Market Access: making the process easier and efficient


By Ron de Graaff,[1] and Yves Tillet [2]

For innovative medical devices and medicines, in addition to clinical development, it is important that it is clear at an early stage of product development (1) what a possible selling price of a new technology can be and (2) whether for this price a reimbursement via regular health insurance policies or otherwise is possible. For start-up technology companies, the question of whether reimbursement is possible is all the more pressing, since such companies are often dependent on one or a few products, for which - often also for external financiers - it should be clear as quickly as possible what these products can "do in the market". Indeed, often the value of such a company is the same as the value of the product under development.

We have developed a new service for starting technology companies as well as for bigger companies: “Early Market Access" of health technologies in order to gather an indication at an early stage of product development (pre-clinical and clinical) of (1) the possible price for a new innovative technology, (2)) make an estimate of a possible reimbursement and (3) provide a strategy, plan and elaboration to realize a possible maximum price and reimbursement in the market.

For instance, in The Netherlands, if the new technology does not fit into an existing performance description with an appropriate remuneration (so always investigate), then apply for a new performance description and obtain a decision that reimbursement is possible. We need the NZa (Dutch Health Authority) for performance descriptions and the ZIN (Dutch Healthcare Institute) for a reimbursement decision. The ZIN states that reimbursement is possible if the new technology meets the State of Science and Practice (StWP). In the Netherlands, the shortest route for reimbursement of a new technology is to request an interpretation of the "State of Science and Practice" (StWP) by the Healthcare Institute (ZIN). If the ZIN has determined that a technology is StWP-compliant, health insurers cannot refuse reimbursement of the technology, since Dutch insured persons are entitled to treatments, the clinical effectiveness of which is established and which is endorsed by Dutch professional groups of doctors. To determine the StWP of a technology by the ZIN, it must be risk-bearing for the package and the clinical efficacy must be established. The latter is usually determined by randomized clinical trials. During this process, the application for the performance description must also be started with the NZA.

Based on an assessment of all clinical data, as well as business plans and other relevant documents, we will first estimate the chances in the Netherlands that the ZIN will provide a positive interpretation of the StWP of an innovative medical technology. In addition, we assess the external framework of the positioning of a new technology by, among other things, looking at the state of the legislation, opinion of patients, health insurers and doctors regarding the new technology, financing and expected market development. The study provides advice on the strategy to be followed for obtaining a performance description, an adequate price and reimbursement for the new technology.

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Important here is, among other things, whether additional data should be collected in the clinical and / or economic field. If requested, we can also pay attention to the consequences of a possible profile of market access outside the Netherlands.

Since 2015, it has been possible in the Netherlands for individual health insurers to carry out the StWP interpretation of a technology themselves. The insurers will only proceed to pay on the basis of an individual interpretation if all insurers agree with the interpretation. This has only been the case a few times to date. Therefore, the interpretation of the StWP by the ZIN can be considered as the "golden standard".

To summarise, services of Seijgraaf BV, founded in 1985 and since then more than 700 companies as customers: process starts with the preparation of a market strategy and plan for market access. For advice on early positioning of market access of innovative medical technology, Seijgraaf BV and partners have developed a unique collaboration. The aim of the collaboration is to assist medical technology start-ups and their financiers in defining prices and reimbursements for new medical technologies, as well as formulate and implement plans and strategies for realizing this in the market.
The advice focuses mainly (but not exclusively) on the Netherlands, Belgium, UK, the German-speaking countries of Germany, Austria and Switzerland and also in France.

In final, Seijgraaf BV provides to customers and manages a large and reliable network of national market access experts in the EU, among them WHITE-TILLET, experts in France.

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***Ron de Graaff**, LL.M, has more than 40 years experience in consulting for pharmaceutical and medtech companies. In 1978 he started his career at the Central Organization of Social Dentistry. Later on at the Dutch umbrella organization of private health insurers, he was responsible for the negotiations with pharmacists, suppliers of medical devices and paramedics. He is the founder of Seijgraaf in 1985, located in The Netherlands. Furthermore, he is one of the founders of the Agora Network in Dublin and the IHC Consulting company in Switzerland. Ron has focussed his professional life on health insurance and health financing issues as well as dental care and reimbursement of medical devices and pharmaceutical products. Ron is a senior expert in issues of DRG financing (or in Dutch DBC) in the Netherlands. Over the years he has advised more than 700 private and public sector health care providers, insurers and manufacturers of pharmaceuticals and medical devices, giving advice mainly in the field of strategy and policy structures, related to and resulting from the finance structures of the Dutch healthcare system (over 2,500 projects). His past duties involved: Chairman of Umbrella Organization of Medical Technology in the Netherlands (SOMT) Chairman of the dentists organization ANT, Chairman of a regional Patient Organization, Chairman of a home healthcare organization and various advisory roles of the Dutch Healthcare Authority and the National Reimbursement Authority.*

Work is currently underway on a number of projects in the field of lung diseases, heart diseases, diabetes, epilepsy, bariatric, medical nutrition, incontinence, spine diseases, dental products, woundcare products, e-health solutions, diagnostics and laboratory tests.

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*In 1994, **Yves Th. Tillet** and **Marie D. White** created the **Cabinet WHITE-TILLET** providing expertise and experience in the field of consulting and assistance in health products, including reimbursement and pricing process in France and in the EU in collaboration with Seijgraaf BV.*