

# History of health technology assessment in Hungary

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In Hungary, the history of the health technology assessment (HTA) dates back to 1993 when HTA and related activities started by professional initiatives. The legal background, institutionalization, and training capacities were created between 1998 and 2004. The main challenges for HTA in Hungary are partly similar to the ones in countries with a developed economy; no question it is time for cost-effectiveness. However, there are very important differences as well, that is why transferability and adaptability issues have to be considered. This article describes the characteristic features of the Hungarian healthcare system, the history and the current role of HTA, and the most important challenges.

**Keywords:** Health technology assessment, Hungary, History

## DESCRIPTION OF HEALTHCARE SYSTEM

### Central Versus Decentralized Control

After the political changes of 1990, the responsibility of providing healthcare services was transferred to local governments in each level of the healthcare system, such as primary care, outpatient care, and inpatient care. Only a few exceptions were made such as university clinics and national medical institutes, which represent the highest level of healthcare services (tertiary care). This decision has had a long-lasting effect on the Hungarian healthcare system up to now (1;8;15;19). The responsibility of financing healthcare services was given to the National Health Insurance Fund Administration (NHIFA), the one and only health insurance fund in Hungary (Országos Egészségbiztosítási Pénztár, OEP), and performance-related financing was introduced. As a general rule, the NHIFA finances the running costs from its separate budget (Health Insurance Fund), whereas covering capital costs is the duty of the owner of the given healthcare institution, mainly the local governments. The Health Insurance Fund consists of more than fifteen sub-budgets for different types of services (primary care, outpatient care, acute and chronic inpatient care, and so on), capped with a national budget ceiling.

The Hungarian healthcare system, therefore, has an ambivalent structure. Whereas the responsibility of delivering health care is decentralized and local authorities (city and county councils) as the owners of healthcare institutions have a strong influence, financing health care is highly centralized at the NHIFA. Although the NHIFA has local offices (branches) in each Hungarian county, they do not have any opportunities for making independent decisions.

### Insurance and Payment

Following the political changes, just like several central and eastern European countries, Hungary returned to the Bismarckian solidarity-based social security system (12). Reforming the healthcare system, a purchaser-provider split has been introduced. The NHIFA, the organization responsible for healthcare financing and maintaining solidarity was established in 1993.

Most of the healthcare budget comes from contributions. Employees pay a contribution of 6 percent of their gross income and employers pay 6 percent without an income ceiling. In 1996, a fixed amount of “health tax” was introduced, currently of 1.950 Hungarian forint (HUF)/month/employee. This health tax is to be eliminated in the coming years. Thus,

the Hungarian system is, according to the traditional classification, a Bismarck-like social insurance system with a single payer. The major actors, such as general practitioners (GPs), outpatient departments, and hospitals are financed through different financial incentives described as follows.

There are three main types of general practices in Hungary: adult, child, and mixed practices. Most GPs are responsible for a certain catchment area (territorial supply obligation) and only 3 percent of the GPs have no catchment area responsibility. Hungarian GPs have a gatekeeper role toward the secondary and tertiary care provided by specialists. The main source of GPs' revenues comes from a capitation fee based on patients' age, with a special point system for different age groups. To avoid GPs getting too many cards (patients), there is a degression in financing trying to limit patient numbers, for example, activity-based points on which the income of the GP practice depends). The second part of the revenue of a general practice is a fixed fee, which covers overhead costs, such as heating, cleaning, etc. The fixed fee varies according to the type of practice (adult, child, or mixed) and the number of patients involved in the practice. The third part of financing is a supplementary fee, which mainly aims to eliminate the differences in practice income due to differences of practice locations (metropolitan area, big city, rural area, practice in more than one village or in outer areas). GPs receive reimbursement for being on duty and for cases not registered on their list (case fee).

In Hungarian outpatient care, an activity-based point payment system (called the German fee-for-service point system) is used for financing. The medical procedures are listed according to the International Classification of Procedures in Medicine (ICPM) code system of the World Health Organization (WHO), and each procedure has a point value. Outpatient care departments make a report on each patient, listing the procedures carried out on the patient, and submit this report to the NHIFA. From the implementation of this adjusted fee-for-service point system in July, 1993 until March, 1999, there was a mixed financing system of input-(base) and output-related (activity-related or fee for service) financing. After gradual changes in the ratio of input (base or fix) and output (activity related) elements of financing, from April 1999, financing is based entirely on activity (adjusted fee for service).

To keep within the budgetary limit, until June, 2000, there was a floating rate system in the fee-for-service financing of outpatient care with the monthly changes in the forint value of one performance point. It meant that a prospective monthly budget was set up for the fiscal year, and this monthly budget was divided by the total number of points reported by the outpatient institutions. In July, 2000 this floating system was abolished and the forint value of one performance point is now announced in advance.

Acute inpatient care is financed through the implementation of a system similar to the American diagnosis-related groups (DRG): in Hungarian, it is called Homogén

Betegségcsoporthok, further referred to as HBCS. The HBCS system has its own characteristics. The cost calculation of acute hospital care started in the late 1980s, and it is based on representative studies carried out in the hospital sector. The regular application of the HBCS system started in July, 1993. The disease groups reflect the epidemiological characteristics of the Hungarian population. The Hungarian HBCS system covers all the costs occurring during hospital care, including diagnosis and therapy, drugs, wages (doctors, nurses, and so on), accommodation costs (heating, cleaning, meals, and so on), and costs of hospital management except for investment costs.

In 2004, in addition to the activity based fee-for-service (in Hungary, it is called as German point) payment system in outpatient care and to the DRG-like financing technique in acute hospital care, the so-called performance volume limit (PVL) (Teljesítmény Volumen Korlát) was introduced forming an artificial financial cap for the activity-based financing of the Hungarian hospitals (2).

Over the past years, the deficit of NHIFA has been increasing considerably, especially between 2003 and 2005. It amounted to HUF310 billion (US\$1.38 billion), HUF343.7 billion (US\$1.70 billion), and HUF375.3 billion (US\$1.88 billion) in 2003, 2004, and 2005, respectively (7). Calculating the deficit as a percentage of total revenue resources available to the NHIFA, it varied from 3.4 percent to 12.6 percent between 1994 and 2002. This deficit significantly increased and reached 30.2 percent, 31.2 percent, and 31.2 percent of total revenues between 2003 and 2005. Although between 2003 and 2005, there was a huge deficit in the Hungarian health insurance budget, in 2006 and 2007, the widening gap between revenues and expenditures was closed. However, closing this gap seems to be more troublesome than expected for both the healthcare sector and society.

## **PUBLIC POLICIES INTENDED TO CONTROL PRACTICE AND HOSPITAL CARE**

Regulation of hospitals and placement of technologies is determined by the current legislation. The Health Insurance Act determines the in-kind and in-cash benefits of the social health insurance, and the rules of their utilization, declares the responsibility of the state to provide services, regardless of the revenues of the NHIFA and defines services that are excluded from social health insurance coverage (basic benefit package) (24). The "Health care law" (23), among others, sets up the general framework for health care including patient rights, the organization of the healthcare system, major actors, and responsibilities for health care, as well as determines the services to be financed from the national government budget. As mentioned earlier, the regulation of coverage policy regarding the inclusion of new medical technologies into the health insurance reimbursement scheme was strongly encouraged with the adoption of the European

Union (EU) transparency directive when Hungary joined the EU (22;26). Systematically reviewing the currently funded health technologies and appraising the new ones, the elaborated coverage policy process is aimed to continuously improve the health insurance package on the basis of scientific evidence.

## **INTRODUCTION, INSTITUTIONALIZATION, TRAINING, AND EDUCATION OF HEALTH TECHNOLOGY ASSESSMENT IN HUNGARY: 1993–2008**

Following the establishment of the Hungarian Coordinating Office for Health Technology Assessment (1993), the Hungarian Society for Health Technology Assessment (1996) was formed and then the *Journal of the Hungarian Society for Health Technology Assessment* (1997) came into life. Those were motivated healthcare professionals, practicing physicians, nurses, staff members of the NHIFA, and other professionals who set up these organizations and maintained their activities on a nongovernmental basis, sponsored by various national and international organizations. This was a typical “low budget/high motivation” project, nobody helping the cause of the health technology assessment (HTA) movement in its early phase received remuneration as a reward for their work. This development was supported by Professor Egon Jonsson (Statens beredning för medicinsk utvärdering, SBU), Professor David Banta (SBU), Professor Frans Rutten (Institute for Medical Technology Assessment [iMTA], Rotterdam), Professor Dev Menon (Canadian Coordinating Office for Health Technology Assessment [CCOHTA]), Professor Mike Drummond (Centre for Health Economics [CHE], York) Professor Ron Akehurst (School of Health and Related Research [ScHAAR], Sheffield). They were of invaluable help, visiting Hungary several times, delivering presentations at various conferences. They met politicians, policy makers, and directors of NHIFA and convinced them that doing HTA is a rewarding activity, even in Hungary. A series of annual national events, Central European, and even world conferences were organized in Budapest between 1992 and 1998 in the field of HTA and quality improvement. These conferences were well populated by professionals from neighboring countries and had a significant impact on the development of HTA in Hungary. The most influential one among these events was the joint conference of the International Society of Quality Assurance in Health Care (ISQua) and the International Society for Technology Assessment in Health Care (ISTACH). An HTA training program was organized as part of the conference in collaboration with the ISQua, ISTACH, WHO, and European Commission, in which more than 100 people participated. This event triggered the HTA development in the Central European region.

The Research Centre of Health Economics and Health Technology Assessment of Corvinus University Budapest (formerly named as research unit) has been a member of

the International Network of Agencies in Health Technology Assessment (INAHTA) since 2001 under the name HunHTA. At this research center, courses on HTA (as well as health economics and health policy and financing) started in 1997 and, since 2002, it has been an elective major. The PhD program in HTA (and health economics) started in 2001.

Probably one of the breakthroughs was that an evidence-based medicine and health economics section was launched in the Hungarian Medical Journal (2002), which helped to highlight the importance of these disciplines. In 2002, the Ministry of Health released guidelines for conducting health economic analyses (31). These guidelines determine the methodological issues of health economic evaluations. The following milestone was passed when the Hungarian Health Economics Association was set up in 2003. On May 1, 2004, Hungary joined the EU; hence, it was necessary to adopt the EU Transparency Directive (11). Due to the introduction of the Transparency Directive, decisions on pricing and reimbursement of drugs are made in accordance with the regulations and practice of the EU (13).

In 2004, some important steps were taken whereby the government officially recognized the importance of the results from health economics analyses and HTA. The Transparency Secretariat (TS) named after the European Transparency Directive and Technology Appraisal Committee (TAC) was formed the same year at the NHIFA by the NHIFA and Ministry of Health to assess the therapeutic value, or clinical benefits of drugs and to compare them with existing therapies to prepare decisions on reimbursement applications. TAC members are delegated by the major stakeholders. They are with (NHIFA, Ministry of Health, Ministry of Finance, Ministry of Economy and Transport) or without voting rights, only with consultation rights (Hungarian Competition Authority, Hungarian Chamber of Pharmacists, Hungarian Chamber of Physicians, Hungarian Association of Medical Societies).

Also in 2004, the National Institute for Strategic Health Research of the Ministry of Health (NISHR) (Egészségügyi Stratégiai Kutatóintézet) was established, which assists with decision making in four major areas of health policy and financing: medical informatics and information policy, health economics, health services research, and HTA. The latter one, the Office of Health Technology Assessment (OHTA), has the task of providing an organizational framework for technology assessment, which serves as the basis for the medicine subsidy approval policy of the NHIFA, and performing the related medical and economic assessment duties. Results from this governmental HTA evaluation agency are the input for the TAC. TAC puts forward proposals on classifying drugs in reimbursement categories. As a result of this development, Hungary has moved toward introducing the “Fourth Hurdle” for pharmaceuticals. This development is well supported by the Act No. CLIV of 1997 on Health, which clearly states among the basic principles that healthcare services have to be evidence-based and cost-effective.

OHTA carries out technology appraisals, a formal procedure including the evaluation of the submitted economic dossier, which is a legally required part of each company submission.

In 2006, Hungary represented by HunHTA became involved in the collaboration of the European network for Health Technology Assessment (EUnetHTA), a project of twenty-seven countries and thirty-five institutions between 2006 and 2008, supported by a grant of the European Commission. The strategic goals for EUnetHTA are to increase the HTA output, reduce the overlap and duplication of efforts, to strengthen the link between HTA and healthcare policy making, and to support countries with limited resources and experience in HTA.

## HTA IN PRACTICE

A drug can be reimbursed in one of the ten reimbursement categories defined by the Act XCVIII of 2006 on safety and efficient supply of pharmaceuticals and medical devices (25). A manufacturer must submit evidence on the therapeutic value and cost-effectiveness of a drug before it can move to one of the refund categories. There are several reimbursement categories in Hungary, the first type of which is percentage-based reimbursement: indication-dependent reimbursement (50, 70, 90, 100 percent) and normative reimbursement (0, 25, 55, 85 percent).

### Indication-Dependent Reimbursement

Important drugs, especially drugs for chronic diseases, are in this category. Physicians with a special permit or recognition (diabetologists, oncologist, rheumatologists, and so on) are authorized to prescribe medication (biological agents, insulin, and so on) belonging to this category: higher refund of 100 percent for drugs for life-threatening chronic conditions and orphan drugs, only in selected indications; higher refund of 90 percent and 70 percent (of the full drug price), co-payment of 10 percent and 30 percent, respectively, for severe and chronic diseases; or lowest refund of 50 percent (of the full drug price), co-payment of 50 percent for drugs for diseases with public health importance.

### Normative Reimbursement

Important drugs, especially prescription drugs for chronic diseases, belong to this category. All registered Hungarian physicians are authorized to prescribe drugs belonging to this category: over average reimbursement (85 percent of the full drug price), average level (55 percent of the full price), below average (25 percent of the full price), zero level reimbursement for drugs administered only in hospitals. In this way, medicines administered only in hospitals are also part of the reimbursement system.

From the aspect of health economics, it is not always clear why certain drugs are classified in that particular category and why classification changes so frequently.

Another reimbursement category in Hungary is fixed reimbursement (reference pricing): generic reference pricing and therapeutic reference pricing. These categories were described elsewhere (15).

The application for reimbursement procedure (Figure 1) can be started by external application, submitted by the holder of the marketing authorization or ex officio, launched by the NHIFA. In general, the manufacturer submits the reimbursement dossier to the Transparency Secretariat of the NHIFA. The transparency Secretariat makes the registration, administrative check, decision on the type of procedure (normal versus simplified) and follow-up. Department of Reimbursement (DR) of NHIFA makes a preappraisal. Afterward, the OHTA at the National Institute for Strategic Health Research makes a critical appraisal based on the submitted dossier (only in the case of a regular procedure). This appraisal is forwarded to the TAC, which proposes a decision to the head of Department of Pharmaceuticals of NHIFA. The head of DR of NHIFA decides about reimbursement and will publish the official decision (Figure 1). Seeking legal remedy against the decision (DR of NHIFA) is an option at the director general of NHIFA (within 15 days). Remedies must be submitted to the Transparency Superior Secretariat of the NHIFA, which is responsible for the registration, administrative check and follow-up of it. The Appeal Committee (AC) consisting of delegates from: Ministry of Health, Ministry of Finance, Ministry of Economy, National Institute of Pharmacy, Prime Minister's Office makes a proposal to the director general of NHIFA, who decides about legal remedy within 60 days.

## DISCUSSION: LOCAL "TASTE" OF HTA IN HUNGARY

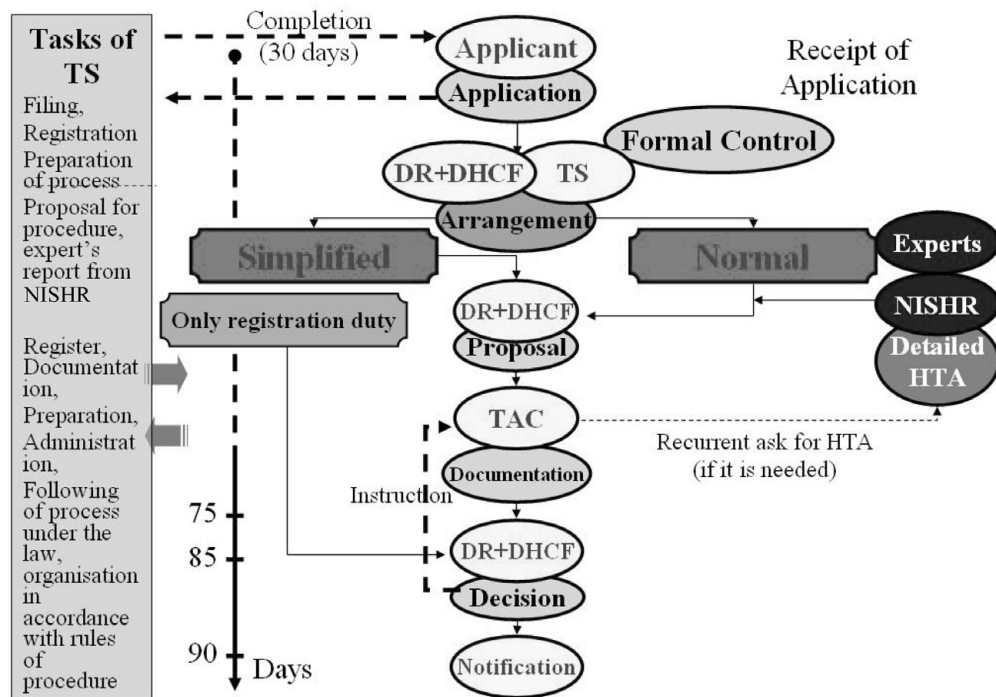
Because HTAs based on national data are not always available, foreign HTAs are also applied, for example, using demography, epidemiology, standard care, healthcare utilization, unit costs, and cost-effectiveness data from National Institute for Health and Clinical Excellence analyses.

### Epidemiology and Costs of Rheumatoid Arthritis

One might assume that the epidemiology (prevalence, incidence) of the diseases are known in Hungary. However, in most of the cases this is not true. From a health policy and drug coverage point of view, it is crucial to know the size of the target population. Budget impact calculations of the various therapies cannot be carried out without these data.

For instance, there were no epidemiologic studies on the prevalence of rheumatoid arthritis (RA, a chronic, inflammatory joint disease leading to considerable disability) in Hungary until the recent past. Assessments were based on former international data, calculating with a prevalence of 1.0 percent to 1.5 percent (100,000–150,000 RA patients). Rojkovich et al. estimated the number of RA patients to be





**Figure 1.** The procedure of submitting a dossier for health insurance reimbursement and the place of health technology assessment (HTA) within this process in Hungary (13). DHCF, Department of Health Care Financing; DR, Department of Reimbursement; NISHR, National Institute for Strategic Health Research; TAC, Technology Appraisal Committee; TS, Transparency Secretariat.

100,000 in Hungary (30). Analysis of the national health insurance database (covering the whole population) revealed a prevalence of 0.5 percent, that is, 50,000 RA patients in 2002 (20). A population-based representative survey of 10,000 inhabitants of the South Transdanubian region found a 0.37 percent prevalence in the age group 14 to 65 years. Extrapolation of this result suggests that the real prevalence of RA on the national level is around 0.5 percent in Hungary (18).

Disease burden and costs of RA in different countries were assessed by Lundkvist et al. (year 2007), calculating with 0.66 percent prevalence in northern and central European countries, that is, 67,000 RA patients in Hungary (21).

The NHIFA approved 92,209 RA patients in its official report (2008) (14). Records from GPs on the national level revealed a prevalence of 0.5 percent in 2005 (50,848 RA patients) (17).

However, several studies confirmed that the number of RA patients who visit a specialist at least once per year is less than 20,000, and the yearly drug consumption of disease modifying antirheumatic drugs (DMARDs) covers approximately 10,000 to 15,000 patient-years, although there is no limit in their reimbursement.

Then, how should we figure out the number of RA patients in Hungary? Furthermore, gross epidemiologic data are rarely sufficient, not even for basic health economic analysis. Information on the main characteristics of subgroups

is also required. RA patients with high disease activity (progressive form) are in worse health status and have higher disease-related costs than others (29).

Challenges in the field of osteoporosis are very similar. Geographic heterogeneity of osteoporosis-related fracture incidence in Europe has been well established, presenting higher rates in northern and much lower ones in southern countries. The differences are robust, for instance, in the age group 70 to 80 years, the incidence of hip fracture is 201/100,000 inhabitants in Spain, whereas it is approximately 4,000/100,000 in Sweden. However, data from Central Europe were not available. Analysis of the NHIFA records in Hungary (years 1999–2003) revealed a 439/100,000 hip fracture incidence in the age group 70 to 80 years. The difference compared with Sweden is very impressive. Although the incidence of hip fracture in women is higher than in men in both countries; the men’s rate in Sweden is higher than that of Hungarian women’s in each age group. A detailed analysis pointed out that fracture rates in Hungary are similar to results from the United Kingdom; thus, important information on subgroups were obtained (e.g., 70 percent of hip fractures occurs over age 75 years). Although important epidemiologic and disease burden inputs are still missing in Hungary, these results confirm that using fracture data either from northern or southern European countries in health economic analysis of osteoporosis drugs would cause a serious bias (28).

## Evaluation of the Coverage Decisions Regarding RA

A small scale study was conducted in 2006 with 25 drugs undergoing a “normal” evaluation process during the randomly selected period of 2005 to investigate the current practice of decision making in drug reimbursement. In this study, twenty-five submission dossiers of medicines were reviewed, including (i) economic dossier submitted by companies, (ii) evaluation by the governmental HTA agency; (iii) opinion/guidance of professional colleges, and (iv) summaries and decrees made by the NHIFA, Department of Reimbursement.

The main aim of the study was to investigate whether the size of the target population, the budget impact and health economics evidence were clearly available or not. (These are required by the official methodological guidelines.) In 48 percent of the cases, the governmental HTA agency did not accept the estimated number of the target population and the number of patients in the target population was not available in 16 percent of the cases. Estimation of the budget impact for Hungary was not available in 64 percent of the cases, and results from health economics analysis with local data were not available, by the Hungarian guideline on health economics analyses, in 92 percent of the cases. Results of health economics analysis from other countries were applied without any adaptation to the Hungarian reimbursement authority. What is even more noticeable is that the size of the target population remained unknown in 64 percent of the cases (16).

## Public Health Screening Programs

Organized, nationwide screening program for the early detection of breast (9) and cervical (4) cancer was introduced in Hungary in 2002 and 2003, respectively. As an undoubtedly positive example, we should highlight that the Hungarian NHIFA carried out a detailed health economics analysis of mammography screening (breast cancer), cervical smear examination with Papanicolaou method (cervical cancer), and immunochemical test of fecal blood (colorectal cancer) (3,5,6,10). The careful evaluation of scientific evidence and a local cost-effectiveness study *before* the decision on public reimbursement of a specific medical intervention (in this case, public health screening programs), has been a very rare example of the appropriate application of HTA in governmental decision-making processes to date.

## Most Important Problems and Challenges

No HTA guidelines have been published in Hungary yet—guidelines for health economics analysis are the not the same as guidelines for HTA. Implementation of the EU-netHTA guidelines on Core Model on Diagnostic Technologies and Core Model for Medical and Surgical Intervention (<http://www.eunetha.net>) might be useful.

Data on disease morbidity (prevalence and incidence), disease progression, quality of life, and disease burden are

missing or unreliable and no registry is required and maintained at all in Hungary. The international literature clearly shows that the public health situation in Hungary is different compared with the more developed countries. In some disease categories, for instance RA, research findings show that health status of the Hungarian patients are worse compared with patients in more developed countries (27).

A financing threshold has not been set yet, which makes financing decisions very difficult.

The drug coverage policy is very complicated, the ten different reimbursement categories make the whole system untransparent and unmanageable. We lack the dissemination of HTA results, and no dissemination strategy has been established yet. A mechanism to transfer HTA results into clinical practice guidelines is also missing. Clinical practice guidelines in Hungary are based exclusively on clinical efficacy data (mainly from randomized controlled trials), which might not result in cost-effective medical practice.

Manufacturers nowadays are developing products targeted at more and more specific subgroups of a specific disease, such as RA, scleroderma, and other immune disorders. Simple cases of the given disease can be cured by drugs that are becoming even cheaper (generic drugs), but companies have to find new biotechnology solutions to address more complex and severe medical conditions. One consequence of this development is that the size of the target population tends to be smaller and consequently many important drugs are becoming more and more similar to the orphan drugs, in the given indications. In this situation, the demand for HTAs based on local data is getting higher and higher.

There are significant developments as well. The basic infrastructure, legal background, and training capacity of the HTA are already being established in Hungary. A series of HTAs (for instance on biological agents) were created, published, and used for coverage decisions in the past years. The activity of the governmental HTA institution and the Technology Appraisal Committee imposes more and more requirements on the pharmaceutical industry in relation to economic dossiers. Successive HTAs and coverage decisions considerably increase the data available and trigger an accumulation of experience as well.

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