HEALTHCARE SYSTEM 2020-2025

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Introduction

In this document we describe potential future developments in the healthcare system, arising from the belief that we, Seijgraaf Consultancy and IHC sarl Switzerland, have a vision and from that vision we can advise our clients.

What we describe and what we expect for the next 5 to 10 years is a total 'game-changer'; from collectively financed to privately financed healthcare, from solidarity to individual responsibility. Gradually, not abruptly, step by step, we will move towards a healthcare system where our individual responsibility will play an increasingly important role which will have as a result that we go from a health insurance system to a health financing system. But also that the passive patient will become an active consumer.

The financing of the uninsurable risks will be executed by a reinvented regional or national health fund. Municipalities will take back their old responsibilities in the field of collective and individual prevention. Companies will develop their own insurance policies in order to provide for their employees. Foreseeable risks can be insured at private health insurance companies. In the market of private health insurers, new, mutual guarantee associations will arise again, organised from community groups.

For manufacturers and suppliers of healthcare products and services there will be a lot of changes. Especially for those components of healthcare where one can take his own responsibility and where there is a matter of low burden of disease, manufacturers and suppliers will be confronted with self-paying consumers. That is the big game-changer.

In this document we will further explain this game-changer

The Netherlands leading in international cooperation

We tend to assume that what happens in The Netherlands stays within the borders, but the opposite holds more truth. Developments from pilots in The Netherlands are monitored with interest elsewhere. For manufacturers and suppliers that are internationally active it is necessary to monitor the developments here and to translate them to their own activities and investments in time.

International cooperation is high on the agenda. Both the Ministry of Public Health and the Dutch Healthcare Institute (ZIN) take initiatives that can be of great influence, not only on the Dutch healthcare system, but also on healthcare systems in other European countries.
Three examples are:

- Continuation (by ZIN) of the SEED project, where health technology outcomes are shared through national authorities such as HAS, GB-A, HVB, IQWIG, NICE and KCE, to mention a few.

- Joint development by ZIN and KCE (Federal Knowledge Centre for Healthcare) from Belgium of future scenarios for the development and pricing of pharmaceuticals, gratefully accepted by the Dutch and Belgian Ministers of Public Health[1].

- Mid-June 2016 Austria will join a cooperation of the Netherlands, Belgium and Luxemburg, which was set up to engage in joint price negotiations with

[1] *Toekomstscenario´s voor de ontwikkeling en prijszetting van geneesmiddelen*, KCE en ZIN, 23 juni 2016

pharmaceutical companies, to exchange information and work together on the challenging developments concerning pharmaceuticals[2].

Conclusion:
Recent developments indicate, that what is going to happen in The Netherlands in the years to come, will not escape the eyes from abroad. An early detection and adequate preparation is needed.

1. Factors that influence the current situation

Political developments

The events from fall 2016 will be of great influence on the politics of the coming years. A major change of policy is to be expected in the fields of security and defence and therefore also in the fields of social security and healthcare. A change of politics, both in the USA and Russia, holds consequences for Europe: the USA invested in security and not in social developments. That is going to change, thereby forcing Europe to invest more in security which will make less money available for social expenditures.
Apart from that it is still uncertain what the consequences of the Brexit will be for the stability of European politics and economy.

Conclusion:
Given the developments in Europe, security and defence will have to be high on the political agenda and therefore will be an important, if not the most important, theme of the elections in Spring 2017.

Social developments

The hitherto characteristic solidarity in the European social security, enshrined in treaties, constitutions and national regulations, is under pressure. Individualization of pensions is the first expression of decreasing solidarity and the shift to individual responsibility for old age. Reduced unemployment benefits cause an intentional or unintentional increase of the number of self-employed without a social safety net. This indicates that having employment and an income brings with it a larger responsibility and there is no or a decreased possibility to fall back on the collective.

<u>Population development in The Netherlands</u>

The current population of The Netherlands is 17.039.654. Prognoses show that the population will continue to grow to 17.837.003 in 2030 and 18.146.753 in 2050. Part of that growth can be attributed to the growth of the number of immigrants. The expected inflow in 2016 is 240.000 people. Set against the outflow of 150.000 people there is an expected growth balance of 90.000. This will not change much in the years to come.

The inflow in the social security system of people that receive from it but do not contribute and the outflow of people that can (partly) still claim reimbursement from the Dutch healthcare system (if one still has the right to a pension or benefit from The Netherlands) will put even more pressure on the system of solidarity. This pressure is heightened by the fact that the population is ageing. This ageing population means there will be higher demands on the healthcare system.
Apart from that, as mentioned before, in the last few years there has already been a process of cutbacks in social security. This process will be accelerated by the pressure of the choices that will be made in the years to come. Healthcare, the largest expense, has

[2] *Oostenrijk sluit zich aan bij geneesmiddelencoalitie, Nieuwsbericht Ministerie van VWS*, 17 juni 2016

until now been spared from major interventions. On the contrary, the expenses for healthcare are still increasing each year. This is going to chance.

Conclusion:
Individual responsibility will increase and there will be less collective regulations.

Technical developments

Technologically a lot is happening and it is happening fast. Big data, nanotechnology, genetic technology, imaging, the internet of things, robotising, 3D printing, virtual reality and augmented reality are innovations that make the world chance rapidly.
Pharmaceutical companies and large information companies are working together on the development of implantable biomedical tools that can measure inside the body. We know now more than before and we can measure and know even more in the years to come. This has consequences for the predictability of being healthy or ill. Predictability also has consequences for the financing of healthcare: after all, only unexpected and unforeseeable issues are insurable.
If the technology exists, people want to access it. This means higher pressure on the healthcare system or the use of alternative means to access it.

Conclusion:
Many health issues will be foreseeable and preventable. This supports the shift from collective care to individual acting.

2. Cost development

According to some international researches, The Netherlands has the best healthcare in Europe and according to other international researches we are somewhere around the European average, but one thing is certain: for European standards we have expensive healthcare.

It is well-known that with unchanged policy the expenses for healthcare will increase enormously in the next few years. Growth percentages up to 40% of our national income have been presented. Ageing, more diagnostics and more expensive pharmaceuticals can already be appointed as causes for the increase. Since October 2007 the cost of brand-name medicines has soared, with prices doubling for dozens of established drugs[3].

If politicians are choosing the expected road of more focus on security and defence, the increase of healthcare is no longer an issue and cutbacks will be the motto. The collective financing will be under pressure and there will simply be less money to spend.

3. Changing views

Efficiency rounds are not productive anymore. Prices can hardly be lowered anymore without governmental intervention. Expense reductions will therefore have to be come about in other ways.

Cost savings for the collective financing can be reached by cutbacks in the package. For the individual user the costs will remain. Cutbacks in the package on a national level can be reached by the intervention of ZIN, by cancelling existing reimbursable therapies but also by not or slowly admitting new therapies to the package. This is especially the case in healthcare that does not meet the criteria for standard of care and daily practice. Cutback in the package will cause problems in the relationship between care provider and

[3] *Big Pharma´s favorite prescription: Higher Prices*, Bloomberg.com, May 2014

patient. Not or delayed admittance to the package limits the therapy arsenal and is an unexpected brake on innovation.

Austerity of the package on the level of health insurance companies is another possibility. The health insurance company can use the instrument of standard of care and daily practice as well. The purchasing health insurer can also choose not to purchase certain forms of healthcare and to replace them by other, more or less equal, forms of care. Furthermore, a health insurer can choose between providers of healthcare. Preference policy is a well-known phenomenon. However, for this a patient can be blamed just as well. The patient chooses the health insurance company and the insurance policy.

Conclusion:
P x V = D. Prices are uncontrolled, volume increases autonomously and the damage gets higher and higher. Delete care from the collective package and leave it to individual initiative.

Governmental package responsibility

The government determines the nature, content and scope of the basic insurance package of the Health insurance act (Zvw). In the Healthcare decision (Bzv) and the Health insurance regulation (Rzv) the description of the basic package is written down. The performances for which a health insurance should provide a claim for the insured are called the 'performances to insure'. Health insurance companies have to include the performances to insure in their policy.

The description of the 'performances to insure' has the following structure: Article 10 of the Zvw contains an enumeration of the risks to be insured. It concerns a broad typing of the performances to which a health insurance should provide a claim. It contains, among others, the following risks:

- Medical care
- Pharmaceutical care
- Medical devices
- Nursing
- Care

The actual description varies per part (per form of care) and knows two extremes: generically described performances (open system) and specifically described performances (closed system). The last concerns the restrictive list of outpatient pharmaceuticals.

Some forms of care are by the legislator deliberately described generically, for example medical care. Apart from that, for the description of that care the formulation 'normally provided' is used. This way it is determined that 'medical care' should include care such as GP's and medical specialists normally provide. Furthermore, there is an extended designation that the care should meet the 'standard of care and daily practice'. Inpatient/specialist medical devices are covered by the insurable performance medical care and therefore fall into this category.

Generically described forms of care offer an open system of insurable performances. There is an automatic inflow and outflow of care to and from the basic package. Care normally provided by medical specialists that meets the standard of care and daily practice is part of the insurable performances. Innovative care that at a certain moment meets those conditions (fall under this generic header) becomes automatically an insurable performance. Prior verification and adjustment of regulations is therefore not necessary. The chosen legal wording as such makes sure that there is always an up-to-date insurance package that follows the latest developments.

As mentioned before, in the Zvw, the Bzv and the Rzv the nature, content and scope of the performances to insure are described and health insurance companies are obliged to translate these in their policies to insured performances. The performance descriptions in the policies are generically described and in the policies the standard of care and daily practice can be found as well as a boundary of the claims. It is primarily up to the health insurance company, according to ZIN, to decide whether a certain therapy falls into a category that is covered by the policy. Previously taken standpoints, from CVZ/ZIN, as reported in 2008 and 2012, are not perpetual valid. Developments from after that date of publication can lead to a new standpoint being taken. That means that the health insurance company at first decides for himself whether the conditions of the policy are met, including the question whether the care meets the standard of care and daily practice. To do so the health insurance company is obliged to research this.

Conclusion:
There is a system in order to reach a verdict about whether care can be reimbursed in the basic insurance or not. For reimbursed care the demands for reimbursement can be increased and applied stricter.

Policy of not reimbursing

Based on the aforementioned, health insurance companies can determine whether or not products or services can be reimbursed. A good example is the discussion of cutting the reimbursement for several wound care products.
Wound care products are part of the medical devices category Care products. Stoma care products are also part of this category. The actions, taken by health insurers in the years 2011 (introduction of request form) and 2012 (reassessment of standard of care and daily practice of wound dressing products) have led to a substantial decrease of the number of users and a, in itself, limited decrease of costs.

2010 Care product users:	1.320.400
2014	802.100

Expenses from €533 million to €515 million.

A survey from us in 2015 among 10 manufacturers of medical devices (8 for the outpatient market, 2 for the inpatient market) showed the following results:

To the question: What do you think will happen to your revenue when the reimbursement of your medical device and that of comparable medical devices is put to a stop?, the answer is:

Decline in sales of 0 to 5%:	1 company
Decline in sales of 50 to 70%:	2 companies
Decline in sales of 70 to 90%:	6 companies
Decline in sales of 100%:	1 company

To the question: What do you think will happen to your revenue when the reimbursement of your medical device is put to a stop and that of comparable devices is not put to a stop?, the answer is

Decline in sales of 0 to 50%:	0
Decline in sales of 50 to 70%:	2 companies
Decline in sales of 70 to 90%:	5 companies
Decline in sales of 100%:	3 companies

It is clear that manufacturers recognize the 'insurance effect'. As long as products are reimbursed there is a certain market, but no reimbursement means a substantial sales decline. But how will that work out?

Conclusion:
No reimbursement, no market.

Low burden of disease approach

Already in 2012 a discussion was started whether diseases with a low burden of disease can be considered a discomfort rather than a disease[4]. The thought behind this is that the expenses that come with a discomfort should be paid from one's own pocket. That way the collective expenditure for healthcare could be reduced. Based on research, a few conditions are appointed 'low burden of disease, including: urinary tract infections, urine incontinence, infertility, COPD, asthma, lung infection and acute bronchitis, upper respiratory tract infections, ear infection, hearing impairments, speech impairments, heart failure, ADHD, eczema and tooth loss. The discussion has not yet led to a package cutback because that is too big a step in the light of all objections:
Conjuncture of many low burdens of disease, up-coding, heavier diagnoses etc.

Improved diagnostics and more insight in predictability will in the years to come be linked to being able to take one's own responsibility. Low burden of disease, combined with individual responsibility will result in the inevitability of package cutbacks.

Conclusion:
What can be solved individually should be solved individually.

4. What can we expect? From health insurance to health finance

Cost control is necessary, politically necessary, so much is obvious. Package discussion is forthcoming, but it is not yet clear in which way the politics will choose to address that.

Risks are already no longer risks. Developments such as the availability of big-data, DNA-research and communication tools make better predictions and diagnostics possible. We know a person gets ill; only the 'when' is unknown yet.

What reimbursable care is, is broadly defined. There is an open package. The government and health insurance companies aim at outflow in order to keep the healthcare affordable in the long-term. Citizens will therefore have to pay more themselves, especially when they have an influence on the onset of the disease, for example smokers. Solidarity between rich and poor, healthy and sick, young and old, we think, is no longer to maintain because of the financial pressure of the large and expensive healthcare package. That is socially undesirable and makes compliance with treaties impossible.

Improvement of efficiency and the stipulation of lower prices do not contribute enough. Neither does the stopping of healthcare innovation. A change of thinking about people's own responsibility possibly does. The discussion about low burden of disease can then be broadened.

Based on our insights the following view of whether or not a product or service should be reimbursed, can be logically expected. A matrix of questions and answers that lead to an answer about reimbursement or individual responsibility.

[4] *Uitvoeringstoets lage ziektelast, College voor Zorgverzekeringen*, 5 maart 2012

The first question is: is the disease

a. Congenital
b. Learned
c. Affected

Congenital is obvious. Learned is for example alcohol abuse or smoking. Affected is something that is caused by a third party.

Is there subsequently within the chosen category a question of

1. Foreseeability
2. Preventability
3. Culpability

With the answer to these question it can be quickly determined whether there is a disease that should be funded from the collectively financed social insurance system or from individual funding.

Random examples are: a congenital disease, which was unforeseeable and unpreventable, should be funded from collective financing. A disease, detectable during pregnancy, which can be avoided, and the decision whether or not to do so, could make collective financing inapplicable. The consequences of smoking are also foreseeable, preventable and culpable, etc.

If the disease should be financed from individual funding there is a possibility of taking out a supplementary insurance, not compulsory and private. These insurance policies will be offered by commercial insurance companies and there will certainly be new parties that, based on 'population-related funding' will establish new, mutual guarantee associations.

In order to answer the questions of a disease being foreseeable, preventable and/or culpable, the individual level of knowledge will have to be accordingly. This calls for collective and individual education. This is prevention 2.0. Municipalities will have to take up this responsibility, especially because municipalities will remain to be the safety net for citizens in straitened circumstances. Investments will have to be made to indeed take individual responsibility where it is possible. In our opinion, informing people about new technological developments, that make it possible for citizens to make choices, will be the task of the municipalities and not that of the performers of the collective health insurance.

Municipalities will have to start acting because of the high costs and their own interest in healthy citizens. The costs are under high pressure and funds coming from the government are decreasing. People with minimum incomes and the weakest are hit hard by the personal contributions for Zvw and Wmo. This leads to more care avoiders and more discontent. Because of the participation law it is in the interest of the municipalities that citizens are healthy in order to work, be or stay active and stop unhealthy behaviour.

If even more care is appointed to the municipalities in future, like district nursing, mental health care and the aforementioned 'discomforts', it will be interesting for them to work together with other parties within the municipality, like employers, and develop their own policies and purchase healthcare. Municipalities can already see that people with their own forces, network and payment they can choose alternatives: it can be organised differently and less expensive. Where the network takes over discomforts and care, as can already be seen in religious municipalities, costs decrease while quality remains the same. Self-reliance and 'joint reliance' will therefore become increasingly commonplace.

The municipalities will keep their responsibility for the weakest. They can offer customized care herein. Since municipalities can get information about income and capital they can compensate citizens, that can no longer afford the personal contributions, excess and out of pocket, through poverty reduction policy, special welfare, taxes and other measures. That way they offer a safety net.

Employers will also start acting because of the high costs and their interest in healthy employees. They can start their own healthcare policies and ensure timely treatment and reimbursement of the products needed for productivity. They can join forces with the municipalities herein.
Municipalities and companies can make a stand together against health insurance companies and that way health insurance companies will become implementing organisations/administrative offices for municipalities and employers.

The healthcare package can subsist, collective financing (a national health fund will suffice for that) through premiums or taxes will be a remaining part of our social system. However, the question whether the individual responsibility can prevent an appeal to the collectively financed healthcare is easier to answer. The health insurance system will largely change into a healthcare financing system.

A national health fund for uninsurable risks, municipalities are responsible for prevention 2.0 and private providers of insurances for insurable risks will populate the future landscape. Not new, but certainly different.

5. Timeline, the 20s

Election programs are drafted for the Second chamber elections in Spring 2017. In the run-up to these elections there is no talk yet about difficult choices and, according to good use, heavy themes are not discussed now, but negotiated after the elections. Therefore, we expect that only in the second half of 2017 and in 2018 the theme of 'how to reform healthcare' will become an issue.

In 2018 the onset is given for changes that should get a majority in parliament in 2019. Changes will then gradually be introduced from 2020 onwards.

These changes will have been made complete in 2025.

Conclusion:
2020 is nearby. If an organisation wants to respond to a change from health insurance to healthcare financing or from a passive patient to an active consumer, one will have to take into account a transitional period of several years.

6. Consequences for our relations, manufacturers and distributors

It is well known that the average lead time from coming up with an idea for a new product until that product being embedded in the healthcare system, is 17 years. An idea that comes up in 2016 will be rooted in the system in 2033. However, we expect that the system will look completely different in 2033. The collective financing will be cut back to care in situations that are not foreseeable, preventable or culpable. Uninsurable care will have to be paid out of pocket. If we make the combination between low burden of disease an individual responsibility, many products and services will no longer be reimbursed. The end of reimbursement means (1) loss of the insurance effect and (2) a shift from the traditional distribution channels to the consumer market; from reimbursement to OTC.

Products that we expect to lose reimbursement are for example:

- Care products (stoma, incontinence, wound care)
- Orthosis and shoe provisions
- Auditory products
- Visual product
- Diabetes products
- Devices for the transport of blood or lymph
- Devices for the respiratory system
- Pharmaceuticals prescribed by GP's for low burden of disease
- Hospital care in case of low burden of disease

A reimbursement market knows passive patients. There is a prescriber, a contracting health insurer and a contracted distributor who must abide by commands and prohibitions.

An OTC market knows active costumers who are leading. He chooses where he buys what.

The difference is that the industry is now used to approaching prescribers and care providers and more or less specialised distributors in a clear and closed market. In the very near future, for a number of pharmaceuticals and devices there will have to be handled with the 'Carrefours and Bol.com's' of this world. Completely different and the lack of brand awareness will break many a manufacturer.

Things will also change in terms of regulation. For the collectively financed market, institutes such as NZa, ZIN and VWS will remain important and and so will acts such as Wmg, Zvw, Wmo and Wlz. To enter this market will become more and more difficult given the increasing demands and obligations.
For a consumer market, on the other hand, the Food and Drug administration and consumer regulations are important. Simpler, faster but also with more competition.

7. What needs to be done?

Manufacturers will have to get a focus, based on the change from the 'passive patient to active consumer'.

In the period 2020-2025 the collective financing will be reduced sharply and the own pocket payments will have increased correspondingly. It is a possibility to privately insure this healthcare and it is the interest of the insurance company to have something to insure. It is also in the interest of the manufacturer to have his products in the insurance. We can see a future cooperation of industry and insurance companies. It is necessary to invest in that relationship.

Given the different pathways in terms of regulation and reimbursement, for reimbursed and OTC products, a manufacturer will have to realise in time, that his marketing and sales model needs to be adjusted. That may involve a shift in staffing. A process of renewal of mind-set and workforce will take years and that time will really not be available.

Manufacturers will have to understand that the competition in the supermarket shelves is not the same as the battle for the health insurance contract, also that in the shelves it will be about the A brand and the generic store brand and not about the preference policy as we know now.

In short, a consumer market is still a black box for many companies.

Seijgraaf Consultancy and IHC sarl Switzerland shall move on the coming chances and will try to inform companies on boardroom level. Apart from that we will continue to offer the concrete services such as guidance in regulatory and reimbursement procedures. A new service is the guidance in the process to a consumer market, everything included.

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