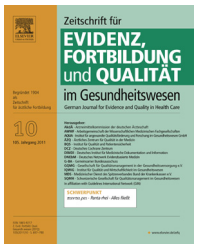
Z. Evid. Fortbild. Qual. Gesundh. wesen (ZEFQ) (2014) 108, 383—389

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: http://www.elsevier.com/locate/zefq



SCHWERPUNKT

Health economic evaluations in reimbursement decision making in the Netherlands: Time to take it seriously?

Gesundheitsökonomische Evaluierungen bei der Entscheidung über Kassenleistungen in den Niederlanden: Zeit, sie ernst zu nehmen?

Margreet Franken*, **Marc Koopmanschap**, **Adri Steenhoek**

Institute of Health Policy and Management (iBMG), Erasmus University, Rotterdam, The Netherlands

Submitted/eingegangen 7 April 2014; revised/überarbeitet 23 June 2014; accepted/akzeptiert 25 June 2014

KEYWORDS
Health economic evaluation;
reimbursement;
policy making;
health technology assessment;
pharmaceutical market;
The Netherlands

SCHLÜSSELWÖRTER
Gesundheits-ökonomische Evaluierung;

Summary Health technology assessment already informed Dutch policymaking in the early 1980s. Evidence of health economic evaluations is, however, only systematically used in drug reimbursement decision making. Outpatient drugs with an added therapeutic value and expensive specialist drugs require evidence from an economic evaluation. Due to many exemptions, however, the availability of evidence of health economic evaluations remains rather low. Although the Dutch reimbursement agency suggested a cost-effectiveness threshold range depending on the severity of the disease (i.e., €10,000 — 80,000 per Quality Adjusted Life Year), it was never confirmed nor endorsed by the Ministry of Health. It is highly questionable whether health economic evaluations currently play a role in actual Dutch reimbursement decision making. Although the requirements exist in policy procedures, recent cases show that Dutch policymakers experience great difficulties in putting restrictions on reimbursement based on evidence from health economic evaluations. The near future will show whether the need will increase to base decisions on societal value for money, and whether Dutch policymakers show the courage to take health economic evaluations seriously.

Zusammenfassung In den Niederlanden werden Qualitäts- und Wirtschaftlichkeitsprüfungen von Gesundheitstechnologie bereits seit den frühen 1980er-Jahren unternommen, um die Entscheidungsfindung über Kassenleistungen zu unterstützen. Gesundheitsökonomische Evaluierungen werden systematisch jedoch nur für Arzneimittel genutzt. Sie sind für die Erstattung von ambulant verschriebenen Medikamenten mit therapeutischem Zusatznutzen und von teuren Spezialarzneien erforderlich. Aufgrund vielfältiger Ausnahmen werden jedoch

* Corresponding author: Margreet Franken, Institute of Health Policy and Management, Erasmus University, P.O. Box 1738, 3000 DR Rotterdam, The Netherlands. Tel.: +31 10 4081372; fax: +31 10 4089081.
E-Mail: franken@bmg.eur.nl (M. Franken).

http://dx.doi.org/10.1016/j.zefq.2014.06.016
1865-9217/

Krankenkassen-leistungen;
Gesundheitspolitik;
Health Technology Assessment (HTA);
pharmazeutische Industrie;
Niederlande

auch hier nur wenige gesundheitsökonomische Evaluierungen tatsächlich durchgeführt. Obwohl die niederländische Erstattungsagentur eine Kosteneffektivitätsgrenze in Abhängigkeit von der Erkrankungsschwere (z.B. €10.000 – 80.000 per qualitätsadjustiertem Lebensjahr) vorgeschlagen hat, wurde diese nie vom Gesundheitsministerium unterstützt oder auch nur bestätigt. Es ist fraglich, ob gesundheitsökonomische Evaluierungen derzeit eine relevante Rolle bei Entscheidungen über Kassenleistungen in den Niederlanden spielen. Obwohl der politische Entscheidungsfindungsprozess gesundheitsökonomische Evaluierungen vorsieht, zeigen aktuelle Fallbeispiele, dass die niederländische Politik sich äußerst schwertut, Kassenleistungen aufgrund von gesundheitsökonomischen Evaluierungen zu begrenzen. Die nahe Zukunft muss zeigen, ob die Notwendigkeit, Entscheidungen auf ‚social value for money' zu basieren, zunimmt und ob die niederländische Politik den Mut hat, gesundheitsökonomischen Evaluierungen ernst zu nehmen.

Introduction

Health Technology Assessment (HTA) became a policy tool in The Netherlands in the early 1980s [1]. Although the contrary is often held to be true [2], we believe, however, that the role and impact of evidence from a health economic evaluation (HEE) still remains limited in actual health care decision making. To arrive at this conclusion, this article firstly describes the Dutch reimbursement system and the applied priority setting principles. Since HEEs are mainly used in drug reimbursement decision making, we focus on the drug reimbursement process, the applied criteria and the requirements regarding HEEs. After that, we assess HEE evidence regarding its availability and quality. Finally, we evaluate the impact of HEE in actual decision making practice.

Health care reimbursement and priority setting in The Netherlands

The Dutch healthcare system is based on a social health insurance system, funded by public and private sources. Since 2006, all residents must join a universal basic health insurance which is provided by competing health insurers. Adults pay a flat rate premium, a subsidy scheme relieves financial burden for lower incomes. Supplementary health insurance is privately offered on a voluntary basis. The Health Insurance Act (*Zorgverzekeringswet, Art. 63-66*), Health Insurance Ordinance (*Besluit Zorgverzekering, Art. 2.8*) and the Health Insurance Decree (*Regeling Zorgverzekering*) establish the legal basis of the reimbursement system.

Since the early 1980s, Health Technology Assessment (HTA) became a policy tool in The Netherlands, mainly due to the increasing numbers of new expensive technologies [1]. HTA-studies already informed policy making in the 1980s, for example on liver and heart transplantation, and screening for breast cancer [3,4]. In 1991, the Dutch Committee on Choices in Health Care pronounced HTA as a priority setting tool by suggesting a funnel, the funnel of Dunning, to determine the basic benefit package. The Dunning funnel has four decision criteria: the technology should be necessary, effective, cost-effective, and affordable (i.e., individuals cannot bear the responsibility for the actual costs) [5]. Ever since, the Dutch government has continued to express the potential importance of the role of HTA in reimbursement decision making.

The Health Care Insurance Board (*College voor Zorgverzekeringen*; CVZ; from April 2014 *Zorginstituut Nederland*), an independent government funded agency, has the responsibility to advise the minister of Healthcare, Welfare and Sports regarding the entitlements of the basic benefit package. It is CVZ's mission to *"safeguard and develop the public preconditions for the health care insurance system, so that Dutch citizens can obtain their right to health care"* [6]. To ensure this mission, CVZ's guiding principles regarding the entitlements of the basic benefit package are: quality, accessibility and affordability [7]. As inspired by the Dunning funnel, CVZ uses four priority setting principles, namely necessity, effectiveness, cost-effectiveness, and feasibility [7].

Consequently, cost-effectiveness is one of the four formal priority setting principles for the basic benefit package. This criterion is, however, not systematically used across the entire benefit package, but mainly used for decision making concerning drugs. Regarding non-pharmaceuticals, only in a few cases considerations of cost-effectiveness may have been taken into account (e.g., smoking cessation programs, and severe dyslexia in children) [8]. Therefore, the next part of the article will only focus on decision making for drugs.

Drug reimbursement and health economic evidence requirements

The aim of the Dutch drug reimbursement system is to guarantee safe and efficient pharmaceutical care according to individual patient's need in concurrence with scientific standards [9]. The CVZ has the legal responsibility to advise the minister whether or not a drug should be included in the basic benefit package and thus funded by public sources.

Briefly, the reimbursement procedure is as follows (see Figure 1). The applicant submits a reimbursement request. Based on the application file, CVZ's secretariat prepares an assessment report. This report is then, at least once, evaluated by the Scientific Pharmaceutical Advisory Commission (*Wetenschappelijke Adviesraad Commissie Geneesmiddelen*, WAR-CG; formerly *Commissie Farmaceutische Hulp*, CFH). Members of the WAR-CG have expertise in various medical disciplines, pharmacology, health sciences, and (health) economics; two representatives of the ministry attend WAR-CG meetings as observers.