EUROPEAN COMMISSION
DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
Unit B4 - Medical products: quality, safety, innovation

SANTE meeting with ESIP and AIM

Date: 23/05/2017

Location: DG SANTE premises

Participants

ESIP (European Social Insurance Platform)**:** Christine Dawson (ESIP), Martin Meissnitzer (EU Representation of Austrian Social Security Institutions) Evert-Jan van Lente (AOK Health Insurance, Germany)
AIM (Association Internationale de la Mutualité): Menno Aarnout

SANTE: D. Schnichels, K. Hanslik, N. Suleiman

Purpose of the meeting

The aim of the meeting was to discuss ESIP and AIM views on the future EU HTA cooperation.

The meeting started with a short introduction by all participants.

Discussion

ESIP and AIM views on HTA

Both organisations expressed their support for HTA cooperation at EU level beyond 2020, however they underlined that within their respective memberships the views are not fully converging regarding the extent of that cooperation.

ESIP and AIM support that European cooperation should cover a broad range of technologies, i.e. pharmaceuticals, medical devices and other medical/surgical interventions and prevention programmes. The organisations stressed that it is not feasible to carry out assessments for all technologies. Therefore, a prioritisation process is called for, in particular in the initial years ("phasing in"). ESIP and AIM maintained that the decisions on prioritisation should not be taken only by Member States (HTA Bodies/Ministries of Health). Rather the prioritisation process shall also foresee a consultation of payers and other users of HTA, including health professionals. In this regard, AIM promised to share with SANTE a document explaining the involvement of payers in the respective national processes.

Regarding the question of whether certain subcategories of technologies are particularly well suited for European HTA cooperation, ESIP and AIM pointed to new products, which are about to enter the market and for which ideally adequate data and evidence are available. At the same time ESIP and AIM are of the opinion that more emphasis should be given, also at EU level, to re-assessments, a few years after a pricing/reimbursement decision has been taken. Also the high budget impact and

the risks associated with a product could be good criteria to assess the relative effectiveness/efficacy of a technology. These criteria could also be useful when deciding on re-assessments, which could lead even to de-listing decisions. Regarding new product launches a reference to the Transparency Directive was made, which contains strict timing obligations for pricing and reimbursement procedures. Considering the complexity of HTA procedures and that HTA reports should be available early on in the process, it was stressed that the reports should ideally be available at the same time as marketing authorisations (in particular for pharmaceuticals going through central marketing authorisation). This speaks in favour of a start of the HTA process well before the marketing authorisation is granted.

ESIP and AIM underlined that many of their members are interested in EU activities on HTA including exchanges in the field of cost effectiveness. They agreed however that the question of whether a technology is cost-effective will differ from country to country. It was, suggested by AIM to launch a discussion at EU level on the concept of "cost effectiveness" (what it is and how to measure it, exchange of best practices) and possibly develop some general guidance on the issue.

Regarding the governance structure for EU cooperation ESIP and AIM do understand that a permanent structure/secretariat is warranted in order to ensure sustainability of the cooperation and to avoid unnecessary administrative obstacles. While some of the members indicated a preference for a rotating presidency by Member States, in the discussions, ESIP and AIM were aware that a rotating presidency by Member States would be difficult to implement in practice. Also entrusting one Member State to carry out the tasks for all others might raise concerns in terms of political acceptability. In any event it would be important to guarantee the independence of the HTA process from marketing authorisation. In this light EMA was not considered the right agency to take over the tasks associated with HTA cooperation at European level. In terms of the decision-making model EMA might however serve as a model, i.e. common decisions by Member States, which are also represented in the management board, and outsourcing of the actual assessments to national agencies where the HTA expertise lies.

Regarding financing ESIP and AIM preferred a mixture of EU budget and Member States contributions (in money/Kind). Fees from industry were not considered appropriate for joint HTA assessments but might be considered for early dialogue procedures. They stressed the need to ensure complete independence and avoidance of conflict of interest in any case.

Regarding the preferred policy options, AIM and ESIP asked how the five options identified in the Inception Impact Assessment and the three options in the public consultations relate to each other. The Commission explained that the option called “voluntary/voluntary” in the public consultation means that the participation of Member States is voluntary (i.e. outside a legal framework) and that the uptake (= national use) of joint work is/remains voluntary. In this light, the option “voluntary/voluntary” corresponds to the options 1 and 2 of the Inception Impact Assessment (status quo or long-term contract). In contrast, the option “mandatory/mandatory” in the public consultation requires a legal framework and obliges all Member States to uptake the joint work. Accordingly, this option corresponds to option 4.2 and by extension option 5 in the Inception Impact Assessment (as the latter is built on option 4.2). Finally, the option “voluntary/mandatory” in the public consultation means that participation in joint assessments is voluntary, but those who participate are bound by law to use the results. This option thus corresponds to option 4.1, which is built on option 3 (harmonisation of tools). In the light of these explanations ESIP highlighted that policy options 3 and 4.1. of the Inception Impact Assessment are the ones which would represent payers' interest in the most optimal way. From the point of view of AIM and ESIP the participation in the joint assessments should be voluntary but at least in the medium and long term there should be an obligation for up-take.

Follow up

ESIP and AIM thanked DG SANTE for the meeting and expressed their willingness to continue the dialogue with the Commission. AIM will forward to the Commission the working document on the description of payers' role in the national process as soon as possible, at the latest right after the summer break.