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Nefarma's healthcare policy advisor discusses the changes in the Dutch reimbursement system over the previous five years, and the need for greater trust between different healthcare stakeholders to allow effective collaboration and negotiation.

How has the pharmaceutical reimbursement system in the Netherlands changed over the last few years?

To start with, it's important to clarify that we have two reimbursement systems in the Netherlands. The first for the retail pharmacy market which we call GVS, while the second is for drugs reimbursed under the hospitals budget. The GVS system is a positive list, where there has to has to be formal advice and a decision from the Ministry of Health before a drug is reimbursed. In the hospital setting, the drugs are part of the total care budget and are automatically reimbursed as soon as there is registration; so on that front, market access is in theory very good, but there can be a few issues in practice.

The biggest changes of the last few years was prompted largely by the large development in the field of oncology with the launch of several exclusive oncolytics. Second In 2012, the reimbursement system was reorganized to some extent, and some therapeutic classes of mostly high priced pharmaceutical products were moved from the GVS budget to the hospital budget. As

such, hospitals are now responsible for their pharmaceutical budgets to a large extent. Moreover, the Ministry of Health, insurance companies, and hospitals have agreed to limit spending growth to one percent overall, which is an unrealistic limit given that the hospital pharmaceutical market is growing at six to seven percent, and due to this change in the reimbursement system overall hospital spending on pharmaceuticals has grown from EUR 600 million to EUR 1.7 billion in the last five years, leading to significant budgetary pressures on doctors influencing their prescription decisions. Overall, pharmaceutical sales were stable during the last 5 years and growing by 4% in the last few months again.

We have also seen the introduction of evaluations by the pricing board within the Ministry of Health, which can be made for existing or newly registered products. Now, products that are defined as high risk, one criteria being a product with expected sales of over EUR 2.5 million, can be subject to re-evaluation in terms of price; as such, the government can pose questions regarding cost-effectiveness, differences between real world and clinical outcomes. During this evaluation process the Ministry can give temporary reimbursement, or come to a temporary financial agreement, and in that time the pharmaceutical company in question can do their best to provide evidence to prove the value and efficacy of their product. If the evidence provided is satisfactory then permanent reimbursement will be granted, while if questions remain then the discussion will continue in terms of requirements for further data, coming to a different financial arrangement, or changing the access criteria in terms of target population and clinical parameters for prescription.

How are companies adapting to this trend?

Companies are prioritizing efforts to make effective financial agreements in the early stages with the Ministry of Health pricing office, as this should in theory give them secure market access and remove the need to negotiate with the National Care Institute (ZIN) regarding cost-effectiveness.

However, this strategy often does not work as expected, as the ZIN does not review a fixed number of cases; this varies based on workload, and they work in order of which products are highest risk. As such, until an at risk product is evaluated there is temporary reimbursement, however the fact that it is on the waiting list for review indicates to doctors and hospitals that their patients could potentially lose access to this product.

How much progress have we seen in terms of the introduction of results based financing or value-based pricing mechanisms in Dutch drug pricing?

When a drug has temporary reimbursement status, after being registered and designated as high risk, if there is a situation where it is difficult or not possible to prove the value of a medication, for an orphan drug with extremely limited data for example, all these cases can lead to a situation where you have to negotiate an agreement with the pricing office; at this stage pay for performance, and price-volume agreements etc. can be discussed. In July, the Ministry of Health reported to parliament that there have been 11 cases of this type of agreement in the Netherlands so far, starting around two years ago for high risk products being evaluated by the pricing office.

On another note, the pricing office is part of the Department of Health and, as such, consists of civil servants for whom the Minister of Health is ultimately responsible; decisions are thus made in in the realm of politics, by civil servants, and without the input of physicians on the public side. This situation is currently being evaluated, and we think before the end of the year there will be a decision of how to proceed.

What do stakeholders need to do to create a better mentality towards finding fair pricing arrangements such that companies have more certainty regarding market access?

From a European perspective, market access is still good in the Netherlands. The Dutch Cancer Foundation prepared a report that was published in July, and Nefarma contributed a document with solutions for pricing that was included in this report. Our overall message is that we want the patients that need access to innovative drugs to have access, and that if pricing is the issue then we need to discuss it with the government; list prices are just that, and pharmaceutical companies are open to negotiating different types of financial agreements, including innovative pricing agreements like the no-cure no-pay agreement. Really, we need the government and payers to extend some trust to the industry at the moment, so that we can effectively collaborate to find effective and fair financing solutions so that patients can have immediate and reliable access to innovative pharmaceutical treatments.

Nefarma also has some concerns regarding how hospital budgets for innovative products are controlled; at present, budgets are cut when medications go off patent, even though new innovations are reaching the market simultaneously for other diseases. Many hospitals would like to be able to directly reallocate the budget to newer products, but instead they have to renegotiate and deal with health insurers about a decreased budget following patent expiries. The Ministry of Health is encouraging hospitals to be well coordinated in terms of their budgetary plans, as some degree of unanimity amongst the different hospital divisions should ensure a relatively efficient allocation of funds.

What makes the Dutch system most different from the other big European markets?

One of the most different things is that we have private health insurers who must negotiate with the public healthcare system, and it is these companies that must allocate healthcare budgets. The Ministry of Health takes a supervisory role and oversees the overall budgetary situation and total spending, while the insurers do the work in terms of budget allocation to doctors, pharmacists, hospitals and other entities, which is quite different from other countries in Europe. One side effect of this is that the primary concern of the insurers is therefore price, and there are relatively few metrics or parameters to ensure that quality is not jeopardized; this is changing to some extent now, as insurers have been working with doctors and hospitals to develop effective quality metrics. However, the challenge here has been a lack of coordination amongst insurers, how do not share their quality assessment data and often disagree on which institutions are better than others, not to mention the administrative requirements that they end up placing on physicians.

On the other hand, while the system is privatized and pricing negations should in theory take place between the individual health insurers and the pharmaceutical companies, there is a price law in the Netherlands such that a maximum price is set by the Ministry of Health. This is done via a reference pricing system that references prices in France, Germany, Belgium and the UK, and still the Ministry sees a hospital or pharmacy prices are on this reference price level they can trigger an evaluation by the pricing office.

Are there other examples of a lack of coordination in the Dutch healthcare market?

One example would be patient registries and data. At present, there are a lot of registries for different diseases in different areas, and the systems they use differ in many cases. Funding is not well organized, so while one registry might be built when a specific company funds the registry as part of justifying the effectiveness of a given product, it might happen that once the efficacy is proven the funding often disappears. Overall, there should be more cooperation between the different insurers and other stakeholders to create larger, better quality registries.

In light of Minister Schippers recent announcement regarding joint orphan drug purchasing between Belgium and the Netherlands, what agenda do you foresee her pursuing during the Netherlands Council of Europe presidency next year?

There is very little information available beyond what was printed in the newspapers regarding this initiative, and from what I do understand, the Belgians and the Dutch are looking at this initiative from different perspectives. For Belgium, this is an opportunity to really focus on bringing down the prices of orphan drugs, while for Minister Schippers this seems also be an attempt to being a

European pricing discussion ahead of the presidency. She knows that it is difficult to have a pricing discussion in the Netherlands, so bringing down prices further in the Netherlands will require that it happen in a European context where the 'payers' have more market power. We will have to see if this has an impact on transparency, prices, and the collaborative environment. In general, it is the opinion of Nefarma and the industry that decentralized pricing can be more efficient that centralized pricing, as it allows for more comprehensive, service oriented agreements to be made, and allows hospitals that have strengths in certain areas to better capitalize upon these strengths; as pricing becomes more centralized, hospitals lose out on the flexibility of these customized agreements, and high-volume hospitals end up paying higher prices than they would under a specific agreement.

In terms of concrete policy, what are the key priorities for Nefarma on the policy front going forward?

The first priority is ensuring fast market access for new products for patients. Although we have open access for hospital medicines A new mechanism was introduced to prevent direct reimbursement of an immunotherapy product while an (cost) effectiveness evaluation is being carried out, and also a financial agreement will be negotiated because of the expected budgetary impact would be very large. However, Nefarma would like to see this evaluation as fast as possible, because at present it is likely to take several months; at present, patient are being provided with this specific product for free by the company, which is not in line with the Dutch law.

Another policy priorities include improving the Netherlands competitiveness as a clinical trial destination, as we have seen the number of trials falling in recent years.

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