

Joint HTA and Drug Pricing Collaborations in EU: By whom and when to be pursued?

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INTRODUCTION

Over the past years, **several cross-country joint Health Technology Assessments (HTA) and drug pricing collaborations have been developed** in the EU with the aim of:

- Improving efficiency of evaluations, and avoiding duplication of decisions
- Accelerating patient access
- Making use of combined payer negotiation power when discussing prices

This topic will remain relevant in the future, as new initiatives are introduced, and the existing bodies evolve

- For example, a recent proposal was made for steps towards allowing confidential net prices to be shared between members of the Valetta Declaration group
- Cross-country collaboration remains politically attractive, as an indicator of actions to address time to reimbursement and affordability of new drugs

OBJECTIVES

The purpose of this research is to:

- Gain an understanding of **pricing and market access implications** of existing joint HTA and drug price collaborations
- Identify and share **Simon-Kucher's future outlook** on joint HTA and drug price collaborations
- Share Simon-Kucher's view on **next steps pharmaceutical companies should consider** when evaluating whether to pursue joint HTA and/or drug price collaboration

METHODS

- We conducted a qualitative in-depth analysis of publicly available information to analyze the P&MA implications for pharmaceutical companies of joint HTA and drug pricing collaborations
- Based on these insights, we **defined the expected future outlook** for joint HTA and drug price collaborations, assessing the drivers and hurdles for future events

Implications of joint HTA and drug pricing collaborations on P&MA varies based on the set-up of the collaboration*

Intro date	Collaboration	Type	Description and aims	P&MA Implications for pharmaceutical companies
2006	EUnetHTA 30 European countries and 80 government appointed organizations		<ul style="list-style-type: none"> Facilitates efficient HTA resource use across Europe 	<ul style="list-style-type: none"> 28 assessments completed (across product types and therapeutic areas) Provides communication point for HTA information exchange and transparent stakeholder consultations (patients, health provider, payer and industry associations)
2015	BeNeLuxA-I Austria, Belgium, Ireland, Netherlands, Luxembourg		<ul style="list-style-type: none"> Drives joint pricing and reimbursement to achieve easier and quicker market access for innovative, expensive therapies 	<ul style="list-style-type: none"> Pharmaceutical company decision to pursue joint negotiation Six joint HTA assessments; of which two also started joint price negotiations One finalized joint HTA and joint price negotiation: Spinraza
2015	Nordic Collaboration/Pharmaceutical Forum Denmark, Finland, Iceland, Norway, Sweden		<ul style="list-style-type: none"> Increases quality of HTA assessments by using best practices from member states Increases effectiveness through joint assessment reports; more HTA information available than from individual national agencies 	<ul style="list-style-type: none"> Currently in discussion, no concrete output publicly available Decreases the regulatory burden for companies
2017	Valletta Declaration Group Croatia, Cyprus, France (observer status), Greece, Ireland, Italy, Malta, Portugal, Romania, Spain, Slovenia		<ul style="list-style-type: none"> Increases negotiation power for smaller collaboration member countries towards pharmaceutical companies to get "fairer prices" Negotiates joint pricing and conducts joint procurement for member countries 	<ul style="list-style-type: none"> Currently in discussion, no concrete output publicly available Provides information regarding products, policies, legislative proposals and procedures
2017	Visegrad + Collaboration Croatia, Czech republic (observer status), Hungary, Poland, Lithuania, Slovakia		<ul style="list-style-type: none"> Part of Visegrad group, covering all social, economic and political topics between members Increases negotiation power towards companies 	<ul style="list-style-type: none"> Currently in discussion, no concrete output publicly available Pilot to explore new models for the organization of negotiations at regional level initiated
2018	FINOSE initiative Finland, Norway, Sweden		<ul style="list-style-type: none"> Committed to EUnetHTA (EUnetHTA reports are the basis for FINOSE HTA reports) Publishes HTA reports based on relative efficacy & health economic analysis 	<ul style="list-style-type: none"> Six HTA assessments and two pilots on joint pricing concluded

Future outlook 1: In 2030 there will be a Europe-wide Health Technology Assessment which is binding for all EU countries

Drivers for European-wide HTA

- Existing HTA collaboration bodies (e.g., EUnetHTA) are expected to further **improve and professionalize their assessments** in the upcoming 10 years
- Tools are in development to realize a standardized methodology**; e.g. HTA Core Model (framework to share HTA information and evidence/HTA databases (POP¹ & EVIDENT² database by EUnetHTA)
- These tools support **efficient use of HTA** in Europe and **facilitate joint work** rather than country individual work, especially in countries which lack a well-structured or established HTA methodology

- Pharmaceutical companies are increasingly considering cross-country evaluations** by HTA collaborations as a beneficial step in preparation for price negotiations (having similar structured assessments with comparable details)

Hurdles for European-wide HTA

- European-wide HTA **may not benefit all EU countries**; well-established European markets (e.g. Germany) argue it may lower the standard of their established approach
- European-wide HTA **may not eliminate national level HTA**, especially where a rapid assessment approach is established
- Quantity of assessments will need to increase** to be able to cover all new products entering the market; e.g., EUnetHTA conducted 28 assessments over 13 years

Simon-Kucher outlook assessment

A European-wide HTA is achievable if:

- It replaces meaningful elements of current national HTA**, even in countries with established approaches
- Capacity to conduct assessments significantly increases**, or limitations (e.g., to specific therapeutic areas or treatment classes) are defined
- It does not slow time to access** for countries with a faster assessment approach

Future outlook 2: In 5 years, more drugs will undergo joint price negotiations than today, but price negotiations for the majority of drugs will remain at national level

Drivers for national price negotiation/objections towards joint price negotiations

- Limited success** in joint initiatives: Only BeNeLuxA has successfully completed a joint price negotiation and so far only for one product
- Significant cross-country differences** in healthcare systems, mentality and willingness to pay generates challenges for both collaboration members and pharmaceutical companies
- Limited interest in collaboration from major markets which are frequently referenced** (e.g., France, Germany)
- Perceived risks for pharmaceutical companies:**
 - Formal or informal disclosure of confidential net prices
 - Missing the ability to use country-specific in-house knowledge/infrastructure
 - Additional capacity and expertise required; does not automatically exclude negotiations on national/regional level
- Perceived risks for pharmaceutical companies:**
 - No guarantee of a "better" price, than when nationally negotiated

Hurdles for national price negotiations/advantages of joint price negotiations

- Showing willingness to cooperate could be **politically attractive**
- By cooperating in joint price negotiations **pharmaceutical companies can learn and shape the process and their preferred role**

Simon-Kucher outlook assessment

- Due to the perceived challenges and risks** by both pharmaceutical companies and payers **cross-country joint price negotiations will not replace national negotiations**
- To shape their preferred role, **pharmaceutical companies should take an active role** in the development of future joint price negotiations rather than wait passively

Future outlook 3: A common healthcare system structure is necessary to support joint price negotiations

Drivers for importance of common structure

- Across country differences** in P&MA and reimbursement can cause challenges when jointly negotiating prices (e.g. retail vs. hospital budget)
- Alignment in policy and/or level of innovativeness** across collaboration members is important to reach an agreement which works for all parties

Observed hurdles

- Collaborations are formed based on geography and population size** while these decision criteria do not cause challenges

Simon-Kucher outlook assessment

- The **success rate** of joint price negotiations is **limited due to challenges faced** (e.g. country differences in healthcare systems, posture towards new products and pharmaceutical companies)
- For joint price negotiations to happen, **all involved collaboration members need to adopt the same line of thinking**

Future outlook 4: The main reason for limited implementation of cross-border joint price negotiations is the potential impact on list and net price

Drivers for limited implementation of cross-border joint price negotiations

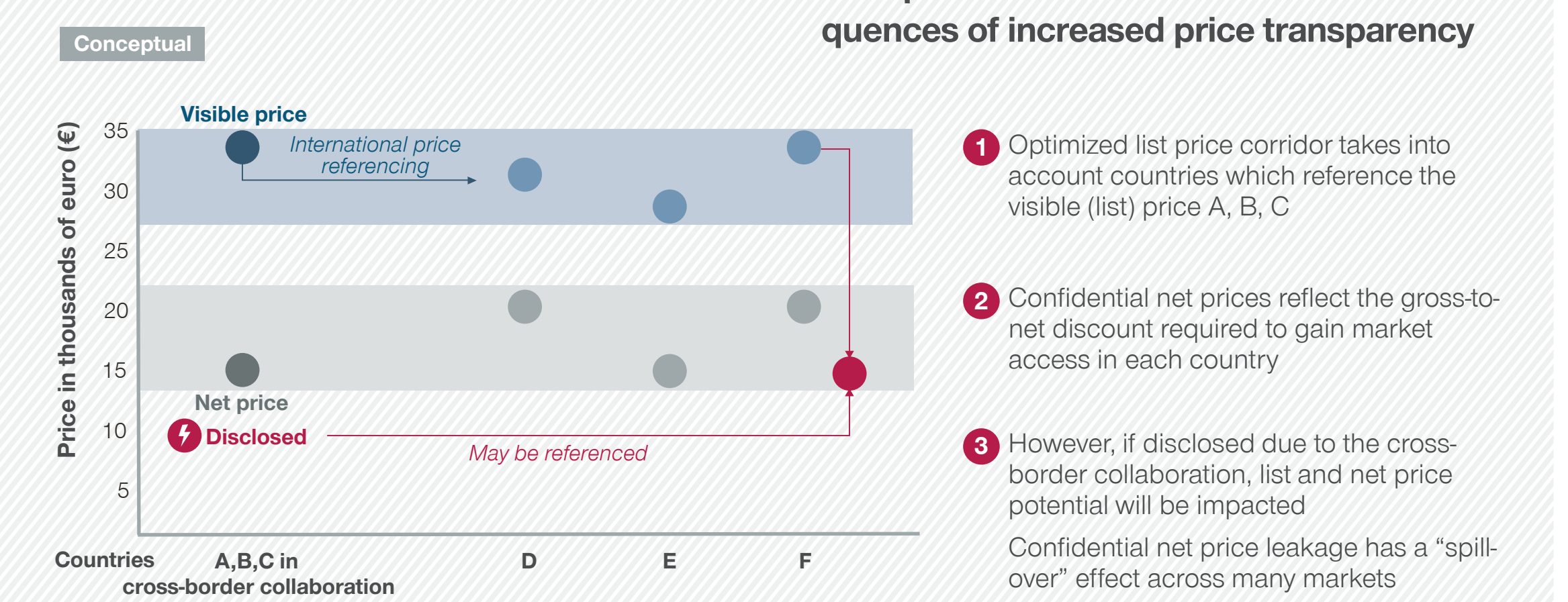
- Informal payer information exchange** across countries is undesirable for pharmaceutical companies since this increases the risk of net prices becoming transparent
- Net price leakage** may impact transparency of net price negotiations across markets, limiting potential for confidential net price agreements
- Price leakage increases the risk of "spill over"**, limiting pharmaceutical companies in offering a one "deal" to gain access in a country which automatically leads to negative implications

Hurdles seen by pharmaceutical companies not pursuing price negotiations

- Manufacturer's involvement is necessary to be able to shape an acceptable implementation** of joint price negotiations for pharmaceutical companies
- Waiver of involvement does not guarantee informal payer information exchange** from happening (e.g., net price leakages have been found through internet research in Italy/Spain)

Simon-Kucher outlook assessment

- Disclosure of confidential net prices could lead to prices below the European price corridor** which **affect manufacturer's financial results** (e.g., return on investment)
- Pharmaceutical companies should explore their preferred role and evaluate consequences of increased price transparency**



- Optimized list price corridor takes into account countries which reference the visible (list) price A, B, C
- Confidential net prices reflect the gross-to-net discount required to gain market access in each country
- However, if disclosed due to the cross-border collaboration, list and net price potential will be impacted. Confidential net price leakage has a "spill over" effect across many markets



European-wide HTA is a realistic target if the procedure accelerates in quantity and shows added benefit towards well-established markets: pharmaceutical companies can benefit from it due to increased efficacy when preparing price negotiations

Cross-country joint price negotiations are not expected to replace national level price negotiations since there is no overall solution for differences in healthcare system structures

Pharmaceutical companies must anticipate evolution of the existing cross-country collaborations, as calls for transparent, affordable drug prices, and rapid patient access increase (e.g., development of strategy for potential consequences of increased net price transparency)

Pharmaceutical companies should evaluate their preferred role in joint assessments and price negotiations: participation will enable pharma to learn about the process, and shape its evolution to ensure the future approaches are mutually beneficial

Sources

Simon-Kucher & Partners; Publicly available reports published by EUnetHTA, BeNeLuxA-I; Visegrad Group, European Commission; "approach to limit price in one country is used in other countries"; "POP: EUnetHTA Planned and Ongoing Projects database"; "EVIDENT: EUnetHTA Evidence database sharing and storage of information on reimbursement/coverage and assessment status of promising technologies and requests or recommendations for additional studies arising from HTA.

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