Interview: Ad Schuurman â?? Head of Business Contact Centre & International Affairs, Zorginstituut, The Netherlands

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Ad Schuurman of the National Health Care Institute of the Netherlands (â??Zorginstituutâ?•) explains the main missions and mandates of this organization with regards to the basic insurance package covering all Dutch citizens, as well as its perception of pay-for-performance models, pan-European joint-reimbursement initiatives, and Zorginstituutâ??s policies on orphan drugs reimbursement and quality of care improvement.

Could you give us a brief outline of the main missions and mandates of the Zorginstituut with regards to basic insurance package management?

The Zorginsituut has two main missions: firstly, we assess new medicines and other interventions that are about to reach the Dutch market, and then we provide the Ministry of Health with advice regarding how this treatment should be covered within the basic insurance package. In the large majority of situations, the Ministry follows our assessment evaluation. Secondly, we also sometimes reevaluate treatments that are already included within the basic insurance package, but for which we have received some complaints about their effectiveness. In this case, we then reevaluate the treatment and decide whether it should remain included within the basic insurance package.

A new responsibility is to improve quality and appropriate care in the Dutch health care system.

For our assessment process, we obviously involve patients and patient groups, doctors, researchers, insurance companies and providers. We always look to involve an increasing number of stakeholders at an early stage of the reimbursement process. Considering this collaborative effort in continuously striving to improve and enlarge, we can say that the Zorginstituut is a very Dutch organization. If we truly value this cooperation, it is firstly to fully benefit from all stakeholdersâ?? knowledge and expertise, but also to favor the implementation of new policies and strategic decisions, by ensuring all key parties will receive the information at the same moment and will be

able to discuss it in a very sound way. We see this way as the best and maybe the only manner to ensure stakeholders accept our decisions.

Finally, I would say that we also enjoy a really collaborative relationship with most of the pharmaceutical companies present on the Dutch market. Nevertheless, our collaboration remains mostly based on a one-to-one approach, as there isnâ??t a single association that could gather together all the pharmaceutical companies. Even Nefarma, which is the Dutch innovatorsâ?? association, represents a number of the pharmaceutical companies, but not all of them.

Could you elaborate on the criteria and assessment process used to monitor the scope of the basic insurance package and estimate which treatments should be included in the package?

Necessity, feasibility and cost effectiveness of the evaluated treatment are the core criteria we consider. The cost-effectiveness criteria, however, has tremendously gained in importance in our evaluation process over the last few years, despite having been part of our assessment criteria for a long time. We also see that affordability has rapidly gained in importance: if you spent your healthcare euro on a very expensive intervention, you cannot spent it on other treatments, with greater potential health gains.

At the beginning, there was a lot of bad media coverage when we decided that a treatment would not be reimbursed because its cost-effectiveness assessment was not convincing enough, despite the product displaying some positive effects for some of the patients. Nevertheless, legislators, media, patients, doctors and the public have clearly begun to understand that we cannot pay for everything. Even patient organizations understand that reimbursing highly expensive treatments with very low patient outcomes is absolutely unsustainable, and they are ready to move forward and look with us in a collaborative demarche on other potential alternatives to continue bringing these treatments to Dutch patients.

Talking about new ways to cooperate, what is your assessment of pay-for-performance models?

We indeed implemented a â??coverage with evidence developmentâ?• system, which concerned around 40 very expensive hospital drugs. We agreed to provide companies with a reimbursement approval, but we asked them to monitor the outcomes in the treatment, which will be reevaluated four years after they initially came on the market. It truly marked a very innovative way to assess new treatments for the Dutch healthcare system.

Nevertheless, after four years, we proceeded to the reassessment of the first ten medicines that received this conditional approval â?? as it was agreed in the first place. It appeared that most of the companies were unable to display the requested data! In four yearsâ?? time, many things can happen: indications and doses could change, new therapies could come up, and companies might not be able to precisely monitor data or not be willing do so.

We thus understood that this coverage-for-performance system raised some structural issues, despite being conceptually extremely interesting. This approach could be suitable for a limited number of very specific treatments, but it is probably not realistic or doable on a larger scale.

Some treatments, such as orphan drugs, can be extremely expensive while targeting a very small patient group, for whom accessing these treatments is absolutely crucial. For these kinds of medicines, will the Zorginstituut deviate from its usual evaluation criteria?

No, we recently decided that we will adopt exactly the same assessment approach for orphan drugs as for any other treatments. Nevertheless, our decisions are not taken by computers, and it is in our

philosophy to then discuss with our stakeholders to find alternative solutions. For orphan drugs, we often see that, even if they already target small patient groups, treatment efficiency will vary a lot from one patient to another. We thus call for more precise guidelines, and the EMA has a great role to play in this regard.

In some cases, we will therefore adopt a patient-by-patient approach to determine if the given orphan drug treatment should be included in the basic insurance package of all patients concerned, by analyzing extremely precisely if the treatment will be efficient on the clinical specificities of every patient. It is obviously enormously time-consuming for us, but we are talking of treatments with a $500,000 annual cost per patient!

Companies that produce expensive treatments often call for a more holistic evaluation of their medicines, by taking into account the long-term and socio-economic impact of their drugs and not only the price of the pills. What is your assessment of the situation?

We adopted this approach more than 15 years ago! The Zorginstituut follows what is called the â??society viewâ?• in pharmaeconomics, which indeed implies considering treatment outcomes in a larger manner and analyzing the socio-economic impacts on patientsâ?? working and social lives.

What could be the impact of the new transnational pricing and reimbursement models, specifically the joint Belgian-Dutch pricing and reimbursement initiative for orphan drugs introduced by Minister De Block and Minister Schippers, on Dutch patientsâ?? access to these treatments?

The Netherlands represents around one percent of global pharmaceutical turnover, which means that obviously we donâ??t hold an important buying power. One of the only ways to increase countriesâ?? buying power is to adopt a multiple EU-state approach. Within a single-state reimbursement procedure, a company can still ultimately decide to not bring some of its products to a given market, mainly because the prices are too low. Nevertheless, companies could never afford to simultaneously withdraw their products from ten different countries.

From a long-term perspective, a multiple-EU states approach is the best guarantee to improving patient access. The main barrier that currently restrains patient access to new treatments is high prices. Joint-negotiation is thus the best option to ensure European patients can access expensive treatments in the future, considering the cost-containment context that is currently hitting most of the European healthcare systems.

In this regard, there is also a great potential to steadily broaden these kinds of initiatives to treatments other than orphan drugs, as, if we look at the current pharmaceutical companiesâ?? pipelines, there is currently a trend of increasingly targeting smaller patient groups (with better patient outcomes but obviously smaller volumes), which means more and more very specialized and expensive treatments will reach the market in the upcoming years. So we will have to develop advanced assessment procedures and accepted decision making to keep the healthcare system alive.

At a European or international level, on which kind of partnerships are you engaged with sister organizations?

Regarding pharmaceutical policies, we are currently partnering with many of our European counterparts through diverse initiatives. I am, for instance, the president of MEDEV, the Medicines Evaluation Committee, which is an informal organization aiming to foster common assessments of upcoming treatments. Most of our assessment criteria are based on scientific evidence; we thus seldom notice differences between the different European organizations. However, there are fewer

consensuses on cost-effectiveness evaluation, which will particularly depend on every individual countryâ??s resources.

Regarding formal cooperative partnerships, the Zorginsituut is also a member of EUnetHTA, the European Network for Health Technology Assessment; concrete evidence that it is possible to achieve EU-wide common assessments. The Zorginstituut also collaborates with MOCA, the Mechanism of Coordinated Access to Orphan Medicinal Products, which specifically deals with smaller companies that generally face bigger difficulties in simultaneously bringing their orphan products to 28 different heathcare systems. We advise these companies at a very early stage of their treatment development, generally at phase II clinical trials, and we then steer their research to ensure they will be able to display the requested clinical outcomes when their products reach the reimbursement phase. Furthermore, European cooperation also only allows these companies to set up a few expert centers throughout Europe, which is also really challenging for reimbursement organizations, as we have to figure out efficient and fast processes to reimburse Dutch patients that could be cured in an expert center in Italy, for instance. We also might end up with common price negotiations, with acceptable prices for all stakeholders involved.

The Zorginstituut also has a Quality of Care Program (â??*Kwaliteitinstituutâ?•*), which aims to encourage the continued improvement of healthcare quality in the Netherlands. On which key element are you currently focusing?

This Quality Institute is a relatively new initiative, whose philosophy is to support physicians and other healthcare providers in ensuring the right treatment (within and outside the basic insurance package) is correctly given to the right patient. In addition, we focus on patient empowerment through better information, e.g. on consumer websites, in the form of comparative performance indicators, decision aids or option grids. There is huge room for improvement for the overall Dutch healthcare system and at the end of the line for Dutch patients by optimizing and coordinating the way physicians and medical staff provide care all over the country. As we see more specialized treatments coming on the market, the overall system has to follow the same trend and adopt a more precise and specialized approach in the way these treatments are provided to patients.

The Dutch healthcare system has been ranked number one in the Euro Health Consumer Index for the fifth year in a row. Looking at the basic insurance package, what will be the key points to focus on in order to maintain this ranking in the upcoming years?

We will have to further develop modern ways to empower patients and assess new treatments; which is a huge responsibility. We also want to foster a better and more coordinated use of treatments within the Dutch healthcare system, thanks to our Quality of Care program. Finally, international collaboration will clearly be the key element of improving patient outcomes, as the benefits would clearly go beyond an increased buying power and should allow European regulators to benefit from each otherâ??s expertise and experiences.

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