Health Policy xxx (2019) xxx–xxx

Contents lists available at ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

Shedding light on the HTA consultancy market: Insights from Poland

Marcell Csanádi[a,*], Piotr Ozierański[b], Olga Löblová[c], Lawrence King[d], Zoltán Kaló[e], Lajos Botz[f]

[a] Doctoral School of Pharmacological and Pharmaceutical Sciences, University of Pécs, 7624 Pécs, Szigeti út, 12, Pécs, Hungary
[b] Department of Social and Policy Sciences, University of Bath, Bath, UK
[c] Department of Sociology, University of Cambridge, Cambridge, UK
[d] Department of Economics, University of Massachusetts, Amherst, MA, USA
[e] Center for Health Technology Assessment, Semmelweis University, Budapest, Hungary
[f] Department of Pharmaceutics and Central Clinical Pharmacy, Faculty of Pharmacy, University of Pécs, Pécs, Hungary

ARTICLE INFO

Article history:
Received 24 May 2019
Received in revised form 26 July 2019
Accepted 12 August 2019

Keywords:
Health technology assessment
Consultancy firms
Evidence submissions
HTA consultancy market
HTA reports

ABSTRACT

Research on health technology assessment (HTA) from a policy perspective typically examines public HTA bodies, with little attention devoted to how manufacturers develop their evidence submissions. Taking Poland as a crucial case, we explored the market of HTA consultancy firms which assist drug manufacturers in developing these submissions, called HTA reports. We reviewed 318 HTA reports from 2012 to 2015, data from the Polish National Company Registry, the content of HTA consulting firms' websites, and appraisal reports developed by the Polish HTA body. We identified HTA consultancy firms which developed 96–98% HTA reports. We found that the transparency of information about the authors of HTA reports provided by the HTA body had improved between 2012 and 2015. Six companies with market shares from 10 to 30% dominated the market. The market size was estimated to be 5–6 million EUR annually. HTA consultancies had a broad service portfolio related to preparation of HTA reports. Over 90% of HTA reports did not meet the official minimum quality requirements, and only half of the resubmissions took into account remarks made by the HTA body. Our study provides insights into the structure, evolution and role of the for-profit HTA consultancy market as a crucial part of the public HTA system. This raises important policy points about transparency and regulation at the intersection of public and private sectors in HTA.

1. Introduction

Policy studies of health technology assessment (HTA) have examined in detail public HTA bodies that evaluate evidence submissions supporting technologies applying for reimbursement [1–5]. However, little attention has been given to how manufacturers prepare these submissions. Recent research suggests that this often involves assistance provided by private sector consultancy firms specialising in data collection, evidence synthesis and report preparation [6–8]. Limited knowledge about the operation and characteristics of these firms is a major gap in research, given their role in the development of evidence underpinning subsequent HTA recommendations, often with major budgetary and public health implications. This paper contributes to addressing this gap by focusing on HTA consultancies in Poland, a country with a well-established HTA system.

Consulting in HTA is part of a broader phenomenon of drug companies outsourcing services to specialist consultancies. A key example of this is subcontracting the conduct of clinical trials to Clinical Research Organizations (CROs) [9], typically explained by the increase in the magnitude of clinical research and the drive towards a more efficient and flexible organization of research and development [10,11]. Similar reasons, namely limited "head-count" within pharmaceutical companies, coupled with the rise in regulatory requirements necessary for obtaining public funding, are likely to drive outsourcing to HTA consultancies.

HTA consultancy firms are private companies that generate or synthesize evidence and input for funding decisions. They employ experts in health economics, medicine, statistics and pharmacology, who can be described as "HTA professionals". Like other experts involved in regulatory science [12], they have their professional conventions, experience and a shared body of knowledge

* Corresponding author.
E-mail addresses: marcell.csanadi@syreon.eu (M. Csanádi), po239@bath.ac.uk (P. Ozierański), ol264@cam.ac.uk (O. Löblová), lpking@econs.umass.edu (L. King), zoltan.kalo@syreon.eu (Z. Kaló), botz.lajos@pte.hu (L. Botz).

https://doi.org/10.1016/j.healthpol.2019.08.008
0168-8510/

Table 1
Summary of study topics, objectives and corresponding data sources and methods.

Topics and objectives	Data sources	Methods
Transparency of information provided by the AHTAPol To identify HTA consultancy firms	HTA reports submitted to the AHTAPol in 2012-2015 *i.e.: each comprising different types of analysis: clinical assessments, economic analyses, budget impact analyses, rationalization analyses*	Extracting the authors of analyses[a]
Market structure To calculate market share per consultancy firm	HTA reports submitted to the AHTAPol in 2012-2015	Calculating the number of analyses prepared by each HTA consultancy firm
Market size To estimate the total size of the HTA consultancy market	Polish National Company Registry	Calculating annual net revenues from sales for each HTA consultancy firm[b]
Qualitative exploration of the consultancy market To describe evolution and the key activities of HTA consultancy firms *i.e.: year of establishment, location, mission statement, number of employees, services provided and partner or collaborator organizations*	Websites of HTA consultancy firms	Quantitative content analyses of data extracted from the websites
Quality of HTA reports To evaluate feedback on quality of HTA reports given to HTA consultancy firms by the AHTAPol *i.e.: the extent to which HTA reports meet the minimum quality requirements set by the Ministry of Health*	Appraisal reports ("verification analysis") of submitted HTA reports published by the AHTAPol	Data extraction to a structured spreadsheet

[a] Detailed description in Appendix I/A.
[b] Detailed description in Appendix I/B.

and methods, developed in national and international networks, such as the International Society for Pharmacoeconomics and Outcomes Research and its local chapters, and specialized training programs, including MSc programs in health economics [13–15]. Given their highly specialized, knowledge based, service oriented and data driven approach, a strong HTA consulting market may function as an incubator of expertise, particularly important given the many recommendations to build capacity in order to strengthen HTA systems [16,17]. On the other hand, especially in countries with low public sector resources, the revolving door between consultancies and public HTA bodies has led to conflicts of interest, and often dramatic loss of expertise in the public sector [6,18–20].

To contribute towards assessing the risks and benefits associated with HTA consultancy markets, we provide a first exploratory overview of the HTA consultancy market in Poland. We focus on the following objectives. First, to identify HTA consulting firms that collectively make up the HTA consultancy market in Poland. Second, to describe the HTA market structure and estimate its size. Third, to examine the evolution of the HTA consultancy market and the key activities of its players. Finally, to analyse the quality of HTA reports given to HTA consultancy firms by the Polish Agency for Health Technology Assessment (AHTAPol).

We select Poland as a crucial case because, first, HTA consultancy firms have developed in parallel to the institutionalization of public HTA in Poland. Notably, the first commercial HTA consultancy firms were established around 2002 in Kraków by former employees of the first public organization working on HTA [21]. Since then, experts representing those firms have contributed to the development of the official HTA guidelines issued by the AHTAPol [22–24]. Second, since its establishment in 2005 [25], the AHTAPol has consistently pursued an HTA model similar to the Single Technology Appraisal (STA) process developed by the Scottish Medicine Consortium and adopted by the English National Institute for Health and Care Excellence in 2005 [26,27]. Within the STA process, the core pharmacoeconomic evidence is generated by manufacturers. These evidence submissions, which we simply call "HTA reports", are then evaluated by internal or external experts, whose appraisal (called "verification analysis" in Poland) forms the basis of subsequent discussions held by the members of an appraisal committee. Consistent reliance on this model of HTA in Poland has created conditions for the emergence of consultancy firms assisting manufacturers in preparing country-specific HTA reports based on the AHTAPol's guidelines. Third, as HTA and the reimbursement processes are interconnected and some staff in HTA consultancy firms have worked for public institutions involved in drug reimbursement, HTA consultancies are uniquely positioned to advise manufacturers on the broader regulatory environment [19,20], which has evolved significantly since the early 2000s [28,29]. Fourth, as Poland is an important European pharmaceutical market there are a steady number of drugs applying for HTA appraisals annually ranging from approximately 80 to 100 [28,29]. This, too, is a good proxy for a strong demand for services provided by HTA consultancy firms. Finally, unlike in some other countries, the analysis of the HTA consultancy market in Poland has been enabled by the public availability of documents generated at various stages of the HTA process [30–34].

2. Materials and methods

We adopted a mixed methods study design, summarized in Table 1.

The extent to which we were able to identify HTA consultancy firms was affected by the transparency of information regarding the authors of the HTA reports, as provided by the AHTAPol. To identify the HTA consultancy firms we extracted data from HTA reports submitted by drug manufacturers and published on the AHTAPol website [35]. We considered HTA reports submitted to the AHTAPol between 2012 and 2015. We selected 2012 as the start date because in this year the AHTAPol started publishing HTA reports under the provisions of the Reimbursement Act in 2011. The AHTAPol has a duty, introduced by the Reimbursement Act, to make HTA reports and corresponding verification analysis publicly available online [36]. We end our analysis in 2015, as this was the last year for which a full set of HTA reports and verification analyses was available at the time of data collection. From January to March 2018, we downloaded and reviewed all analyses available as part of each HTA report, namely decision problem analysis, clinical assessment, economic analysis, budget impact analysis, and rationalization analysis (these are proposals for addressing additional expenditure resulting from the reimbursement of the health technology; they outline where savings could be achieved in the pharmaceutical spending to ensure sufficient resources for the new drug). Given frequent redactions in the available analyses (e.g. author names or organizational details removed), we had to rely, where necessary, on logos, document design or website links to identify authors of analyses.

Please cite this article in press as: Csanádi M, et al. Shedding light on the HTA consultancy market: Insights from Poland. Health Policy (2019), https://doi.org/10.1016/j.healthpol.2019.08.008

Appendix I/A describes the complete process of identifying HTA consultancy firms.

To analyze the HTA market structure we calculated the market share of each identified company based on the HTA reports. We calculated the number of HTA reports prepared by HTA consultancy firms on a yearly basis. As one type of analysis in the HTA reports, decision problem analysis, was sometimes a subsection of the clinical assessment analysis or, at other times, a standalone document, we excluded decision problem analyses from the analysis.

We estimated the size of the Polish HTA market using the number of HTA reports prepared by each HTA consultancy firm and their annual net revenues from sales obtained from the Polish National Company Registry [37]. As the data included in the Registry was limited and insufficiently detailed, our calculations are based on certain assumptions, which are detailed in Appendix I/B, including our approach to market size estimation.

To describe evolution and the key activities of HTA consultancy firms we analyzed data downloaded in June and July 2018 from the websites of HTA consultancy firms we had identified. We extracted the year of establishment, location, mission statement, number of employees, services provided and partner or collaborator organizations from the English language version of the websites [38–43]. Due to the heterogeneity of information available on services and mission statements, information was coded inductively, and then at a later stage codes were merged and code families and networks were established, to best reflect the main themes emerging from the data.

Finally, we investigated the quality of the HTA reports, understood as compliance with the submission requirements specified by the Ministry of Health (MoH) [44]. Specifically, we examined verification analyses (VAs), which are documents in which the AHTAPol appraises HTA reports [36]. We considered VAs issued in 2012–2015 in which all four types of analyses included in this study (that is, clinical assessment, economic analysis, budget impact analysis, and rationalization analysis) were prepared by the same consultancy firm. We downloaded and analyzed the VAs in June 2018 and extracted data from sections in which the AHTAPol judged whether HTA reports had met the regulation on minimum requirements set out by the MoH [44]. For each company we calculated the percentage of HTA reports that met the MoH requirements among the total HTA reports. We also collected data from VAs on whether 1) at least one specific reason for not meeting the minimum requirements was provided by the AHTAPol; 2) the MoH requested the applicant to supplement the reimbursement application, including the HTA reports; 3) revised HTA reports were provided by the applicant; and 4) the revised HTA reports took into account the remarks for not meeting the minimum requirements.

We analyzed all data descriptively in Excel.

3. Results

In total, we analyzed 336 manufacturer submissions, with 63, 80, 106 and 87 coming from 2012, 2013, 2014 and 2015, respectively. We excluded 12 submissions as they were either not available online or were duplicated in the database. Duplication occurred when a manufacturer submitted exactly the same HTA report for different forms of administration of the same drug. We excluded six further applications because the analyses comprising the HTA reports were prepared jointly by more than one consultancy. Following on from this, 318 manufacturer submissions were analyzed (inclusion rate: 94.6%).

Table 2
Number analyses reviewed for each year, percentage of the cases when the author name was recorded and percentage of the cases when company name was visible.

Different types of analyses part of the HTA report	Number of analyses	Author identified	Company name visible
2012			
Clinical assessment	57	52 (91%)	25 (44%)
Economic analysis	57	53 (93%)	26 (46%)
Budget impact analysis	56	50 (89%)	24 (43%)
Rationalization analysis	40	35 (88%)	16 (40%)
2013			
Clinical assessment	75	75 (100%)	51 (68%)
Economic analysis	75	75 (100%)	51 (68%)
Budget impact analysis	74	73 (99%)	49 (66%)
Rationalization analysis	58	56 (97%)	41 (71%)
2014			
Clinical assessment	98	96 (98%)	83 (85%)
Economic analysis	97	95 (98%)	81 (84%)
Budget impact analysis	98	95 (97%)	81 (83%)
Rationalization analysis	74	74 (100%)	66 (89%)
2015			
Clinical assessment	85	84 (99%)	81 (95%)
Economic analysis	85	84 (99%)	81 (95%)
Budget impact analysis	85	84 (99%)	81 (95%)
Rationalization analysis	70	69 (99%)	67 (96%)

3.1. Transparency: identification of HTA consultancy firms

The analyzed HTA reports contained 315 clinical assessments (CA), 314 economic analyses (EA), 313 budget impact analyses (BIA), and 242 rationalization analyses (RA). The company name was visible in 76%, 76%, 75% and 79% of the cases for CA, EA, BIA and RA, respectively. We were able to identify the HTA consultancy firms based on logos, document design or website links in additional 21%, 22%, 21% and 20% of the cases for CA, EA, BIA and RA, respectively. As a result, authors' names were identified in 97%, 98%, 96% and 99% of the cases for CA, EA, BIA and RA, respectively. Transparency of the AHTAPol's reporting in relation to consultancy firms increased steadily between 2012 and 2015, as the company name was visible in only around 40% of the cases in 2012, and around 95% of the cases in 2015 (Table 2). There were 227 HTA reports where the same HTA consultancy firm was identified for all four types of analyses.

3.2. Market structure: calculation of market shares

For those CA, EA and BIA analyses with identifiable authors, all analyses had been prepared by an HTA consultancy firm, while in case of RA there were 2 cases where we identified a drug manufacturer and no HTA consultancy firm.

More than 90% of HTA report analyses were prepared by 6 HTA consultancy firms: HealthQuest, MAHTA, Instytut Arcana, HTA Consulting, Aestimo and Centrum HTA (Table 3). During this period, HealthQuest had the largest market share with more than 25% for all four types of analyses. Two additional consultancy firms were identified, too, namely Pracownia HTA, NUEVO HTA. However, these companies prepared the analyses included in only 10 HTA reports over the four-year period.

The market shares of the six major companies were relatively stable over the years. The largest changes were observed in 2014, when the market share of HealthQuest increased over 30% and the market share of Centrum HTA decreased below 5% (Appendix 2). While HealthQuest maintained its market leader position in each year, the company with the lowest market share varied. Nevertheless, each major HTA consultancy firm developed at least four HTA reports annually.

Please cite this article in press as: Csanádi M, et al. Shedding light on the HTA consultancy market: Insights from Poland. Health Policy (2019), https://doi.org/10.1016/j.healthpol.2019.08.008

Table 3
Market share of HTA consultancy firms according to the four types of analyses in the HTA reports.

Total study period (2012-2015)								
	HealthQuest	MAHTA	Instytut Arcana	HTA Consulting	Aestimo	Centrum HTA	Other firms	Not identified
Clinical assessment	27.9%	16.2%	14.9%	14.6%	10.5%	9.5%	3.8%	2.5%
Economic analysis	28.3%	16.2%	14.6%	14.3%	10.8%	9.6%	3.8%	2.2%
Budget impact analysis	27.5%	16.3%	14.4%	14.4%	10.5%	9.6%	3.8%	3.5%
Rationalization analysis	28.9%	18.2%	12.4%	15.3%	9.9%	8.3%	3.7%	3.3%

3.3. Market size: estimation of the HTA consultancy market

Based on the Polish National Company Registry data, we estimated the average annual market size at approximately €5.5 million (details of the assumptions behind the analysis are included in Appendix 1/B). Based on the annual revenues and the annual number of HTA reports we considered that the average revenue per HTA report was €70 000. Since our market estimation reflects the number of HTA reports per year, the largest market size was observed in 2014 with more than €6.5 million, and the lowest was observed in 2012 with €4 million. In a scenario analysis assuming lower revenues per HTA report (€60 000), we estimated approximately €4.5 million average annual market size, with the highest in 2014 around €5 million and lowest in 2012 around €3.5 million. In a scenario analysis assuming higher revenues per HTA report (€85 000) we estimated approximately €6.5 million average annual market size, with the highest in 2014 around €8 million and lowest in 2012 around €5 million.

3.4. Evolution and the key activities of HTA consultancy firms

There were two waves of establishing HTA consultancy firms in Poland, with the first two companies established in 2002 (HTA Consulting and Instytut Arcana), while the remaining four major companies were established between 2008 and 2011. The two companies with minor market shares, Pracownia HTA and NUEVO HTA, were also established around the second wave, in 2010 and in 2012, respectively. There were two companies established in Warsaw (HealthQuest, MAHTA), which were also the market leaders during the study period. All remaining companies, including the two smaller ones, were based in Kraków. This also indicates that the market shares by the two largest cities were almost even (a little higher in Kraków). Numbers of employees were available only for four companies from their websites. The two oldest companies, HTA Consulting and Instytut Arcana had the largest number of employees with more than 50 and more than 40, respectively, according to their websites. HTA consultancy firms established in the second wave had lower number of employees with reportedly more than 20 for MAHTA and 12 for Aestimo. We found no information on the number of employees in the remaining companies, including the market leader (HealthQuest).

Companies' mission statements were centered around supporting decision-making on medical technologies. Only one company (HealthQuest) did not state clearly in the mission statement that developing HTA reports was their core activity; instead, it implied as much by saying: "to support decision making in healthcare [based] on credible data and proper methods". Evidence-based medicine is another key concept used by HTA consultancy firms, which appeared in the mission statement of several companies. Yet another key concept is credibility, since 4 out of the 6 major companies mentioned it in their mission statement. Many mission statements emphasized the length of experience, especially in case of the more established consultancies, and the large number of HTA reports they had created.

The service portfolio of HTA consultancy firms was very wide. The core service offered by all companies was preparing HTA reports including all types of analyses required by the MoH and the AHTAPol. Three or more companies provided the following additional specialized services: strategic consulting, preparing qualitative studies (surveys, interviews), qualitative database analysis, consulting on negotiation strategies with payer representatives, real world data analyses and training courses. One or two HTA consultancy firms provided the following services: participating in advisory boards, performing systematic literature reviews, conducting network meta-analyses, performing feasibility studies or rapid reviews and conducting epidemiological or pharmacovigilance studies.

Two companies (Instytut Arcana, HTA Consulting) emphasized providing services outside Poland – in the Central and Eastern European region. Further, three companies mentioned partner organizations. Specifically, HTA Consulting established an alliance in collaboration with a Hungarian consultancy firm; Instytut Arcana was found to be part of a global organization in population health intelligence; and HealthQuest started a strategic cooperation with a company focusing on medical data management, statistics and programming. Collaborations with universities were not mentioned, although it was apparent that some companies' key personnel had university affiliations as well (e.g. Warsaw School of Economics, Medical University of Warsaw and Jagiellonian University in Kraków).

3.5. Quality of HTA reports evaluated by the AHTAPol

According to the reviewed VAs issued by AHTAPol, out of the 227 HTA reports in which all four reviewed analyses were prepared by the same company, only 15 (6.6%) satisfied the minimum quality requirements set out by the MoH. According to the AHTAPol, 207 (91.2%) HTA reports did not meet the requirements, and the remaining five cases (2.2%) were unclear. The AHTAPol explained why the requirements were not met only in 70 (33.8%) cases, did not provide any reasons in 136 cases (65.7%), and in one case the reason was redacted. Within reports that did not meet the requirements, the MoH requested the applicant to revise the HTA report in 162 (78.3%) cases, and in the remaining 45 (21.7%) cases this was not clear from the VAs. Within the 207 reports that did not meet the requirements the applicant provided revised analyses in 157 (75.8%) cases. In 47 (22.7%) cases this was unclear, and in 3 (1.5%) cases revised analyses were not provided. Finally, we analyzed those sections of the VAs which reported whether the revised analyses took into account all AHTAPol's remarks. From those 157 revised analyses when the applicant provided revised analyses, 71 (45.2%) took into account the remarks, 62 (39.5%) did not and in 24 (15.3%) cases it was not clear.

There were small differences between the consultancy firms in the share of HTA reports not meeting the MoH requirements as reported by the VAs (Table 4). The highest percentage was observed for Centrum HTA (95%) and the lowest for HTA Consulting (88.9%) However, a relatively larger difference was observed in terms of the reasons for not meeting the requirements. In this regard, reports by MAHTA and Instytut Arcana received reasons by the AHTAPol for not meeting the minimum requirements in 39.5% and 39.3% of the cases, respectively. However, for instance reports by HTA Con-

Please cite this article in press as: Csanádi M, et al. Shedding light on the HTA consultancy market: Insights from Poland. Health Policy (2019), https://doi.org/10.1016/j.healthpol.2019.08.008

Table 4
Analysis of verification analyses per HTA consultancy firm.

	HealthQuest	MAHTA	HTA Consulting	Instytut Arcana	Aestimo	Centrum HTA	Other
Number of HTA reports where all four types of analyses were submitted by the same consultancy firm	68	42	36	30	24	20	7
% of HTA reports not meeting the MoH requirements	91.2%	90.5%	88.9%	93.3%	91.7%	95.0%	85.7%
% of HTA reports where reason was provided for not meeting MoH requirements	33.9%	39.5%	21.9%	39.3%	27.3%	36.8%	50.0%
% of HTA reports where the MoH requested to supplement the application	82.3%	76.3%	78.1%	82.1%	72.7%	73.7%	66.7%
% of HTA reports where revised analyses were provided by the applicant	79.0%	78.9%	71.9%	78.6%	68.2%	68.4%	83.3%
% of resubmitted HTA reports where the revised analyses took into account AHTAPol's remarks	46.9%	33.3%	56.5%	45.5%	60.0%	30.8%	40.0%

sulting received reasons for not meeting the requirements only in 21.9% of the cases. The percentage of HTA reports in which the MoH requested supplementing the reimbursement application ranged from 82.3% (HealthQuest) to 72.7% (Aestimo). The share of HTA reports for which revised analysis was submitted ranged from 79% (HealthQuest) to 68.2% (Aestimo). We observed a relatively large difference in the percentage of the reports in which the revised analyses took into account the AHTAPol's recommendations for revising the analyses. Here, the rate of reports building on AHTAPol's advice was the highest for Aestimo and HTA Consulting (60% and 56.5%, respectively); this rate was the lowest for MAHTA and Centrum HTA (33.3% and 30.8%, respectively).

4. Discussion

In this paper, we identified key players of the Polish HTA consultancy market for pharmaceuticals, described its size, structure and evolution, and analysed the AHTAPol's feedback on the quality of HTA reports prepared by HTA consultancy firms. Our research contributes to the literature on stakeholder involvement in HTA [45–47] by demonstrating that the scope of stakeholders in HTA to consider is broader and may include private-sector companies. Further, in contrast to studies focusing on later stages of the HTA process, especially the discussions held by appraisal committees, here we point to the less visible stage of technology assessment [28–30,36], which has so far largely escaped research attention.

Researching HTA consultants reflects broader transparency challenges facing HTA systems. Unlike many public HTA bodies, expert consulting has no specific regulations pertaining to, for example, putting information on its activities in the public domain. The availability of information on consultants, then, largely depends on the openness of the public bodies with which they interact. In the field of HTA, any systematic examination of the market for HTA services requires, at the very least, publicly available HTA reports, which include the names of their authors. In this regard, countries like Poland, which adopted HTA later, can, perhaps surprisingly, could be more transparent than early adopters [36]. In this regard, consistent with recent research on the transparency of the AHTAPol's work [30], we found that the transparency of information about the authors of HTA reports provided by the AHTAPol had improved steadily between 2012 and 2015. The evaluation of the quality of analyses developed by consultants requires even more detailed information about the outcomes of appraisal processes undertaken by HTA bodies. For instance, a recent study into HTA in Hungary was unable to use documentary analysis, unlike the present paper, because relevant data was not publicly available [6].

We found that the HTA market for pharmaceuticals in Poland was dominated by six companies, with new market entrants unable to gain larger shares. This suggests that the dominant HTA consultancy firms have accumulated significant expertise and created strong working relationships with their clients. These findings are consistent with earlier research showing the sustained influence on the Polish HTA system of the first cohort of experts who received formal training in HTA [20,21]. A similar market structure including 3–4 major HTA consultancy firms was also found in Hungary, a country with a comparable HTA model and history [6]. Future empirical research could test whether this model holds in Western European countries.

The size of the Polish HTA consultancy market for pharmaceuticals, estimated at €5–6 million annually, reflects Poland's role as an important market in the region. Correspondingly, the market was almost two times larger than the same market in Hungary estimated at around €3-3.5 million annually using a similar method of calculation [6]. Notably, the size of Poland's HTA market for pharmaceuticals considerably exceeds the AHTAPol's annual budget of €2.5 million [48]. Similarly, with at the least 120 employees, HTA consultancy firms together dispose of significant manpower compared to the AHTAPol, which has 65 full-time equivalent employees [48]. The contrast between resources available to the public and commercial HTA sector is a function of the Single Technology Appraisal model of the HTA process, which confines the role of public HTA bodies to evaluating evidence submitted by manufacturers. In the Polish context, this model of HTA was introduced and solidified, via subsequent versions of AHTAPol's HTA guidelines, largely based on contributions from experts from the major HTA consultancies [22–24]. In fact, the emergence of some of the first consultancies preceded the establishment of the AHTAPol as such, which can be interpreted as the public HTA body complementing the nascent HTA market, and not the other way round. This may be problematic, especially given the well-documented permeability of the commercial and the public HTA sectors, including high-level transfers from the AHTAPol to HTA consultancies, which potentially leads to conflicts of interest [19,20].

Our results also suggest that HTA consultancy firms considerably expanded their services. They started their activities by preparing HTA reports for manufactures in the early 2000s [35], and although this remains their core activity, new types of services, such as strategic consulting, organizing training courses or preparing qualitative studies emerged throughout the years.

Finally, our findings based on AHTAPol's assessments of commercial HTA reports, called verification analyses, are perhaps the most puzzling. Here we established that the majority of HTA reports did not meet official MoH criteria, and only about half took into account the AHTAPol's formal feedback in their resubmissions. Although, as noted below, our findings are themselves determined by the quality and consistency of reporting of relevant information by the AHTAPol, this finding raises concerns about a HTA process relying heavily on the quality of manufacturer submissions. Of course, the commercial evidence is scrutinized by AHTAPol's staff developing verification analyses, and the number of shortcomings identified underscores the critical importance of the appraisal stage of the HTA process. However, the apparent scale of the problem is considerable, and is likely to translate into increased workload

Please cite this article in press as: Csanádi M, et al. Shedding light on the HTA consultancy market: Insights from Poland. Health Policy (2019), https://doi.org/10.1016/j.healthpol.2019.08.008

for the publicly funded HTA body, which, as mentioned above, is significantly under-resourced compared to the consultancy sector.

The apparent low quality of HTA reports might have several reasons. One, it could suggest that the MoH minimum requirements are not fit for purpose and their guidance does not correspond to the practical possibilities of what data HTA consultancies, or perhaps their industry clients, can deliver. However, this interpretation does not sound plausible because there seem to have been no formal policy discussions on calls for the revision or refinement of the minimum requirements. Two, the AHTAPol might not use the requirements faithfully (e.g. by interpreting them overly strictly or expansively). To explore whether this is the case it would be important to check whether the scope of AHTAPol's requests for revisions was consistent for all consultancies and pharmaceutical companies, to exclude possible preferential application of rules for some. Finally, some consultancies might have not understood the requirements and are unable, or unwilling, to learn from their past mistakes, as suggested by the variable and relatively low rates of companies taking the AHTAPol's comments into account when submitting revised analyses. Given that the HTA consultancy market comprises just a handful of key players, this would be worrying and put a question mark over whether the HTA market operates in the public interest.

Our study has several important limitations. First, our codebook for identifying the HTA consultancy firms was developed via an iterative process, possibly not identifying all authors. Second, the market size estimation is only a rough estimate, since data from the Polish National Company Registry was limited. Future research could possibly verify our indicative findings regarding the estimated market size via primary data collection from HTA consultancy firms. Third, the thematic analysis of the websites of the HTA consultancy firms relied on companies' self-presentations. While this is useful to gain a sense of the companies' public presence, it does not necessarily provide reliable information on the full spectrum of their business activities and priorities. Fourth, one specific part of the HTA reports, decision problem analysis, was not included in our study, given the lack of consistency in HTA reports. Finally, our analysis of the quality of HTA reports was limited to the understanding of "quality" as per the minimum quality requirements by the Ministry of Health, which could be better framed as formal completeness or comprehensiveness of HTA reports, rather than an assessment of more substantive quality issues such as the choice of comparators or validity of economic models. Furthermore, the information included in verification analyses was often unclear, which is why we were unable, at times, to collect the explicit reasons of why HTA reports did not meet the official requirements.

5. Policy recommendations

Based on our Polish case study, we can extrapolate several takeaways regarding HTA consultancy markets for other countries, particularly those that rely on the STA model. First, there is a clear need for detailed reflection on conflicts of interest that may emerge at the intersection of public HTA bodies and HTA consultancies. The permeability of the two sectors is likely not a Polish exception and appropriate, context-specific regulation of the "revolving door" in HTA should be considered. Second, when HTA reports are not meeting the official requirements, further investigations are required to explore the underlying reasons. Third, HTA bodies should periodically subject their relationships with individual HTA consultancies to conduct critical analysis to eliminate potential bias. Fundamentally, to allow for external analysis, public availability of documentation of HTA submissions, including information on authors of HTA reports, is paramount to ensure the transparency of the HTA process. Reasons for confidentiality of this information should be re-interrogated in countries that practice extensive redactions or do not make HTA documentation public.

Funding

The authors received no specific funding for this work.

PO's work on this study was supported by the scientific (non-commerical) grant "What can be learnt from the new pharmaceutical industry payment disclosures?" awarded by the Swedish Research Council for Health, Working Life and Welfare (FORTE #2016-00875).

Declaration of Competing Interest

CM reports that he is also employed by Syreon Research Institute. However, his current work at Syreon Research Institute has no relevance for the research underpinning this article.

PO's work on this study was supported by the scientific (non-commerical) grant "What can be learnt from the new pharmaceutical industry payment disclosures?" awarded by the Swedish Research Council for Health, Working Life and Welfare (FORTE #2016-00875).

OL reports consultancy fees from A&R Partners, Baxter AG and GADDPE.

LK has no conflict of interest to report.

ZK reports that he is also employed by Syreon Research Institute. However, his current work at Syreon Research Institute has no relevance for the research underpinning this article.

LB has no conflict of interest to report.

Acknowledgements

We would like to thank Natalia Nicholls for working on the data collection and Katharina Blankart for providing feedback on the earlier version of the manuscript.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.healthpol.2019.08.008.

References

[1] Akehurst RL, Abadie E, Renaudin N, Sarkozy F. Variation in health technology assessment and reimbursement processes in Europe. Value Health 2017;20(1):67–76, http://dx.doi.org/10.1016/j.jval.2016.08.725.
[2] Allen N, Pichler F, Wang T, Patel S, Salek S. Development of archetypes for non-ranking classification and comparison of European National Health Technology Assessment systems. Health Policy 2013;113(3):305–12, http://dx.doi.org/10.1016/j.healthpol.2013.09.007.
[3] Allen N, Liberti L, Walker SR, Salek S. A comparison of reimbursement recommendations by European HTA agencies: is there opportunity for further alignment? Frontiers in Pharmacology 2017;8:384, http://dx.doi.org/10.3389/fphar.2017.00384.
[4] Angelis A, Lange A, Kanavos P. Using health technology assessment to assess the value of new medicines: results of a systematic review and expert consultation across eight European countries. The European Journal of Health Economics 2018;19(1):123–52, http://dx.doi.org/10.1007/s10198-017-0871-0.
[5] Panteli D, Eckhardt H, Nolting A, Busse R, Kulig M. From market access to patient access: overview of evidence-based approaches for the reimbursement and pricing of pharmaceuticals in 36 European countries. Health Research Policy and Systems 2015;25(13):39, http://dx.doi.org/10.1186/s12961-015-0028-5.
[6] Csanádi M, Harsányi A, Ozieranski P, Löblová O, Kaló Z, King L, et al. When health technology assessment is confidential and experts have no power: the case of Hungary. Health Economics, Policy and Law 2019;14(2):162–81, http://dx.doi.org/10.1017/S1744133118000051.
[7] Löblová O. Who's afraid of institutionalizing health technology assessment (HTA)?: interests and policy positions on HTA in the Czech Republic. Health Economics, Policy and Law 2018;13(2):137–61, http://dx.doi.org/10.1017/S174413311700024X.

Please cite this article in press as: Csanádi M, et al. Shedding light on the HTA consultancy market: Insights from Poland. Health Policy (2019), https://doi.org/10.1016/j.healthpol.2019.08.008

[8] Towse A, Devlin N, Hawe E, Garrison L. The evolution of HTA in emerging markets health care systems: analysis to support a policy response. (Consulting report); 2011. January, Available at: https://www.ohe.org/system/files/private/publications/347%20-%20Evolution_of_HTA_Jan2011.pdf?download=1 (Assessed January 2019).
[9] Sariola S, Ravindran D, Kumar A, Jeffery R. Big-pharmaceuticalisation: clinical trials and contract research organisations in India. Social Science & Medicine 2015;131:239–46, http://dx.doi.org/10.1016/j.socscimed.2014.11.052.
[10] Lowman M, Trott P, Hoecht A, Sellam Z. Innovation risks of outsourcing in pharmaceutical new product development. Technovation 2012;32(2):99–109, http://dx.doi.org/10.1016/j.technovation.2011.11.004.
[11] Piachaud BS. Outsourcing in the pharmaceutical manufacturing process: an examination of the CRO experience. Technovation 2002;22(2):81–90, http://dx.doi.org/10.1016/S0166-4972(01)00081-5.
[12] Expertise Demortain D. Regulatory science and the evaluation of technology and risk: introduction to the special issue. Minerva 2017;55(2):139–59, http://dx.doi.org/10.1007/s11024-017-9325-1.
[13] Banta D, Kristensen FB, Jonsson E. A history of health technology assessment at the European level. International Journal of Technology Assessment in Health Care 2009;25(Jul Suppl. 1):68–73, http://dx.doi.org/10.1017/S0266462309090448.
[14] Kaló Z, Bodrogi J, Boncz I, Dózsa C, Jóna G, Kövi R, Pásztélyi Z, Sinkovits B. Capacity building for HTA implementation in middle-income countries: the case of Hungary. Value in Health Regional Issues 2013;2:264–6, http://dx.doi.org/10.1016/j.vhri.2013.06.002.
[15] Banta D, Jonsson E, Childs P. History of the international societies in health technology assessment: international society for technology assessment in health care and health technology assessment international. International Journal of Technology Assessment in Health Care 2009;25(Jul Suppl. 1):19–23, http://dx.doi.org/10.1017/S0266462309090369.
[16] Evers H, Menkhoff T. Expert knowledge and the role of consultants in an emerging knowledge-based economy. In: Book chapter in management consulting an introduction. ISBN 9788131403099. ICFAI. University Press; 2006. p. 3–27 http://works.bepress.com/hdevers/24/.
[17] EUnetHTA Work Package 8. EUnetHTA handbook on health technology assessment capacity building. Barcelona (Spain): Catalan agency for health technology assessment and research. Catalan Health Service. Department of Health Autonomous Government of Catalonia; 2008. Available at: https://www.eunethta.eu/wp-content/uploads/2018/01/EUnetHTA-Handbook-on-HTA-Capacity-Building.pdf (Accessed January 2019).
[18] Ozierański P, McKee M, King L. Pharmaceutical lobbying under postcommunism: universal or country-specific methods of securing state drug reimbursement in Poland? Health Economics, Policy and Law 2012;7(2):175–95, http://dx.doi.org/10.1017/S1744133111000168.
[19] Ozieranski P, McKee M, King L. The politics of health technology assessment in Poland. Health Policy 2012;108(2-3):178–93, http://dx.doi.org/10.1016/j.healthpol.2012.10.001.
[20] Ozierański P, King L. The persistence of cliques in the post-communist state. The case of deniability in drug reimbursement policy in Poland. British Journal of Sociology 2016;67(2):216–41, http://dx.doi.org/10.1111/1468-4446.12193.
[21] Nizankowski R, Wilk N. From idealistic rookies to a regional leader: the history of health technology assessment in Poland. International Journal of Technology Assessment in Health Care 2009;25(Suppl. 1):156–62, http://dx.doi.org/10.1017/S0266462309090588.
[22] The Agency for Health Technology Assessment and Tariff System. Health technology assessment guidelines. Version 3.0 Warsaw; 2016. August, Available at: http://www.aotm.gov.pl/www/wp-content/uploads/wytyczne_hta/2016/20161104_HTA_Guidelines_AOTMiT.pdf (Accessed July, 2019).
[23] Lach K, Dziwisz M, Rémuzat C, Toumi M. Towards a more transparent HTA process in Poland: new Polish HTA methodological guidelines. Journal of Market Access & Health Policy 2017;5(1):1355202, http://dx.doi.org/10.1080/20016689.2017.1355202.
[24] Kolasa K, Wasiak R. Health technology assessment in Poland and Scotland: comparison of process and decisions. International Journal of Technology Assessment in Health Care 2012;28(1):70–6, http://dx.doi.org/10.1017/S0266462311000699.
[25] Lipska I, McAuslane N, Leufkens H, Hövels AA. Decade of health technology assessment in Poland. International Journal of Technology Assessment in Health Care 2017;33(3):350–7, http://dx.doi.org/10.1017/S0266462317000563.
[26] Cairns J. Providing guidance to the NHS: the Scottish medicines consortium and the national institute for clinical excellence compared. Health Policy 2006;76(2):134–43, http://dx.doi.org/10.1016/j.healthpol.2005.05.006.
[27] Ford JA, Waugh N, Sharma P, Sculpher M, Walker A. NICE guidance: a comparative study of the introduction of the single technology appraisal process and comparison with guidance from Scottish Medicines Consortium. BMJ Open 2012;2(1):e000671, http://dx.doi.org/10.1136/bmjopen-2011-000671.
[28] Kawalec P, Malinowski KP. Relating Health Technology Assessment recommendations and reimbursement decisions in Poland in years 2012-2014, a retrospective analysis. Health Policy 2016;120(11):1240–8, http://dx.doi.org/10.1016/j.healthpol.2016.09.021.
[29] Kawalec P, Malinowski KP, Trąbka W. Trends and determinants in reimbursement decision-making in Poland in the years 2013-2015. Expert Review of Pharmacoeconomics & Outcomes Research 2018;18(2):197–205, http://dx.doi.org/10.1080/14737167.2018.1384696.
[30] Bochenek T, Kocot E, Rodzinka M, Godman B, Maciejewska K, Kamal S, et al. The transparency of published health technology assessment-based recommendations on pharmaceutical reimbursement in Poland. Expert Review of Pharmacoeconomics & Outcomes Research 2017;17(4):385–400, http://dx.doi.org/10.1080/14737167.2017.1262767.
[31] Kolasa K, Schubert S, Manca A, Hermanowski T. A review of Health Technology Assessment (HTA) recommendations for drug therapies issued between 2007 and 2009 and their impact on policymaking processes in Poland. Health Policy 2011;102(2-3):145–51, http://dx.doi.org/10.1016/j.healthpol.2011.05.001.
[32] Kolasa K, Dziomdziora M, Fajutrao L. What aspects of the health technology assessment process recommended by international health technology assessment agencies received the most attention in Poland in 2008? International Journal of Technology Assessment in Health Care 2011;27(1):84–94, http://dx.doi.org/10.1017/S0266462310001236.
[33] Malinowski KP, Kawalec P, Trąbka W. Impact of patient outcomes and cost aspects on reimbursement recommendations in Poland in 2012-2014. Health Policy 2016;120(11):1249–55, http://dx.doi.org/10.1016/j.healthpol.2016.09.016.
[34] Niewada M, Polkowska M, Jakubczyk M, Golicki D. What influences recommendations issued by the agency for health technology assessment in Poland? A glimpse into decision makers' preferences. Value in Health Regional Issues 2013;2(2):267–72, http://dx.doi.org/10.1016/j.vhri.2013.05.002.
[35] Website of the website of the polish HTA agency; 2018. Available at: http://bip.aotm.gov.pl/zlecenia-mz-2012-2015/ (Accessed July 2018).
[36] Ozierański P, Löblová O, Nicholls N, Csanádi M, Kaló Z, McKee M, et al. Transparency in practice: evidence from' verification analyses' issued by the Polish Agency for Health Technology Assessment in 2012-2015. Health Economics, Policy and Law 2019;14(2):182–204, http://dx.doi.org/10.1017/S1744133117000342.
[37] Website of the polish national company registry; 2018. Available at: http://www.krs-online.com.pl/ (Accessed July 2018).
[38] English website of HealthQuest; 2018. Available at: http://www.healthquest.pl/11,Index.html (Accessed July 2018).
[39] English website of MAHTA; 2018. Available at: http://www.mahta.pl/en (Accessed July 2018).
[40] English website of Instytut Arcana; 2018. Available at: http://inar.pl/en/homepage/ (Accessed July 2018).
[41] English website of HTA consulting; 2018. Available at: https://hta.pl/ (Accessed July 2018).
[42] English website of Aestimo; 2018. Available at: https://aestimo.eu/en/ (Accessed July 2018).
[43] English website of Centrum HTA; 2018. Available at: http://centrumhta.com/home (Accessed July 2018).
[44] Rozporządzenie ws. minimalnych wymagań – Rozporządzenie Ministra Zdrowia z dnia 2 kwietnia 2012 r. w sprawie minimalnych wymagań, jakie muszą spełniać analizy uwzględnione we wnioskach o objęcie refundacją i ustalenie urzędowej ceny zbytu oraz podwyższenie urzędowej ceny zbytu leku, środka spożywczego specjalnego przeznaczenia żywieniowego, wyrobu medycznego, które nie mają odpowiednika refundowanego w danym wskazaniu (Dz.U. z 2012 r. Nr 0, poz. 388).
[45] Cavazza M, Jommi C. Stakeholders involvement by HTA Organisations: why is so different? Health Policy 2012;105(2-3):236–45, http://dx.doi.org/10.1016/j.healthpol.2012.01.012.
[46] Nielsen CP, Lauritsen SW, Kristensen FB, Bistrup ML, Cecchetti A, Turk E. Involving stakeholders and developing a policy for stakeholder involvement in the European network for health technology assessment. EUnetHTA International Journal of Technology Assessment in Health Care 2009;25(Suppl. 2):84–91, http://dx.doi.org/10.1017/S0266462309990729.
[47] Brereton L, Wahlster P, Mozygemba K, Lysdahl KB, Burns J, Polus S, et al. This is a repository copy of Stakeholder involvement throughout health technology assessment: an example from palliative care. International Journal of Technology Assessment in Health Care 2017;33(5):552–61, http://dx.doi.org/10.1017/S026646231700068X.
[48] European Commission. Mapping of HTA national organisations, programmes and processes in EU and Norway; 2017. May. Available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2018_mapping_npc_annexes_en.pdf (Accessed February 2019).

Please cite this article in press as: Csanádi M, et al. Shedding light on the HTA consultancy market: Insights from Poland. Health Policy (2019), https://doi.org/10.1016/j.healthpol.2019.08.008