

What would be the impact of fair prices for medicines in Belgium?

Research based on 7 cases

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Chapters

INTRODUCTION	5
A. Cost of high-priced medicines.....	5
B. Medicine pricing mechanism.....	7
C. Creation of a fair price model and fair price calculator.....	8
D. Objective of the study	10
1. DATA AND METHODOLOGY	
1.1. Cases selected for the study.....	11
1.2. Data integrated in the calculator	13
2. RESULTS OF THE CALCULATOR FOR THE 7 CASES	15
2.1 Calculating the fair price	15
2.2 Impact on health care spending in Belgium.....	17
3. DISCUSSION OF RESULTS	19
3.1. Discussion of the results by medicine	19
3.2. Discussion of the parameters of the fair price model.....	19
CONCLUSIONS AND RECOMMENDATIONS	21
BIBLIOGRAPHY	23
APPENDIX - USE OF AIM/SOLIDARIS CALCULATOR FOR THE 7 CASES	
1. Zolgensma – 4.878 patients	2
2. Zolgensma – 0,17/100.000	2
3. Spinraza.....	2
4. Entresto.....	2
5. Jardiance.....	4
6. Cosentyx	1
7. Opdivo	3
8. Lonsurf.....	1

Table of figures

Figure 1 Average cost per patient in 2020 for the 5 most expensive oncology medicines for the health insurance ..	6
Figure 2 Overview of the Association Internationale de la Mutualité (AIM) fair price model.....	8
Figure 3 Description of the components of the Association Internationale de la Mutualité (AIM) fair price model	9
Figure 4 Percentage of the price that is fair according to the model, compared to the price currently paid (price per treatment)	15
Figure 5 Comparison of medicine costs between net current expenditures and fair expenditures.....	17

Table of tables

Table 1 : Average cost per patient per year for the 10 most expensive medicines	5
Table 2: Total cost and average cost per patient for the 5 most expensive oncology medicines for the health insurance - Solidaris patients.....	6
Table 3: Potential savings using the AIM fair price calculator in Germany	10
Table 4: Medicines and indications selected for the study of potential savings using the AIM Fair Price Calculator	11
Table 5: Actual expenditures for the 7 study medicines in 2020.....	12
Table 6: Data used to calculate the fair price	14
Table 7: Ratio of current price per treatment to fair price	16
Table 8: Actual Expenditures and Potential Savings with Fair Price.....	18
Table 9: Potential savings as a function of the amount of R&D (in euros)	20

INTRODUCTION

A. Cost of high-priced medicines

Reimbursed medicines account for a large part of health care expenditures in Belgium : more than 5,4 billion euros per year out of a budget of nearly 32 billion euros for the compulsory health insurance in 2022 (*Insurance Committee, 2022*), and recent medicines are one of the main causes of cost growth for the public health insurance (*NIHDI-MORSE, 2021*). Indeed, it is the expenditure for **medicines delivered in hospitals to outpatients** (in day hospitalisation) that has exploded in recent years **with growth rates around 20% per year¹** .

These new medicines delivered by hospitals to outpatients (treated during the day, without staying overnight) are often very expensive. They treat serious diseases, some of which are fatal, and affect a small number of patients but at an extremely high cost per patient : from 188.000 to more than 450.000 euros per patient per year for the 10 most expensive medicines per patient (table 1). These 10 medicines are all so-called "orphan medicines", i.e. medicines that treat rare diseases (such as metabolic diseases or cystic fibrosis) for which they often slow down the evolution of the disease without curing the patient.

The costs presented in Table 1 are the costs paid by the health insurance on average for each patient treated among Solidaritis members in 2020² . To estimate the total cost per patient for each medicine, it is necessary to multiply by the duration of the treatment, which is often equal to the patient's life span (10 years or much more): we therefore reach **amounts per patient of several million euros!**

Table 1 : Average cost per patient per year for the 10 most expensive medicines

Indication/disease	Molecule	Brand name	Cost per Solidaritis patient in 2020 (in euros)	Number of Solidaritis patients
Mucopolysaccharidosis type VI	Galsulfase	Naglazyme[®]	454.217	3
Atypical hemolytic-uremic syndrome / Paroxysmal nocturnal hemoglobinuria	Eculizumab	Soliris[®] *	264.304	20
Pompe disease	Alglucosidase alfa	Myozyme[®]	255.378	9
Spinal muscular atrophy (SMA)	Nusinersen	Spinraza[®] *	255.316	46
Gaucher disease type I	Imiglucerase	Cerezyme[®]	246.027	12
Gaucher disease type I	Eliglustat	Cerdelga[®]	245.056	5
Mucopolysaccharidosis type II	Idursulfase	Elaprased[®]	239.031	4
Cystic fibrosis	Ivacaftor	Kalydeco[®] *	195.928	12
Fabry disease	Migalastat	Galafold[®]	192.707	5
Haemophilia A	Emicizumab	Hemlibra[®] *	187.810	29

** For these 4 medicines, a "managed entry agreement" (see section B.) with confidential refunds was signed between the company and the Minister of Social Affairs; the actual cost is therefore lower.*

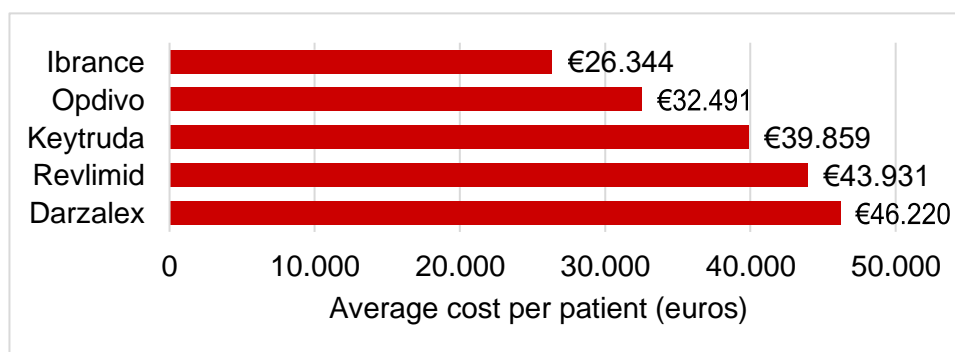
Source: Solidaritis (2020)

¹ Figure taken from Table 14 p.19 of the NIHDI-MORSE reference.

² Solidaritis is a mutual fund managing the compulsory universal health insurance for 28% of the Belgian population. The study uses costs and budgets for medicines in 2020 due to the unavailability of complete NIHDI data for 2021 at the time of writing.

Other medicines dispensed in hospitals have a slightly lower price per patient but affect a larger number of patients and are therefore among the medicines that cost the most to the compulsory health insurance. This is the case for cancer medicines, which are the largest expenditure item for hospital medicines. In 2020, the health insurance spent (gross³) more than 1,3 billion euros⁴ for antineoplastic medicines and immunomodulating agents of the ATC class L01⁵ used to treat cancers.

Figure 1 Average cost per patient in 2020 for the 5 most expensive oncology medicines for the health insurance



Source: Solidaris (2020)

These 5 most costly cancer medicines (Figure 1) cost the health insurance system 686 million euros (gross) in 2020, i.e. 12% of total (gross) expenditure on medicines. Keytruda alone accounts for more than 300 million euros of (gross) expenditure.

Table 2: Total cost and average cost per patient for the 5 most expensive oncology medicines for the health insurance - Solidaris patients

Molecule	Brand name	Position	Number of patients	Solidaris expenses (in euro)	Average cost in 2020 per Solidaris patient (in euro)
Pembrolizumab	Keytruda [®]	1st	1441	57.436.858	39.859
Lenalidomide	Revlimid [®]	2nd	679	29.828.970	43.931
Nivolumab	Opdivo [®]	5th	589	19.137.360	32.491
Palbociclib	Ibrance [®]	8th	705	18.572.723	26.344
Daratumumab	Darzalex [®]	26th	209	9.660.000	46.220

*brand name = commercial name

Position = position in the ranking of the highest expenditure per medicine for Solidaris members

Source: Solidaris (2020)

³ Gross expenditure ie before deduction of refunds made under confidential managed entry agreements (see section B.).

⁴ Source: NIHDI data.

⁵ World Health Organization Anatomical Therapeutic Chemical (ATC) classification.

For these 5 oncology medicines, a "managed entry agreement" with confidential refunds is or was signed between the company and the Minister of Social Affairs and the real cost is therefore lower.

The cost per patient presented in Table 2 does not reflect the cost of a **full** treatment for most medicines. On the one hand, a large number of patients have to interrupt their treatment (due to side effects, among other things) or unfortunately die during treatment. As the data from the Intermutualist Agency (*IMA-AIM 2022*) show, more than 2/3 of the patients treated with immunotherapy between 2016 and 2018 had indeed died by the end of 2019.

Furthermore, the table shows expenses in 2020, but some treatments straddle several years and/or last longer than 12 months. **For Opdivo, for example, if we look at the average cost for Solidaris members still alive 1 year after the start of the treatment, we come up with €126.939**, for an average treatment duration of 550 days.

A minority of medicines, either very specific (as for cancers) or concerning a very small number of patients (rare diseases), represent a large part of the expenditure for medicines and are the source of a real explosion of costs; **medicines against cancer of the ATC class L01⁶ have indeed increased from 368 million to 1.370 million between 2013 and 2020, that is to say an increase of 1 billion euros in 7 years⁷.**

B. Medicine pricing mechanism

The price of every newly reimbursed medicine is the result of negotiations between the pharmaceutical company and the Minister of Social Affairs, based on a proposal from the NIHDI's Commission for the Reimbursement of Medicines.

The price that is initially requested by the pharmaceutical company is free, and is in no way linked to research or production costs. Negotiations then focus on the therapeutic value of the medicine⁸ and its budgetary impact, and often constitute a tug of war between the pharmaceutical industry and representatives of the health system.

For expensive medicines, and in particular for cancer medicines, the **price agreements between the minister and the pharmaceutical company are usually secret**. These agreements are often called "article 81 managed entry agreements" or "article 111" in reference to the article in the royal decree that regulates the reimbursement of medicines⁹.

There is **no transparency on the rebates granted for each medicine**, which makes it impossible to carry out any cost analysis for these medicines, both with possible comparators in Belgium and abroad. This system of secret negotiations allows pharmaceutical companies to ask for high prices, in order to claim that they have obtained this list price and to negotiate this same alleged price in neighbouring countries. Then the companies grant more or less important, and equally confidential, rebates to most countries.

In Belgium, only the average percentage of refunds on all medicines under managed entry agreement during a year is made public (*NIHDI-MORSE, 2021*). In 2020, it amounted to 41.19% of the list price and refunds represented 754 million euros.

⁶ Other cancer medicines in ATC classes L02, L03, and L04 increased from 50 million in 2013 to 239 million in 2020.

⁷ Gross expenditure, i.e., before deduction of refunds made under confidential managed entry agreements (see section B.). Source: NIHDI data.

⁸ By using value-based pricing models that involve the theoretical concept of "Willingness to pay" of health systems.

⁹ Initially it was Articles 81 et seq. of the Royal Decree of December 21, 2001 that regulated these agreements. This decree has been replaced by the decree of February 1st 2018 where these managed entry agreements are regulated by articles 111 et seq.

It could be difficult to keep in mind that these refunds are simply "cash flows" with no meaning in terms of the value of the medicine; indeed, the more a company charges an "inflated" starting price, the more rebates it will give to reach the price it was willing to accept. There are no additional savings, just "inflated" expenses offset by "inflated" rebates.

For 2023, according to NIHDI's technical estimates, **refunds will amount to more than 1,4 billion euros** (*Insurance Committee, 2022*). In only 3 years, these refunds have therefore almost doubled. How can this growth be interpreted? Is it that the list prices charged are increasing or that the real prices are decreasing? It is obviously the list price, since real expenditures (after deducting these refunds) will increase by 812 million over the same period.

The international literature shows the same reality; for example between 2009 and 2021 the net entry price on the market (after rebates) of medicines in the United States increased by 20% each year, from a median price per medicine of \$2.115 to a median price of \$180.007 (*Rome B. et al., 2022*).

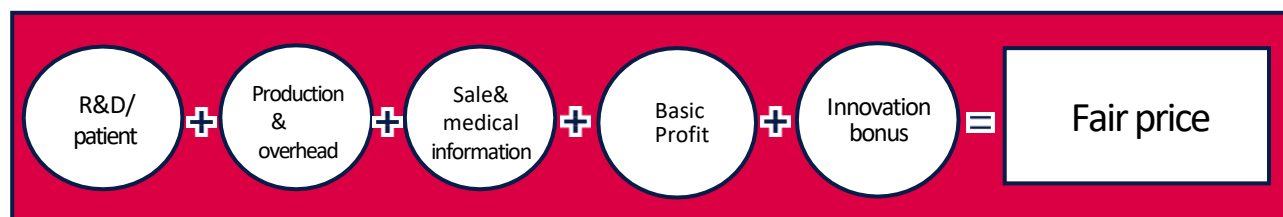
C. Creation of a fair price model and fair price calculator

In the face of this organised opacity on the real prices of medicines, the constant increase in prices charged and the increase in expenses related to reimbursed medicines, the Association Internationale de la Mutualité – AIM (International Association of Mutual Benefit Societies)- in close collaboration with Solidaris, has developed a model¹⁰ to **calculate fair and transparent prices for medicines** (*AIM, 2019*).

The objective of the model is to strike a delicate balance between the divergent interests of the companies that develop the medicines and must market them, on the one hand, and the health systems that finance them and must continue to have the means to provide access to innovative medicines, on the other.

This model aims to provide a fair price for both health systems and the pharmaceutical companies that bring medicines to market. It is based on predefined objective criteria that include manufacturers' costs and reasonable margins, and rewards innovation linked to the therapeutic value of the medicine (Figure 2). European fair prices would be totally transparent: they would be public and their method of calculation known to all.

Figure 2 Overview of the Association Internationale de la Mutualité (AIM) fair price model



Source: AIM (2019)

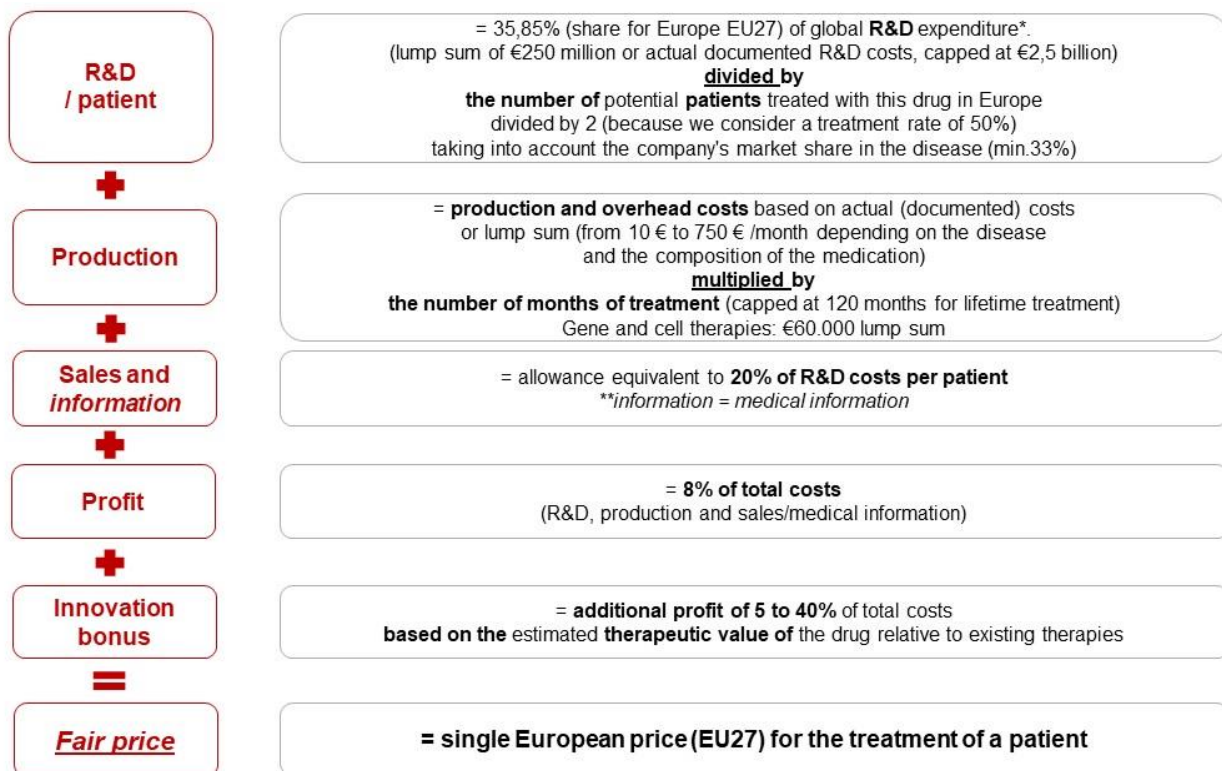
The fair price model sets a **single European price per treatment** when a new medicine comes to the market for a new indication.

¹⁰ See: https://www.aim-mutual.org/wp-content/uploads/2021/06/AIMs-fair-pricing-model-Accompanying-paper-to-the-fair-pricing-calculator_June2021.pdf

It does, however, allow for price differentiation according to the purchasing power¹¹ of each European country, thus increasing intra-European solidarity between the richest countries and those with lower purchasing power. In order to avoid parallel trade generated by different prices between countries, which would risk slowing down accessibility in low-income countries, a kind of "compensation" funds between countries should then be put in place, with richer countries compensating for the lower prices of weaker countries. Pharmaceutical companies would then have the same interest in marketing their medicines in each country.

Each parameter of the model is further defined in Figure 3.

Figure 3 Description of the components of the Association Internationale de la Mutualité (AIM) fair price model



*Research and development expenses (fixed or actual costs) cover all of the firm's R&D costs up to the time of the drug's market authorization. The costs charged to new drugs include the research costs for other drugs whose R&D was abandoned and which did not reach the market ("cost of failure").

Source: Solidaris (2022) based on AIM model (2019)

Based on this model, AIM has developed a practical tool; a "calculator" that helps determine a fair price for new treatments, freely available on the internet <https://fairpricingcalculator.eu/>.

Solidaris has developed the French version of the **calculator**, also available at www.lejusteprixdesmedicaments.be.

¹¹ Calculated by gross domestic product per capita.

AIM member, the German health insurance company Techniker Krankenkasse (TK), in collaboration with the University of Bremen, studied the use of the AIM calculator on 7 recent medicines representative of various growth areas (Muth L., 2021)¹².

The study showed that prices in Germany today are two to thirteen times too high¹³.

According to this German study, if the average rebate calculated by weighting the rebate of each of the 7 medicines selected for the study by the sales volume of each of these medicines (i.e. **63,34%**) was applied to all medicines under patent, the statutory health insurance (GKV) in **Germany would save 13 billion euros annually** (Table 3).

Table 3: Potential savings using the AIM fair price calculator in Germany

Molecule	Brand name	Net GKV Expenditures 2019	GKV expenses at AIM price 2019	Potential savings GKV prices 15.07.2021	Savings potential GKV price 15.07.2021 [%]
Onasemnogen-Abeparvovec	Zolgensma	NA		NA	
Nusinersen	Spinraza	13.729.200 €	1.571.137 €	12.158.063 €	88,56%
Sacubitril-Valsartan	Entresto	186.611.500 €	86.421.551 €	100.189.949 €	53,69%
Empagliflozin	Jardiance	198.084.200 €	221.467.133 €	-23.382.933 €	-11,80%
Secukinumab	Cosentyx	336.341.700 €	51.255.204 €	285.086.496 €	84,76%
Nivolumab	Opdivo	453.619.400 €	82.197.307 €	371.422.093 €	81,88%
Trifluridin/Tipiracil	Lonsurf	23.807.800 €	1.497.111 €	22.310.689 €	93,71%
		1.212.193.800 €	444.409.443 €	767.784.357 €	63,64%
GKV- net medicines under patent		20.637.000.000 €		13.071.148.992 €	63,34%

Source: TK (2021)

D. Objective of the study

Solidaris used the fair price model developed in collaboration with AIM and calculated the fair price in Belgium for the 7 medicines used in the German TK study, and extrapolated the results to all new medicines reimbursed since 2015.

Indeed, 2015 marked a symbolic turning point with the reimbursement for the first time of treatments affecting a large population (affected by hepatitis C) with prices¹⁴ of more than 40.000€ per patient. Furthermore, out of the 10 medicines that cost the most to the NIHDI are reimbursed since 2015 or later.

¹² https://www.aim-mutual.org/wp-content/uploads/2021/10/TK_AIM-Fair-Pricing-Calculator-EN_Rev.pdf

¹³ Except for the medicine Jardiance for which TK calculated a price increase with the calculator following the use of the monthly flat rate of 50€ for the production cost (higher than the price).

¹⁴ List prices (i.e. before refunds in managed entry agreements).

1. DATA AND METHODOLOGY

1.1. Cases selected for the study

We used the calculator with the same 7 molecules as in the German TK study in order to benefit from the expertise offered by this insurer and the University of Bremen. These molecules are also relevant because they are representative of the diversity of innovative treatments currently reimbursed. They include:

- 2 treatments for **(ultra-)rare** diseases, including one **gene therapy** (Zolgensma) which has the highest (face) price per administration (almost 2 million euros for a single administration) at present;
- 2 treatments for **cancer**, which is the disease for which medicine expenditures are increasing the most, and one of which (melanoma) is **10 times more frequent** than the other (metastatic gastric cancer);
- 3 **chronic** treatments, one of which affects more than **1,5% of the population**, which allows for very low production costs.

This selection reflects the current cost of innovative treatments as orphan medicines treating rare diseases (such as metabolic diseases) and cancer treatments now exceed one billion in net expenditure.

3 medicines (Entresto, Cosentyx and Lonsurf) among the 7 are also not reimbursed under managed entry agreement, which is increasingly rare, and therefore allows an accurate calculation of the impact of the application of the model.

The calculation of the fair price is done for each indication¹⁵ of a medicine. Research costs, the number of patients to be treated and the duration of treatment can vary greatly from one disease/condition to another treated with the same medicine. The indications analyzed in the TK and Solidaris study are presented in Table 4.

Table 4: Medicines and indications selected for the study of potential savings using the AIM Fair Price Calculator

<u>Molecule</u>	<u>Medicine</u> (brand name)	<u>Indication in the TK/Solidaris study</u>
Onasemnogen-abeparvovec	Zolgensma [®]	Spinal muscular atrophy (SMA) 5q type 1 or up to 3 copies of the SMN2* gene
Nusinersen	Spinraza [®]	Spinal muscular atrophy (SMA) 5q*
Sacubitril-Valsartan	Entresto [®]	Chronic symptomatic heart failure with reduced ejection fraction*.
Empagliflozin	Jardiance [®]	Type 2 diabetes (as monotherapy or in combination with other treatments)*.

¹⁵ An indication for a medicine is a medical condition/disease for which that medicine is used. It may be the entire population of patients with the disease or only a portion limited to a subtype of the disease, a certain line of treatment, or a specific age category.

Secukinumab	Cosentyx®	moderate to severe plaque psoriasis, spondyloarthritis ankylosing spondylitis, psoriatic arthritis and non-radiographic axial spondyloarthritis
Nivolumab	Opdivo®	advanced unresectable or metastatic melanoma (as a single agent or in combination with ipilimumab)***.
Trifluridine/Tipiracil	Lonsurf®	Metastatic gastric cancer (mGC) including gastroesophageal junction adenocarcinoma (previously treated with at least two systemic treatment protocols in advanced disease)***

* The only existing indication for the medicine

** Calculated for all indications

*** Other indications not included: melanoma is the first indication for which Opdivo is approved, but it is also used for many other cancers¹⁶; for Lonsurf, gastric cancer is the second indication reimbursed (after metastatic colorectal carcinoma).

For these 7 medicines, the Belgian health insurance paid out nearly 190 million euros in gross expenditure.

After deducting the average rebate for 2020 for medicines under managed entry agreement of 41,19%, we obtain net expenditure in 2020 of around 130 million euros for these 7 medicines. This method of estimating the net cost is the only possibility, given the total confidentiality of the rebates actually granted under the secret agreements.

Table 5: Actual expenditures for the 7 study medicines in 2020

<u>Medicine</u> (brand name)	<u>Molecule</u>	<u>Net Expenditure 2020</u>
Spinraza®	Nusinersen	23.421.350 € (1)
Entresto®	Sacubitril- Valsartan	14.508.150 €
Jardiance®	Empagliflozin	10.358.238 € (1)
Cosentyx®	Secukinumab	25.920.955 €
Opdivo®	Nivolumab	52.146.329 € (1)
Lonsurf®	Trifluridine/Tipiracil	3.221.352 € (2)
Zolgensma®	Onasemnogen- abeparvovec	0 € (3)
Total		129.576.374 €

(1) For medicines under managed entry agreement, estimate by removing 41,19% (= average rebate in 2020

- MORSE 2021 report p.65) to gross expenditures.

(2) Special case: medicine in category F (list price differentiated from reimbursement level but published) so net expenditure is known.

(3) Zolgensma was not yet reimbursed in 2020.

Source: NIHDI - Solidaris calculations

¹⁶ Non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC), classical Hodgkin's lymphoma (cHL), squamous cell carcinoma of the head and neck (SCCHN), urothelial carcinoma, and squamous cell carcinoma of the esophagus (SCC).

The AIM fair price model and its calculator calculate a single European price. However, the model allows for price differentiation according to the purchasing power of each European country, thus increasing intra-European solidarity between richer countries and countries with lower purchasing power via a compensation fund for example. TK has chosen for its study the option of a differentiated price (i.e. + 20% for Germany) and Solidaris has followed the same method. For Belgium, the price is therefore the average European price + 18%.

1.2. Data integrated in the calculator

In order to integrate in the calculator the most relevant data for the 7 selected molecules, we validated the data used in the German study.

After checking, for each medicine the assumptions made by TK in terms of patient population and research and development (R&D) cost, i.e. 250 million euros for each medicine for the indication(s) studied¹⁷ was kept. The prevalence of disease for each molecule and indication used in our calculation is taken from the TK study (German data) and is consistent with that for Belgium.

Minor corrections have been made in order to comply more strictly with the assumptions made in the AIM model or to be consistent with the reimbursement file submitted in Belgium.¹⁸

For Zolgensma, 2 simulations are presented:

- The first one uses the number of patients with SMA type I and II calculated on the basis of the prevalence and incidence of this pathology in a recently published scientific article (*Thielen 2022*), i.e. 13.607 patients potentially treated over a 10-year period. This total number of patients is then restricted in our study to the proportion that the European Union represents in the AIM model, i.e. 35,85% of the total, which gives **4.878 potential patients**;
- The second, much more conservative, calculation uses the prevalence used by TK in its study, i.e. 0,17/100 000 inhabitants for the European population, which gives **761 potential European patients (EU 27)** over a 10-year period. This calculation only considers type I SMA and does not take into account the new patients (incidence) that will be born during the 10-year period considered.

The fair price per treatment calculated according to these 2 simulations increases from 250.000 euros for the first simulation¹⁹ to more than 1 million for the second.

It is important to keep in mind that in both simulations it is assumed the cost of Zolgensma that this gene therapy (which replaces a defective gene) at a list price of nearly 2 million Euros will be administered only once per patient. However, it is not excluded that a re-treatment will be necessary after some years.

The price of 250.000 euros is used in Part 2 of the study, which describes and analyzes the results.

Table 6 provides the detailed parameters used for each medicine.

¹⁷ as will be explained later, higher R&D costs would have had very little influence on the final result.

¹⁸ Adaptations are:

- Duration of Spinraza treatment: 120 months (versus 34 in the TK study)
- Opdivo treatment duration: 24 months (versus 60 in the TK study)
- Monthly treatment cost of Jardiance: 10 € due to the very high volume (versus 50 in the TK study).

¹⁹ The author also simulates a price for Zolgensma according to a cost-based approach with the addition of a profit based on the therapeutic value of the medicine, and calculates a price of 380.000 euros.

Table 6: Data used to calculate the fair price

	Zolgensma	Spinraza	Entresto	Jardiance	Cosentyx	Opdivo	Lonsurf
Global R&D	Lump sum of €250 million						
Prevalence or incidence of the indication(s) included in the study	4 878 patients - 0,17 /100.000	1,22 /100.000	0,66% of the population	1,51% of the population	0,13% of the population	254,9 /100.000 /year	22,2 /100.000 /year
European target population of this/these indications*	4.878 - 761	5.460	2.953.500	6.757.250	581.750	11.406.775	993.450
= R&D/patient	73.493€ - 471.245 €	32.833 €	182 €	80 €	924 €	47 €	180 €
Production costs	60.000 €	250 € /month	50 € /month	10 € /month	150 € /month	150 € /month	50 € /month
X treatment duration	once	120 months	120 months	120 months	120 months	24 months	2 months
= Production	60.000 €	30.000 €	6.000 €	1.200 €	18.000 €	3.600 €	100 €
Sales & medical info	20% R&D						
Profit	8% of all costs (R&D, production, sales and info)						
Innovation bonus % of all costs (R&D, production, sales and info)	35%	40%	15%	10%	35%	15%	10%
Fair price (Belgium)**	250.059 € - 1.055.460 €	121.199 €	9.026 €	1.804 €	32.245 €	5.307 €	441 €
Share of R&D in the price	29% - 45%	27%	2%	4%	3%	1%	41%
Share of production in the price	24% - 6%	25%	66%	67%	56%	68%	23%

*Number of patients affected by this disease/indication over 10 years (divided by 2 for the number that will be treated for this disease/indication).

** In the study we use the European fair price for Belgium, adapted to the Belgian standard of living (i.e. +18%)

Source: Solidararis - using the AIM/Solidararis calculator

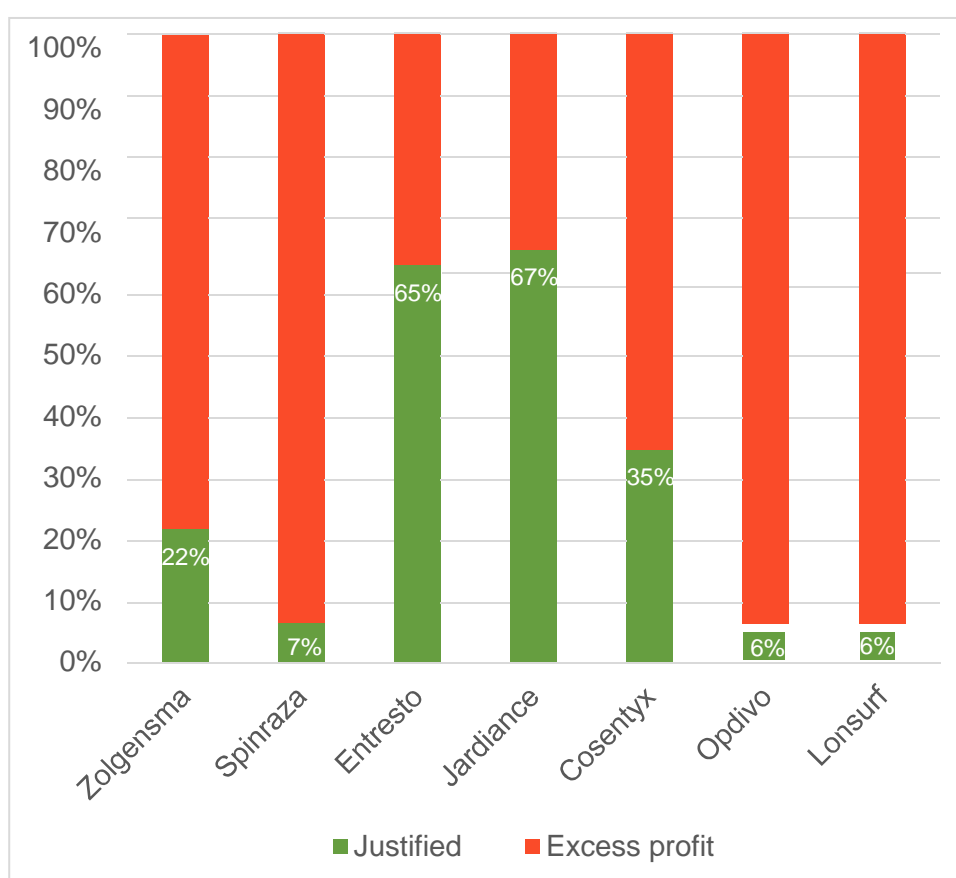
2. RESULTS OF THE CALCULATOR FOR THE 7 CASES

2.1 Calculating the fair price

By applying the parameters of the AIM fair price model, Solidaris has calculated the fair price for Belgium for 7 medicines. This calculation takes into account the purchasing power in Belgium compared to other European countries, i.e. the European fair price + 18%.

Applying the model, **the fair price is between 6% and 67% of the current actual price**, depending on the medicine.

Figure 4 Percentage of the price that is fair according to the model, compared to the price currently paid (price per treatment)



Source : calculs Solidaris (2020)

With the current negotiations (including rebates in secret managed entry agreements), pharmaceutical companies have their costs covered by a wide margin and make **excess profits ranging from 33 to 94% of the price**.

As shown in Table 7, for 3 medicines (Spinraza, Opdivo and Lonsurf), **the current price is more than 10 times higher than a price considered "fair"**.

Table 7: Ratio of current price per treatment to fair price

	Zolgensma	Spinraza **	Entresto **	Jardiance **	Cosentyx **	Opdivo	Lonsurf
Current Price* (\$)	1.143.855	1.665.617	13.943	2.683	92.661	93.568	7.191
Fair price*	250.059	121.199	9.026	1.804	32.245	5.307	441
Current/fair	5 times	14 times	1.5 times	1.5 times	3 times	18 times	16 times

*per treatment, in euros
** price for 10 years of treatment

Source: Solidararis calculations

The current costs paid for treatments are all the more disturbing because these medicines, like all medicines, have limited effectiveness.

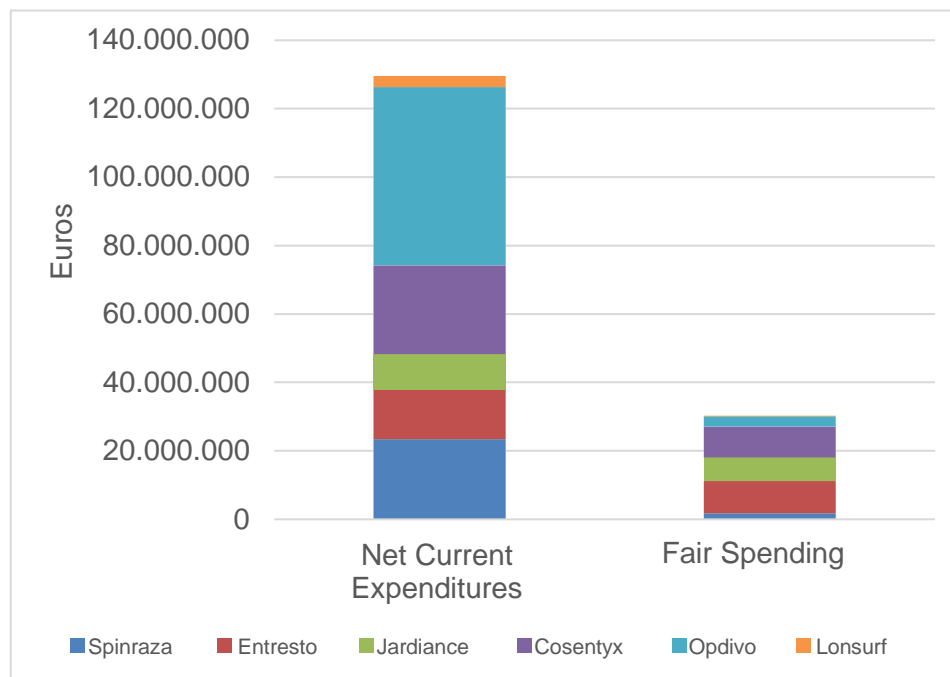
The case of cancer treatments is particularly challenging in light of the findings of various studies, including a research by the Federal Center of Expertise for Health Care (*KCE, 2021*) showing the significant increase in gross expenditures and average treatment costs, with no clear improvement in overall survival.

This is in line with Solidararis figures showing that for the 2 cancer treatments studied, only 19% of the patients treated²¹ with Lonsurf and 32% of those treated with Opdivo are still alive today. For the deceased patients, average (list) treatment costs of respectively € 7.411 and € 34.356 have been charged to the health insurance for these treatments.

**If the fair price had been applied for the 7 medicines in the study for which 130 million were spent in 2020,
more than 99 million euros would have been saved,
or an average of 76.67% or three-quarters of the price currently paid.**

²¹ since reimbursement began in 2017 for Lonsurf and 2016 for Opdivo.

Figure 5 Comparison of medicine costs between net current expenditures and fair expenditures



Source: Solidaris calculations (NIHDI 2020 expenditures)

2.2 Impact on health care spending in Belgium

New medicines reimbursed from 2015 represented just under €2 billion in gross spending in 2020²². For nearly 1,4 billion of spending on these medicines, there is a confidential managed entry agreement with refund. After removing the average rebate granted in managed entry agreements in 2020 (41,19%), 1,381 billion was spent on medicines reimbursed since 2015 or later.

With the fair price, we would have paid only 322 million for these medicines and saved more than 1 billion euros (Table 8).

²² Solidaris calculation based on NIHDI data.

Table 8: Actual Expenditures and Potential Savings with Fair Price

Expenditure 2020	Amount (euros)
Patented medicines reimbursed from 2015 onwards	1.949.245.638
Of which with managed entry agreement	1.379.426.580
Average refund of 41,19%.	(568.185.808)
Net Actual Expenditures	1.381.059.830
Calculating the fair price	
Average percentage of savings	-76,67%
Fair price	322.201.258,32
Savings if the fair price was applied	1.058.858.572

Source: Solidaris calculation (NIHDI 2020 expenditures)

If the fair price as calculated for the 7 selected medicines was applied, Belgium would pay 4 times less for innovative medicines.

The amount that could be saved each year is 1 billion euros and accounts for 20% of medicine expenditures.

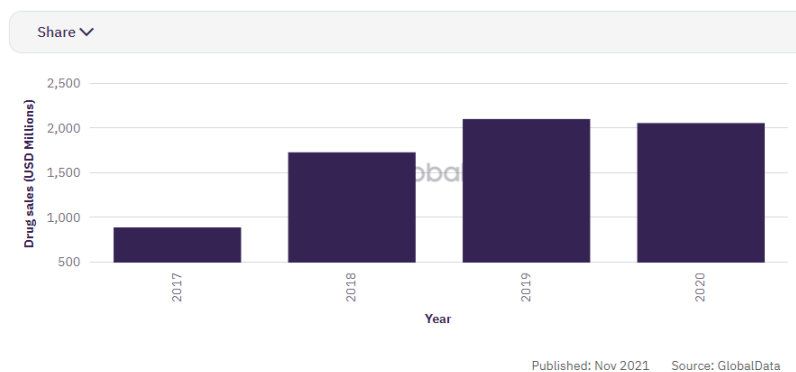
3. DISCUSSION OF RESULTS

3.1. Discussion of the results by medicine

An orphan is not an orphan!

Orphan medicines treat rare or even ultra-rare diseases. As shown in Table 1, the price paid per patient is particularly high (more than 180.000 € per year per patient for the 10 most expensive medicines). Pharmaceutical companies justify this price because of the small number of patients and the need to amortize research on this small target population. The need for research support for rare diseases is not in doubt, **however, small numbers of patients does not necessarily mean too small for a reasonable price.** Spinraza with a potential of 5.460 patients in Europe and a treatment cost of 255.000€ per year per patient (gross in Belgium) generates revenues of more than 2 billion dollars per year worldwide, far from the assumption that orphan medicine implies fragile profitability!

The Global Drug sales of Spinraza (2017 - 2025, USD Millions)



This nuance in the size of the medicine's target population is not sufficiently taken into account today. In the fair price model, research is distributed over the number of patients specific to the medicine. A medicine that reaches 10 times as many patients will therefore have a research cost component divided by 10. This fair price distributes resources more equitably among pharmaceutical companies that do useful research and prevents some from profiteering.

Cancer treatments are overpaid.

Analyzing two oncology medicines administered for cancers of very different frequencies shows that for both the 11.406.775 European patients potentially treated with Opdivo (only for the melanoma indication) and for the 993.450 potentially treated with Lonsurf, **the price is respectively 18 and 16 times too high!** Knowing that more than 1 billion euros are spent annually in Belgium on cancer medicine treatments, the waste of resources is gigantic.

With a fair price, the savings for the health system of the richest countries would be enormous, but it is especially the situation of the countries with the lowest incomes that would be improved.

3.2. Discussion of the parameters of the fair price model

- R&D :

The argument frequently put forward by pharmaceutical companies to defend the high prices of new treatments is the cost of research and the need to recoup investments made to develop new medicines. It is important to keep this in mind if we want to continue to support innovation²³.

The model defaults to a lump sum (i.e., no justification to be provided) of 250 million euros per medicine for the worldwide R&D costs allocated to that medicine. The model also allows the pharmaceutical company to amortize higher actual costs (with accounting justification) up to a ceiling of 2,5 billion euros. This ceiling was set taking into account analyses giving the cost calculated according to the most advantageous methodology for the industry²⁴.

If we apply this maximum amount of 2,5 billion for research, the results change surprisingly little. As Table 9 shows, the health insurance would still save 59% of its current spending on new medicines, or more than 800 million euros per year.

This weak influence of global R&D costs can be better understood by analyzing the last row of Table 6, which shows that the amount of research and development per patient is an element of very little influence (representing 1 to 4% of the fair price) for 4 out of the 7 cases.

The size of the patient population on which the research is amortized has, on the other hand, a greater impact on the share of R&D, as can be seen for the three medicines studied with small populations, where this share represents between 27 and 41% of the fair price.

Table 9: Potential savings as a function of the amount of R&D (in euros)

	Spinraza	Entresto	Jardiance	Cosentyx	Opdivo	Lonsurf	Weighted average
Current (2020) Net Expenditures	23.421.350	14.508.150	10.358.238	25.920.955	52.146.329	3.221.352	
Economy:							
if 250 million R&D :	93%	35%	33%	65%	94%	94%	76,67%
if 800 million R&D :	84%	30%	22%	61%	94%	85%	72,4%
if 2,5 billion R&D :	56%	15%	-	47%	94%	56%	59,2%

Source: Solidaris calculations

- Production costs :

Production costs represent 2/3 of the costs for chronic or long-term treatments in the model. These production costs are based on lump sums ranging from €50 to €250 per month, which are large when compared to actual costs found in the literature (*Barber, 2020*).

²³ The AIM/Solidaris model particularly supports "useful" innovation via the Innovation bonus, which allows an additional profit of 5 to 40% in relation to the value of the medicine for the patient.

²⁴ "The medicine development process requires investments, estimated at between \$60 million and \$2,6 billion, although most estimates are around \$800 million." (*Van der Gronde, 2017*). The maximum cost of 2,6 billion includes opportunity costs, i.e., the profit the company could have made by investing otherwise, for half the value of the investment.

CONCLUSIONS AND RECOMMENDATIONS

The prices of new medicines are negotiated in secret most of the time and are constantly increasing. The weight of recent medicines in health care spending is problematic. Orphan medicines and cancer medicines in particular benefit from the current pricing system and get prices more than 10 times higher than what would be necessary to cover the development and production costs of these medicines while remunerating shareholders and valuing useful innovation. The model developed by AIM and Solidararis is a clear illustration of this. The potential annual savings of 1 billion euros should make more than one patient and more than one political decision-maker think...

In order to move towards a fair price for medicines in Belgium, Solidararis recommends to :

1) Use the "fair price" as a negotiating element for the price of new medicines.

The Commission for the Reimbursement of Medicines set up at the NIHDI currently formulates proposals for the reimbursement of new medicines to the Minister of Social Affairs without taking into account any element relating to the real cost of the medicines for the manufacturer. **Solidararis recommends adding a criteria for the evaluation of reimbursement files; the fair price calculated on the basis of the AIM/Solidararis model and its calculator.** This price can then be used as a starting point in negotiations with the company, in addition to the price requested by the company. The discussion on a pricing model based on the costs of the pharmaceutical companies should allow to create some transparency on costs.

2) Review the price of orphan medicines based on their cost-effectiveness.

5²⁵ of the 10 most expensive orphan medicines are off patent or about to go off patent. For orphan medicines, even if the patent has expired, the market may be so small or complex that no generic or biosimilar alternatives are marketed. Some originator companies even use strategies to delay the arrival of alternatives, as is the case for Soliris (*GaBi, 2020*). These medicines thus maintain their huge cost indefinitely²⁶. **Solidararis recommends applying the principles of the AIM/Solidararis cost and value model to determine whether orphan medicines justify maintaining current prices.**

3) Restore price transparency.

Experts and policy makers are unable to decide on correct prices due to lack of information on both foreign and Belgian prices for alternatives. Applying the fair price model at European level would allow full transparency on prices and costs. Pending this complete transparency, **Solidararis recommends increasing transparency at the Belgian level by relaxing the confidentiality around managed entry agreements, in particular in order to :**

- **provide access to actual negotiated managed entry agreement prices to members of the Committee for Reimbursement of Medicines (CRM/CTG);**

²⁵ Naglazyme, Soliris, Myozyme, Cerezyme, and Cerdelga have been reimbursed for more than 12 years, which is the typical length of time a medicine is under patent protection.

²⁶ Except for the price cuts imposed on "old medicines": <https://www.NIHDI.fgov.be/fr/themes/cout-reimbursement/by-mutuality/medicament-products-health/reimbursement/specialties/Pages/measure-diminution-old-medicines.aspx>

- **make the amounts of refunds by class of medicines publicly available** (without disclosing the amount per individual medicine, which is protected by managed entry agreement confidentiality).

4) Support the use of AIM/Solidaris model at European level.

Belgium will hold the Presidency of the Council of the European Union during the 1^{er} semester of 2024. **Solidaris recommends to seize this opportunity to put the discussion between member states on the implementation of a European fair price model on the European agenda.**

5) Test the calculator!

Simulations for the 7 medicines used in the study using the Solidaris fair price calculator available at www.lejusteprixdesmedicaments.be can be found in Appendix.

Test the calculator with one or more of these examples in order to get familiar with its use and to be able to assess for yourself the fair price that the social security should pay for new medicines.

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APPENDIX - USE OF AIM/SOLIDARIS CALCULATOR FOR THE 7 CASES

1. Zolgensma – 4.878 patients

DESCRIPTION OF THE MEDICINE AND THE PATIENT POPULATION

Type of disease

Manual

Estimated total patient population (prevalence/incidence/number of patients)

4 878 patients /10 years period

Target population (automatic)

4 878 patients (10 year period)

Treated population (automatic)

50%

Global R&D cost for the medicine developer

€250 000 000

Number of expected competitors (market share)

1 competitor (1/2 of the market)

Composition of the medicine/Production cost

Gene or cell therapy (€60 000/full treatment)

Average duration of treatment in months

1

Sales and medical information (automatic)

20% of R&D cost

Basic profit (automatic)

8% of total cost

LEVEL OF INNOVATION BASED ON THE THERAPEUTIC VALUE

5

The medicine is indicated for a life-a or chronically debilitating disease

30

The medicine is curative (the disease is cured) or has a major impact on the course of the disease

FAIR PRICE COMPONENTS (per treatment per patient)

R&D cost	€73 493,23
Production cost	€60 000,00
Sales and medical information	€14 698,65
Basic profit	€11 855,35
Innovation bonus	€51 867,16

FAIR PRICE CALCULATION

Fair price per treatment per patient	€211 914,39
--------------------------------------	--------------------

Comments:

Fair price for Belgium	€250 058,98
------------------------	--------------------

2. Zolgensma – 0,17/100.000

DESCRIPTION OF THE MEDICINE AND THE PATIENT POPULATION

Type of disease
Ultra-rare disease

Estimated total patient population (prevalence/incidence/number of patients)
0,17 /100 000 (prevalence)

Target population (automatic)
761 patients (10 year period)

Treated population (automatic)
50%

Global R&D cost for the medicine developer
€250 000 000

Number of expected competitors (market share)
1 competitor (1/2 of the market)

Composition of the medicine/Production cost
Gene or cell therapy (€60 000/full treatment)

Average duration of treatment in months
1

Sales and medical information (automatic)
20% of R&D cost

Basic profit (automatic)
8% of total cost

LEVEL OF INNOVATION BASED ON THE THERAPEUTIC VALUE

5

The medicine is indicated for a life-threatening or chronically debilitating disease

30

The medicine is curative (the disease is cured) or has a major impact on the course of the disease

FAIR PRICE COMPONENTS (per treatment per patient)

R&D cost	€471 245,48
Production cost	€60 000,00
Sales and medical information	€94 249,10
Basic profit	€50 039,57
Innovation bonus	€218 923,10

FAIR PRICE CALCULATION

Fair price per treatment per patient	€894 457,25
--------------------------------------	-------------

Comments:

Fair price for Belgium	€1 055 459,55
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3. Spinraza

DESCRIPTION OF THE MEDICINE AND THE PATIENT POPULATION

Type of disease

Ultra-rare disease

Estimated total patient population (prevalence/incidence/number of patients)

1,22 /100 000 (prevalence)

Target population (automatic)

5 460 patients (10 year period)

Treated population (automatic)

50%

Global R&D cost for the medicine developer

€250 000 000

Number of expected competitors (market share)

0 competitor (total market)

Composition of the medicine/Production cost

Orphan chemical (€250/month)

Average duration of treatment in months

120

Sales and medical information (automatic)

20% of R&D cost

Basic profit (automatic)

8% of total cost

LEVEL OF INNOVATION BASED ON THE THERAPEUTIC VALUE

5

The medicine is indicated for a life-threatening or chronically debilitating disease

5

The medicine has no alternative

30

The medicine is curative (the disease is cured) or has a major impact on the course of the disease

FAIR PRICE COMPONENTS (per treatment per patient)

R&D cost	€32 832,68
Production cost	€30 000,00
Sales and medical information	€6 566,54
Basic profit	€5 551,94
Innovation bonus	€27 759,68

FAIR PRICE CALCULATION

Fair price per treatment per patient	€102 710,83
Fair price per month of treatment per patient	€855,92
Fair price per year of treatment	€10 271,08

Comments:

Fair price for Belgium	€121 198,78
------------------------	-------------

4. Entresto

DESCRIPTION OF THE MEDICINE AND THE PATIENT POPULATION

Type of disease

Chronic disease

Estimated total patient population (prevalence/incidence/number of patients)

0,66% of total population

Target population (automatic)

2 953 500 patients (10 year period)

Treated population (automatic)

50%

Global R&D cost for the medicine developer

€250 000 000

Number of expected competitors (market share)

2 competitors (1/3 of the market)

Composition of the medicine/Production cost

Chemical (€50/month)

Average duration of treatment in months

120

Sales and medical information (automatic)

20% of R&D cost

Basic profit (automatic)

8% of total cost

FAIR PRICE COMPONENTS (per treatment per patient) i

LEVEL OF INNOVATION BASED ON THE THERAPEUTIC VALUE

5%

The medicine is indicated for a life-threatening or chronically debilitating

10%

The medicine has shown a major improvement of the quality of life (QoL)

R&D cost	€182,07
Production cost	€6 000,00
Sales and medical information	€36,41
Basic profit	€497,48
Innovation bonus	€932,77

FAIR PRICE CALCULATION i

Fair price per treatment per patient	€7 648,74
Fair price per month of treatment per patient	€63,74
Fair price per year of treatment	€764,87

Comments:

Fair price for Belgium	€9 025,51
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5. Jardiance

DESCRIPTION OF THE MEDICINE AND THE PATIENT POPULATION

Type of disease

Chronic disease

Estimated total patient population (prevalence/incidence/number of patients)

1,51% of total population

Target population (automatic)

6 757 250 patients (10 year period)

Treated population (automatic)

50%

Global R&D cost for the medicine developer

€250 000 000

Number of expected competitors (market share)

2 competitors (1/3 of the market)

Composition of the medicine/Production cost

Manual

Manual medicine/Production cost

€10,00

Average duration of treatment in months

120

Sales and medical information (automatic)

20% of R&D cost

Basic profit (automatic)

8% of total cost

LEVEL OF INNOVATION BASED ON THE THERAPEUTIC VALUE

5

The medicine is indicated for a life-threatening or chronically debilitating

5

The medicine has shown an overall survival (OS) gain vs the comparator

FAIR PRICE COMPONENTS (per treatment per patient) i

R&D cost	€79,58
Production cost	€1 200,00
Sales and medical information	€15,92
Basic profit	€103,64
Innovation bonus	€129,55

FAIR PRICE CALCULATION i

Fair price per treatment per patient	€1 528,69
Fair price per month of treatment per patient	€12,74
Fair price per year of treatment	€152,87

Comments:

Fair price for Belgium	€1 803,85
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6. Cosentyx

DESCRIPTION OF THE MEDICINE AND THE PATIENT POPULATION

Type of disease

Chronic disease

Estimated total patient population (prevalence/incidence/number of patients)

0,13% of total population

Target population (automatic)

581 750 patients (10 year period)

Treated population (automatic)

50%

Global R&D cost for the medicine developer

€250 000 000

Number of expected competitors (market share)

2 competitors (1/3 of the market)

Composition of the medicine/Production cost

Biological (€150/month)

Average duration of treatment in months

120

Sales and medical information (automatic)

20% of R&D cost

Basic profit (automatic)

8% of total cost

LEVEL OF INNOVATION BASED ON THE THERAPEUTIC VALUE

5

The medicine is indicated for a life-threatening or chronically debilitating disease

30

The medicine is curative (the disease is cured) or has a major impact on the course of the disease

FAIR PRICE COMPONENTS (per treatment per patient) i

R&D cost	€924,37
Production cost	€18 000,00
Sales and medical information	€184,87
Basic profit	€1 528,74
Innovation bonus	€6 688,23

FAIR PRICE CALCULATION i

Fair price per treatment per patient	€27 326,21
Fair price per month of treatment per patient	€227,72
Fair price per year of treatment	€2 732,62

Comments:

Fair price for Belgium	€32 244,93
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7. Opdivo

DESCRIPTION OF THE MEDICINE AND THE PATIENT POPULATION

Type of disease

Cancer

Estimated total patient population (prevalence/incidence/number of patients)

254,90 /100 000 (yearly incidence)

Target population (automatic)

11 406 775 patients (10 year period)

Treated population (automatic)

50%

Global R&D cost for the medicine developer

€250 000 000

Number of expected competitors (market share)

2 competitors (1/3 of the market)

Composition of the medicine/Production cost

Biological (€150/month)

Average duration of treatment in months

24

Sales and medical information (automatic)

20% of R&D cost

Basic profit (automatic)

8% of total cost

LEVEL OF INNOVATION BASED ON THE THERAPEUTIC VALUE

5%

The medicine is indicated for a life-threatening or chronically debilitating disease

10%

The medicine has shown an overall survival (OS) gain vs the comparator of more than 6 months or has a moderate impact on the course of the disease

FAIR PRICE COMPONENTS (per treatment per patient)

R&D cost	€47,14
Production cost	€3 600,00
Sales and medical information	€9,43
Basic profit	€292,53
Innovation bonus	€548,49

FAIR PRICE CALCULATION

Fair price per treatment per patient	€4 497,58
Fair price per month of treatment per patient	€187,40
Fair price per year of treatment	€2 248,79

Comments:

Fair price for Belgium	€5 307,15
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8. Lonsurf

DESCRIPTION OF THE MEDICINE AND THE PATIENT POPULATION

Type of disease

Cancer

Estimated total patient population (prevalence/incidence/number of patients)

22,20 /100 000 (yearly incidence)

Target population (automatic)

993 450 patients (10 year period)

Treated population (automatic)

50%

Global R&D cost for the medicine developer

€250 000 000

Number of expected competitors (market share)

0 competitor (total market)

Composition of the medicine/Production cost

Chemical (€50/month)

Average duration of treatment in months

2

Sales and medical information (automatic)

20% of R&D cost

Basic profit (automatic)

8% of total cost

LEVEL OF INNOVATION BASED ON THE THERAPEUTIC VALUE

5%

The medicine is indicated for a life-threatening or chronically debilitating disease

5%

The medicine has shown an overall survival (OS) gain vs the comparator of up to 6 months or has a minor impact on the course of the disease

FAIR PRICE COMPONENTS (per treatment per patient)

R&D cost	€180,43
Production cost	€100,00
Sales and medical information	€36,09
Basic profit	€25,32
Innovation bonus	€31,65

FAIR PRICE CALCULATION

Fair price per treatment per patient	€373,49
Fair price per month of treatment per patient	€186,75

Comments:

Fair price for Belgium	€440,72
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