Document 02

From: [redacted] (SANTE)
Sent: lundi 27 janvier 2020 11:01
To: [redacted] (SANTE)
Subject: FW: Follow-up Paris

From: [redacted]@efpia.eu>
Sent: Thursday, December 12, 2019 8:48 PM
To: [redacted] SANTE) <[redacted]@ec.europa.eu>
Subject: Fwd: Follow-up Paris

Dear [redacted],
I hope you are well, and getting closer to vacation!
fyi, I wanted to share with you a quick summary of what we want to follow-up from the latest 2 interactions with EUnetHTA. In particular the point on the 'issue resolution mechanism' is important in my view. Some countries have really no expertise in HTA and will not be able to deal with a company 'complaining' about a JCA.
Best
[redacted]

[redacted]

EFPIA - European Federation of Pharmaceutical Industries and Associations
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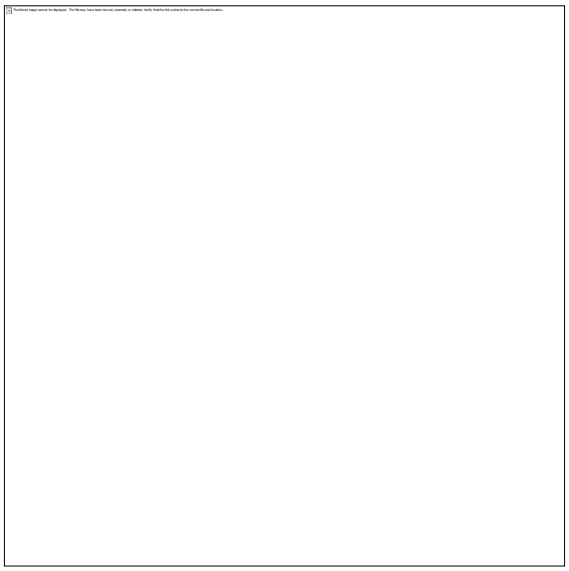

---------- Forwarded message ---------
From: [redacted]@tlv.se>
Date: Thu, 12 Dec 2019 at 15:32
Subject: Sv: Follow-up Paris
To: [redacted]@efpia.eu>
Cc: [redacted]@zinl.nl>

Dear [redacted]

Thank you for receiving us!

Thank you also for your thoughts and notes.

I briefly spoke to [redacted] and our joint view is that the Nov 15 meeting was probably the most important for us as well.

We will consider how to take this forward and will come back to you.

[redacted]

Från: [redacted]@efpia.eu>
Skickat: den 10 december 2019 16:08

Till: [redacted]@tlv.se>
Ämne: Follow-up Paris

Hi [redacted]

nice to see you and [redacted] earlier! These are my notes of some actions following the 15 November and 2 December.

Best

[redacted]

Publication/citation policy

- EUnetHTA to check feasibility of setting up a Committee to review requests for marking specific aspects of reports as confidential
- Engage in EFPIA-EUnetHTA discussion on publication policy/liaise with journals
- EFPIA to clarify with concrete examples confidentiality issues raised by the current EUnetHTA policy

For your personal information I have also checked with German colleagues the policy in Germany. The AMNOG process requires a manufacturer submission with 5 modules, one of which (module 5) includes confidential information. The practice at IQWIG however is to sign an agreement for each assessment with the manufacturer leading to the ability for IQWIG to quote exclusively from study results and methods that are included in module 5, otherwise IQWIG will consider the dossier is incomplete and will conclude on no added benefit. This looks very similar to the EUnetHTA approach except that EUnetHTA applies it as a standard rather than a case by case, and except that at the EUnetHTA level it's possible to quote broadly and not exclusively just study results and study methods. Also the German publication is 3 months delayed compared to the German process, since AMNOG takes place later. We are therefore quite concerned that the German model would be used at the European level without even the safeguards used in Germany.

Submission template

EUnetHTA to further discuss internally how to involve EFPIA moving forward in the development of the template

Assessment phase/Interaction with manufacturer

We raised our wishes for a systematic factual accuracy check, a review meeting and an issue resolution mechanism. I guess we agreed to disagree on this point, but for info it will be part of the recommendations we put forward when we publish the results of the CRA analysis in a publication. What we are seeking is very much something that is standard at the national level for example in Germany the 'Stellungsnahmemöglichkeit' on an IQWIG report that opens the door to an oral hearing at GBA. We understand the argument that the challenge is and should remain at the national level. However it should neither be considered satisfactory nor efficient if a European report is considered flawed and is forward to 27 countries and needs to be challenged in 27 countries, taking into account that not all countries will have the necessary structures and expertise in place.

Scoping meeting

EUnetHTA to clarify the documents needed ahead of assessment initiation and scoping.

Methodologies

EUnetHTA to discuss whether it would be possible to organise a dedicated EFPIA-EUnetHTA meeting on methodologies

Evidence Generation

Consider specific information sharing in January on new financing mechanism (eg webinar with EFPIA members)

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