PHP212

EARLY PAYER SCIENTIFIC ADVICE PROCEDURES IN THE EU: WHICH ONE IS MOST SUITED FOR PHARMACEUTICAL COMPANIES?

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Introduction/objective

- Pharmaceutical companies are increasingly seeking payer guidance to provide insights on how to build payer value into the clinical trial program.
- There are multiple ways to seek payer guidance throughout clinical development, either at an EU-wide or a country-specific level.
- The objective of this research was to understand the processes and outputs from different European payer scientific advice procedures (PSAPs) to determine the most suitable approach for pharmaceutical companies.

Methods

- Information on four major European PSAPs (NICE, G-BA, EMA-HTA parallel scientific advice, and SEED's multi payer pilot program) were obtained from secondary sources. Clarifications on the PSAP processes were gained from respective health technology assessment (HTA) bodies.
- The procedures and outputs for the four European PSAPs were analyzed in order to determine the: evidence submission requirements; processes; timelines; fees; submissions conducted and outputs.

Results

Notification of request → Development of briefing book incorporating key questions to HTA bodies → Face-to-face (NICE and EMA-HTA parallel) or teleconference (G-BA and SEED) discussions between HTA body and manufacturer → Formal minutes provided by NICE and G-BA
Approval of company submitted minutes for EMA-HTA parallel scientific advice and SEED

Figure 1. Overview of a typical early payer scientific advice process

- Manufacturers seek early payer scientific advice from NICE, G-BA, EMA-HTA parallel scientific advice and SEED to ensure their clinical development program is relevant to payers.
- The four main areas in which guidance is sought are:
  - Choice of comparators
  - Choice of endpoints
  - Study design
  - Health economics.
- The process for scientific advice is similar for NICE, G-BA, EMA-HTA parallel scientific advice and SEED involving four steps (Figure 1). However the level of complexity varies between the procedures.
  - The number of stakeholders (HTA bodies involved), the level of feedback and the cost differ between PSAPs (Table 1).
  - PSAPs are time intensive, varying from 10 weeks for the G-BA to 26 weeks for EMA-HTA parallel scientific advice (Figure 2).
- Overall the number of PSAPs increased over a five-year period from 2011 to 2015 (Figure 3).
  - The numbers of PSAPs undertaken by EMA-HTA parallel and G-BA have tripled since 2011 (Figure 3).
  - In Germany, an increase was seen following the introduction of AMNOG in 2010, however the number of German PSAPs have plateaued in recent years (Figure 3). It can be hypothesized that the short review time (10 weeks) and relative low fees (~€20,000) are supporting factors behind the large number of G-BA requests.
  - Both NICE and G-BA are engaged in an increasing number of EMA-HTA parallel scientific advice as well as SEED PSAPs (Figure 4). It is hypothesized that his might account for the reduction in the number of NICE requests.

Table 1. Overview of the early payer scientific advice procedures

Criteria	National		EMA-HTA parallel	SEED
	NICE	G-BA		
Number of HTAs bodies involved			EMA + 5 national HTA bodies	14 members
Feedback provided on	Individual country		Individual HTA/EMA	HTA consensus
EMA perspective provided	✖		✓	If requested
Cost	Up to £50,000	Up to €20,000	~€80,000	Free (moving to fee-based funding)

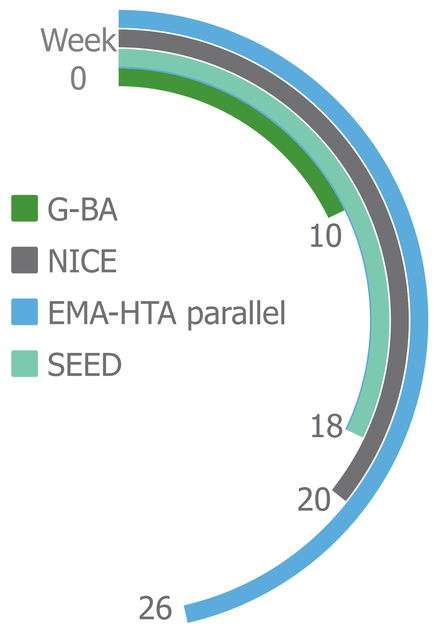

Figure 2. Number of weeks taken for the HTA bodies to complete a payer scientific advice procedure

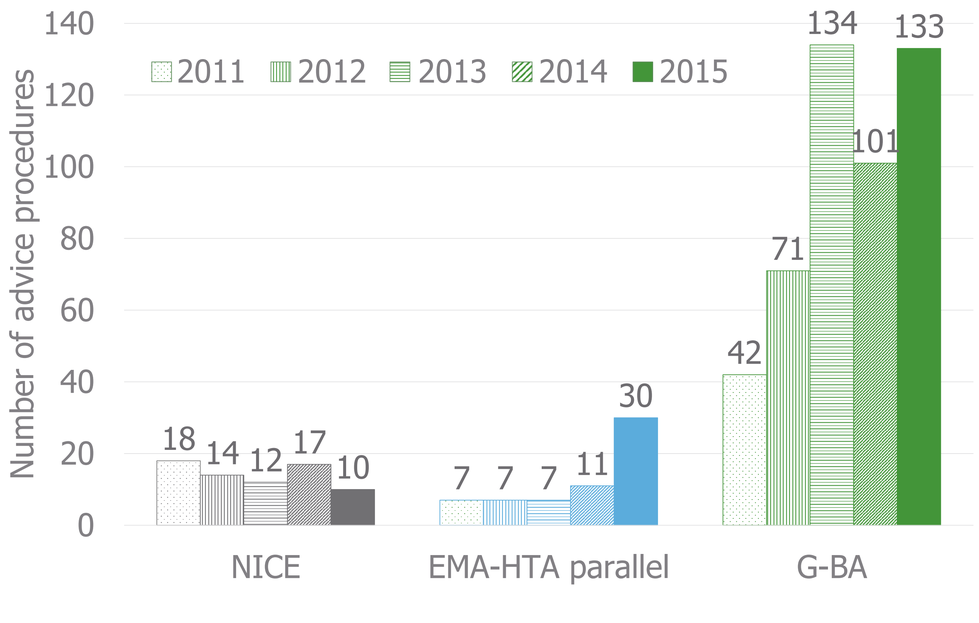

Figure 3. Number of early payer scientific advice procedures undertaken by NICE, G-BA and EMA-HTA parallel scientific advice

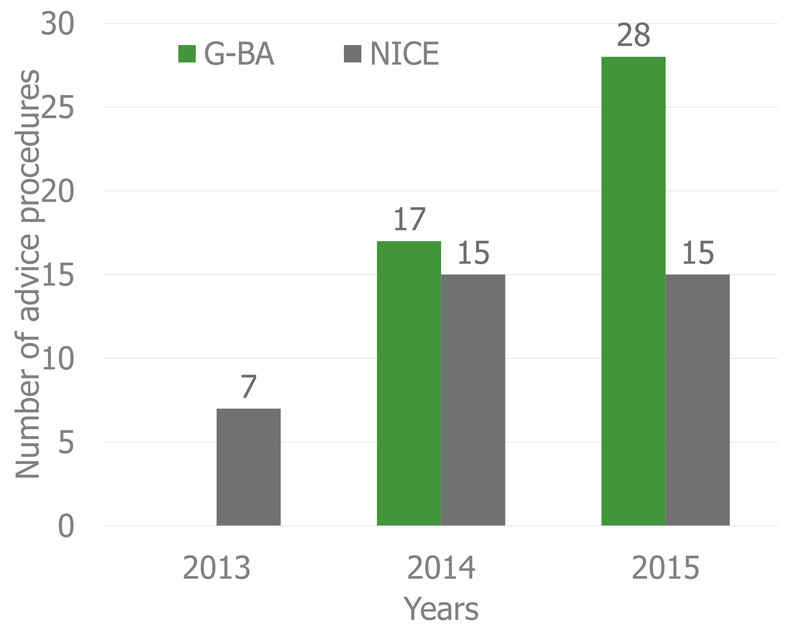

Figure 4. Number of joint early payer scientific advice procedures (EMA-HTA parallel, SEED, EUnetHTA) which involved either the G-BA and/or NICE

Note: NICE data are for UK financial year April–March, G-BA data are for calendar year

Discussion and conclusion

- PSAPs can provide pharmaceutical companies with valuable insights into phase III trial design, health economics, and payer expectations at time of launch. Typically, the level of product and therapy area uncertainty can drive PSAP selection.
- If there is significant uncertainty, national advice procedures (e.g. NICE, G-BA) should be sought to gain detailed country specific insights. However, this must be balanced against the additional cost and resource implications when seeking advice from more than one country.
- EMA-HTA parallel scientific advice is most suited for products with limited uncertainty where companies are looking for confirmation that their clinical program is acceptable to payers across multiple markets.

EMA: European Medicines Agency; G-BA: Gemeinsame Bundesausschuss (federal joint committee); NICE: National Institute for Health and Care Excellence; SEED: Shaping European Early Dialogues)
European Medicines Agency, Annual Report 2015. http://www.ema.europa.eu/docs/en_GB/document_library/Annual_report/2016/05/WC500206482.pdf, Accessed September 2016
https://www.nice.org.uk/, Accessed September 2016
https://www.g-ba.de/, Accessed September 2016
Additional information sought from official communication with sources within NICE and G-BA

ISPOR 21st Annual International Meeting, 29 October to 2 November 2016, Vienna, Austria

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