in the national systems remains at the full discretion of the Member States.** While HTA bodies cooperate on developing common guidelines and even produce joint assessments, they can – and in practice do – still carry out parallel national processes. They can also decide whether to use or not the joint work (so called *re-use* or *uptake*). In the same way, also industry can decide whether and, if so, which health technologies they submit for joint assessments, thus possibly giving priority to products with a high profit margin over products with a high potential benefit for patients.

POLITICAL CONTEXT

In recent years, **many key players have called for reinforced EU cooperation** in the area of HTA. This section summarises the current views of Member States, the EU institutions and key stakeholders. As regards **Member States**, a clear orientation was contained in the "Strategy for EU Cooperation on HTA"[30], which was adopted by the Member States representatives in the HTA Network in October 2014. In this document, the HTA Network called upon the Commission to explore how to secure support for the joint work in the long-term. Moreover, the **Council,** in its conclusions on "Innovation for the benefits of patients"[31] adopted in December 2014, acknowledged the key role of HTA and called on the Commission to continue to support sustainable cooperation. Furthermore, in the Council conclusions on "Personalised medicines for patients" of December 2015[32], the Member States and the Commission were invited to reinforce HTA methodologies applicable to personalised medicine. The Council conclusions on "Strengthening the balance in the pharmaceutical systems" in June 2016[33] confirmed again that Member States see a clear added value of EU HTA cooperation. At the same time Member States have also emphasised that the cooperation between Member States should be voluntary and that the national competences should be respected.

The European Parliament is also asking for a reinforcement of the HTA cooperation at EU level.

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28 Parallel early dialogue/scientific advice is defined in the HTA Strategy: "At the same time point/ location, but not necessarily together, scientific advice of regulators and HTA organisations on the prerequisites for phase III trials that are going to be initiated by the manufacturer for market registration and reimbursement."

29 As estimated in EUnetHTA Joint Action 3 Project Proposal, Annex B. It should be noted, however, that at the start of Joint Action 2 a target of 17 joint reports was fixed, while only 15 were actually completed, because of several delays affecting REA (clinical assessment) on pharmaceuticals in particular.

30 Available at: http://ec.europa.eu/health/technology_assessment/docs/2014_strategy_eucooperation_hta_en.pdf .

31 Council conclusions on innovation for the benefit of patients (2014/C 438/06) .

32 Council conclusions on Personalised medicine for patients (2015/C 421/03),

33 Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States (2016/C 269/06)

In its joint motion for a resolution on the Commission Work Programme 2016, the Parliament called for "*a step forward towards a common European Health Technology Assessment*"[34]. Also certain MEPs have repeatedly suggested stepping up cooperation at EU level. Moreover, the Parliament commissioned a study on HTA, highlighting its interest in the subject.[35]

The **Commission** has at several occasions referred to HTA. For example, in the Commission Communication on effective, resilient and accessible health systems[36], which suggested HTA as one way to build resilience. In a recent Staff Working Document, the lack of "*binding mechanisms for mutual recognition of joint assessments*" was identified as one of the major shortcomings of the current HTA system[37]. The Staff Working Document "Better Regulation for innovation driven investment at EU level" pointed out that the fragmentation of HTA systems in the EU is currently "*very high*" and that the rise of personalised medicines will accelerate the concerns of fragmentation[38]. The recent Commission Communication "*Upgrading the Single Market: more opportunities for people and business*" contained a commitment that the Commission will introduce an initiative on HTA with a view to improving the functioning of the Single Market of health technologies, in particular in order to avoid duplication of efforts for Member States and industry.[39]

Key stakeholders have also expressed their views on the issue of HTA.

Patients, **health professionals** and **public health organisations** are calling for a strengthened HTA coordination at EU level, in order to avoid unnecessary duplications of efforts and promote more evidence based health policies. **Patient** organisations[40] stressed the need to be involved in the process of HTA and the necessity to prepare REA reports in a timely manner after marketing authorisation, for the benefit of quicker access to new technologies for patients. Other civil society organisations[41] emphasised the need for HTAs to be driven by public health outcomes.

The **pharmaceutical industry**, via its trade organisations,[42] has repeatedly supported a strengthened cooperation on HTA at EU level, specifically on REA. In particular, the sectors focused on the development of innovative/new technologies called for increased consistency of the data requirements and clinical assessments, and for the obligation for Member States to duly consider the joint REA reports established at EU level during subsequent decisions steps at national level (i.e., a better uptake of joint work). On the other hand, the pharmaceutical industry is

34 European Parliament resolution on the Commission Work Programme for 2016 (2015/2729(RSP)).

35 Van Wilder, P. (Vrije Universiteit Brussel and SMART&BI), Mabilia V. (Milieu Ltd.), Kuipers CavacoY. (Milieu Ltd.) and McGuinn J.(Milieu Ltd.), "Towards a Harmonised EU Assessment of the Added Therapeutic Value of Medicines", Report commissioned by the committee of Environment, Public Health and Food Safety at the European Parliament, 2015.

36 Commission Communication "On effective, accessible and resilient health systems", COM (2014) 215 final

37 Commission Staff Working Document, "A Single Market Strategy for Europe – Analysis and Evidence", SWD(2015) 202 final

38 Commission Staff Working Document "Better Regulation for innovation driven investment at EU level" SWD (2015) 298 final.

39 Commission Communication "Upgrading the Single Market: more opportunities for people and business" (COM (2015) 550 final.

40 Rare Diseases Europe (EURORDIS), European Patients' Forum (EPF).

41 E.g. European Public Health Alliance (EPHA).

42 European Federation of Pharmaceutical Industries and Associations (EFPIA), Association of the European Self-Medication Industry (AESGP), European Association for Bioindustries (Europabio).

generally not in favour of Full HTA at EU level.

Medical devices industry associations[43] raised concerns that the EU cooperation on HTA is focusing on the "pharma model" for market access, based on harmonised marketing authorisation procedures and national pricing and reimbursement decisions. They asked that any initiative on HTA at EU level should consider the specificities of their sector, in which market access and pricing decisions are often taken at local level.

The associations representing the **payers**[44] (i.e. health insurers etc.) expressed an interest to be involved in the HTA cooperation (REA and Full HTA), notably for the sake of commissioning clinical evidence to value the comparative performance and cost/effectiveness of technologies.

In view of the above, an EU initiative on HTA to strengthen cooperation would respond to the calls of key stakeholders and would seem in line with the position so far expressed by the EU institutions/Member States. However, depending on the nature of the initiative and its modalities, the support of stakeholders might vary. As regards Member States it is generally accepted that all could benefit from strengthened EU cooperation and the resulting sharing of expertise could have a beneficial effect on resources. However, their support to an EU initiative is likely to depend, not only on the indispensable respect of national competences on pricing and reimbursement decisions, but also on the specific functionality of the initiative and of its level of ambition.

There is also growing recognition of the significant benefits of HTA **at the international level**. For example, the World Health Organisation has urged its members to develop and apply HTA and to strengthen inter-country collaboration to obtain efficiencies.[45] Also a number of countries outside the EU have set up HTA systems. Canada decided - after many years of decentralised HTAs - to centralise parts of the HTA process, to increase consistency of approaches and to reduce the divergences between the different provinces[46]; in the evaluation performed by the Canadian Ministry of Health the move towards harmonisation appears to have been successful.[47]

Australia also has a well-established HTA system, which is comparable to the ones in place in several EU Member States. The Australian model is based on an independent body providing recommendations. The Australian authorities have identified duplication and fragmentation of the HTA processes in their different states as having cost and time implications for economic stakeholders, patients and administrations; therefore, they are regularly reviewing the system to reduce such fragmentation and duplication.[48]

EVALUATION OF EXISTING POLICY

A number of documents contain a preliminary assessment of the current level of EU cooperation on HTA. The Commission Report on the operation of Directive 2011/24/EU on the application of

[43] European Medical Technology Industry Association (Eucomed), European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), European Diagnostic Manufacturers Association (EDMA).

[44] International Association of Mutual Benefit Societies (AIM) ('mutualités') and European Social Insurance Platform (ESIP).

[45] WHO resolution on Health intervention and technology assessment in support of universal health coverage.

[46] CADTH Common Drug Review Update.

[47] Health Council of Canada. 2009. A status report on The National Pharmaceuticals Strategy: A Prescription Unfilled, p 25.

[48] Australian Government-Productivity Commission Research Paper (2015) Efficiency in Health, p20

patients' rights in cross-border healthcare reached *inter alia* the conclusion that the Commission should "*propose measures to ensure long-term sustainability*" of HTA cooperation.[49] This is based on the fact that the current financing of Joint Action 3 expires in 2020. By definition, a sustainable HTA cooperation would require a long-term effort not only in producing and implementing assessments, but also in ensuring capacity building and alignment with technological process.

A recent document by the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA)[50] concluded that despite a challenging environment (high number of partners involved and fragmented HTA systems, with multiple players at national and regional level), EUnetHTA Joint Actions played a key role in advancing EU cooperation on HTA at scientific and technical level. In addition, the EUnetHTA 2 Final Technical Report confirms that the Member States and industry started to recognize the value of the jointly produced HTA information.[51]

At the same time, the discussions within the Joint Action and the HTA Network also revealed as the **main weakness of EUnetHTA** its limited impact on national HTA activities, in terms of uptake of joint HTA reports at national level. This can be attributed to legal, organisational and even linguistic barriers.

HTA Network also identified as a key shortcoming the lack of **long-term sustainability**, which is the result of a financing model associated with Joint Actions.

COHERENCE WITH OTHER EU POLICIES

An EU initiative on HTA is/would be **fully compatible with and supportive of key EU policies**, in particular with:

- **the internal market strategy**, as the initiative is expected to reduce national differences in HTA approaches that affect access to health technologies by streamlining an important step in the market access path of the health technologies.
- the efforts of the Commission to assist Member States in ensuring **budget/fiscal stability and sustainability** as HTA provides a tool for evidence based decision making for the Member States to further improve the allocation of resources.
- the **research and innovation** agenda of the Commission, as HTA is also a promising tool that could gear the industry to invest in innovations with significant therapeutic benefits for patients.

An initiative for a stronger EU approach on HTA would be in line with the **10 political priorities of the Juncker Commission.**[52] Of relevance are in particular priority area: "1 - boost for jobs, growth and investment, by improving the predictability of the legal framework and the investment climate", and priority area: "4 - deeper and fairer internal market with a strengthened industrial base".

The initiative also fully fits into the mission letter of Commissioner Andriukaitis,[53] which states that the EU should – in the health sector – "*help Member States address the challenge of (...) complex technological choices at a time of intense pressure on public finances*" – for which HTA

[49] Commission Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, COM (2015) 421 final.
[50] EU support for key public health initiatives 2008-2013 Joint Actions.
[51] EUnetHTA JA2 Final Technical Report – EXECUTIVE SUMMARY
[52] Available at: http://ec.europa.eu/archives/juncker-commission/priorities/index_en.htm
[53] Available at: https://ec.europa.eu/commission/sites/cwt/files/commissioner_mission_letters/andriukaitis_en.pdf.

is a key tool.

Issue

HTA offers – as explained above – significant potential for Member States in terms of **maintaining sustainable health systems** and **stimulating innovation** for the benefit of patients. The cooperation on HTA at EU level has an essential role to play in fully exploiting the benefits of HTA. However, at this stage HTA cooperation at EU level is largely dependent on EU funding. Also, the full benefits are not yet exploited, because of the four following **shortcomings**:

1. The **uptake of joint work at EU level into national decision-making processes has remained low, leading to duplication of work by national/regional HTA authorities** (*problem 1*). Despite joint work, several Member States still perform assessments on the same technology and they do not benefit from the work done jointly or by other Member States, leading to unnecessary duplications.[54] The analysis on the national uptake of joint HTA report[55] suggests that most national HTA bodies, despite having willingly and actively taken part in the joint assessments, did not adequately make use of the resulting output (e.g. by adopting the results of joint REA or full HTA Reports, or by using common datasets and/or implementing common templates), thus not avoiding duplication of efforts. As a consequence, full-fledged uptake has been the exception rather than the rule so far.

   It is not rational to invest public funds into HTA cooperation at European level, if the uptake of the work is not improved and the **duplication of efforts** is not avoided. Each national HTA assessment is estimated to cost around EUR 30.000 to national bodies and EUR 100.000 to the industry[56]. Assuming that 10 Member States carry out HTAs for one (and the same) technology and that these could be replaced by one joint report, 70% savings could be realised, even assuming that, due to increased need for coordination, the costs of one joint assessment are three times higher than those of a single national report. These resources can be saved or reallocated to other HTA-related topics. It should be also noted that besides the assessments of specific technologies, HTA bodies are also developing guidelines, opinions and technical consultations, which could equally benefit from reduced duplications. For industry, the potentials for optimisation of resources and savings are even greater, not least as the figures indicated above do not include the expenditures of collecting additional data to meet the different requirements of national HTA bodies.

2. The second shortcoming relates to the significant **differences in the *procedural framework* and administrative capacity of Member States** (*problem 2*). In the EU there are more than 50 national and regional HTA bodies, all embedded in different institutional settings. They apply diverse national procedures and the nature of the reports also differs (e.g. recommendations vs. legally binding reports). Whilst the institutional set-up at national level falls into the responsibility of Member States, the procedural framework and administrative capacities have an impact *inter alia* on (1) the duration of procedures (e.g. whether assessments are carried out in parallel process or in a consecutive manner), (2) the product scope (pharmaceuticals, medical

[54] As shown in the EUnetHTA database on National Uptake and Adaptation, the uptake level of each joint report issued by Joint Action 2 has been, on average, of only 3 Member States, and in many cases, the joint work was just indirectly used in cross-checking evidence.

[55] http://www.eunethta.eu/national-uptake

[56] Average price of a rapid assessment. For a full assessment, the HTA agency costs are estimated at 100.000 € and the total costs for industry at 200.000 €. These cost figures do not capture the full costs, as they only refer to the human resources needed to prepare the submission dossiers (for industry) and for the actual assessments (for HTA bodies). European Cooperation on Health Technology Assessment: Economic and governance analysis of the establishment of a permanent secretariat, Ecorys 2013.

devices and other health technologies) and (3) the number of assessments carried out per annum. Even advanced HTA bodies do not have expertise in all areas and/or are confronted with resource constraints, which in turn mean that not all health technologies can be assessed or that no reassessment is possible after launch.[57, 58, 59]

The following figure shows the diverging timelines for national REA and Full HTAs:

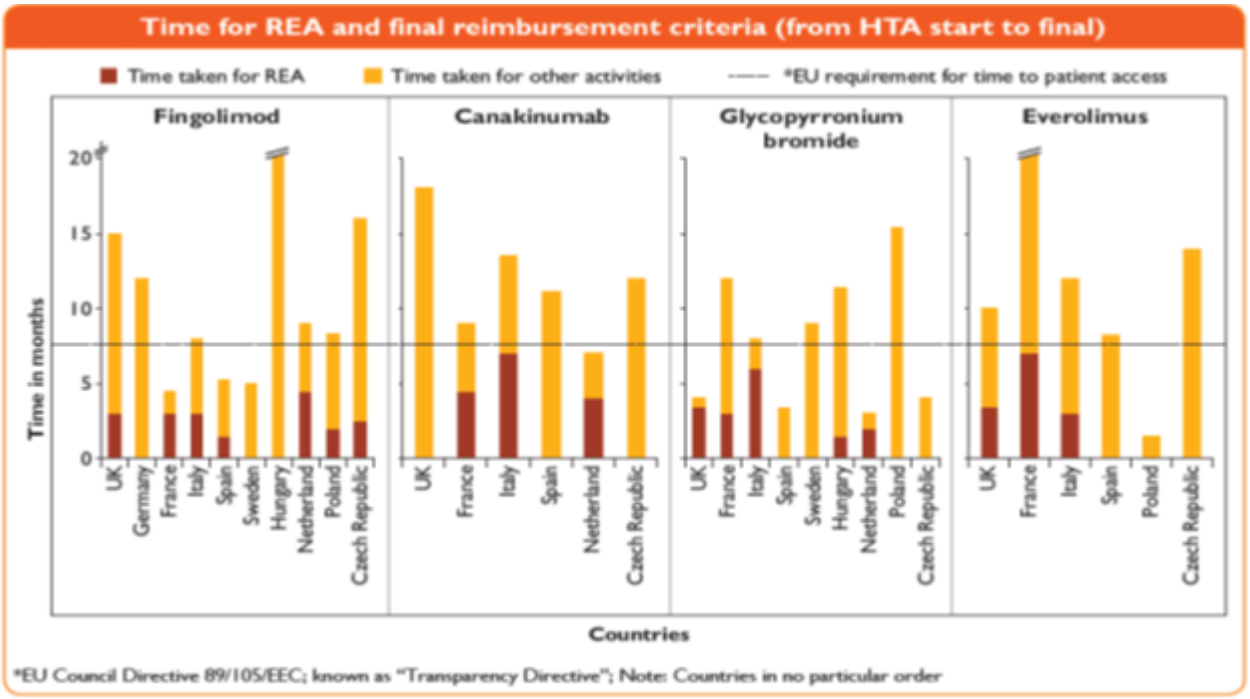

Figure 2: Time for REA and final reimbursement criteria. Source : Weber, S., et al. (2015)[60]

3. Apart from the divergences in the procedural framework, there are also significant **differences in national methodologies**, which explain the variety of data requirements for industry and the divergent outcomes of the evaluations (*problem 3*). The complexity caused by the fragmentation is not ideal for investments, in particular by Small and medium Enterprises (SMEs), which require a predictable framework. Good examples of such differences are the data requirements of the submission dossier, the choice of the comparator (i.e. the intervention against which the new technology is benchmarked), or the way in which the added therapeutic value is expressed (scale or simple "yes/no" assessment).

The following table provides an overview of diverging requirements as applied by national HTA

[57] Kleijnen, S., George, E., Goulden, S., d'Andon, A., Vitré, P., Osinska B., Rdzany, R., Thirstrup, S, Corbacho, B., Nagy, BZ, Leufkens,Z., de Boer, A, Goettsch, W. `Relative Effectiveness Assessment of Pharmaceuticals: Similarities and Differences in 29 Jurisdictions.` Value In Health 15 (2012) 954 – 960

[58] Allena, N., Pichlerb, F., Wangb, T., Patela, S, Saleka, S., `Development of archetypes for non-ranking classification and comparison of European National Health TechnologyAssessment systems` Health Policy 113 (2013) 305– 312

[59] Gulacsi, L., Rotar A., Niewada, M., Loblova O., Rencz F., Petrova G., Boncz I., Klazinga, N.S. Health technology assessment in Poland, the Czech Republic, Hungary, Romania and Bulgaria. Eur J Health Econ (2014) 15 (Suppl 1):S13–S25

[60] Weber, S., Jain, M., Nallagangula, T. K., Jawla, S., Rai, N., Dev, D., & Cook, N. Heterogeneity in Relative Efficacy Assessments (REA) across European HTA Bodies: Opportunity for Improving Efficiency and Speed of Access to Patients? Poster presented at ISPOR 18th Annual European Congress, 7–11 November 2015, MiCo - Milano Congressi, Milan, Italy

bodies. While clinical trial data is a core requirement for all agencies, industry indicates that differences exist in the type of trials requested. Safety data, quality of life data and economic analyses are commonly requested, but not by all HTA bodies. Real world evidence and other sources (e.g. additional studies) are required by few.

Figure 3. Comparison of data accepted/requested in the submission dossier for anti-diabetic drugs by HTA bodies versus EUnetHTA.[61]

Diverging methodologies, including different data requirements, lead to diverging outcomes. Whilst a study is under way to investigate further the dimension of this concern, the following example demonstrates the divergence:

Type 2 Diabetes: HTA evaluation — Positive outcome — Positive with limitations — Negative

	Forxiga (dapagliflozin)	Invokana (canagliflozin)	Jardiance (empagliflozin)
France	ASMR V: modest glycemic control; safety; unknown place within Tx paradigm	ASMR V:non-inferiority; lack of superiority vs Januvia; lack of LT safety	ASMR V: modest glycemic control (non-inferiority); superiority study vs. SU.
Germany	No added benefit: no relevant data	No added benefit: differences in Tx arms and lack of relevant data	No added benefit: no relevant data and starting dose too high
UK (Nice)	• Comparable glycemic control,↓ in weight • Insufficient evidence for triple therapy (+met+SU) • Cost effective: similar vs. DPP4s	• Comparable glycemic control, ↓in BP,↓ weight • Cost effective	Under review
UK (SMC)	• Non-inferior to SU ↓ in weight, hypos • Insufficient economic evidence in combo with insulin	• Non-inferior to SU and DPP4, ↓ in BP, ↓ weight • Cost effective	• Non-inferior to SU • Cost effective
Sweden	• Clinical: glycemic control ↓ weight • Cost effective	Not reviewed	Not reviewed

Note synthesis based on interpretation of clinical and economic in manufacturer HTA submissions and published guidance.
Abbreviations: SU, sulfonylurea; met, metformin; BP, blood pressure (IMS health, 2015)

Figure 4: case study showing diverging outcomes of HTA assessments for a sample of anti-diabetes drugs.[62]

4. The current model of HTA cooperation at EU level is **not financially sustainable over time** *(problem 4)*. This is because the funding of the current Joint Action - through the Public Health

[61] Adapted form: Understanding EU market HTA submission evidence requirements for diabetes products: potential implications of a joint European relative efficacy assessment, DRG Consulting, March 2015.

[62] IMS Health. Situational Analysis to Support EFPIA Workshop for EU collaboration on Health technology Assessment. 2015.

Programme - ends in 2020 and the Third Health Programme is not expected to fund recurrent actions/interventions, including Joint Actions.[63] Without EU funding, it is unlikely that the cooperation would continue.[64]

In **conclusion**, the benefits of EU cooperation on HTA are not fully exploited (there is no comprehensive uptake of joint work) and the long-term sustainability of the EU cooperation is not guaranteed. The **fragmentation of national HTA systems** (procedures and methodologies) leads to duplication of efforts and diverging outcomes across the EU. According to industry, the lack of business predictability has also an adverse impact on the investment climate. From the Member States' perspective, there is also a risk of misallocation of resources. Ultimately, all these shortcomings impact market and patient access to health technologies, leading to delays and health inequalities.

An initiative on HTA at EU level could address the shortcomings highlighted above, however it will/would not eliminate all divergences in patient access to innovative technologies, as these depend also on other factors. These include pricing and reimbursements decisions, as well as the organisation and delivery of healthcare systems, which are under the responsibility of Member States.

Subsidiarity check

LEGAL BASIS

If it is decided to continue on the basis of the current cooperation model, Article 15 of the Cross-border Healthcare Directive provides an adequate legal basis. It would however be necessary to solve the budgetary issue in order to ensure long term financing of the cooperation.

The key legal basis for a legislative proposal is Article 114 TFEU. A legislative proposal on HTA contributes to the objectives set out in **Article 114 (1) TFEU** aiming at improving the functioning of the internal market, whilst ensuring a high level of public health. Essentially it would address the current fragmentation of the national HTA systems (divergences of procedures and methodologies, which impact on market access). The legal basis could be supplemented by means of Article 168 (4) (c) TFEU.

Any legal proposal would need to respect Article 168 (7) TFEU which stipulates that the Union shall respect the responsibilities of Member States for the definition of their health policies and for the organisation and delivery of health services and medical care. This includes decisions on pricing and reimbursement levels, which are not within the scope of this initiative.

SUBSIDIARITY

Under the principle of subsidiarity, the Union may act only if and in so far as the objectives of the proposed action **cannot be sufficiently achieved by the Member States**, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, **be better achieved at Union level**.

The on-going cooperation – namely the Joint Actions and the HTA Network – demonstrated the

[63] "The JA activities are supposed to build on already existing evidence, tools, platforms, based on previous project or JA outcomes and results, and so on. A JA strongly supports knowledge transfer, policy implementation at National and/or European level and so on the wider EU scale, by involving all the relevant stakeholders to ensure sustainability." http://ec.europa.eu/chafea/documents/health/guide-for-applicants_en.pdf

[64] This is also pointed out by the HTA Network in HTA Network Reflection Paper on "reuse of Joint work in national HTA Activities", April 2015

benefits of the EU cooperation (both in economic terms and on the quality and quantity of reports and other tools), while this cooperation model did not remove the fragmentation of the national systems and the duplication of efforts. It is thus concluded – on the basis of the current experience – that the objectives cannot be sufficiently achieved at national level. An initiative strengthening cooperation and increasing synergies and reducing duplication of efforts would therefore be best pursued at EU level.

Main policy objectives

GENERAL OBJECTIVES

The general objectives of the initiative are:

1. Enable Member States to strengthen their cooperation on HTA in a sustainable manner
2. Ensure a better functioning of the internal market of health technologies;
3. Contribute to a high level of human health protection, as stated in Article 168 TFEU and Article 35 of the Charter of Fundamental Rights.

SPECIFIC OBJECTIVES

The specific objectives of the initiative are:

1. Reduce duplication of efforts for HTA bodies and industry;
2. Promote convergence in HTA procedures and methodologies;
3. Improve the uptake of joint work in Member States; and
4. Ensure the long-term sustainability of EU HTA cooperation.

B. Option Mapping

OPTIONS:

1. **The status quo** – Joint Action until 2020;
2. **Long-term voluntary cooperation** (financed by the EU beyond 2020);
3. **Cooperation on collection, sharing and use of common tools and data**;
4. **Cooperation on production of joint REA reports** and their uptake (cooperation on clinical/medical matters);
5. **Cooperation on production of joint Full HTA reports** and their uptake (cooperation on cost-effectiveness).

Option 1: Status quo – voluntary cooperation until 2020

The *status quo* is described above (section A: state of play). HTA is regulated and organised at national/regional level. In parallel, the Commission and the Member States have set up a voluntary cooperation mechanism through the Joint Actions and the HTA Network.

As a result of the Joint Actions, national HTA bodies *inter alia* have developed joint methodological approaches and are able to carry out joint HTA assessments. However, the number of joint assessment performed is limited so far (an increase to a total of 80 joint assessments and 35 early dialogues is however envisaged under the third Joint Action, ie by 2020), and the Member States can still decide whether they want to use joint HTA reports or other agreed output (such as methodologies, templates or tools) in their national HTA activities. Parallel assessments are currently done, and are expected to remain a reality in the future. Industry too still freely decides whether and which new technologies it wants to submit for joint HTA reports.

Moreover, since current cooperation is financed by the EU Health Programme and by the Member

States through in kind contribution, following the expiry of the third Joint Action in 2020 and assuming that no further action is taken (base line scenario), no EU cooperation scheme will be in place. It is very likely that without EU funding, the cooperation will not continue or will be very limited and the achievements of the cooperation to date (on common tools, methodologies and joint assessments) are at risk. Member States are expected to rely again primarily on their own national procedures and budgets.

Option 2: Long-term voluntary cooperation (beyond 2020)

This option foresees the continuation of the current cooperation model, but on a longer-term basis. The main difference to option 1 is that the short-term financing of Joint Actions will be replaced by a long-term mechanism so the sustainability of the cooperation is ensured/improved.

As explained in option 1 above, considering the current experience with the cooperation model, it would focus on joint methodological approaches and joint tools. The production of joint HTA assessments would be voluntary (for Member States and industry) and conducted for a limited number of health technologies. The uptake of the joint outputs in national HTA activities would also be voluntary. Parallel national processes would continue. Industry would also continue to decide whether – and if so which – technologies to submit for joint assessments. As the cooperation would remain voluntary, incentives for using common tools, methodologies and assessments would need to be explored.

A sustainable financing mechanism from EU budget has to be identified, most likely the Public Health Programme. Article 15 of the Directive on the application of patients' rights in cross-border healthcare[65] foresees the possibility of the provision of Union aid to fulfil the objectives of the cooperation. Member States would need to continue to co-fund, by providing at least in kind contribution.[66]

Option 3: Cooperation through the collection, sharing and use of common tools and data

This option foresees the introduction of a legal framework for HTA cooperation, enabling the efforts by national bodies to be compatible, shared and used. This will facilitate cooperation of Member States, and ultimately allow for the production of joint REA reports on a voluntary basis. The legal framework would set out how data is collected, shared and used. It would also create common tools/IT platforms, building on the solutions already developed within the current cooperation model. Key elements of this option are:

(1) a notification to other HTA bodies about planned and ongoing assessments (e.g. via an IT platform);
(2) collaboration between HTA bodies on the prioritisation of technologies to be assessed;
(3) the use of common tools (e.g. use of submission templates) and possibly methodologies (e.g. the HTA Core Model developed by EUnetHTA);
(4) a mechanism to share results of national HTAs reports;
(5) cooperation on early dialogues and
(6) cooperation on the generation of post marketing data to streamline clinical evidence requirements
(7) possibility for preparing joint HTA reports on a voluntary bases.[67]

[65] DIRECTIVE 2011/24/EU on the application of patients' rights in cross-border healthcare
[66] The average annual budget of the JA3 is roughly 5 million EUR.
[67] as in options 1 and 2

Some form of organisational structure would need to be identified and/or set up, in particular, for the implementation of elements (5), (6) and (7).

This option would require financial support from the EU to maintain and possibly develop some of the tools. In addition, to ensure sustainability fees from industry for certain activities (e.g. early dialogues, HTAs reports) would have to be considered as well as financial contributions by Member States.

Option 4: Cooperation on production of joint REA reports

This option foresees that Member States jointly produce REAs (i.e. reports on the relative effectiveness in terms of clinical/medical benefits of the technology), available to all through a shared repository, with measures for the uptake of the joint work at national level. The cooperation – and therefore the uptake – is limited to REA reports; the assessment of non-clinical domains would remain under the responsibility of Member States.

This option also entails the set-up of the legal framework and list of activities already envisaged by option 3.
Two sub-options of option 4 can be envisaged:

a) participation by Member States in the preparation of joint REA reports is voluntary, but Member States that opted in are bound by the results of the joint work and commit not to replicate it. In other words, the duplication at national level of assessments for the same technologies under the same conditions (i.e. same comparator, same targeted population) would not be allowed, or
b) both participation in the joint clinical/medical assessments and their subsequent uptake are mandatory for all Member States.

On financing, this option is expected to require permanent/continuous support from the EU, including for a supporting organisational structure to implement the option. As already mentioned in option 3, financial contributions from the Member States for the tools and services, and fees from industry to support the development of joint reports would have to be considered.

Option 5: Cooperation on production of joint Full HTA reports

This option foresees the joint production of Full HTA reports, thus comprising not only the assessment of clinical/medical domains (as already provided in the REA reports, see option 4), but also the assessment of economic, ethical, legal and organisational domains. This means that the joint work will also include a substantial amount of context-specific information and parameters. Again, two sub-options can be envisaged:

a) participation by Member States in the preparation of joint Full HTA reports is voluntary, but their subsequent uptake is mandatory, as described in option 4a, or
b) both participation in the joint full assessments and their uptake are mandatory for all Member States, as described in option 4b.

On financing, this option also requires permanent/continuous support from the EU, including for an organisational structure; fees from industry and contributions from Member States would be necessary under this option too. However, as the range of activities is larger than the ones set out under the previous options, the costs would be higher.

In conclusion, options 1 and 2 are essentially based on the continuation of the current cooperation model, which is largely based on voluntary cooperation from all stakeholders and depending on EU funding (which is going to run out in 2020, as per option 1). Options 3, 4 and 5 are of increasing complexity as concerns convergence/harmonisation, and in particular options 4 and 5, by establishing a permanent central structure in charge of managing the preparation, coordination and follow-up of joint HTA reports, could bring higher added value in terms of quantity, quality and ensured uptake of the joint reports. Of course, it is also possible to select certain elements from each (sub)option in order to build new ones.

As regards the scope of the health technologies to be assessed, all of them are suitable and designed to be covered. However, their implementation may follow different modalities (in terms of selection, procedures, tools etc.) according to the various product categories, in order to take into account the specific conditions and requirements (e.g. market access path) inherent to each of them.

A future impact assessment and the stakeholder consultation following this Inception Impact Assessment should give a comprehensive idea on the preferred options and will be key steps to support the further definition of the possible options outlined above. The following table below summarises the main characteristics of the options:

Key characteristics	Option 1 The status quo –voluntary cooperation on HTA (until 2020)	Option 2 Long term voluntary cooperation on HTA (beyond 2020)	Option 3 Cooperation on collection, sharing and use of common tools and data	Option 4 Cooperation on the production of joint REA reports	Option 5 Cooperation on the production of joint full HTA reports
Regulatory	Non-legislative	Non-legislative	Legislative	Legislative	Legislative
Participation of HTA bodies and industry	Voluntary	Voluntary	Compulsory (tools) Voluntary (HTA)	Compulsory (tools) Voluntary / compulsory (HTA)	Compulsory (tools) Voluntary / compulsory (HTA)
Uptake joint output	Voluntary	Voluntary	Compulsory for tools	Compulsory for tools and REA	Compulsory
Financing	Largely depending on EU budget Ending 2020	Largely depending on EU budget Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term
Main joint output					
a. Common Tools/templates	(✓)	(✓)	✓	✓	✓
b. Joint REA	(✓)	(✓)	(✓)	✓	✓
c. Joint Full HTA	(✓)	(✓)	(✓)	(✓)	✓
d. Early Dialogue	(✓)	(✓)	✓	✓	✓

(✓): partial delivery

✓: complete delivery

Alternative policy instruments

REGULATORY VERSUS NON REGULATORY ALTERNATIVES

The non-regulatory solutions correspond to the options 1 and 2 – which correspond to the *status*

quo or its prolongation through long-term financing by the EU.

Alternative/differentiated scope

Small and medium sized companies are key sources of innovation in the sectors covered by this initiative. They are particularly concerned by the fragmentation of the EU market, as SMEs have less resource for managing the differences of HTA approaches across Member States. This is further developed in section E.

Options that take account of new technological developments

The proposed initiative will build on **existing IT tools** and is likely to expand them. The database for sharing the assessments produced by individual HTA bodies (i.e. Planned and On-going Projects (POP) database) has already been established and piloted in the framework of EUnetHTA. However, it is clear that additional financial and staff resources are needed to ensure the continuation and sustainability of these platforms. Ultimately, increased use of these platforms will enhance access to evidence for the benefit not only of national authorities, but also for industry, payers, health professionals and patients.

Preliminary proportionality check

The Commission will only pursue options that are **proportionate** to the objectives to be achieved.

Option 1 (*status quo*) raises concerns in terms of achieving the objectives as the current Joint Action ends in 2020, putting at risk the achievements. The objectives of reducing duplication of efforts (in terms of methodologies and procedures) and of ensuring/increasing uptake of joint work are expected to be difficult to reach following the expiry of the Joint Action.

Option 2 is more in line with the specific objectives, but is expected to deliver only partially (e.g. limited uptake of joint work in a coherent manner). Option 2 presupposes long-term financing from the EU budget, however without a guarantee that the uptake of joint work substantially increases. This option also raises questions as regards reducing duplication of efforts, which triggers concerns in terms of its proportionality.

Option 3 makes a further contribution in reducing differences between national HTA approaches (procedures and methodologies), making it easier for national HTA bodies to share results produced by them individually or jointly. Once again, though, there is no guarantee that the uptake of joint work will increase significantly, or that the duplication efforts will be adequately reduced, while a greater financial support is required, so this option does not remove all concerns about proportionality.

Option 4 would make a greater contribution to reduce duplication of efforts and some form of uptake is foreseen (for all or for participating Member States) in both envisaged sub-options, whose proportionality will be assessed separately. Both sub-options would contribute to sustainable financing through industry fees and contributions from the Member States.

Option 5 would also make significant contribution to reduce duplication of efforts and increase uptake. Its proportionality (to be assessed for each of the sub-options envisaged) will be affected by the level of context-specific information needed for the performance of joint full HTA.

C. Data Collection and Better Regulation Instruments

Data collection

Studies are launched in 2016 to accommodate the information needs. Areas which require further data collection include the mapping of the national HTA frameworks (procedures and methodologies – updates only), the establishment of the base line scenario and its impacts on stakeholders, as well as the impacts of the options on key stakeholders. Furthermore, it will be important to gather additional input about how to structure the coordination at EU level from an organisational and financial perspective.

Consultation approach

Stakeholder consultation – on a continuous basis - will be a key success factor for the envisaged initiative. Understanding and assessing the concerns of stakeholders will be crucial to develop an initiative that meets expectations, demonstrates EU added value and allows for effective implementation. The public consultation of all stakeholders will be launched in the autumn of 2016.

The consultation strategy consists of a mix of open consultation and targeted meetings, which will include the following stakeholders:

- Member States at both political (HTA Network/Health Ministries) and scientific/technical level (EUnetHTA/HTA bodies);
- Economic stakeholders (industry, SMEs, HTA consulting etc.);
- Civil society representatives (e.g. patients, public health organisations, etc.);
- Healthcare providers (e.g. professional associations, hospitals, healthcare managers);
- Payers (e.g. health insurance representatives, "mutualités");
- Research and innovation community (e.g. academia); and
- Relevant international organisations such as WHO, OECD, INAHTA (International Network of Agencies for Health Technology Assessment) and ISPOR (International Society for Pharmacoeconomics and Outcomes Research).

The EC consultation online:

The launch of the public consultation will be announced in the consultation planning that can be found at: http://ec.europa.eu/yourvoice/consultations/index_en.htm.

Will an Implementation plan be established?

☐ **Yes** **X No**

D. Information on the Impact Assessment Process

The impact assessment process will start in the third quarter of 2016 with the setting up of an Interservice Steering Group (ISG). Next to the SG (Secretariat-General) and LS (Legal Service) the following Commission services will be invited to take a part in the ISG: BUDG (Budget), GROW (Internal Market, Industry, Entrepreneurship and SMEs), RTD (Research and Innovation), CNECT (Communications Networks, Content and Technology), ECFIN (Economic and Financial Affairs), EMPL (Employment), TRADE (Trade), COMP (Competition) and the JRC (Joint Research Centre).

The ISG would meet at least three times during the process of the impact assessment.

E. Preliminary Assessment of Expected Impacts

The following section will provide an initial, preliminary assessment of the impacts of the various

options introduced in Section B.

Likely economic impacts[68]

Option 1. If the *status quo* is maintained, the differences between HTA approaches persist and might even increase when the current Joint Action comes to an end in 2020. The possible additional benefits which may be achieved within the next four years will be jeopardised as - without additional financial support - it is unlikely that the cooperation would continue. In any case, costs and administrative burden for the national bodies will increase, as a result of the likely progressive expansion of HTA activities, especially considering the current pace in the development of novel health technologies; the countries with lesser experience in HTA, not counting on the benefits of cooperation anymore, will be affected the most. Costs for industry are likely to increase too, due to the increasing number of Member States with functioning HTA bodies and differences in national approaches. Industry will continue to need to prepare multiple submissions for different Member States. All this may also negatively affect business predictability and hence the capacity of industry to innovate and will need to be investigated in depth

Option 2. There is a possibility that differences in HTA approaches and their adverse effects could be reduced over time as the current cooperation model would continue. However, there is a distinct risk that the uptake of joint work would not increase significantly. On the contrary, the latter is expected to remain limited and national procedures would continue to apply. In this light, the negative impacts described for option 1 would still apply, even if potentially at a somewhat reduced level. Ultimately, business predictability and the capacity of industry to innovate would remain hampered by the limited level of cooperation.

Option 3. Aligned HTA methodologies, common templates and tools for national HTA reports will improve consistency and sharing of results, thus possibly reducing some duplication and the relative costs (mainly linked to human resources) for both national bodies and industry, compared to the previous options. However, multiple submissions – following different procedural rules - are expected to remain. Business predictability may benefit, but not significantly. The early dialogue and alignment of data requirement post market launch (if it is made part of this option) is expected to further reduce costs for industry linked to production of additional data requirements in different Member States.

Option 4 and 5. Extending the cooperation to joint assessments of the clinical (option 4) or also economic domains (option 5) of HTA would improve the cost efficiency of national bodies' resources, by allowing them to save time in order to generate more reports[69] and further improve the average quality of HTAs in terms of management, relevance, transparency. Moreover, joint assessments would also reduce costs and administrative burden for industry, due to the reduction in the number of submissions to be performed and a greater harmonisation in data requirements. These options are foreseen to increase business predictability for industry, and provide clearer incentives for technologies with added value[70], possibly having a positive impact on the investment climate. For option 5, however as economic, organisational and other additional

[68] This section also covers potential impacts related to competitiveness and innovation.

[69] A centralised structure would be highly beneficial, for example, in building a stable and sound relationship with manufacturers, regulators and other stakeholders, whose lack has been reported as a major cause of delays during Joint Action 2.

[70] J. Rovira. Health technology assessment and the Incentives to Innovation in the life Cycle of a Health technology. In. Health Technology Assessment and Health Policy Today: A Multifaceted View of their Unstable Crossroads, 2015.

aspects of the assessments depend on the specific national context, and therefore context specific data may need to be provided, reduction of administrative burden and operating costs for this option is expected to be limited.

Likely social (health) impacts[71]

Option 1. Due to inter alia the diversity of legal frameworks, patients in some Member States might have no or delayed access to innovative technologies (health inequalities).[72] In Member States with no functioning HTA systems it will be more difficult to ensure sustainability in health care due to the risk of financing expensive technologies with little or no added value.[73]

Option 2. The continuation of the current cooperation model, just on a long-term basis, is not expected to mitigate substantially the differences in access to health technologies. The cooperation may support Member States in further developing their HTA systems for better and more sustainable allocation of resources, however there is no guarantee that this will happen. In any event, it would take significant time and financial investment without adequate assurance of success.

Option 3. Stronger EU cooperation on the basis of harmonised tools could improve consistency and quality of HTAs throughout the EU. This could result in a better allocation of resources in the health sector, improving public health and leading to more efficient and resilient health systems.[74] However, as divergent HTA outcomes are still expected, a favourable climate to invest into new technologies meeting patients' needs is less likely.

The rather positive effects described for option 3 are expected to increase further in **options 4 and 5** as much more work is done jointly. In **option 4**, the clinical aspects of the assessment are conducted jointly by pooling the expertise from several Member States; its results, therefore, would provide consistent evidence in the subsequent steps of national decision-making. Even more notably, a centralised strategy in topic selection would improve the prioritization of innovative tools and unmet needs, thus reducing inequalities in patient access for the most valuable technologies. **Option 5** takes a further step forward and includes other domains in the assessment. Some of such additional aspects of the assessments depend on the specific national context; this will in some cases reduce the relevance and feasibility (and ultimately the added value) of the joint assessment.

Likely impacts on simplification and/or administrative burden

One of the key impacts of an initiative on HTA is the reduction and rationalisation of administrative burden both for Member States and industry.

Option 1. In the current regime, there is significant duplication of efforts for Member States and industry. Experience so far indicates that the current model of cooperation is unlikely to overcome

[71] The section on environmental impacts was deleted, as it was not considered relevant for the purpose of this inception impact assessment.

[72] Report requested by European Parliament's Committee on Environment, Public Health and Food Safety. Differences in Costs of and Access to Pharmaceutical Products in the EU, 2011.

[73] Evidence suggest that the overwhelming majority of new treatment does not have significant/major therapeutic added value. HAS annual report for 2014 (France) or Wisløff T, Hagen G, Hamidi V, Movik E, Klemp M, Olsen J-A. Estimating QALY gains in applied studies: a review of cost-utility analyses published in 2010. Pharmacoeconomics. 2014;32(4):367–75.

[74] Sorenson, C., 'Use of Comparative Effectiveness Research in Drug Coverage and Pricing Decisions: A Six-Country Comparison', The Commonwealth Fund, July 2010.

such duplication, therefore simplification is not expected and administrative burden on Member States (repeating assessments) and industry (submitting multiple dossiers) are expected to remain and possibly increase.

Option 2. In the long run, differences in HTA approaches and their adverse effects are expected to reduce compared to option 1. Alignment of methodologies will mean that work conducted jointly or in other Member States becomes more accessible, but, due to the nature of the cooperation, the uptake of this work will be limited and duplication of efforts are likely to continue both for public administrations and industry.

Option 3. The envisaged alignment of methodologies and tools is likely to reduce the administrative burden associated with multiple submissions and assessments, both for public administrations and industry. It could also provide incentives for possible voluntary cooperation on the production and sharing of REA reports.

Option 4, by providing a centralised management of the joint reports on REA, would significantly reduce the duplication of efforts, both for public administrations and industry, especially considering that the evaluation of the clinical domains is less affected by the national context. This option would facilitate the uptake of the joint work.

Option 5 is also expected to significantly reduce duplications. However, some of the non-clinical domains are context-specific. Therefore, specific data would still be required, limiting the desired simplification (see also economic impacts). Developing a joint Full HTA report and using it in national settings could be more complicated than in the case of clinical domains.

Likely impacts on SMEs

Due to their limited resources and the higher dependence on a limited number of innovations, it is a particular challenge for SMEs to navigate through the different national HTA systems. The economic impacts of the options described above also apply to SMEs.

Options 1 and 2. It is particularly challenging for SMEs to submit multiple HTA dossiers in different Member States - both for the administrative burden and for the costs associated with the compliance to multiple evidence requirements.

Option 3. The high administrative burden for SMEs is reduced, which facilitates market access for innovative technologies that received a positive assessment.

Option 4 and 5 are expected to have positive impact on SMEs as they will reduce administrative burden, increase simplification and possibly reduce costs linked to development of multiple data requirements. On the other hand, considering the high dependence of SMEs on few technologies, a negative joint assessment may have serious consequences on the sustainability of the SME. However, such challenge may also be an opportunity to stimulate innovation and attract investors.

Likely impacts on public administrations

Option 1. As explained above, due to the voluntary nature of the cooperation, the duplication of efforts for HTA bodies is not removed under this option (see also administrative burden/simplification). Also the sustainability of the national health system is not improved.

Option 2 and 3 would allow for some alignment of methodologies and provide better access to information about on-going or recent assessments. Still, the assessment of the new technologies would be largely conducted at national level, leading to duplications. Option 3 would further

improve the current situation, as the use of certain tools and templates would be mandatory (see also administrative burden/simplification). The higher the quality of the joint work is, the greater is the potential impact on the sustainability of the health systems.

Option 4 and 5. The duplication of efforts for HTA bodies would be significantly reduced. Member States without a functioning HTA system would have a tool at their disposal to contribute to the sustainability of their health care systems. Even advanced Member States could benefit, e.g. by relying on specialised expertise from other Member States. While there are certain costs associated with organising the joint work, there is no need to change the current institutional structures in the Member States and the IT tools are already available. This initiative should not be considered as an opportunity to reduce expenditure in national HTA bodies, but rather as a better use of resources across borders. High quality HTA reports will also allow Member States to maximise the benefits in terms of sustainability of their healthcare systems. However, the reluctance of Member States towards mandatory cooperation for Full HTA reports is expected to be high.

Establishing EU wide figures will require thorough analysis, as the cost savings depend on a number of factors such as a) the design of the HTA system (e.g. which types of technologies are included: pharmaceuticals, medical devices, others, and how many assessments are carried out per annum), b) the complexity of the REA and/or full HTA report, as there are existing variations in the national standard of care (i.e. a new technology might bring significant cost-benefits in one country, but only limited benefits in another, as its standard treatment is different) or c) different perspectives in Member States, e.g. the type of savings to be included in the calculations (e.g. how actual savings or also life years gained – so called QALYs are considered).

Likely impacts on third countries, international trade or investment

Considering the size of the EU market, a predictable framework attracts investments. Such a framework can also become a world standard, which could allow European HTA bodies to market their expertise outside the EU. For some companies, the positive assessment might be a marketing tool outside the EU.