Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU - Swedish comments on Presidency paper WK 12510/2019 and WK 11333/2019

SE would like to thank the Presidency's for the efforts that has been done to find solutions for continued HTA cooperation at EU level and to move the discussions in the working party forward.

WK 12510/2019 (medical devices)

1. Do you think that medical devices and in vitro diagnostic medical devices should be included in the regulation?

Yes. The field of medical devices is large and will become more and more important. This also applies to the field of combinations of medical devices- medicinal products. There may be opportunities to get faster introduction and equal care for more products through European cooperation.

However, it is necessary that the regulation considers the differences that exist compared to medicinal products.

2. What is the correct timing to provide added value for the member states? Could you envisage an initial JCA at the time of the expert panel opinion, followed by updates later on?

It is important to have an assessment of medical devices before a broad market introduction takes place, otherwise we run the risk of high costs and unequal use. SE would like to see an early assessment which can be followed up if necessary.

3. If JCAs are done only on those devices for which an expert panel has given its opinion, are the selection criteria needed given that the number of devices to undergo the scrutiny procedure is estimated to be around 5/year?

SE notes that the number of evaluations for medical devices seems to be low and could be increased. In addition, the number of evaluations per year could grow over time as the methodological expertise on medical device assessments increases. If the number of medical technology products that could be relevant for JCA becomes larger it is advisable that there are clear selection criteria.

4. Selection criteria

SE notes that there are a great number of definitions of "Unmet need", see link below to article: https://www.valueinhealthjournal.com/article/S1098-3015(19)32303-4/fulltext

5. Given the fact that the Coordination Group has no legal personality, it would not be possible for it to select the devices that undergo JCA. Therefore, please state your preference for a selection by Commission Decision (based on criteria in the Regulation) or laying down the obligations directly in the Regulation.

SEs preliminary view is that the selection be made via a Commission decision following proposals from the Coordination Group.

6. How much time is needed to develop the methodological expertise necessary for the JCA on medical devices?

Experience from EUnetHTA shows that it has been easier to collaborate on evaluation of medical technology. More reports have been published for medical devices than for pharmaceuticals. There is a need to develop methods for evaluating medical devices because the clinical evidence is often more limited than for drugs.

WK 11333/2019

SE can generally support the Presidency's suggested approach on Article 7 and Article 8 as a basis for continued discussion. SE welcomes continued cooperation at EU level in the HTA area and there is now a need to find a way forward in the Council.

However, the question of timelines/timeliness remains very important for SE. These should continue to be reviewed in a comprehensive manner and we must therefore return to this.

Art 6

6 1b

It is important that MS's different perspectives and needs are considered in the preparation of the assessment scope. This is missing from the Presidency's proposal, which was also addressed by other MS, and should be adjusted.

6 2 f

SE suggest that "may" be replaced by "shall". "The sub-group *shall* also use…., Where deemed relevant to complement…"

Art 6 a

X. "<u>The assessors shall take into consideration the submission material from the health technology developer in Article 6.2.b and the CHMP assessment report when made available.</u>"

It is not clear from the current articles that the CHMP's assessment report should be considered in the JCA. SE suggests that this could be introduced as it would provide the JCA

authors earlier access to the CHMP evaluation compared with waiting for the European Public Assessment Report (EPAR) to be published following EC approval.

EMA should therefore be required to send the adopted CHMP Assessment Report (AR) together with the decision on positive opinion to the Coordination Group at the same time as it is sent to the health technology developer applying for Market Authorizsation in accordance with Article 9 of Regulation 726/2004.

The rationale for this proposal is that it is essentially the same data that is the basis for the evaluation in the EMA's application process as in the planned JCA evaluation. In addition, further data and analyses that affect the market authorization are requested during the EMA procedure and are thus only available in the CHMP AR (and subsequently in the EPAR)., By securing early access to the CHMP assessment, the risk of duplication of work and divergent conclusions due to incomplete information, etc., is reduced.

As the CHMP report is usually covered by confidentiality, this may need to be regulated as regards the exchange of information between the CHMP and the coordination group / subgroup. (Sections of the AR containing commercially sensitive information on quality/biotechnology aspects may be redacted by the CHMP, as is presently done for EPARs, before sending it to the Coordination Group in order not disseminate company intellectual property.)

Therefore, the Regulation 726/2004 that regulates the work of the EMA, would need an amendment as outlined below (bold, underlined):

Article 9.3 (REGULATION (EC) No 726/2004)

"Within 15 days after its adoption, the Agency shall send the final opinion of the said Committee to the Commission, to the Member States and to the applicant, together with a report describing the assessment of the medicinal product by the Committee and stating the reasons for its conclusions. **If applicable, (if a joint HTA assessment is planned or ongoing) according to article 5 in the HTA regulation X, the Agency shall send the documents listed above also to the Coordination Group on Health Technology Assessment within the time frame above."**

It is necessary with communication between the EMA and the Coordination group in order to inform the EMA of ongoing or planned JCAs.

Alternatively, and potentially an easier option, would be to amend the Article 6.2.b in the HTA regulation according to the below (bold, underlined):

Art 2b. For medicinal products, the dossier shall include:
(a) the clinical safety and efficacy modules of the submission file to the European Medicines Agency;
(ba) published and unpublished information on and analyses from completed, ongoing and discontinued clinical studies relevant to the assessment scope set in accordance with point 1b, including the clinical study reports and clinical study protocols if available to the health technology developer;

(e) where applicable and available to the health technology developer, HTA reports on the health technology subject to the joint clinical assessment;
(f) clinical information on all comparators included in the assessment scope;
(g) **the CHMP assessment report when available.**

6 a p.7

"The members of the designated sub-group shall provide their comments during the preparation of the draft reports. **In addition, any other member state may comment on the draft report"**

Comments from member states on the JCA in order to increase the quality of the report and enhance use of the report (Article 6a) During the EMA assessment phase all member states may comment on the report in order to make the report more relevant for all member states and increase the quality of the report. A similar procedure in the HTA setting would be beneficial in order to increase the quality of the report and enhance use of it.

Recital 15b (on clinical added value)

It is important that the reports provide the support they need to be useful for the conclusions to be drawn at national level. SE consider that the proposed recital 15b reflects what is needed.

Council of the European Union
General Secretariat

Interinstitutional files:
2018/0018(COD)

Brussels, 25 November 2019

WK 13452/2019 INIT

LIMITE

PHARM
SAN
MI
COMPET
IA
CODEC

WORKING PAPER

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

WORKING DOCUMENT

From: To:	General Secretariat of the Council Working Party on Pharmaceuticals and Medical Devices (HTA)
N° Cion doc.:	5844/18 PHARM 6 SAN 49 MI 61 COMPET 53 IA 43 CODEC 133 + ADD 1 + ADD 2 + ADD 3 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU - suggestions from the Swedish delegation

With a view to the meeting of the Working Party scheduled for 3 December 2019, delegations will find attached comments from the Swedish delegation on joint clinical assessments of medical devices and *in vitro* diagnostic medical devices and suggestions for changes to the text in WK 11333/2019 .