**2018-06-20 Meeting between First Minister and Mr Eric Nordkamp (Pfizer)**

Attendees: First Minister, Mr Wheelhouse, Eric Nordkamp (Pfizer), Tracey Bowden (Pfizer)
Officials: Gordon Watt (CSO), Alison Strath (Medicines Policy)

Also in attendance: P/S FM, Davie Hutchison

Mr Nordkamp was interested to know how he could help to create and bring to life a Scottish life sciences industrial strategy. He was of a view that the best of examples of collaborative working came from small countries. FM agreed and acknowledged that it was easier to be agile and scale things up as a smaller country.

Mr Nordkamp used the example of Belgium where there was a pact between the pharmaceutical industry, academia and the Government which has facilitated partnership working, secured excellent market growth and prosperity and ensured a sustainable health care budget. He gave examples of how this had stimulated the growth of the bio-tech sector. Mr Nordkamp was keen to explore ways to deepen similar collaborations in Scotland. He offered to share the Belgium pact.

FM highlighted that the Life Sciences sector was a priority for Scottish Government. She described how, in Scotland, the sector had helped to identify and focus on areas to galvanise opportunities for joint working, including priority disease areas and stratified medicines. FM spoke about Scotland's strengths and expertise in data, including the availability of a comprehensive patient health record system. She flagged the recent announcement about the Medicines Manufacturing Innovation Centre (MMIC) which had also been financially supported by Astra Zeneca and GSK.

FM touched on her Government's priority to improve access to new medicines and to work more closely with the pharmaceutical industry and other stakeholders so that they could together tackle the big issues. This included ensuring that medicines costs were sustainable. In return, Mr Nordkamp welcomed opportunities for further collaboration.

Mr Wheelhouse described the purpose and focus of the Government's Industry Liaison Group (ILG) which he jointly chairs with Dave Tudor from GSK and of which Ms Campbell (Minister for Public Health) is also a member. He explained she makes the link across to health. He explained that there were specific work-streams and that the healthcare system was very much integral to the work programme.

Mr Nordkamp advised that he was very keen to hook into the ILG. He saw it as an opportunity to elevate Scotland within his and other company global head-quarters. He went on to say that he felt that it was generally more difficult to connect to the healthcare system in the UK.

FM acknowledged the challenges with integration however she also highlighted the progress that has been made in Scotland where integration is better than elsewhere in the UK - for example health and social care, and between industry, academia and health in terms of research.

Mr Nordkamp described the capacity challenges which often materialised during the implementation of service development and/or improvement. He shared the work Pfizer had contributed to in Swansea as part of their City Deal which focused on digital healthcare solutions, resulting in productivity increases. This has been achieved through developing a formal partnership.

He highlighted two areas that Pfizer would be keen to develop in Scotland:

- transforming the health care system using real world data (which had the potential to generate cost savings)
- Regenerative medicine (cell and gene therapy)

Mr Nordkamp went on to say that Pfizer was keen to be a partner in ensuring sustainable medicine costs, to actively connect to strengthen the economy and to share learning from other partnerships they were involved in.

**FM offered for Alison Strath to liaise Enterprise colleagues in order that Mr Wheelhouse and Ms Campbell can consider how to take forward these discussions in more formal way in order to align interest and thinking.**

Mr Nordkamp was of a view that how a country values innovation is very important. He was encouraged by the way Scotland dealt with its access to new medicines policy. He said he was a stronger supporter of SMC. He went on to highlight some of the areas where he thought Scotland was leading the way: including the patient perspective; the use of flexibilities; ultra-orphan medicines. He also advised that whilst he had concerns initially about the Single National Formulary, he now understood what Scotland was seeking to do and was on board with the principles. In return he acknowledged that the Pharmaceutical Industry needed to deliver on their side and that included being fair about the price.

FM highlighted rare diseases and the assessment of orphan and ultra-orphan medicines as being a challenging area. She went on to say that whilst it was difficult to create the perfect system, SG tried to get it as right as possible. She was a view that it was about being pragmatic.

Mr Nordkamp shared that he was Chair of the American Pharmaceutical Group (APG). He had facilitated dialogue and engagement between the group and UK Ministers and was keen to do something similar in Scotland.

Mr Nordkamp could see from his visit today that Scotland had potential. However, he hadn't previously known about what was being done and the opportunities. He suggested that Scottish Government should be doing more to make companies aware of what is happening in Scotland and the opportunities for collaboration. Scotland's outputs were never discussed elsewhere in the UK.

FM suggested that one option might be for Mr Nordkamp to present to the ILG to help make those strategic connections.

Mr Wheelhouse advised that work was underway to review the communications and marketing budgets and that Mr Nordkamp's comments and feedback would be helpful in informing some of those decisions.

Mr Nordkamp thanked the FM and Mr Wheelhouse for their time. He reaffirmed his commitment to ensure a more focused discussion on areas of joint interest and to raise awareness with his Board and others about the opportunities to link and work more collaboratively with Scotland.

**Medicines Policy Team**
**21 June 2018**

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## Worldwide Biopharmaceutical Businesses

The First Minister
The Scottish Government
St Andrew's House
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18th July 2018

Dear First Minister,

I wanted to take this opportunity to thank you for your time during my visit to Edinburgh.

As I mentioned in our meeting, I was hugely impressed with Edinburgh BioQuarter. The vision behind the partnership between Scottish Enterprise, the City of Edinburgh Council, the University of Edinburgh and NHS Lothian is impressive, and has the potential to establish Scotland as a global leader.

The ability to create a link between the NHS, academia and pharmaceuticals is the foundation for improving health outcomes. The presence of this type of link led to our investment in Wales, in collaboration with Swansea University, and I am satisfied that those same conditions exist in Scotland, at BioQuarter.

I have committed with the team at BioQuarter to explore the opportunities further.

A critical factor in the success of any such investment is to analyse the successes and failures of similar collaborations in comparable countries. With that in mind, as we discussed, I have enclosed with this note (electronic copy only) details on the relationship between the government, the health service and the pharmaceuticals industry in Belgium. I consider Belgium to be the European leader in collaborative working.

I intend to monitor Scotland closely and do hope that we can meet again to discuss progress the next time I am in Edinburgh or alternatively arrange a visit to our project in Swansea.

I followed your reshuffle with interest, and I look forward to also engaging with Ms Freeman and Mr Mackay in due course.

Yours sincerely,

[redacted]

Erik Nordkamp
Managing Director, Pfizer UK

# *Pact of the Future*
# *for the patient*
# *with the pharmaceutical industry*

**Pact signed by the Belgian Minister of Health Maggie De Block, with representatives of the industry associations in Belgium.**
**Brussels, July 27th 2015**

## Foreword

This Pact of the Future with the pharmaceutical industry is all about the patient. Medicines are literally a vital link in the therapeutic process. I want to ensure that patients continue to have access to the best medical care and that medicines meet the highest quality standards. Medicines must be as effective as possible, and in Belgium, we must continue to have access to the most innovative therapies.

We can only achieve that aim through an innovative pharmaceutical industry that invests in research and development (R&D), in safety and in unmet medical needs. Fortunately, Belgium is a fertile terrain for pharmaceutical innovation. We have reaped the rewards of an excellent collaboration between our knowledge centres, the high quality of our medical care, an advantageous tax system that reduces the cost of R&D, our culture of permanent dialogue between industry and the government, etc. The figures speak for themselves: this sector accounts for 35,000 direct high-skilled jobs and 11.2% of our export. Each year more than 170,000 Belgian patients receive early access to innovative medicines by participating in clinical trials. In this regard, we are the absolute leaders within Europe and rank second in the world. In many cases, participation in clinical trials is the last hope for patients to extend their life expectancy, improve their quality of life or even have a chance of recovery. Moreover, many Belgian academics have achieved worldwide recognition as scientific leaders precisely thanks to their involvement in such clinical studies. The Belgian hospitals receive severaltens of millions of euros per year for participating in clinical trials.

But we cannot remain complacent. Nothing guarantees that we will be able to maintain this privileged position. Technological progress is nothing short of spectacular. Recent breakthroughs in ATMP and cell therapy, and the potential of nanotechnology and biotechnology, are opening the door to diagnostic and therapeutic options that would have been unimaginable only a few years ago. There has been a lot of discussion about personalised medicine and the potential for treatment of very rare diseases has risen considerably. That is a good thing, for with the benefit of genotyping, some people say that all disorders will *de facto* become very rare, because of the individualisation of treatments.

In the next 4 years we will set aside 1.4 billion euros for innovative products by enhancing the efficiency of the system by, among other things, injecting more competition into the post-patent market. Every euro we spend on medicines must deliver optimal health gains. Belgium in fact uses a unique operational model for the pharmaceutical market. As Minister, I will ensure that, both the companies that bring the original medicines to market and those that produce generics and biosimilars, can operate here within a sustainable framework. The manufacturers of generics are also very important in order to secure the necessary competition on the market, thus pushing the prices down.

The development of potential wonder medicines, niche medicines and biomarkers come with a price tag. These innovations oblige us to think about new financing and reimbursement vehicles. I will therefore have to make room within my budget to ensure that innovative and often lifesaving medicines with proven effectiveness reach the patient. The solidarity of our system must work for everyone.

In addition, increasing amounts of investment are going to the emerging markets. This competition is healthy and keeps us on our toes, but also means that we have to improve our system constantly in order to remain competitive. The Clinical Trials Regulation could lead to an erosion of our lead over our European partners, but can also serve as a lever to consolidate and strengthen our top position.

In short, we face important challenges and must take the necessary measures in the interests of the patient.
The government must rise to the challenges of the coming years.
The industry needs perspective and predictability.
These, in a nutshell, are the goals of this Pact of the Future.

First of all, this pact strives for greater patient access to innovative therapies. This is the most important aim of this agreement. More international, and especially European, collaboration is one of the guiding themes of the pact. In addition, we will more than halve the portion of the price of medicines borne by the patient, so that the entire patient bill will fall by more than 50 million euros in the coming years. We will shorten a number of procedures so that innovative medicines can reach the patient sooner, among others via greater international and European cooperation and better use of risk-sharing agreements. A knowledge system will be developed for patient registers, and we are looking for an adequate answer to the problem of shortages. Patient Support Programmes will be continued and expanded, and we guarantee independent and high-quality information about medicines. Finally, we are looking into whether the simultaneous reimbursement of predictive tests carried out prior to a medicinal treatment is feasible.

Innovation is the cornerstone of the second pillar of this Pact of the Future. Investing in innovation today is a form of insurance against the illnesses of tomorrow. We are devoting all our efforts to a *big data* and *real-world data* strategy in order to be in a better position to separate the wheat from the chaff. Orphan medicines are a key element of my policy. In consultation with the pharmaceutical industry, a new business model will be developed that guarantees both the production of older and the development of new antibiotics and other anti-infective agents. With regard to clinical trials, we are developing in consultation with the hospitals, the Federal Agency for Medicines and Health Products (FAMHP) and the industry, a strategic plan in order to hold on to our 'yellow jersey' within Europe. Recruiting patients is facilitated by the establishment of shared and communicating registers and by means of legislation anticipating the latest technological developments for patient recruitment. A clear legal framework is being created for biobanks that fosters both the development and the production by the industry of advanced therapy medicinal products (ATMPs), including those bearing an orphan medicine designation. C*entres of excellence* are being set up, including for vaccines, an area in which Belgium is considered a world leader.

Thirdly, we want to draw up a new ethical framework for the industry. How do we organise our interactions? What practices need to be reined in? A few examples: my staff and I will no longer meet with representatives of companies while scientific and evaluation procedures are in progress. All results of clinical trials will have to be published on a centralised portal, and any conflicts of interest will have to be reported in advance. Finally, strict rules of transparency will be imposed via the BeTransparent.be project.

The capstone of this Pact of the Future is a multi-year budgetary framework and accompanying growth path. This is a unique approach which offers the industry perspective and predictability. At the same time, the industry contributes to the efforts at budget control included in the government coalition agreement.

The pharmaceutical industry makes an extraordinary contribution to the health of Belgians and of the Belgian economy. With this Pact of the Future, I would like that to continue and to be further strengthened for the coming generations.

**Maggie De Block**
Minister of Social Affairs and Public Health

## 1. Accessibility

Access to care is one of the basic pillars of health care policy.

That is why this Pact strives first of all for greater patient access to innovative therapies., This is the most important objective of this agreement. As mentioned in the foreword, Belgium currently holds a top position in the world within the innovative pharmaceutical industry. Therefore we must also maintain our ambition of being a pioneer within Europe with regard to patient access to innovative medicines and of The government commits itself to fulfil this ambition, and to that end will conduct **analyses** at regular intervals, in cooperation with all stakeholders, to determine **the extent to which Belgian patients have access to innovative medicines**, as compared to those in other European countries. A working group may develop a methodology for this purpose. The results will enable the government to evaluate its policy, based on the data obtained, and to make adjustments where necessary. Moreover, this analysis will be a regular agenda item for the semi-annual bilateral consultation between the Minister and the innovative pharmaceutical industry.

In addition to these aims, the pact is intended to attain a number of other objectives or identify pathways that can be grouped under the following headings:

- Supporting the patient in accessing care
- Patient access to innovative medicines
- Effective use of medicines
- Availability of medicines

### 1.1. Supporting the patient in accessing care

Health care begins and ends with the patient. The cost to be borne by the patient is thus an important aspect. Via the first package of measures implemented in 2015[1], the total bill to patients has been reduced by 23 million euros. The measures taken in this Pact will reduce the cost of medicines paid by patients by a further 30 million euros. In other words: **patients save more than 50 million euros** in structural terms.

The ***safety margin*** **will be limited to 5 euros** instead of the current 10.8 euros. As well, the ***Patient Support Programmes*** will be continued and extended in collaboration with the National Institute for Health and Disability Insurance (NIHDI) and the Federal Medicines Agency (FAMHP). This joint effort will take the form of a generic "memorandum" in collaboration with the sector, the FAMHP and the NIHDI. Patient Support Programmes will also be included in the evaluation of the user-friendliness and added value of new medicines.

[1] A price reduction of 6.5% for medicines to which the standard referencereimbursement system applies for 6 years, Price ceiling for escitalopram, telmisartan, anti-Alzheimer drugs, the most inexpensive prescription rule.

## 1.2. Access to innovative medicines

*1.2.1. Accessible innovation*

Both the actual availability of innovation and the speed with which it is made available to Belgian patients are important considerations here.

Medicines that are approved for reimbursement by the Minister for Social Affairs and Public Health, after they have gone through the reimbursement process, will be reimbursed as soon as possible after notification. Taking into account a minimum period for updating the ICT systems for the pricing services, reimbursements will come into effect as soon as the positive decision has been published on the website of the NIHDI, as is already the case for implants. **This means that innovations will reach the patient at least two months sooner.** The law will be amended to this effect.

It is important that new medicines that have been approved at European level or in another EU Member State should become available to Belgian patients as quickly as possible. For that reason, the government will continue to improve the existing procedures by further reducing the waiting periods wherever possible and by avoiding **that work that has been done at other (international) levels will be repeated**. With regard to innovative ideas for earlier access to innovative medicines and the collaboration with health technology assessment (HTA) organisations, it is important that the FAMHP plays a leadership role both at the level of the European Commission and in the Consilium.

The regulatory framework for this aspect will be evaluated and if necessary adjusted in order to make this possible. This can be done, for example, by systematic use of the relevant elements of European assessment documents (in this case the (draft) EPAR) for clinical evaluation of medicines for reimbursement. The aim is to limit, wherever possible, local repetition of data analysis that has already been carried out by the European Medicines Agency (EMA), taking into account of course the limited scope of the latter (this does not apply, in particular, to an HTA or an analysis of relative effectiveness). Another approach is to **shorten**, as far as possible, **the time** taken for the entire reimbursement procedure, by limiting wherever possible the evaluation of medicines that have been through the ETA/ETR procedure to the new data and knowledge gathered during the period of the temporary authorisation for reimbursement. The declaration of intent that Belgium has entered into with The Netherlands for greater collaboration in the reimbursement of orphan medicines (see 1.2.3.) will make it possible to shorten the time taken by the Belgian reimbursement procedure, by harmonising it with that of The Netherlands.

In addition, we are also investigating the conditions under which Class 2 and 3 dossiers could be handled within the NIHDI administration, as a result of which the procedure could be simplified and the time to reimbursement reduced.

In order to continue to guarantee patients' access to innovation, the industry is encouraged to submit dossiers for the **extension of indications for market authorisation and reimbursement**. To this end, an innovation-stimulating method will be developed that will help foster a more objective pricing, related to the product's clinical value and the number of patients treated.

With regard to risk-sharing agreements (article 81), the government's policy will be to encourage **contracts that place health results for the patient at the centre ('Pay for Performance')**, rather than purely financial agreements. This approach is in line with the general policy approach taken by the Minister, which focuses on maximising the quality of patient care. To make this possible, we will proceed with the creation of a framework in which existing data systems (invoicing systems, registers, etc.) could be used for data collection in the context of reimbursement procedures. The anonymity of patient data will be safeguarded at all times, and patient privacy will be guaranteed. The confidentiality of the annexes to these agreements, which often contain sensitive company-specific information, will be protected and enrolled in law. Such confidentiality cannot be an obstacle to joint initiatives with one or more other countries in respect of the reimbursement of a medicine, considering the NIHDI and the foreign authorities responsible for reimbursement respect that confidentiality.

Access to new, innovative medicines in hospitals will be guaranteed by keeping these medicines – as is already largely the case today - outside of the flat rate paid to hospitals, on the basis of evidence-based medical criteria. The guidelines for establishing the type of medicines concerned are being determined in consultation with the Commission for Reimbursement of Medicines (CRM).

In addition, there are a number of plans of a more administrative or organisational nature, which can also be important for patients' access to innovation. As such, we are examining whether **simultaneous reimbursement of predictive tests (biomarkers) carried out prior to treatment with medicine** is feasible. We are also looking into whether prescribing of certain complex and expensive medicines can be reserved to a number of centres of diagnostic expertise. A framework will be created to define and homologate the centres of expertise, where necessary in consultation with Belgium's Communities. Furthermore, there are plans to register low-cost off-patent cancer drugs in chapter 1, allowing these medicines to be exempted from "chapter 4 procedures". A solution will also be sought for monitoring

and follow-up of the use of these medicines, with a view to continuing to guarantee that they are used in a medically responsible and rational manner.

*1.2.2. Focus on unmet medical needs*

Belgium will strive to develop, in collaboration **with other Member States and the EMA, criteria that prioritise indications for areas with the greatest unmet medical needs**, in order to foster research in these domains. There will be a consultation with the Member States, in the context of preparing a long-term agenda for better innovation in the interests of patients, to which the European Council committed itself on 1.12.2014, for example in view of launching the "prioritising orphan designations" project during the EU presidencies of Luxembourg (2/2015) and The Netherlands (1/2016). Belgium will aim, among other things, to set up pilot projects for joint negotiations between Member States and companies with regard to prices and reimbursement, in particular in the case of orphan medicines. The industry will contribute actively and examine, in consultation with the government, how valuable pilot projects with regard to research and with regard to reimbursement could be initiated.

Furthermore, the **new procedure for unmet medical needs** will be evaluated at the end of 2016 and, depending on the result of the evaluation, the procedure and the budget will be adjusted. As well, based on the recommendations of the study by the Belgian Health Care Knowledge Centre (KCE) on off-label use, it will be examined how this new procedure can be implemented, with regard to off-label use of medicines for unmet medical needs.

*1.2.3. Focus on orphan medicines*

We are working on a more **international approach to orphan medicines.** Our country has announced more intense collaboration with The Netherlands in this area, and also wishes to investigate the possibility of further collaboration within Europe (including with regard to negotiations).

The need for approval for reimbursement via the College of medical doctors for orphan medicines will be limited to cases where a **simple electronic authorisation system** cannot provide a solution. Applications for the reimbursement of orphan medicines for which the intervention of such a college continues to be necessary could be linked to electronic data collection (similar to the Tardis system).

Orphan medicines that still meet the orphan drug definition after the 10-year period is over, will continue to be eligible for the **reduced levy on orphan medicines**.

The **market exclusivity** for which orphan medicines are eligible, has served as a stimulus for developing new pharmaceutical specialities. In some cases, certain companies abuse that

exclusivity, which can give rise to pernicious effects. For this reason we are looking into whether the conditions for granting that exclusivity are still sufficiently decisive, and how this issue could be addressed at European level.

### 1.3. Effectiveness

In line with the government coalition agreement, physicians will be encouraged to be more focused on effectiveness in their prescribing of medicines, as regards both the price and the volume. Since 1 January 2015, the definition of "cheap medicine prescribing" has been revised. The aim is to encourage practitioners to prescribe the cheapest medicines for their patients, so that the patient will have to pay less for the medicine and the government will have more resources left over to invest in, amongst others, innovation. In 2016, the system will be evaluated one year after its launch: have physicians succeeded in attaining the new quota of 'prescribing the cheapest medicines'? Do we have to adjust the quota?

More objective information will be provided to prescribers, in collaboration among others with EBMPracticeNet via **electronic decision-support systems**, and we are examining whether incentives could be attached to effective changes in prescribing practice in favour of cheap prescribing, without hampering the diagnostic and therapeutic freedom of prescribers, which is also confirmed in the government coalition agreement. This will be done, as provided for in the 2015 'medico-mut agreement', on the basis of the conclusions from the special conference on rational prescribing and good use of medicines that will also investigate the necessary indicators to be developed for the purpose. Thereafter, a working group will be established, chaired by an academic expert chosen by consensus and composed of representatives of prescribers (health care providers), the government and the pharmaceutical industry. This working group on 'effective prescribing' will draw up an initial proposal for the Minister of Social Affairs and Public Health by 1 September 2016.

**Competition on the off-patent market** will be tightened in order to achieve lower prices on behalf of the patient and the health insurance, while ensuring that this has no negative effect on the availability of medicines. In a number of specific cases, the conditions for reimbursement of a number of in-patent medicines could also be reviewed, based on arguments regarding their therapeutic value and cost effectiveness, in line with evidence-based medicine. Products with equivalent effectiveness within ATC-5 will have to meet the same reimbursement conditions.

A **knowledge system of patient registries** will be developed to make possible reciprocal communication between registers, similar to the model of the more efficient gathering of epidemiological data via healthdata.be, based on recommendations of EMA and of European Member States, in collaboration with our EU partners, and maintaining respect for privacy.

Finally, we are also investing in simple **decision-supporting applications** for prescribers and patients, whichwill be integrated into the software packages used by health care providers as well as into the Electronic Patient Dossier or users' smartphones. Applications that enhance therapeutic adherence should be considered a quality-enhancing feature of an application for reimbursement.

### 1.4. Availability

An appropriate solution will be sought for the problem of shortages and unavailable medicines. In the meantime, a central **interactive portal** will be integrated within the FAMHP, intended to make more efficient management and communication regarding unavailabilities possible. ICT systems that can reduce the risk of shortages can count on the necessary political and administrative support.

The pharmaceutical industry will make every effort to supply the Belgian market in order to minimise shortages of stock for Belgian patients. In addition, the Minister will see to it that all other actors within the distribution chain of medicines contribute to this objective.

Since the legislation on public tendering now applies to hospitals, the manufacturers of medicines that are intended specifically/principally for use in a hospital setting sometimes do not sell any medicines for more than a year if they fail to obtain such hospital contracts. In order to **prevent these medicines from being subsequently deleted from the list of medicines eligible for reimbursement** and thus no longer being able to participate in a following government call for tenders, an exception must be provided to the automatic deletion from the reimbursement list of these medicines after one year of unavailability. This period shall be extended to 5 years.

## 2. Growth and innovation

We must have the ambition to develop a patient-friendly and innovation-driven environment within the European context. Three policy priorities are directed to achieving this end: guaranteeing a stable, predictable and reliable environment, keeping up with developments elsewhere in Europe and supporting innovation.

### 2.1. Biotech

Our country is a model in the field of biotech policy, according to the OECD. We are praised for the quality of our higher education and close collaboration with the industry. The Flemish Institute for Biotechnology (VIB) brings together 1,300 scientists and is the absolute world leader in the field of basic research. In addition, thanks to the appropriate fiscal stimulus, we have been able to attract the capital and investments that make possible the rise of Belgium, the country of biotech. While in 1990, Belgium had 2 'life sciences' companies, today there are more than 120. A study by KBC calculated that the entire sector is worth more than 11 billion euros, representing a 30% market share in Europe and more than 30,000 high-skilled jobs. We want to keep it that way and do even better.

In order to create a stable regulatory framework and to support and promote the R&D activities of the innovative Belgian pharmaceutical sector, the "**Biopharma R&D consultation platform**" that brings together the government, representatives of the major pharmaceutical investors (HST), and pharma.be, will be continued. A working group, in which the NIHDI and the Federal Public Service Economy are represented, will examine the **transparency of the prices of medicines**. The price of a medicine at the time of the submission of its dossier for pricing and reimbursement will take into consideration not only all the COGs (Cost of goods), but also the prior investments in research.

The **fiscal measures** that have enabled innovation will be maintained and, upon examination and evaluation, possibly further strengthened or extended. These measures include the existing 80% tax-exemption on movables for researchers, the existing tax deduction for patent revenues ('patent box'), the existing system of tax modulation on the sales levy on reimbursed medicines (in consultation with Europe), and the existing exemption from the sales levy for orphan medicines. In addition, in consultation with the Minister of Finance and the government, the introduction of a **biotech tax shelter** for the early development phase will be considered.

A central contact point for start-ups and SMEs will be developed so that biotech spin-offs and start-ups may obtain the necessary **regulatory support** for the development of their activities. To this end, the FAMHP will set up a national innovation office, in a network with EMA and other national agencies. The Minister for SMEs will be consulted for this purpose.

**Human body material** is an essential instrument for the research and development conducted by biotech companies seeking innovative medicines for "unmet medical needs". The existing legal framework for biobanks will therefore be evaluated and improved, in order to consolidate the future of R&D based on human body material in both public and private settings in Belgium. Greater sharing of samples of human body material from academic biobanks with industry, and vice versa, will be instituted in order to optimise their use in R&D. The European BBMRI initiative, aimed at improving the harmonisation of research with biological body material and making that material more readily accessible, is an example of this effort, as are tumour biobanks.

After evaluation, a clear legal framework will be created to stimulate and develop the **production by the industry of advanced therapy medicinal products** (ATMPs), including those designated as orphan medicines. Specific cases may receive a "hospital exception". The standards to which the ATMPs produced in hospitals must fulfil, have to be set out in an implementing decree, with a view to guaranteeing the quality, safety and effectiveness of ATMPs.

### 2.2. Observatory

The innovative pharmaceutical industry in Belgium is one of the best in the world. But that is no reason for complacency. Other (European) countries are determined to attract more of this innovative industry. If we wish to maintain and strengthen the innovative pharmaceutical industry in Belgium, we must **continually monitor its competitive position**.

For this reason, in consultation with the Ministers of Finance and of Economy, we shallestablish a working group known as the "Pharmaceutical industry observatory", which will look into the possibility of designing an instrument to analyse, observe and monitor the added value of the various industry segments, based on which recommendations can be made for optimising our position on the world market.

### 2.3. Leader in clinical trials

It is essential for Belgium to remain the European leader in the area of clinical trials. Various initiatives need to be taken to this end. The **expertise of the FAMHP** for a fast evaluation and authorisation of requests for clinical studies **will be further strengthened**. We will do everything possible to secure recognition for the FAMHP by 1 July 2016 as "preferred reporting member state" within Europe for multinational clinical trials for specific syndromes. The competitive environment for phase 1 (mono-national) clinical trials will be enhanced, given that today we have the **fastest approval times** for phase 1 studies within Europe and already enjoy a good collaborative relationship with sponsors and the FAMHP. We will develop a unique representation of ethics committees. Moreover, we will have to look at the extent to which the **patient's voice** can be represented on ethics committees. The

procedures (applications, protocols, advice, etc.) will be streamlined. **Simplified systems** will be introduced for a coordinated evaluation by the FAMHP and the ethics committees. The recruitment of patients will be simplified, among other things by harmonising **registers and databases with each other,** via the creation of a collaborative network of specialised centres or via the availability of centralised information on ongoing clinical trials in Belgium. The government will support a pilot project running in all university hospitals in which electronic **patient dossiers, with the necessary guarantees for privacy, will be scanned automatically**. If this project receives a positive evaluation, the federal government will begin working on designing a legal framework.

In addition, a constant dialogue will be held between the government (FAMHP, NIHDI, and KCE), the innovative medicines industry and the academic centres with respect to research into medicines and innovative applications that meet the criteria for clinical research and 'unmet medical need'. Moreover, as recommended by the KCE, independent clinical research with a focus on orphan medicines will be encouraged.

### 2.4. 'Open, Big and Real-world Data'

Based on a needs analysis, it will be investigated how the industry may gain access to anonymised data on the use of medicines and health care for the purpose of scientific epidemiological research. The possibility of **using databases** (such as for instance farmanet or the permanent sampling by the inter-mutual agency IMA-AIM) for purposes of data collection, for example in the course of a reimbursement application procedure, and after irreversible anonymisation (and thus only on the basis of a specific information need), will be examined and rolled out. This will be done on the basis of a protocol to be evaluated, for each application, by a 'trusted third party' to determine whether the data available make it possible to provide a relevant answer to the question being posed. We will ensure that these requests shall be addressed quickly and at cost.

There has been a lot of discussion about personalised medicine and the potential for treatment of very rare diseases has risen considerably. That is a good thing, for with the benefit of genotyping, some people say that all disorders will *de facto* become very rare because of the individualisation of treatments. But that means that it is becoming ever more costly and difficult to find sufficient numbers of participants in clinical trials of therapies targeting very specific patient groups. In line with the recommendations, among others, of the EMA, we therefore encourage conditional reimbursement agreements (could be further refined, for instance, within the framework of the article 81 procedure) that place **less emphasis on data from clinical trials and more on real-world data**. Support will therefore be given to systems that can collect and disclose such real-world data in an anonymised manner that fully respects privacy. This does not, of course, detract from our commitment, as already stated, to remain an attractive country to perform clinical trials.

### 2.5. The spearhead field of vaccinology

The "Vaccine centre of excellence" as a spearhead field is intended to develop into a reference institution within Europe. This means, among other things, organising **clinical cohort research**, partly by setting up a **one-stop shop**, as well as by an optimised system for recruiting patients/volunteers. Other components of this plan include the establishment of national registers, thanks to which the vaccinated cohorts (also in 'real life') will be monitored during the entire lifetime of the patient/volunteer and a **state-of-the-art vaccination vigilance** will be developed, allowing the results to be used globally.

### 2.6. Rational use of antibiotics

Following the lead of the World Health Organisation (WHO), initiatives will be developed to promote the rational use of antibiotics (for human and animal use). In consultation with the pharmaceutical industry, BAPCOC, AMCRA and if possible in collaboration with other member states, a **new business model will be developed that guarantees both the production of older and the development of new antibiotics** and other anti-infective agents. The sector will also be involved in designing this new business model. A data collection system, managed by the government, will be developed for this purpose.

## 3. Ethical framework

### 3.1. General

Medicines contribute to the highest human good: health and quality of life. It is the social role of the pharmaceutical industry to bring the people and the financial resources together in a sustainable manner to conduct research into medicines, to develop them, to manufacture them and to bring them to market.

It is precisely this task that puts the pharmaceutical industry in a position of social tension: the medicines it commercializes have to do with what is most precious to us; their purchasing is, moreover, financed to a large extent with public funds, alongside the personal contribution of the patient. In order to be successful and to be able to survive, pharmaceutical companies often have to make major investments and take considerable risks.

Therefore, it is no coincidence that since the 1960s, the pharmaceutical **sector is one of the most highly regulated sectors in the world**. The strict registration procedure is meant to guarantee that every medicine brought to market in the EU is safe, of high quality and effective.

Next to that, the pharmaceutical industry itself has taken more and more initiatives of self-regulation over the past few years. Many sectoral organisations have thus draw up their own **codes of professional ethics**, for example regarding the information on and promotion of medicines which they bring to market. Self-regulation has the advantage of being quick, cost-effective, flexible and able to operate in a well-informed manner. A typical example of this is the Belgian Mdeon platform. Mdeon succeeds each year in handling around 6,000 requests for approval ("visas") within 5 working days. All stakeholders agree that Mdeon has made a significant contribution to improving the quality of the scientific events supported or organised by Belgian pharmaceutical companies. The Belgian Mdeon model is unique in Europe.

Over the years, the understanding has grown that self-regulation within the sector can be complementary to the role of government. This conviction has found expression, for example, in the creation in 2013 of the "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector". That text came into existence under the auspices of the EU and was co-signed by EFPIA and EGA, the European umbrella organisations to which pharma.be and FebelGen belong.

Self-regulation is characterised by a proximity that a government oversight body can never attain. Conversely, self-regulation comes up against a number of limitations, in particular because it cannot intervene with companies that do not consider themselves bound by it. It is precisely on this point that the government can be – and must be – complementary in its

approach, by establishing **a general binding framework and sanctioning any actors that do not submit to self-regulation.** At the same time, the government must ensure that the self-regulation works as it should. In Belgium, this is done for example by providing an official recognition to Mdeon; this recognition can, however, always be revised by the government.

The year 2015 has not, of course, seen the completion of this project. Although the vast majority of the pharmaceutical companies act in an ethical manner, a number of incidents, both here and abroad, have unfortunately demonstrated that some enterprises are not able to deal appropriately with the areas of social tension in which they are involved. The environment is also changing at lightning speed. To give one example: whereas until about five years ago patient organisations were almost unknown actors in health care, today they have evolved into fully fledged opinion leaders with whom the pharma companies aim to have good working relationships.

In what follows, a number of general principles, measures and action plans have been formulated with regard to specific areas of concern which have come to the fore in the past few years. All these suggestions fit within the efforts at complementarity between the ethical, self-regulatory approach of the industry on the one hand and the monitoring and, where necessary, sanctioning role of the government on the other hand.

### 3.2. The patient as the ultimate ethical touchstone

Although the social, economic, scientific and societal context in which pharmaceutical companies must operate is highly complex, the signatories nevertheless agree that the **ultimate ethical touchstone for their own behaviour and that of their members must be the interest of the patient**. The objective must be that the individual patient, as well as all present and future patients must be able to enjoy the best possible treatment.

### 3.3. Maximum transparency

The workings of the pharmaceutical industry must be made more transparent. Both self-regulation and the legislative framework are being strengthened. Pharmaceutical companies are therefore showing **maximum transparency** in their relations with health care workers and their organisations, health care institutions (such as hospitals), patients and patient associations. As this is the case in every economic sector, it is therefore to be expected that the pharmaceutical industry engages in relations with actors from its own environment. But society rightfully expects the pharmaceutical industry to be transparent about this. That is possible, for instance, by publishing on a centralised portal all donations made by the pharmaceutical companies to patient associations.

Transparency must also apply to all 'Transfers of Value' made directly or indirectly, in cash or in kind or in any other manner, to the persons or organisations mentioned above. Goods, services or personnel who are the subject of a transfer of value are also subject to the requirement of transparency. Transparency may not be undermined by maximising legislative

or other legal boundaries. **Where there are several legal options, preference is to be given to the option with the greatest transparency.**

The **multi-stakeholder platform** BeTransparent.be will serve to implement transparency in the transfer of value. The public will be able to consult the data made available via the portal of BeTransparent.be. The BeTransparent.be portal works on the principle of self-regulation. As has been the case with Mdeon, self-regulation via BeTransparent.be will also be endowed with a legal framework so that the government can have the necessary assurance that it is working appropriately, and can ensure that transparency is mandatory for all pharmaceutical companies. The law will lay down, among other things, the conditions for recognition for BeTransparent.be. The functioning of BeTransparent.be will be subject to regular audit.

All partners will endeavour to limit any additional administrative procedures to a minimum.

### 3.4. Conflicts of interest

The pharmaceutical science can only make progress if there is continuous interaction between the pharmaceutical industry on the one hand, and academics, health workers, patients and other stakeholders on the other hand.

However, a conflict of interest can arise if the above-mentioned persons - with whom the pharmaceutical industry maintains professional relations - also sit in official bodies that must decide about, or give advice on, the safety, efficacy, effectiveness, price, reimbursement, cost-effectiveness or any other characteristic of a medicine.

The point of departure of this pact is that, if a person has a real or alleged conflict of interest in a certain medicine dossier, he may not participate in the voting on it. However, one must deal carefully with this point of departure, since there are different **degrees in conflicts of interest**. It is also a fact that the (top) scientific expertise is very limited in certain research areas. A proper balance has to be found. The policy conducted by the EMA on the subject via its ´European Medicines Agency policy on the handling of declarations of interests of scientific committees´ members and experts´ can serve as a reference point here.

First of all, in order to make this nuanced approach possible, it is necessary that **all persons sitting in an official body (e.g. CRM, Medicines Commission) must make in advance, and periodically, a detailed statement on the direct and indirect interests that they may have in pharmaceutical companies**. They must not be allowed to sit in the involved body, as long as this declaration of interests has not been made (and has not been validated)..

Notification of conflicts of interest must also be done in the case of ad hoc consultation with the Minister or other policy makers, as well as with other government authorities such as the

FAMHP and the NIHDI. A **special procedure** must also be provided **in case of a breach of trust**, like the one that is also used at the EMA.

### 3.5. Clinical trials

For pharmaceutical science to progress, it is important that **all results of clinical trials are published**, even when they are negative or unfavourable. All results of clinical trials shall therefore be made known via a centralised portal, within reasonable periods; the ´raw data´ will also be made available on request; data related to the safety of the medicinal product will be reported in a transparent manner and in such a way that they are clinically relevant. In order to ensure coherence, one will strive as much as possible to adopt a **European approach**, taking the ´only once principle´ into account.

### 3.6. High-quality information

*3.6.1. General*

The **information on medicines may only encourage their rational use** and must correspond to their marketing authorisation. The publication of the patients leaflets by the FAMHP must be further optimised along these lines, amongst other things via user-friendly apps. The information on medicines must be based on observations that are accurate, objective, complete, honest and verifiable. The elements substantiating the information must be communicated to each stakeholder who submits a reasonable request for this, without prejudice to the legal provisions.

*3.6.2. Medical information agents*

Medical information agents play a key role in the dissemination of information on medicines amongst health workers. Medical information agents must be adequately trained by the company where they are employed and must possess sufficient health-economic and medical-pharmaceutical knowledge in order to provide information that is accurate and as complete as possible about the medicines they represent.

Therefore, a method will be developed in consultation with the pharmaceutical sector, in order to further optimise the **quality control on the information provided**; the internal delegation of responsibility within the companies is being further developed, for example by analogy with currently-existing mechanisms for pharmacovigilance.

*3.6.3. Advertising for self-care medicines: better protection of the patient*

Under currently-applicable legislation, pharmaceutical companies may also engage in advertising for their products amongst the general public, at least when it involves self-care medicines (advertising amongst the general public is prohibited for medicines requiring a prescription). This public advertising is regulatorily embedded within a very detailed framework, of which one may fairly ask whether it actually serves the interests of the patients. For example, at present all public advertising must be accompanied by a large number of

obligatory communications, resulting in a risk that the truly important messages are not being fully received by the public; the legislation should be evaluated on this point. In any case, **the patient must be informed that medications can never be used over the long term without the necessary medical supervision**.

## 4. Budgetary sustainability and predictability[2]

### 4.1. Multi-year perspective

The capstone of this Pact of the Future is a multi-year budgetary framework and accompanying growth path[3]. This is a unique approach which offers the industry perspective and predictability. At the same time, the industry contributes to the budgetary efforts contained in the government coalition agreement.

Thanks to a smart policy of maximum competition on the off-patent market, in the coming 4 years more than 1.6 billion euros of budgetary room is being created in order to reimburse innovative therapies. Given the ageing population and the advent of innovative therapies, the needs will be high as well. In total, we proceed on the assumption of an average annual growth of 1.39%. **This means that we are freeing up 1.4 billion euros for new, innovative medicines!**

In 2015, reforms were already implemented that resulted in estimated annual budgetary savings for the health insurance of 100 million euros. To ensure that the medicine sector contributes to the budgetary effort in the coming years as well, we are striving for an **average growth path of 0.5% per year**. Concretely this means that from 2016 through 2018, measures must be taken which generate at least 126 million euros in structural savings. **Over the entire legislative term, the pharmaceutical industry will thus be delivering an additional structural contribution of approximately 230 million euros!**

In order to guarantee access to the latest medical developments for our patients and protect the innovation capacity of our companieswe make savings on the post-patent market. In a number of specific cases, the reimbursement conditions for a number of in-patent medicines can also be revised on the basis of arguments concerning their therapeutic added value and cost effectiveness, in line with evidence-based medicine.

[2] With regard to 2015, there is a difference between the estimation included in this document (4,074 billion euros) and the amount included in the 2015 Royal Decree on pharmaceutical specialities (4,030 billion euros). However, as far as the budget balance of Entity I is concerned, this difference is budget-neutral, given that the difference will be adjusted via the clawback in October-November.

[3]Based on a methodological memorandum contained in an annex and which was technically validated by pharma.be, FebelGen, the NIHDI and the policy unit on 26 May 2015.

The following tables present the agreements for the coming 3 years[4]:

| **Preparation budgetary multi-year framework medicines** | | | | | |
|---|---|---|---|---|---|
| *(in million euros)* | | | | | |
| | 2015 | 2016 | 2017 | 2018 | 2019 |
| **Budgetary framework** | | | | | |
| Established evolution of the budget objective | 23,852 | 23,737 | 24,093 | 24,455 | 24,822 |
| Estimated growth of the expenditures by the Planning Office and HCF | - | 23,880 | 24,382 | 24,894 | 25,417 |
| Estimated annual structural budget effort (including 236 million euros) | - | 200 | 203 | 208 | 156 |
| | | | | | |
| **Estimation of the expenditure evolution for medicines** | | | | | |
| IMS estimation of the expenditures for medicines (converted into NIHDI figures) | 4,074 | 4,187 | 4,226 | 4,261 | 4,324 |
| Percentage annual growth of the expenditures | 0.41% | 2.76% | 0.94% | 0.84% | 1.47% |
| | | | | | |
| **Estimation of the expenditure evolution for medicines – growth standard** | | | | | |
| Expenditures for medicines on basis of the growth standard | 4,074 | 4,135 | 4,197 | 4,260 | 4,324 |
| Percentage annual growth of the expenditures | 0.41% | 1.50% | 1.50% | 1.50% | 1.50% |
| | | | | | |
| **Expenditures for medicines in the Pact of the Future** | | | | | |
| Expenditures on basis of the growth pact | 4,074 | 4,127 | 4,130 | 4,135 | - |
| Percentage annual growth of the expenditures | 0.41% | 1.29% | 0.08% | 0.13% | - |
| | | | | | |
| **Savings achieved** | | | | | |
| Vis-à-vis IMS estimation - cumulative | | | | | |
| Vis-à-vis IMS estimation | | 60 | 36 | 30 | - |
| Vis-à-vis the growth path of 1.5% | | | | | |
| | | 60 | 96 | 126 | - |
| Vis-à-vis the growth path of 1.5% - cumulative | | 9 | 67 | 125 | - |

[4] The calculations were performed in consultation with the policy unit by the NIHDI on 19 June 2015 on the basis of the list of pharmaceutical specialities of June 2015 and the observed quantities and expenditures in Pharmanet (December 2013-November 2014) and the PH documents (quarters 2013Q4-2014Q3).

| Year | 2016 | 2017 | 2018 |
|---|---|---|---|
| **Growth in %** (average 0.5% / year over 3 years) | 1.3% (60) | 0.1% (36) | 0.1% (30) |
| **Measures and budgetary benefit for patient and government** | - Patent cliff "R"<br>Patient: 11<br>Government: 59.3<br>- Max safety margin 5:<br>Patient: 3.2<br>Government: 0.9<br>- Increase in sales levy<br>Patient: 0<br>Government: 1.1<br><br>TOTAL<br>Patient: 14.2<br>Government: 61.3 | - EBM on ATC 5 level<br>Patient: 6.4<br>Government: 32<br>- Δ definition application R<br>Patient: 0.6<br>Government: 3.1<br>- Biosimilars and biologicals[5]<br>Patient: 4<br>Government: 20<br>- Patent cliff "not yet R"<br>Patient: 3<br>Government: 16<br>- Increase in sales levy<br>Patient: 0<br>Government: 1.1<br>TOTAL<br>Patient: 14<br>Government: 72.2 | - Ceiling price, e.g. βblockers<br>Patient: 0.7<br>Government: 3.5<br>- Volume antibiotics<br>Patient: 0.5<br>Government: 2.5<br>- 1% more 'cheapest':<br>Patient: 5<br>Government: 25<br>- Increase in sales levy<br>Patient: 0<br>Government: 1.1<br><br>TOTAL<br>Patient: 6.2<br>Government: 32.1 |
| **Reduction of the sales levy for the companies** | / | 1% (-35) | / |
| **Positive measures and budgetary cost** | Strengthen administrations and implementation of pact (-1.1) | Strengthen administrations and implementation of pact (-1.1) | Strengthen administrations and implementation of pact (-2.5) |
| ***Total, net structural savings*** *(cumulative)* | - For the patient: 14.2<br>- For the government: 60.3 | - For the patient: 28.2<br>- For the government: 96.4 | - For the patient: 34.4<br>- For the government: 126 |

Hence this budgetary framework **also gives the patient greater access** to pharmaceutical care in the amount of more than 50 million euros over the period 2015-2018.

### 4.2. Innovation in tax and budgetary support

In order to support the innovative potential of the pharmaceutical companies - a large number of which are established in Belgium - that do research, development and production, **additional supportive tax measures** are necessary.

- The sales levy of 7.73% is being reduced to 6.73%, a decrease of 13%.
- Refunds within the framework of article 81 (bis) contracts will be exempted from the sales levy.
- We are studying whether the refunds above a certain amount, for example 30 million euros, within the framework of the art. 81 (bis) contracts can be deducted from the ´clawback´.
- In consultation with the Minister of Finance, we are examining within the framework of the biopharma platform whether a biotech tax shelter can be introduced for ´early developments´.

[5] The measures will respect the 80-20 rule for original and generic medicines, respectively.

**In brief, via this Pact of the Future 1) the patient bill is structurally reduced by more than 50 million euros, 2) the government saves approximately 130 million euros and 3) the taxes on the sales for the pharmaceutical sector decrease by 13%!** All of this is financed via structural measures that do not harm the innovation.

**Boxed text: Binding budgetary agreements of this Pact of the Future**

Clear budgetary agreements are important in order to offer the perspective and the predictability that this pact is aiming for. A number of supplementary clarifications must therefore be made:

- The expected annual effort is based on an estimation and is used to be able to anticipate as quickly as possible to the savings that will be made in the coming years in order to remain on the agreed path.
- The annual assessment of the medicines expenditures continues to take place on the basis of the annual technical estimates by the NIHDI.
- The current legislation will thus be maintained. A possible overrun of the budget in 2015 will not be carried along over several years, but will only have to be compensated once in 2016. During the budget preparation for 2016 and the coming years, the technical estimates by the NIHDI will thus still constitute the basis and will play a role for drawing up the budget. The umbrella organisations will be involved in this.
- As also provided for in the government coalition agreement, the necessary savings will be made on the off-patent market[6], with as point of departure the 20/80 rule with regard to the share of generic/original medicines; this also includes savings in the non-generic off-patent market, which takes into account the limited volumes[7].
- When measures save more than expected, they can be offset the same year through the settlement of the reimbursement via the ´claw back´, subject to the approval of the other coalition partners.
- If the saving is structural, it can be adjusted via revision of planned savings measures, and/or a further reduction of the levy on the sales of the following year.
- On the other hand, if the proposed savings should not suffice to respect the growth path, an additional exercise can be requested.
- If, within the framework of the budget policy of the government, the latter should be incapable of respecting this budgetary framework, additional efforts may be requested, even if there is a resultant risk that this pact's objectives might be endangered.
- Bilateral price negotiations between the policy unit of the Minister and a company are always possible, for example if an alternative would be available for an equal effectiveness, and at a lower price and lower reimbursement basis, in accordance with the agreements of 1.3.
- The regulations concerning "no switch – no INN prescription recommendation" will be revised.

### 4.3. Hepatitis C

[6] By "off-patent market" is understood the genericised and non-genericised specialities that may or may not be contained in the reference reimbursement.

[7] For an estimation of the distribution of the savings effort between originals and generics, see annex 2.

In addition, a number of specific themes with an important budgetary impact require our particular attention. For example, a structural system will be developed for the reimbursement of **Hepatitis C medicines**. A national register, patient support programmes, an extension to fibrosis stage 2 for which there is a high medical need and an extension to certain peripheral centres will form a part of this.

### 4.4. Patent cliff

A ´**patent cliff**´ is also entering into force. This means that when the reference cluster is opened, a one-time decrease in the basis of reimbursement is implemented (this amounts to 54.35% for category B medicines, and 60.73% for category A medicines) instead of successive price reductions within the framework of the reference reimbursement system/old medicines[8]. This system offers the advantage of simplicity, transparency and administrative simplification, but will also stimulate innovation by shortening the innovation cycle: companies have every interest in having a sufficiently effective ´R&D pipeline´ in order to be able to offset the steep losses of revenue due to the ´patent cliff´ on innovative products. The more limited price reductions, applying at present for certain forms, naturally also continue to exist within the new system.

### 4.5. A re-start for biosimilar medicines in Belgium

Biological medicines form an ever-growing expenditure item in the medicines budget. For the affordability of health care, a price competition in the sector of biological medicines is absolutely necessary. Promotion of the use of biosimilar medicines is a strong lever for this. It is important to emphasise here that these products are subject to the strictest safety standards at the European level. The registration procedure for a biosimilar guarantees that there are no therapeutically relevant differences between the biosimilar and the reference medicine.

Therefore, in order to **give a perspective to biosimilars in Belgium**, the following concrete agreements are made:

- A working group[9] monitors the market developments and the uptake of biosimilar medicines and will report on the evolution of the uptake, both inside and outside the hospital, to the Minister of Social Affairs and Public Health a first time for 1 October 2015, and then every two months thereafter.

[8] For the medicines that have not yet gone through all successive price reductions, there comes a one-time regularisation exercise up to the "cumulative" level of 54.35% for category B medicines, and 60.73% for category A medicines.

[9] Composed by at most 2 representatives of pharma.be, 2 representatives of FebelGen, 2 representatives of the Minister, 2 representatives of the NIHDI and 3 academic and/or clinical experts, 1 designated by pharma.be, 1 by FebelGen and 1 in consensus who will chair the working group.

- Therefore, as of July 2015 an uptake system will be elaborated in consultation with pharma.be and FebelGen, based on the proposal of the working group, guaranteeing a minimal uptake in DDD of 20% biosimilars for bio-naive patients for those medicines where biosimilars exist, and taking into account the characteristics of the pathologies involved. This uptake system applies for a period of at most five years.
- In so doing, account will be taken of 1) the advice of the doctors and hospitals; 2) the interchangeability of medicines; and 3) the scientific evaluation of the EMA and the FAMHP; the evaluation of the scientific community; the EU "Consensus Information Paper" that was approved in 2013 by the European umbrella organisations of doctors (CPME), the generic and biosimilar medicines companies (EGA) and the original drug companies (EFPIA).
- This Pact of the Future will be amended for 1 October 2016 in order to incorporate measures that take into account the proposals of the working group, which, as of 1 January 2017, guarantee the minimum uptake of biosimilar medicines should this uptake not yet be derivable before 1 July 2016 from the most recent figures. The government is committed to create the appropriate framework sufficiently in advance so that the eventual policy measures actually enter into force as of 1 January 2017.
- In accordance with the government coalition agreement for the use of post-patent biological medicines, the possibility is also provided to conclude covenants concerning the appropriate use of biological and biosimilar medicines. These covenants are concluded between the Minister and her administrations, the doctors, the hospitals, the scientific community and the pharmaceutical sector. In so doing, the proposals of the working group are taken into account.
- The resulting savings that are not contained in the trend calculation of the technical estimates shall be taken into account in the 2016-2018 budgetary effort.

## 5. Practical agreements

### 5.1. Clear and transparent agreements between the sector and the government

In addition to the realisation of this pact, close monitoring will be crucial for its success. With a view to successfully elaborating this Pact of the Future, each quarter a technical consultation will be held between the pharmaceutical industry and staff members of the policy unit and every six months there will be a consultation between the pharmaceutical industry and the Minister on the basis of a concrete substantive agenda. Pharma.be and FebelGen are the privileged interlocutors which represent the pharmaceutical industry during the consultation.

Furthermore, a monitoring committee is being composed wherein representatives of the FAMHP, NIHDI, pharma.be, FebelGen and the policy unit will monitor the technical elaboration of this Pact of the Future on the basis of a policy scenario worked out by mutual agreement. Within the monitoring committee, at least 4 working groups are being set up with a specific objective and composition that was already described in this Pact of the Future: there will be working groups on accessibility, effective prescription, biosimilars and transparency.

The competent administrations are involved in these consultation moments, given that they play a crucial role in the elaboration of the policy measures; and in the event that the

measures will have an impact on care providers and/or hospitals, their representatives will be involved in both the elaboration and the implementation thereof.

It is self-evident that all parties who are involved in the consultation will respect the Pact of the Future and guarantee the accuracy of the information provided, which is based on the most recent validated data. The industry is obliged to use the calibrated procedures with respect for the prevailing rules. The Minister is committed not to conduct any ad hoc policy and to apply the same rules in the same way for everyone. In addition, the interlocutors undertake to demonstrate the necessary discretion and to ensure that their members shall do likewise. All measures that are taken related to the realisation of the Pact of the Future shall respect the real intellectual property within the patent protection framework.

The policy unit will involve pharma.be and/or FebelGen in every decision with general impact concerning medicines, and this as a function of the action radius of the organisation involved. For example, within the framework of the Belgian-Dutch declaration of intent the sector will be involved in any regulatory anchoring. Consultation moments will also be organised between the policy unit and the industry in order to discuss subjects that are related to the European *Better Regulation* and to medicines for veterinary use.

With regard to the individual reimbursement applications, consultation with the policy unit is only possible after the formulation of a definitive proposal by the Commission for Reimbursement of Medicines, or if it does not pass here by a 2/3$^{rd}$ majority, unless the company in the reimbursement application has shown interest in an article 81 agreement, which allows consultation already after the final assessment report R90. Exceptional circumstances permit divergences from this working method, for example in the case of an extraordinary, life-threatening disorder for which a medical need exists. Pharma.be and FebelGen may of course at any time contact the policy unit of the Minister when in an individual reimbursement application there is a policy option with an impact on patients or the industry whose importance transcends the individual file.

The above agreements are made with the current Minister, pharma.be and FebelGen and are valid through 31 December 2018. All provisions of the Pact of the Future are to be carried out in good faith, including the responsibilities, possibilities and limits of each party. They are not legally enforceable.

### 5.2. Strengthening the medicine administrations

*5.2.1. FAMHP*

The financing of the FAMHP shall take maximum account of the ´fee for service´ principle. In order to develop budgetary sustainability, the ZBB technique (**Zero Based Budgetting**) will be used. With a view to optimising the use of the FAMHP's resources (such as the budget equilibrium and the fee-for-service approach), one will also evaluate whether greater budgetary **flexibility** can be given to the FAMHP. Aiming for greater flexibility in its

functioning - e.g. the attraction of top profiles with the necessary scientific, regulatory and clinical practical experience, experts (contractual) among other things to develop bioplatform projects - one will evaluate whether the status of the FAMHP must be adapted. Where necessary this will be done in consultation with the Minister of Civil Service Affairs.

The announced **spearhead fields** (vaccinology, paediatric oncology, ´early phase development´) will be systematically developed by the FAMHP, with as first the ´Early Phase development´ and the ´Centre of Excellence Vaccinology´ (see further under 2.5.) A centralised contact point (national innovation office, see also 2.1) specifically for starters and SMEs will be developed within the FAMHP (the advice of the Minister of SMEs will be requested). M**odern evaluation/inspection/recognition/certification** mechanisms will be used within the FAMHP by emphasising the consolidation of inspections (´only once inspection´) and co-regulation with the pharmaceutical sector: high-tech R&D and production units of pharmaceutical companies in Belgium are already subject to strict inspections by foreign agencies (e.g. FDA). From the perspective of administrative simplification, a system will be worked out by the FAMHP in order to take over these inspection reports.

The FAMHP will also ensure that the pharmaceutical companies respect the regulations with regard to the obligations on compliance with the law on information and the promotion of medicines. In addition, the FAMHP - as necessary in collaboration with other government institutions - will play an active role in the **dissemination of accurate information concerning matters on which an information gap clearly exists** (such as the biosimilar medicines); where possible, the FAMHP will base itself on already-validated information. The FAMHP will continue to give a central place to the patient's role through (amongst others) the patient platform, the representation of patients in Commissions (such as the renewed Medicine Commission "human") and more specifically through the further development of the therapeutic area coordinators as well as the further harmonisation of its information and communication policy with this.The *Better Regulation* with regard to medicines for veterinary use will be monitored and implemented.

*5.2.2. NIHDI*

In the new 2016-2018 management contract between the federal government and the NIHDI, additional funds will be provided for the administrative follow-up of this Pact of the Future. Moreover, we are counting on **administrative simplifications** that will free up resources for the further monitoring and implementation of the reforms provided for in this pact. If necessary, additional funds can be provided. In order to be able to attract top profiles with the necessary scientific, clinical and practical experience, the NIHDI will be able to apply more flexible hiring rules, after consultation with the Minister of Civil Service Affairs. The data and forecast capacity will also be reinforced.

*5.2.3. Commission for Reimbursement of Medicines (CRM)*

Reforms are being introduced in order to ensure that patients in Belgium can get fast and sustained access to innovative medicines at a justified cost/price for the Belgian health care system and the company. These reforms strive to further strengthen the quality of the reimbursement decision-making process and further shorten the current reimbursement procedure.

Belgium has top experts with international and clinical experience in the use of new and innovative medicines. We wish to valorise this clinical experience by involving it in the reimbursement procedure. In order to guarantee the **opposability** of the evaluations, and without prejudice to the HTA methodology, alongside the existing procedure for external expertise, the possibility will be created to add the advice of a clinical expert with experience in the use of the medicine involved to the file, an expert who has been designated by the pharmaceutical company. With a view to a uniform methodological approach, such advice will formulate a response to standard questions and will be joined in full to the provisional evaluation report "day 60". The internal evaluator will state his reasons for any comments he may have on this. In addition, the use of health-economic and budget impact analyses is being optimised.

An **anonymous voting system** is being introduced, as well as a voting right for the chairman of the CRM, in order to bring the academic votes into equilibrium with those of the insurance institutions.

As already cited in the Accessibility section, the (draft) EPAR will be used systematically in the clinical evaluation and a methodology is being worked out for the extension of indications based on the study of Professor dr. L. Annemans.

Group and individual reviews at the initiative of the CRM must in the first place be done for scientific reasons, on the basis of medical evidence that was collected as a result of new/amended (inter)national directives.

With a view to **administrative simplification -** for the NIHDI administration, the companies and the CRM - one is studying how the file composition and processing can be brought into accordance with the necessity of evaluation: if a medicine is already reimbursable for a particular indication, a subsequent medicine application would, in a number of cases, no longer have to undergo the evaluation concerning therapeutic value/place in medical practice. Rules that are unambiguous, non-discriminatory and known in advance are being drawn up to define the reimbursement basis upon registration in the reimbursement for the medicine packages that no longer have to undergo the evaluation concerning therapeutic value/place in medical practice. In addition, the possibility is being studied of limiting administrative procedures for parallel import.

Once the reference reimbursement has effectively entered into force for the reference medicine, the medicine packages that no longer have to undergo the evaluation for therapeutic value/place in medical practice can only be included on the list of pharmaceutical specialities if they meet the definition of **the cheapest prescription**.

With regard to the risk-sharing agreements ("art. 81"), the **maximum contract period will be extended from 3 to 5 years**. The composition and the functioning of the art. 81 working group is being evaluated. **Incentives are being associated with the use of pay-for-performance systems** and other, more sophisticated risk-sharing agreements. The confidentiality of the annexes to these agreements, which often contain sensitive company-specific information, is ensured and inscribed in the law. In the case that a company enters into a joint reimbursement procedure with one or more partner countries, the confidentiality cannot form an obstacle, in so far as the NIHDI and the foreign reimbursement authority (or authorities) respect this confidentiality. With a view to reducing the time the reimbursement procedure takes, the company will be able to indicate its intention for an article 81 agreement already in the reimbursement application, with it being understood that the CRM remains competent for the clinical evaluation.

The decision to exclude from the reimbursement is no longer entrusted to the article 81 working group, given that this falls within the competence of the CRM. It is being evaluated whether one can drop the report filed after expiry of the contract period and replace it by incorporating the data collected during the period of the contract into the new reimbursement application to the CRM, in accordance with the above-described ambition to use **more "real data"**.

The recent change of the definition from the cheap prescription to the ´**cheapest prescription**´ might have created the impression that available generic medicines - as of their launch - would not count for the quota of low-cost prescriptions as long as the reference reimbursement had not yet actually entered into effect for the reference medicine. Given that generic medicines as of their inclusion on the list of reimbursable specialities already find themselves on the level of the reference reimbursement, this will be clarified in the Programme Law of 2015. It goes without saying this must concern generic medicines that are either prescribed by international non-proprietary name or belong to the cluster of cheapest medicines. Furthermore, it is clarified that the speciality with the lowest basis of reimbursement per unit, which is used as a reference for calculating the cluster of cheapest medicines, obviously also must be actually available at the time of the effective formation of the cluster.

## 6. Conclusion

This is our pact.

Our population is ageing, and as a result it also has increasing numbers of chronic patients. Moreover, science is evolving at lightning speed and offering ever greater possibilities in terms of personalised medicine. At the same time, the government budget to pay for these innovations is limited.

We must take measures to meet these challenges. This is one of the most important objectives of our government coalition agreement.

With this pact we, as government and industry, are laying the foundations to ensure that we will be able to meet the needs of our patients in the coming years. Thanks to this pact, patients will have new medicines at their disposal more quickly. For the industry, we are creating room to invest in innovation, safety and unmet medical needs. For example, we are strengthening our basis for more international, and above all European, cooperation on orphan medicines.

Through this pact, we are also reducing the medicine bill for our patients, while at the same time we are giving the pharmaceutical industry enough oxygen to remain at the top, both worldwide and in our own country. In the coming four years we are freeing up 1.4 billion euros for this purpose.

Finally, we are establishing agreements for an ethical framework for the industry, so that the relations between industry and government are transparent and correct.

Together we are undertaking long-term reforms, because we are convinced that this is the right path towards accessible, sustainable and high-quality health care.

We care to change, and we change to care.

Vilvoorde, 27 July 2015

**Maggie De Block**
Minister of Social Affairs and Public Health

**Catherine Rutten**
pharma.be
CEO

**Sonja Willems**
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Chairman

**Joris Van Assche**
FebelGen
Managing Director

**Jef Hus**
FebelGen
Chairman

## Annex 1: Methodological note on the budgetary multi-year framework

### *Estimation of NIHDI expenditures 2015-2019 on the basis of IMS sales data*[10]

### I – IMS study "Five year outlook on the Belgian pharmaceutical market"

IMS was commissioned by the NIHDI to do a 5-year forecast study on the Belgian pharmaceutical market (limited to reimbursable medicines, for both the public and the hospital sector).

1) Framework:

- Forecast made with top-down approach on 3 markets: Retail market, Hospital ambulatory and Hospital non-ambulatory market (with corrections for past government savings)
- Includes unique and extensive data from IMS on expected patent end dates and product pipeline knowledge: Loss of exclusivities and launches
- IMS data and expertise was combined with NIHDI input on past price cuts and reimbursement dates as well as planned cost containment measures to make the estimations more exact

The following were defined as ´events´:

- New products launched
- Cluster opened
- Additional price cut after 2 y
- Additional price cut after 4 y
- Additional price cut after 6 y
- Price cut after 12 y
- Price cut after 15 y
- Price ceiling

Additionally:

- Macroeconomic parameters
- Demographic events

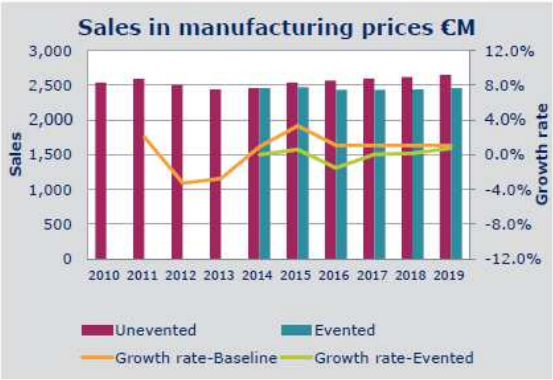
In the "unevented" scenario: trend analysis (for the package of medicines, without application of the events in the period 2015 – 2019), but including the impact of the macroeconomic and demographic events.
In the "evented" scenario: application of the events in the period 2015 – 2019, also including the impact of the macroeconomic and demographic events.

[10] This methodological note was approved by the representatives of pharma.be, FebelGen, the NIHDI and the policy unit on Tuesday 26 May 2015

2) Results ("evented" scenario):

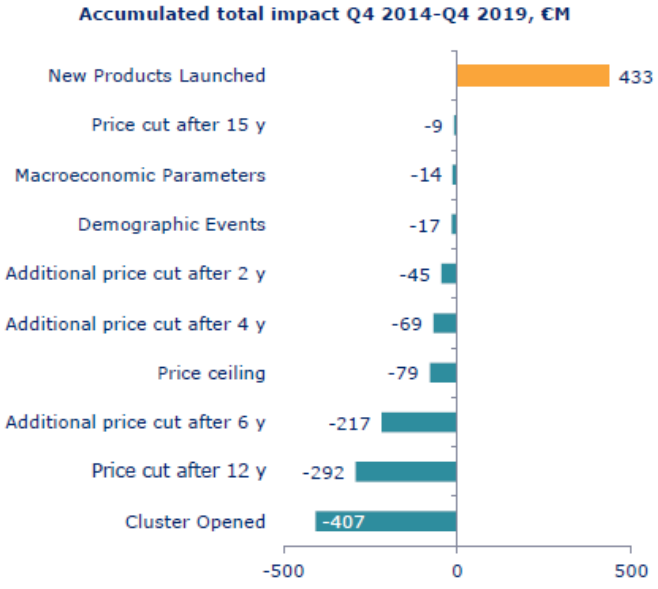
Retail:

**RETAIL**



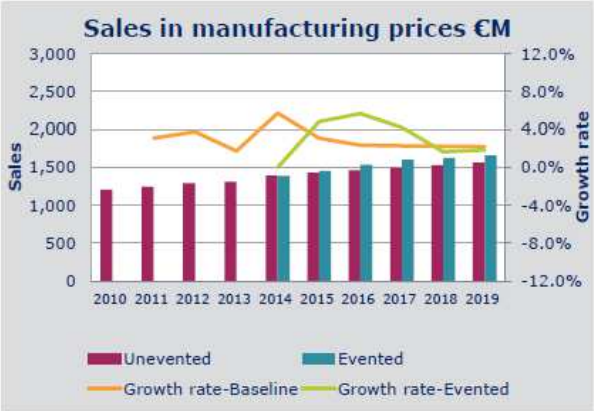

| Period | Year-on-year Growth (Unevented) | Year-on-year Growth (Evented) |
|---|---|---|
| 2010-11 | 2.0% ▲ | |
| 2011-12 | -3.3% ▼ | |
| 2012-13 | -2.7% ▼ | |
| 2013-14 | 0.9% ▲ | |
| 2014-15 | 3.3% ▲ | 0.6% ▲ |
| 2015-16 | 1.1% ▲ | -1.5% ▼ |
| 2016-17 | 1.1% ▲ | 0.0% ▲ |
| 2017-18 | 1.1% ▲ | 0.2% ▲ |
| 2018-19 | 1.0% ▲ | 0.8% ▲ |

**CAGR (2010 - 2013) :** **-1.4%**
**CAGR (2014 - 2019) :** **0.0%** (Evented)
**1.5%** (Unevented)



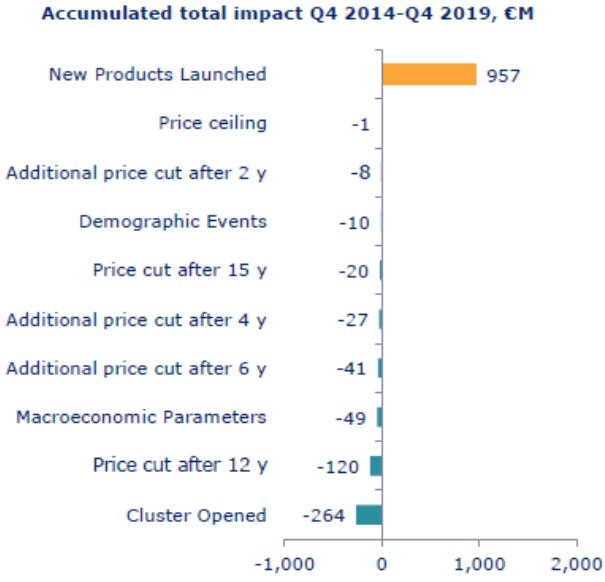
Hospital – total:

## HOSPITAL TOTAL



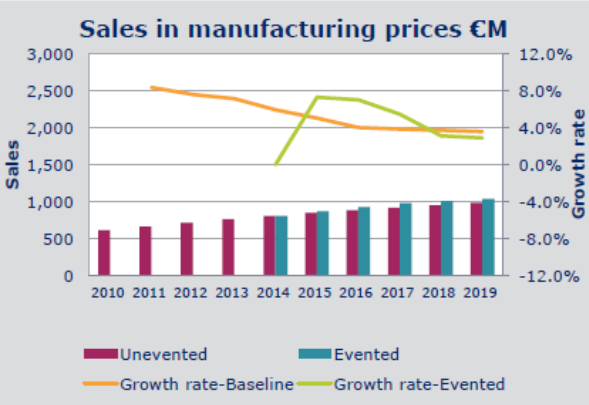

| Period | Year-on-year Growth (Unevented) | Year-on-year Growth (Evented) |
|---|---|---|
| 2010-11 | 3.1% ▲ | |
| 2011-12 | 3.7% ▲ | |
| 2012-13 | 1.7% ▲ | |
| 2013-14 | 5.7% ▲ | |
| 2014-15 | 3.1% ▲ | 4.8% ▲ |
| 2015-16 | 2.3% ▲ | 5.7% ▲ |
| 2016-17 | 2.3% ▲ | 4.2% ▲ |
| 2017-18 | 2.2% ▲ | 1.6% ▲ |
| 2018-19 | 2.2% ▲ | 1.8% ▲ |

**CAGR (2010 - 2013) :** **2.8%**
**CAGR (2014 - 2019) :** **3.6%** (Evented)
**2.4%** (Unevented)



Hospital – ambulatory:

## HOSPITAL AMBULATORY

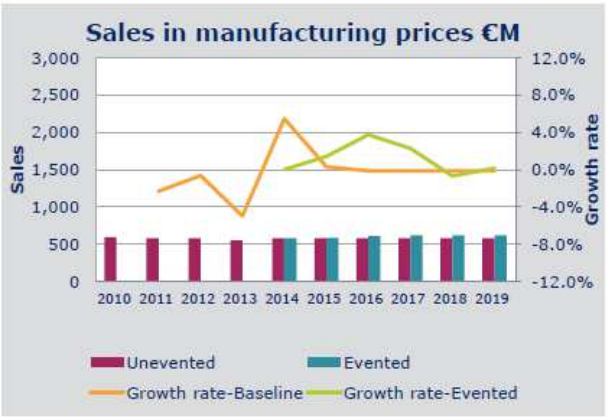



| Period | Year-on-year Growth (Unevented) | Year-on-year Growth (Evented) |
|---|---|---|
| 2010-11 | 8.4% ▲ | |
| 2011-12 | 7.6% ▲ | |
| 2012-13 | 7.1% ▲ | |
| 2013-14 | 5.9% ▲ | |
| 2014-15 | 5.0% ▲ | 7.3% ▲ |
| 2015-16 | 4.0% ▲ | 7.0% ▲ |
| 2016-17 | 3.9% ▲ | 5.5% ▲ |
| 2017-18 | 3.7% ▲ | 3.1% ▲ |
| 2018-19 | 3.6% ▲ | 2.9% ▲ |

**CAGR (2010 - 2013) :** **7.7%**
**CAGR (2014 - 2019) :** **5.1%** (Evented)
**4.0%** (Unevented)

Hospital – non-ambulatory:

## HOSPITAL NON-AMBULATORY




| Period | Year-on-year Growth (Unevented) | Year-on-year Growth (Evented) |
|---|---|---|
| 2010-11 | -2.3% ▼ | |
| 2011-12 | -0.7% ▼ | |
| 2012-13 | -5.0% ▼ | |
| 2013-14 | 5.5% ▲ | |
| 2014-15 | 0.3% ▲ | 1.4% ▲ |
| 2015-16 | -0.1% ▼ | 3.7% ▲ |
| 2016-17 | -0.1% ▼ | 2.3% ▲ |
| 2017-18 | -0.1% ▼ | -0.7% ▼ |
| 2018-19 | -0.1% ▼ | 0.1% ▲ |

**CAGR (2010 - 2013) :** **-2.7%**
**CAGR (2014 - 2019) :** **1.4%** (Evented)
**-0.1%** (Unevented)

In sum: evolution of IMS sales (ex-factory) per sector and in total:

Information table (original source NIHDI):

| | IMS manufacturing prices (in million EUR) | | | | |
|---|---|---|---|---|---|
| year | Hospital – Non-ambulatory | Hospital - Ambulatory | Hospital - Total | Retail | Total |
| 2010 | 594.26 | 611.78 | 1,206.04 | 2,538.18 | 3,744.22 |
| 2011 | 580.44 | 662.86 | 1,243.30 | 2,590.08 | 3,833.38 |
| 2012 | 576.65 | 713.13 | 1,289.79 | 2,505.15 | 3,794.94 |
| 2013 | 547.90 | 764.08 | 1,311.98 | 2,436.55 | 3,748.53 |
| 2014 | 577.33 | 808.64 | 1,385.96 | 2,457.31 | 3,843.28 |
| 2015 | 585.47 | 869.11 | 1,454.58 | 2,473.82 | 3,928.39 |
| 2016 | 608.66 | 928.16 | 1,536.82 | 2,433.22 | 3,970.04 |
| 2017 | 620.86 | 980.21 | 1,601.06 | 2,435.63 | 4,036.69 |
| 2018 | 617.05 | 1,009.25 | 1,626.31 | 2,439.03 | 4,065.34 |

Table consolidated with data pharma.be:

| | IMS manufacturing prices (in million EUR) | | |
|---|---|---|---|
| year | Hospital - Total | Retail | Total |
| 2010 | 1,206.04 | 2,538.18 | 3,744.22 |
| 2011 | 1,243.30 | 2,590.08 | 3,833.38 |
| 2012 | 1,289.79 | 2,505.15 | 3,794.94 |
| 2013 | 1,311.98 | 2,436.55 | 3,748.53 |
| 2014 | 1,390.00 | 2,434.00 | 3,824.00 |
| 2015 | 1,457.00 | 2,449.00 | 3,906.00 |
| 2016 | 1,561.00 | 2,431.00 | 3,992.00 |
| 2017 | 1,649.00 | 2,395.00 | 4,044.00 |
| 2018 | 1,700.00 | 2,394.00 | 4,094.00 |

**II – Conversion and correction factors**

Conversions (IMS results expressed in sales) and corrections must be applied to the IMS results:

1) Conversion factors:

Because of conversion from ex-factory sales data IMS to net expenditures NIHDI (booked)

| Net NIHDI expenditures (in EUR) | | | IMS sales (in EUR) | | Conversion factor | |
|---|---|---|---|---|---|---|
| year | public | hospital | public | hospital | public | hospital |
| 2010 | 2,714 | 1,298 | 2,538 | 1,206 | 1.06937 | 1.076622 |
| 2011 | 2,774 | 1,369 | 2,590 | 1,243 | 1.07120 | 1.101041 |
| 2012 | 2,705 | 1,401 | 2,505 | 1,290 | 1.07970 | 1.085842 |
| 2013 | 2,615 | 1,393 | 2,437 | 1,312 | 1.07312 | 1.062119 |
| 2014 | 2,607 | 1,450 | 2,434 | 1,390 | 1.07115 | 1.043165 |
| 2015 | | | | | 1.07455 | 1.04201 |
| 2016 | | | | | 1.07510 | 1.03142 |
| 2017 | | | | | 1.07565 | 1.02084 |
| 2018 | | | | | 1.07620 | 1.01026 |
| | | | *standard error* | | *0.00454* | *0.01683* |

2) Correction factors:

Because of:

a. Inclusion of data for not-reimbursed reimbursable medicines (e.g. medicines used by those who are not insured, delivered as "cash payment", used outside the limitations of chapter IV, etc.)
b. Measures that were not taken into account in the IMS study:
    - Measure new definition of "cheap medicines"
    - Volume measures (e.g. TPE)
    - Acetylcysteine (individual measure)
    - Measure "cheapest" generic (only in 2016)

➔ Need for recalibration of the zero point “expenditures 2015” up to the level of 4,074,000 thousand euros
(= 2,541,000 thousand euros public + 1,533,000 thousand euros total hospitals) = re-estimated 2015 objective (level of booked expenditures, increased by the expenditures for imbruvica and new hep c medicines)

Expressed as sales (application of conversion factors public and hospital) = 3,836 million euros
(= 2,365 million euros public + 1,471 million euros total hospitals) in the case that the 2015 conversion factor is calculated with a trend on the last 5 years (period 2010-2014).

**III – Translation of IMS sales data to net NIHDI expenditures**

Methodology:

- recalibration of the zero point "2015 expenditures" up to the level of 4,074,000 thousand euros (NIHDI booked)
- conversion of this zero value into IMS sales figures
- application of the IMS growth trend
- application of the separate conversion factors for public and hospitals (sales → expenditures)

1) evolution of IMS manufacturing prices (in million EUR) – recalibrated data

| Estimation of evolution of IMS manufacturing prices (in million EUR) – original (consolidated pharma.be) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 |
| Hospital | 1,206 | 1,243 | 1,290 | 1,312 | 1,390 | 1,457 | 1,561 | 1,649 | 1,700 |
| Retail | 2,538 | 2,590 | 2,505 | 2,437 | 2,434 | 2,449 | 2,431 | 2,395 | 2,394 |
| Total | 3,744 | 3,833 | 3,795 | 3,749 | 3,824 | 3,906 | 3,992 | 4,044 | 4,094 |

| Estimation of evolution of IMS manufacturing prices (in million EUR) - recalibrated | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 |
| Hospital | | | | | | 1,471 | 1,576 | 1,665 | 1,717 |
| Retail | | | | | | 2,365 | 2,347 | 2,313 | 2,312 |
| Total | | | | | | 3,836 | 3,924 | 3,978 | 4,028 |

2) Estimated impact of future events on the NIHDI expenditures (public and hospitals):

*with application of calculated conversion factor*

| Estimation of evolution of NIHDI net expenditures (million EUROS) – booked expenditures | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2010* | 2011* | 2012* | 2013* | 2014* | 2015 | 2016 | 2017 | 2018 |
| Hospital | 1,298.45 | 1,368.93 | 1,400.50 | 1,393.48 | 1,450.00 | 1,533.00 | 1,625.74 | 1,699.77 | 1,734.17 |
| Retail | 2,714.26 | 2,774.49 | 2,704.81 | 2,614.71 | 2,607.19 | 2,541.00 | 2,523.61 | 2,487.51 | 2,487.74 |
| Total | 4,012.70 | 4,143.42 | 4,105.32 | 4,008.19 | 4,057.19 | 4,074.00 | 4,149.35 | 4,187.28 | 4,221.91 |

*with application of calculated conversion factor + 1 standard error (retail 0.0045 hospital 0.0168)*

| Estimation of evolution of NIHDI net expenditures (million EUROS) – booked expenditures | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2010* | 2011* | 2012* | 2013* | 2014* | 2015 | 2016 | 2017 | 2018 |
| Hospital | 1,298.45 | 1,368.93 | 1,400.50 | 1,393.48 | 1,450.00 | 1,533.00 | 1,652.27 | 1,727.79 | 1,763.06 |
| Retail | 2,714.26 | 2,774.49 | 2,704.81 | 2,614.71 | 2,607.19 | 2,541.00 | 2,534.26 | 2,497.99 | 2,498.22 |
| Total | 4,012.70 | 4,143.42 | 4,105.32 | 4,008.19 | 4,057.19 | 4,074.00 | 4,186.53 | 4,225.79 | 4,261.28 |

* source: NIHDI booked expenditures

**IV – Re-estimation of the 2015 expenditures**

On the basis of the consultation "**budgetary multi-year pact medicines**" of Monday 11 May at 1.30 p.m. in the offices of the Minister of Social Affairs and Public Health, the following results can be presented with regard to the six-point approach.

1) On the basis of the initial results of the year 2015, the real expenditures of the year 2014 were composed. On the basis of the ratio 2014 booked expenditures / 2014 real expenditures and the comparison thereof with the years 2010-2013, in 2014 **EUR 22.5 million** (see table 1) too little was booked. Of this **EUR 18.8 million** relate to 2013 performances (which were booked in accelerated fashion in 2013) and **EUR 3.7 million** relate to 2014 performances (they will be booked in 2015).

In an e-mail from 18/05/2015 another amount of EUR 17.3 million (as first analysis) as too little booked for 2014 was passed on, but a more accurate analysis afterwards gives an amount of EUR 22.5 million as too little booked for 2014.

| table 1: analysis of financial year 2014 | A<br>booked expenditures 2014 | B<br>increased booked expenditures 2014 | C = B - A |
|---|---|---|---|
| ambulatory market | 2,607,185 | 2,607,185 | 0 |
| hospital market | 1,427,592 | 1,450,045 | 22,453 |
| total | 4,034,777 | 4,057,230 | 22,453 |
| | | | |
| retail hospital market | | | |
| 2013 performances | 218,707 | 237,497 | 18,790 |
| 2014 performances | 1,208,885 | 1,212,548 | 3,663 |
| | 1,427,592 | 1,450,045 | 22,453 |

2) 2015 was then re-estimated on the basis of these increased 2014 expenditures, with no account being taken of the 2015 savings in the analysis. So here the 2015 estimates (before deduction of 2015 measures), done in September 2015, are compared to the 2015 re-estimation (also before deduction of 2015 measures) (see table 2).

| table 2: 2015 re-estimation | A<br>estimation 2015 | B<br>re-estimation 2015 | C = B - A |
|---|---|---|---|

| | | | |
|---|---|---|---|
| ambulatory market | 2,655,788 | 2,650,963 | -4,825 |
| hospital market | 1,511,966 | 1,529,536 | 17,570 |
| total | 4,167,754 | 4,180,499 | 12,745 |
| | | | |
| objective 2015 | 4,030,194 | 12,745 | 4,042,939 |

The 2015 re-estimation (before deduction of 2015 measures), is thus **EUR 12.7 million** higher than the 2015 estimation (also before deduction of 2015 measures).

The amount of the 2015 objective (4,030 million EUR) must therefore also be increased by **EUR 12.7 million** to an amount of **EUR 4,043 million**.

3) The price reductions bilaterally negotiated by the Ministerial policy unit that are not yet included in the 2015 estimation can be found in table 3 and amount to **EUR 3.8 million** for 2015.

table 3: price reductions

| | | | |
|---|---|---|---|
| ambulatory market | | | -1,703 |
| hospital market | | | -2,143 |
| total | | | -3,846 |
| | | | |
| 2015 objective | 4,042,939 | -3,846 | 4,039,093 |

The increased amount of the 2015 objective (EUR 4,043 million - see table 2) must therefore be reduced by **EUR 3.8 million** to an amount of **EUR 4,039 million**.

## Annex 2: Distribution of the savings effort originals-generics

| **Measure** | **Estimated benefit** | **Original-Generics allocation formula** |
|---|---|---|
| EBM at ATC5 level | 32 | 81-19 |
| Patent cliff "R" | 75.3 | 81-19 |
| Maximum safety margin: from 10.8 to 5 euros | 4.1 | 100-0 |
| Biosimilars and biologicals | 20 | 81-19 |
| βblockers | 3.5 | 66-34 |
| antibiotics | 2.5 | 34-66 |
| cheapest | 25 | 85-15 |
| Adaptation of definition of application R | 3.1 | 0-100 |
| **Distribution of the effort** | 166.2 million euros – 100% | **79.4% - 20.6%** |