A Public Eye Report – May 2018

Protect patients, not patents

How medicine prices are leading to two-tiered healthcare in Switzerland

Public Eye

IMPRINT Protect patients, not patents. How medicine prices are leading to two-tiered healthcare in Switzerland. A Public Eye Report, May 2018, 44 pages | **Authors** Patrick Durisch and Alexandre Gajardo | **Editing** Mary Louise Rapaud | **Acknowledgments** Oliver Classen, Timo Kollbrunner, Christa Luginbühl and Géraldine Viret | **Publisher** Raphaël de Riedmatten | **Layout** Karin Hutter, karinhutter.com | **Cover picture** © Karin Hutter/Public Eye, photos: MarkHenley/Panos

PUBLIC EYE Avenue Charles-Dickens 4, CH-1006 Lausanne | Phone +41 (0)21 620 03 03
Fax +41 (0)21 620 03 00 | contact@publiceye.ch | www.publiceye.ch | CP 10-10813-5

Executive summary

According to the World Health Organization (WHO), at least half of the world's population still lacks access to health services, and an estimated 2 billion people have no access to essential medicines. "These people will not enjoy the right to health", said former WHO Director General Margaret Chan at a session of the Human Rights Council in June 2017.

The lack of access to medicines has historically been a poor country issue, but in the last few years it has become a worldwide problem as high-income countries also start to encounter major barriers to guaranteeing universal access to medicines. Indeed, since the progressive implementation of a global patent system, with the adoption in 1995 of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS Agreement), prices of new medicines have significantly increased and are putting a staggeringly high burden on health budgets. By conferring a monopoly, and thereby creating pricing power, patents are the backbone of the business model used today by pharmaceutical companies and have the potential to drive the price of medicines to very high levels.

At the same time, high-priced medicines do not necessarily add significant value and their claimed benefits are not always supported by scientific evidence. Governments, payers, doctors, civil society and patients regularly demand that pharmaceutical companies disclose the cost of developing a new drug, so as to facilitate the setting of affordable prices. However, the cost of research & development (R & D) remains one of the best-kept secrets in this very profitable industry, or is subject to highly-inflated estimates when used by commercial entities.

As a result, most governments, including Switzerland, are toothless and forced to accept tremendously high prices for new medicines that have no proven correlation with actual R & D and production costs. These spiraling prices are threatening the sustainability of universal health coverage systems.

This is particularly the case for cancer medicines, the prices of which are skyrocketing despite the fact that cancer is one of the leading causes of death worldwide. If we do not stop this trend, only the most privileged will be able to afford these drugs. Millions will die and millions will be left behind.

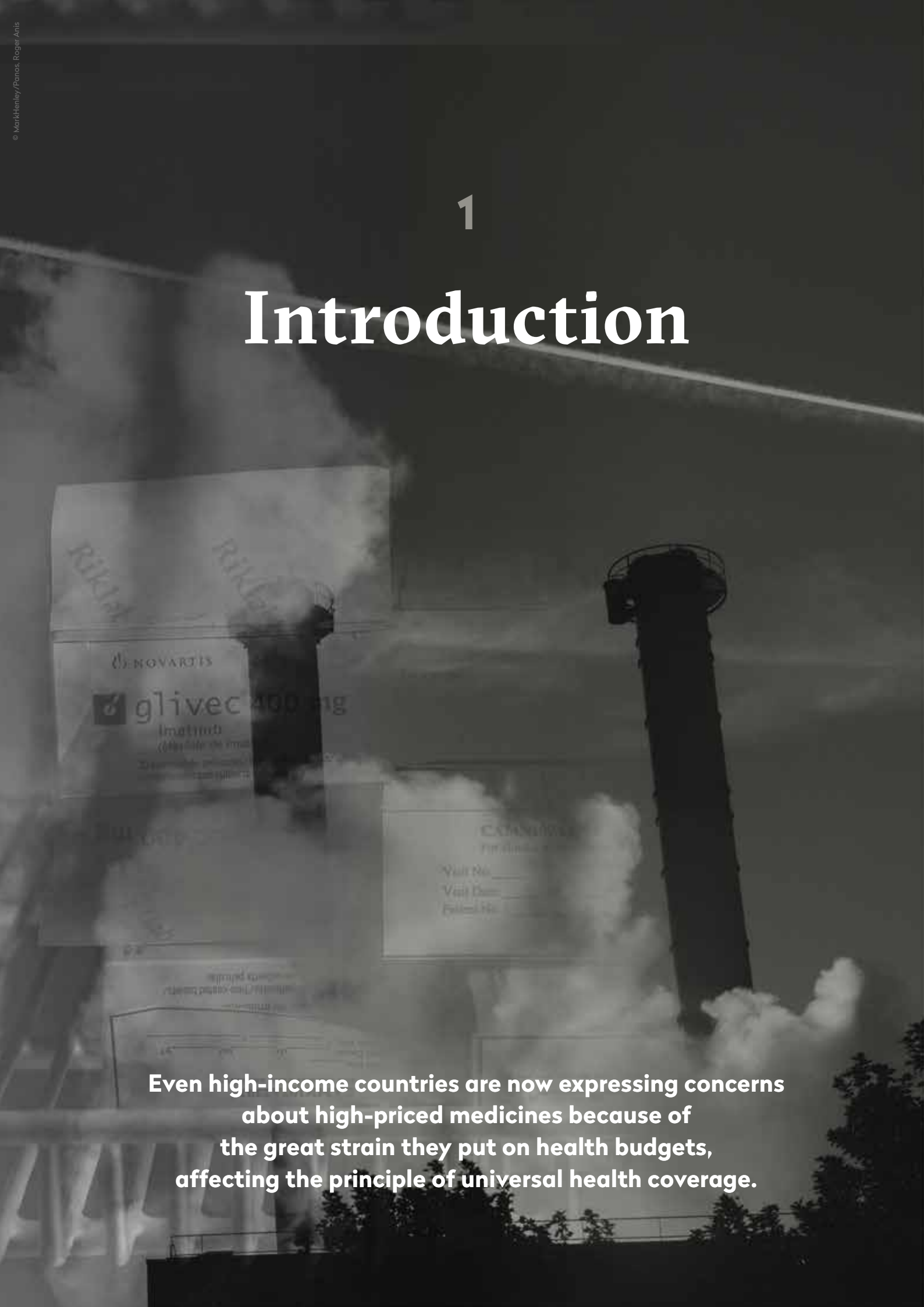
Yet solutions do exist. Whilst the WTO TRIPS Agreement has globalised a minimum standard for patent protection – including on pharmaceuticals for which exceptions existed in several of its 164 member states – it also includes some important public health safeguards. These so-called TRIPS flexibilities are intended to mitigate the adverse effects of patent protection and achieve a sound balance between public and private interests. Among them, compulsory licensing is considered an effective government tool to ensure affordable access to life-saving medicines, as it allows a third party (i.e. a generic producer) to use a patented product or process without the consent of the patent owner. But it has also been the subject of intense debate and misleading information because it supposedly threatens the financial interests of transnational pharmaceutical companies.

Compulsory licenses are legitimate legal tools to protect and promote public health. Although evidence shows that they significantly improve access to affordable medicines, many countries wanting to issue compulsory licenses have faced strong pressure and opposition from some governments and pharmaceutical companies. Swizerland in particular, despite its recurrent statements in favor of human rights and access to affordable medicines, has put undue diplomatic pressure on some countries, such as Thailand and Colombia, not to issue compulsory licenses. Further it regularly negotiates agreements with low- and middle-income countries which can potentially deter them from using tools such as compulsory licencing to protect public health.

When our societies can no longer afford unsustainable drug prices, an imbalance between private and public interests has been created. Public Eye considers that the current pharmaceutical pricing model, reliant on patent-based monopolies, works against the public interest, threatens the sustainability of all health systems around the world, and undermines universal health coverage even in a rich country like Switzerland. We believe that every person should have access at all times to quality, safe, efficacious and affordable medicines – regardless of where they live.

Public Eye calls on the Swiss authorities: (1) to adopt a clear and unequivocal stance against unjustifiable price hikes of medicines and to make use of compulsory licensing as required by public interest; (2) to refrain from spreading misleading information and imposing diplomatic pressure on countries wanting to protect public health; (3) to stop negotiating agreements with low- and middle-income countries that include provisions that go beyond the TRIPS standards, and that may undermine development and adversely affect human rights, especially access to medicines.

High medicine prices are not predestined and can be acted upon with political will.



1

Introduction

Even high-income countries are now expressing concerns about high-priced medicines because of the great strain they put on health budgets, affecting the principle of universal health coverage.

The lack of access to lifesaving medicines has historically been confined to developing and emerging countries,[1] [2] [3] [4] and reflects the blatant disparities and inequalities between the different regions of the world. The data shows that most of the largest pharmaceutical companies are located in a few high-income countries (World Bank term - HIC).[5] [6] [7] In 2004, an estimated 90 per cent of the global production of medicines was concentrated in the economically developed regions of the world.[8] From 2004–2008, 95 per cent of sales of newly introduced medicines were in North America, Europe and Japan and only 5 per cent in Africa and Asia, where more than two-thirds of the world's population lives.[9] Unlike patients in high-income countries (HICs) who benefit from national insurance reimbursement systems, patients in low- and middle-income economies (World Bank term – LMIC) cannot afford the high prices and so have not constituted an attractive market for transnational pharmaceutical companies.

Although markets in developing countries especially middle-income countries are becoming increasingly important to pharmaceutical companies in the face of a slow-down in their European and North American markets,[10] [11] access to affordable medicines in LMICs remains a distant dream, despite tireless calls from civil society to remedy this situation. Pharmaceutical companies target the wealthiest patients, pricing their products beyond the reach of the majority, even if prices seem comparatively lower than in high-income economies. [12] [13] If available at all, newer generation medicines in LMICs are accessed with the support of charities, or limited to those patients who can afford to pay the high prices themselves. The reality that most people in LMICs have to pay for their medicines out-of-pocket is simply not recognised. [14]

However, even HICs are now expressing concerns about high-priced medicines because of the great strain they put on health budgets, directly affecting the principle of universal health coverage. This trend has led many HICs to rationing decisions, depriving thousands of patients from access to much-needed medicines. As a result, access to affordable medicines is now a global problem and the issue is gaining traction in the international arena, as seen in the last US presidential elections.

High-priced medicines have serious consequences for public health. A major cause of this inflationary trend has been the progressive globalisation of patent protection through the adoption of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS Agreement) in 1995.

In the pharmaceutical field, patents are used by transnational pharmaceutical corporations to impose and sustain their technological domination, and to secure profits. By conferring a 20-year monopoly on drug manufacturers, patents create pricing power[15]. As a result, companies can potentially push medicine prices to exorbitant levels – regularly beyond the bar of USD 100,000 per year for a cancer medicine, even going as high as USD 450,000 for a single treatment. Unfortunately, these trends are today's reality.

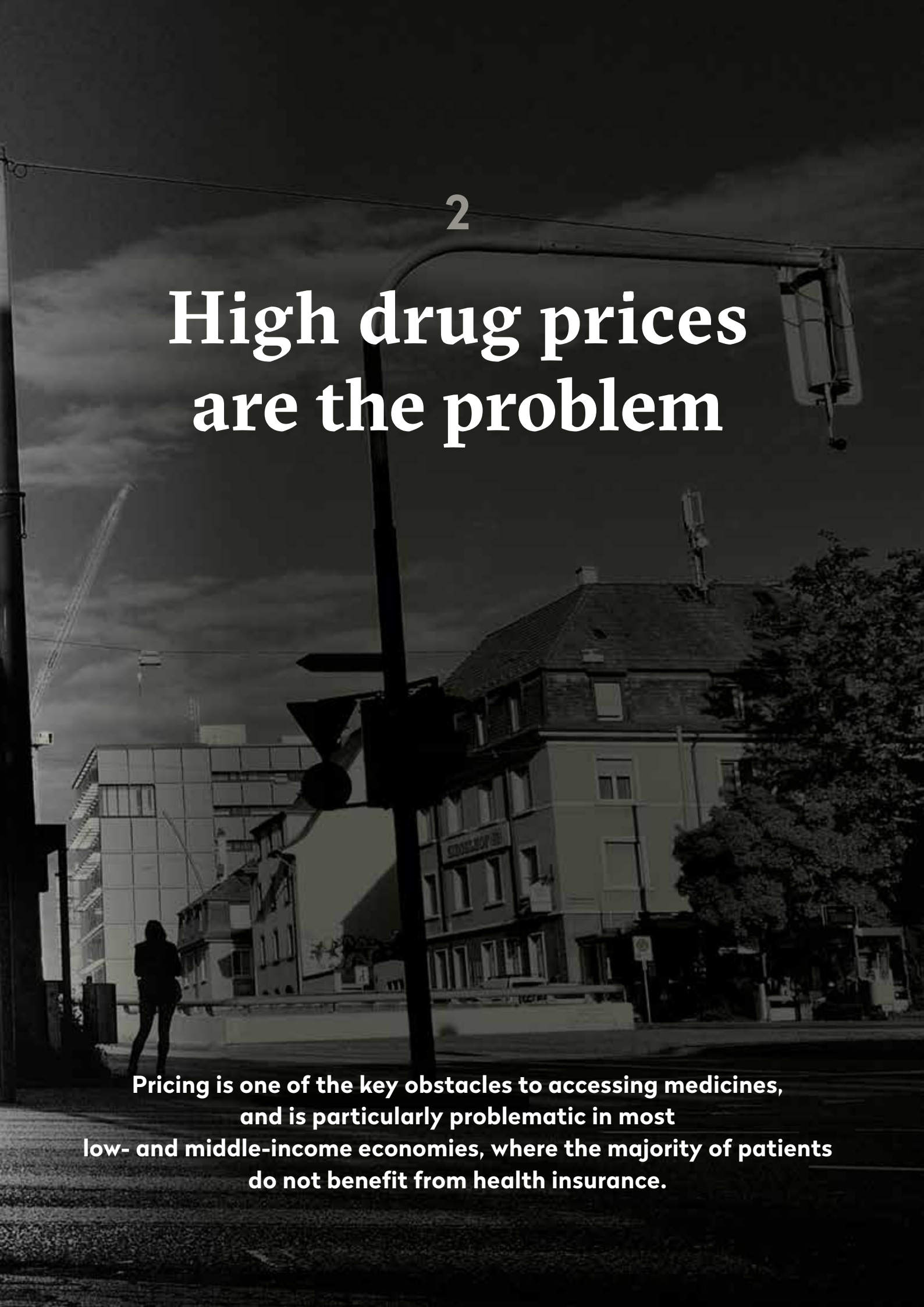
In addition to globalising patent protection, however, the WTO TRIPS Agreement also includes safeguards, commonly called TRIPS flexibilities, intended to mitigate the adverse effects of patent protection and achieve a sound balance between public and private interests. Among these flexibilities is compulsory licensing, a legal tool that allows a government to authorise a third party (for example, a company that can manufacture a cheaper version of a medicine) to use a patented product or process without the consent of the patent holder in order to protect public health.

Although these TRIPS flexibilities form an integral part of the patent system, HICs – mainly those hosting big pharmaceutical companies, including Switzerland, other European countries, the United States and Japan – have regularly denigrated them by spreading misleading, or even false, information about the tool, or by exercising undue diplomatic pressure on LMICs to discourage them from using compulsory licensing. Although these safeguards have the potential to save thousands of lives, countries hosting pharmaceutical companies are keen to prevent other countries from using TRIPS safeguards in the belief that it will affect their domestic financial interests.

If available at all, newer generation medicines in low- and middle-income economies are accessed with the support of charities, or limited to those patients who can afford to pay the high prices themselves.

However, as previously mentioned, even pharma industry host countries are facing tight budgetary constraints and are struggling to finance the medicines needed by their populations. Rather than challenging patent-based monopolies or the business model of pharmaceutical companies, these countries prefer to ration treatments, to the detriment of the right to health and access to medicines, substantially affecting the principle of universal health coverage.

This practice contradicts the state's duty to protect the human right to health, and to preserve the public interest of achieving and maintaining the highest standards in health. People should not be the victims of flawed business models. People should not be sacrificed on the altar of profit. Patients must be protected, not patents.



2

High drug prices are the problem

Pricing is one of the key obstacles to accessing medicines, and is particularly problematic in most low- and middle-income economies, where the majority of patients do not benefit from health insurance.

2.1 – LOW- AND MIDDLE-INCOME COUNTRIES ARE THE PRIMARY VICTIMS OF THE LACK OF ACCESS TO LIFE-SAVING MEDICINES

At least half of the world's population still lacks access to essential health services.[16] Estimates specifically on medicines vary depending on the source, but, as cited recently by Margaret Chan, former Director-General of the World Health Organization (WHO), it is generally accepted that an estimated 2 billion people[17] do not have access to essential medicines.[18] [19] This means that thousands of people are dying of treatable diseases every day. This problem mainly affects those living in LMICs.

There are two main explanations for this situation. Firstly, in addition to the communicable diseases that traditionally affect the poor, LMICs are now also facing the burden of an increasing incidence of chronic, non-communicable conditions. People in low-income countries still die predominantly of infectious diseases, such as lower respiratory infections, malaria, diarrheal diseases and HIV/AIDS.[20] In middle-income economies, tuberculosis and HIV/AIDS are still the leading causes of death.[21] However, the data shows that today non-communicable diseases (NCDs) disproportionately affect LMICs, which face 80 % of the global NCD burden.[22] Chronic diseases, such as cardiovascular disease, chronic obstructive pulmonary disease, cancers, diabetes or dementia have become the major killers in middle-income countries, just as they are in high-income countries (HICs). It is also worth noting that while cancer is often categorised as an NCD, 20 % of cancer deaths in LMICs are related to viral infections such as hepatitis (liver cancer) and human papilloma virus (HPV, cervical cancer).[23]

Secondly, pricing is one of the key obstacles to accessing medicines, and is particularly problematic in most LMICs, where the majority of patients do not benefit from health insurance. As a result, out-of-pocket payments are required to cover much of the costs of medicines (from 50 % to 90 %), including those for chronic conditions.[24] Such payments have dramatic consequences, pushing approximately 100 million people into poverty every year.[25]

The situation specifically regarding cancer is deeply worrying. Although more than 60% of the world's cancer cases occur in Africa, Asia, and Central and South America, high-priced medicines and the poor availability of cancer treatments continue to create significant barriers to access in many LMICs.

For example, in the Philippines, the cost for cervical cancer treatment is more than double the average annual income. In Pakistan, which has an annual per capita income of USD 2,860, the cost of treating leukemia[26] is USD 20,000. In Rwanda, with over 75 % of the population living on USD 1.25 a day, the average cost of treating AIDS-related Kaposi's sarcoma is USD 278.[27] Furthermore, according to Margaret Chan, former WHO Director-General, *"in some South American countries, the cost of treating a single women with breast cancer, using a drug included on the WHO model list of essential medicines, is equivalent to nearly twice the annual per capita income"*.[28]

Finally, data from 2011 shows that of the 24 essential medicines included on the World Health Organization's (WHO) essential medicine list (EML) for the treatment of the 10 most common cancers, 17 were not widely available in developing countries[29] and, when available, were often unaffordable for all but the richest patients.[30] In 2015, WHO updated the EML and included a range of new medicines, especially expensive, new targeted cancer therapies.[31] Recent studies have shown that despite this inclusion and the fundamental importance of these medicines, cancer treatments remain largely unavailable[32] and unaffordable for poor patients, especially in LMICs.[33] [34] [35]

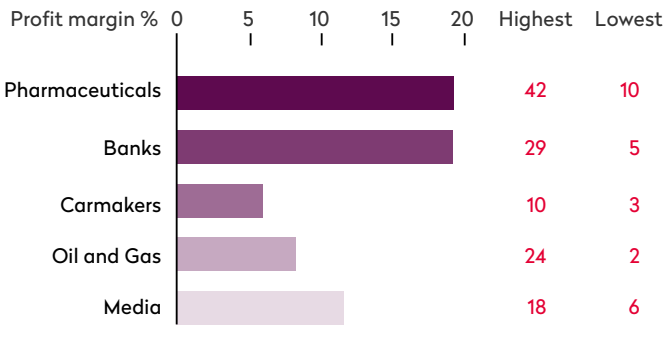
2.2 – A BARRIER TO HEALTH COVERAGE, EVEN IN EUROPE

Nowadays, even HICs are encountering greater barriers to access and have to bear painfully high public health costs due to the price explosion of certain 'new' medicines – among them many cancer drugs.

In the United Kingdom, for example, the National Health System (NHS) does not reimburse new cancer drugs deemed by independent Health Technology Assessment agencies (HTA, also known as "drug watchdogs") as not cost effective due to their exorbitant price. Patients continue struggling to access these medicines.[36] [37] [38] In several European countries,[39] [40] [41] [42] [43] new hepatitis C drugs have been rationed because their skyrocketing prices were threatening the sustainability of the respective healthcare systems. In almost every part of the world, people are facing difficulties in accessing the medicines they need primarily due to the explosion of the price of medicines.[44]

While healthcare systems and patients are struggling to pay the burgeoning prices of medicines, the figure below shows the exceptionally high profit margin of today's pharmaceutical sector.

Figure 1 – AVERAGE NET PROFIT MARGIN OF FIVE MAIN INDUSTRIAL SECTORS[45]



Highest/lowest profit margins achieved by an individual company

Source: BBC, November 2014

2.3 – SWITZERLAND HAS NOT BEEN SPARED

Switzerland is not immune to this worrying trend. According to Helsana, one of the biggest Swiss-based health insurers, drug costs in the mandatory health insurance system have increased by CHF 964 million since 2013.[46] According to statistics, medicine expenditure by pharmacies, doctors and outpatient departments of hospitals accounted for between 20.8 %[47] and 24.6 %[48] of the entire cost of healthcare covered by the mandatory health insurance system in 2016 (depending on the source – see details in figure 2). This represents CHF 6.5 billion out of a total CHF 31.5 billion. It does not include the costs of medicines dispensed to patients staying in hospital (inpatient) or in social health-care institutions (nursing homes).

Rising drug prices have come under close scrutiny in recent years.[49] Increases even led to an unprecedented rationing decision in 2014, following the entry onto the Swiss market of highly expensive antivirals for the treatment of Hepatitis C, a life-threatening, chronic infectious disease leading to liver cirrhosis and cancer. [50] As a result, not all patients that could have benefited from the new drug – which can potentially cure the disease in 95 % of cases – were granted access. Only those who were severely ill or belonged to risk groups could have their treatment reimbursed by their health insurance; others had to wait until the disease progressed, or pay for the treatment out-of-pocket. In response to a lengthy public outcry, the price was reduced moderately, and the Swiss health authorities finally agreed to end the rationing towards the end of 2017. This situation highlights how high drug prices and related rationing are jeopardizing the universal health coverage and the human right to health – even in a high-income economy like Switzerland.

Since 2009, some measures have been undertaken by the Swiss authorities to lower the prices of reimbursed medicines, but they have faced strong opposition from pharmaceutical companies.[51] In the face of such opposition, authorities are quick to insist that they lack room to negotiate reasonable prices (see sections 4.2 and 4.3). So although there have been some effective savings by the Federal authorities, the cost of medicines in Switzerland continues to rise despite the growing concerns.

2.4 – THE NEW TREND IN CANCER DRUG PRICES

Recent criticisms have focused specifically on the unsustainable prices of cancer drugs, of particular concern as the disease is becoming the top health priority for countries worldwide.

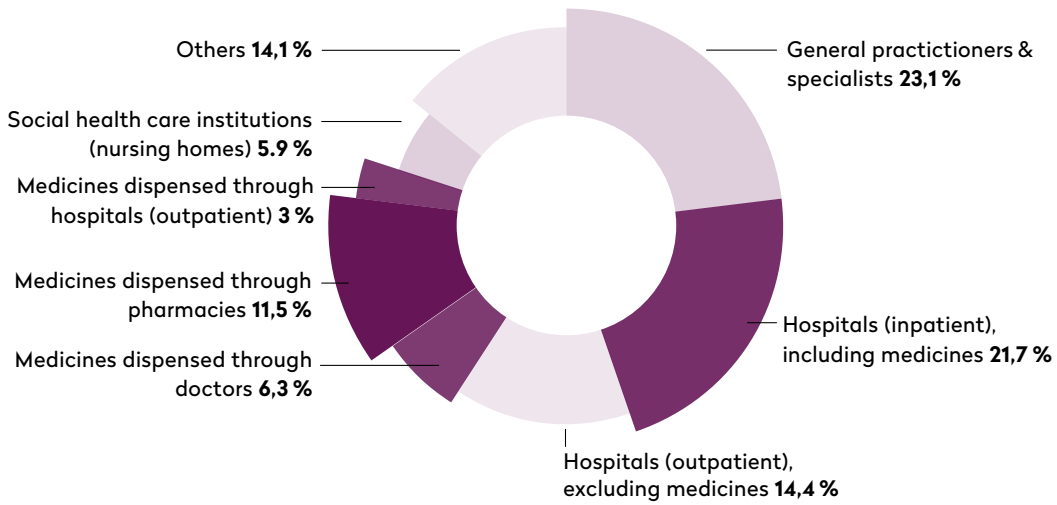
Indeed, cancer is one of the leading causes of morbidity and mortality worldwide, with approximately 14 million new cases in 2012.[52] It is the second leading cause of death globally after cardiovascular diseases, and was responsible for 8.8 million deaths in 2015. Of these, 6 million (over 60 %) occurred in LMICs – more than for HIV, tuberculosis and malaria combined.[53] According to WHO, the number of new cases is expected to rise by a further 70 % over the next two decades.[54]

In Switzerland, cancer is the second most common cause of death after cardiovascular diseases, responsible for 15,000 deaths per year. It is the leading cause of death in 45–84 year old men and 25–84 year old women.[55] Every person will be directly or indirectly confronted by cancer in their life: according to the Federal Office of Statistics, 4 out of 10 people will have a cancer[56]. Estimates also show that each year 40,000 people are diagnosed with cancer in Switzerland, that this figure is constantly rising, and that while people have better chances of surviving cancer, they are likely to be under treatment for longer.[57]

2.4.1 – UNSUSTAINABLE PRICES OF CANCER MEDICINES

The high prices of cancer medicines are challenging the sustainability of health systems worldwide.[58] Annual global spending

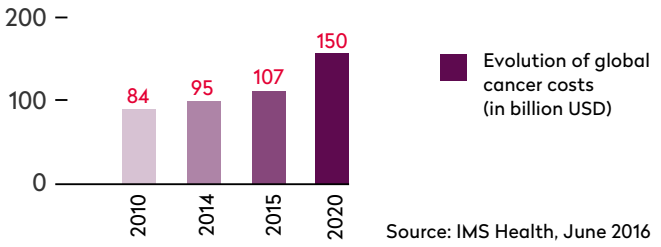
Figure 2 – COST CATEGORIES IN SWITZERLAND'S MANDATORY HEALTH INSURANCE SYSTEM IN 2016



Source: Federal Office of Public Health – Statistics of the mandatory health insurance 2016 (Excel sheet 217d)

on cancer treatments and the drugs used for supportive cancer care hit USD 107 billion globally in 2015 (+11.5 % from 2014 on a constant dollar basis, and up from USD 84 billion in 2010). The Institute for Healthcare Informatics (IMS) calculates that global oncology spending will reach USD 150 billion globally by 2020 if nothing is done (see figure 3).[59]

Figure 3 – EVOLUTION OF GLOBAL CANCER COSTS

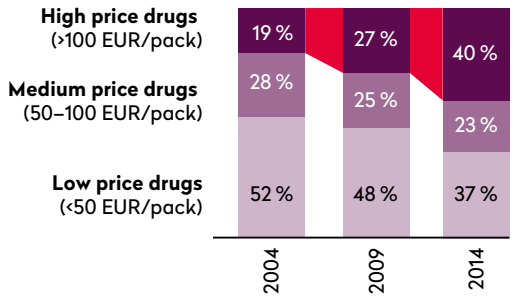


Source: IMS Health, June 2016

This trend can be explained partially by sales volumes, aging populations and demographic factors, but it is also largely due to the high prices of cancer drugs.[60] Prices of newly approved cancer drugs have increased from an average of USD 5,000 per month to more than USD 10,000 per month over the last decade, and this trend is likely to continue[61] as the business model used by pharmaceutical companies is increasingly dependent on highly expensive drugs (see figure 4).

Figure 4 – PHARMA'S INCREASING DEPENDENCE ON HIGH-PRICED MEDICINES[62]

Share of different price levels in top 10 pharmas' revenues*



* An analysis of the top 90 % of pharmaceutical products in each of the top ten pharma companies (by revenue) for 2004, 2009 and 2014.

Source: IMS MIDAS, April 2015

2.4.2 – QUESTIONABLE ADDED THERAPEUTIC VALUE DESPITE SKYROCKETING PRICES

The trend of soaring prices for newly approved cancer drugs cannot be explained by their added therapeutic value or clinical benefit. Indeed, studies show that escalating prices are not necessarily accompanied by significant added value,[63] [64] [65] [66] and claimed benefits are not always supported by evidence.[67]

In 2015, the OECD questioned the sustainability and the legitimacy of cancer drug prices.[68] It noted that of the 12 new FDA-approved cancer drugs in 2012, only one offered a survival benefit of greater than 2 months. More recently, in a report entitled "New health technologies: Managing access, value and sustainability", the OECD reiterated its concern and noted that *"the proliferation of high-cost medicines calls current pricing models into question"*. The report adds that *"[t]he launch prices of drugs for cancer and rare diseases are increasing, sometimes without commensurate increase in health benefits for patients. Payers increasingly struggle to pay for high-cost medicines targeting very small populations, which are becoming the 'new normal' in the pharmaceutical sector"*.[69]

A recent study also demonstrated that of the 48 cancer drugs approved by the European Medicine Agency (EMA) between 2009 and 2013, 57 % showed no benefits and some benefits were *"clinically meaningless"*.[70] In a study conducted in the USA on 47 FDA-approved cancer drugs between April 2014 and February 2016, only 9 (19 %) met the modest standard of meaningful clinical benefit regarding overall survival, as set by the American Society of Clinical Oncology (ASCO).[71]

Experts claim that *"expensive therapies are stifling progress by (1) encouraging enormous expenditures of time, money, and resources on marginal therapeutic indications and (2) promoting a 'me-too' mentality that is stifling innovation and creativity"*.[72] The same authors mention: *"many cite the high number of FDA drug approvals as evidence of progress in the therapy of cancer. [...] But if one looks at the therapies approved for solid tumors between 2002 and 2014, the median gains in progression-free and overall survival (OS) were a very modest 2.5 and 2.1 months, respectively. While any patient facing imminent death from cancer might welcome the respite that 2 months might bring, in fact, time and again surveys have indicated that patients expect much more"*.[73]

Finally, in reviewing the launch price of cancer drugs approved between 1995 and 2013 in the USA, authors found that patients and insurers paid USD 54,100 for a year of life gained in 1995, USD 139,100 a decade later and USD 207,000 in 2013 for the same benefit.[74] This drastically surpasses the cost-effectiveness threshold of USD 33,000–49,000 (GBP 20,000–30,000) per Quality-Adjusted Life Year (or QALY) used by the UK's drug watchdog, NICE, in deciding which treatments should be reimbursed by the NHS.[75]

2.4.3. – THE EXPLODING COSTS OF CANCER TREATMENTS IN SWITZERLAND

For some years now, many cancer drug treatments in Switzerland have exceeded the symbolic threshold of CHF 100,000 per year of treatment. This trend has been widely criticised by doc-

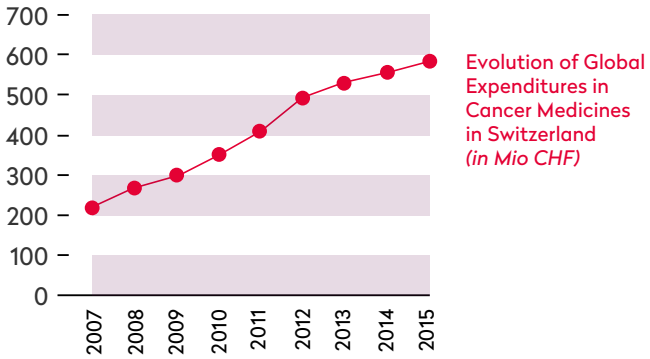
tors and health insurers, among others, for jeopardising the sustainability of our health system.[76] [77] [78] [79] [80] [81]

From 2007 to 2012, cancer medicine expenditure in Switzerland increased by 132%, from CHF 213 million to CHF 494 million.[82] In the following four years, expenditure rose further to CHF 605 million. Therefore, from 2007 to 2016, the costs of oncology drugs rose by 184% – a nearly threefold increase due mainly to ever-increasing drug prices.[83] According to data from health insurance companies, only 650 patients relied on a treatment costing CHF 100,000 or more in 2011, while 1,650 patients did so just 4 years later.[84]

equivalent to 18.1% of the total volume of the Swiss drug market. And this with biologicals and biosimilars constituting only 0.9% of all medicine claims.[86]

From 2007 to 2016, the costs of oncology drugs rose by 184% – a nearly threefold increase due mainly to ever-increasing drug prices.

Figure 5 – EVOLUTION OF GLOBAL EXPENDITURE OF CANCER MEDICINES IN SWITZERLAND



Source: Helsana Oncology Report, p. 20 and Helsana Drug report 2016, p. 165

According to Helsana's 2017 drug report, cancer treatments and immunosuppressive drugs have been the primary cost drivers since 2013, amounting to nearly a quarter of the total drug costs.[85] This trend may be explained by the fact that new cancer and immunosuppressive drugs are generally biologic drugs, which are likely to be more expensive than chemical drugs and therefore more remunerative. As a result, the market for biologic pharmaceuticals is growing strongly, with a sales volume of biologicals and biosimilars of nearly CHF 1.3 billion in 2016,

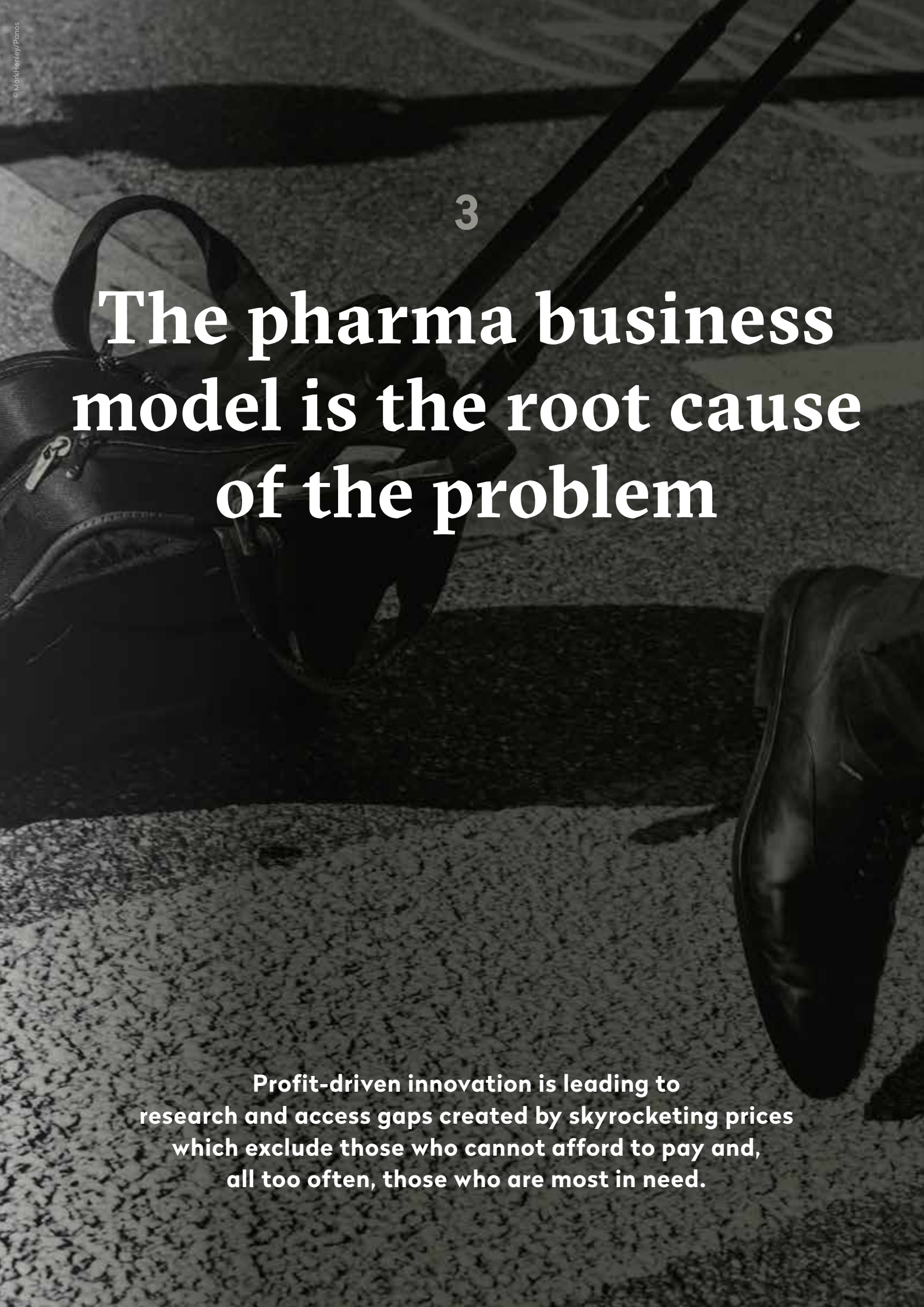
These developments are directly threatening the sustainability of our mandatory health insurance system, as illustrated by a simple calculation. Assuming an average annual cost of CHF 100,000 per cancer treatment, and using the Swiss Cancer League incidence estimate of 40,000 new cancer cases per year (all types), the total cost of reimbursing all treatments through the mandatory health insurance system would amount to some CHF 4 billion for a single year. This does not include the costs of existing cases (cancer is a chronic disease sometimes necessitating several years of continuous treatment). This CHF 4 billion bill alone would have represented over 60% of the medicine expenditure for the whole of Switzerland and for all pathologies (not just cancer) in 2016. This estimate is even conservative if we consider Novartis' recent announcement that its new treatment for leukemia, Kymriah®, will cost some CHF 450,000 per treatment.

It is an illusion to think that our present health insurance system will continue to be able to reimburse today's costs of cancer treatments without significantly increasing insurance premiums in the very near future, which will penalise poor families and result in massive public spending, or without making sensitive, if not arbitrary, rationing decisions. Already today there are serious cracks in the system, with problematic political inaction and discriminatory decisions being taken, as witnessed by the recent hepatitis C treatment rationing. A two-tiered system of access to medicines is literally around the corner – if not already present – and cancer treatments are next on the list. As highlighted by the announcement of Novartis' Kymriah, *"countries won't be able to avoid formulating maximum amounts"*.[87]

Table 1 – EVOLUTION OF CANCER MEDICINE EXPENDITURES UNDER THE SWISS MANDATORY HEALTH INSURANCE

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	EVOLUTION SINCE 2007 (in %)
All drug expenditures (in mio CHF)	3,966	4,229	4,545	5,232	5,692	5,948	6,123	6,280	6,677	7,087	+ 79 %
Cancer drug expenditures (in mio CHF)	213	264	299	351	409	494	531	559	584	605	+ 184 %

Sources: Helsana Oncology Report (2013) & Helsana Annual Drug Reports (2014 to 2017)



3

The pharma business model is the root cause of the problem

Profit-driven innovation is leading to research and access gaps created by skyrocketing prices which exclude those who cannot afford to pay and, all too often, those who are most in need.

To understand how prices as high as CHF 100,000 or more per year per patient can arise, it is imperative to understand the market mechanisms of this sector and the business model of the pharmaceutical companies. Patents are the backbone of this system, and are establishing distinctive market rules, thereby preventing a free market. But pharmaceutical companies also use other monopolies to exclude competitors, such as market and data exclusivity, which allow them to maximise profit to the detriment of public health.

Pharmaceutical companies justify their pricing strategies by citing an estimate from the Tufts Center for the Study of Drug Development of USD 2.56 billion to develop a new drug.[88] However, this figure is highly controversial, and independent studies have clearly shown it is flawed[89] because it is based on a selected sample from among the most costly drugs and includes both products that made it to the market and a much larger number that did not.[90] Further, it does not take into account generous tax credits and other kind of subsidies given to the pharmaceutical industry, and half of the amount calculated corresponds to the estimated cost of opportunity. [91] The cost of opportunity refers to the resources that a company had to renounce when allocating them to other projects: the Tufts Center argues that the money allocated to failed drug candidates could have been invested in other remunerating areas. However, strictly speaking, the opportunity cost is not a cost.

Even Andrew Witty, former Glaxo SmithKline's CEO, contested a previous, lower figure from the Tufts Center and argued that it was *"one of the great myths of the industry"*.[92]

Alternative estimates from the Drugs for Neglected Diseases initiative (DNDi), a not-for-profit product development partnership, place development costs in the range of EUR 6–20 million for an improved treatment, and EUR 30–40 million for a New Chemical Entity (NCE). Taking failed drug candidates into account, costs lie between EUR 10–40 million for an improved treatment and EUR 100–150 million for a NCE.[93] [94]

For cancer drugs specifically, a recent study published in the medical journal JAMA estimated a median R & D cost for a single cancer drug of USD 648 million (USD 757.4 million when opportunity costs are included) for a company that had no similar product on the market. In a short period of time, development costs were more than recouped; some of the sampled companies earned ten times more than they spent on R & D – a sum not seen in other sectors of the economy.[95]

These estimates show how figures can vary widely, depending on the context and the methodology applied, and how complex it is to accurately estimate the R & D cost of a new drug.[96] The real cost of R & D therefore remains one of the best-kept secrets in this very profitable industry.

3.1 – PATENT-BASED MONOPOLIES

A patent is an exclusive right granted by governments to people or companies that invent something new (novelty), non-obvious (inventive step) and useful (capable of industrial application). As a result, a patent holder can prevent others from commercially making, using, distributing, importing or selling their

Box 3.1

SWITZERLAND WAS A LONGTIME OPPONENT OF PATENTS

Before the WTO TRIPS Agreement enforced minimum patent standards in its 164 member states, countries varied in the types of patents they granted, in the conditions for granting patents (patentability criteria) and/or in the periods of protection, especially between developing and developed countries. Many countries used to exclude foods and pharmaceuticals from patent protection, as it was considered against the interests of the state.[97] [98]

For example, towards the end of the 19th and beginning of the 20th century, Swiss industrialists, especially from the chemical and pharmaceutical sectors, were strongly opposed to the patent system because they were concerned that it could undermine their own development. Indeed, industrialists in Switzerland, as in many developed countries, used to copy foreign technologies extensively for their own development. As a result, Switzerland excluded foods and pharmaceuticals from being patentable as they were considered of 'public interest', and therefore of strategic interest.[99] [100] In this context, the term 'public interest' mainly refers to economic and industrial interests.

The following excerpt best illustrates how Swiss industry viewed patents at that time: *"Moreover, the principle of patent protection is at its core entirely selfish. In this selfishness lies the seed of destruction for the cooperative spirit of Swiss industry which alone allows us to compete with the other countries and has often saved us in times of crisis. No meaner blow could be dealt to our industry than an institution that only serves the individual and would most likely be detrimental to the collective whole".*[101]

It was only in 1976, when Swiss industries became sufficiently competitive, that patents on pharmaceutical products were adopted and integrated into a new version of the Patent Act.

Equally, low- and middle-income countries, such as India, that did not grant patents on pharmaceutical products were able to produce quality-assured, cheaper generic versions of Western technologies and to develop their own manufacturing capacities.[102] This decisively helped to increase access to affordable medicine for millions of patients living in the global South. Indian generic manufacturers, for example, account for more than 80 % of the generic antiretroviral drugs used in developing countries through international donor-funded programmes.[103] This has contributed significantly to the massive increase in HIV/AIDS treatments globally, from 2 million in 2005 to more than 20 million in 2017.

invention for a limited period of time, generally 20 years from the date of filing the patent. The protection ends when a patent expires and an invention enters the public domain; thereafter, anyone can commercially exploit the invention without infringing the patent.[104]

Patents are an exception to the ruling free market economy because inventors benefit from a monopoly, allowing them to set the highest possible price for their products (pricing power) in exchange for disclosing the invention, ideally for the benefit of the society.

The power conferred by a patent is considerable and can be abused or lead to situations where the invention is unaffordable, or where the patent impedes progress. These effects are especially problematic concerning patents on goods in the public interest, such as medicines. Patents play a critical role in the public health system, because they prevent competition and increase the prices of vital medicines,[105] [106] which may exclude consumers who are unable to pay.

Therefore, the patent system requires a sound balance between private and public interests. Article 7 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS Agreement) echoes the need to strike such a balance:

"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".[107]

3.2 – GLOBALISATION OF PATENT RULES AND THE WTO TRIPS AGREEMENT

At the instigation of big transnational companies, some HICs during the Uruguay round of the General Agreement on Tariffs and Trade (GATT) lobbied to adopt a global intellectual property framework intended to establish and harmonise minimum protection standards worldwide.

This led to the adoption of the WTO TRIPS Agreement in 1994, which came into force on 1 January 1995. As a result, all 164 WTO members[108] can grant patents for 20 years[109] for *"any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application"*[110] (emphasis added). Developing countries that did not grant patents in 1995 on some products, such as pharmaceuticals, were given a transition period i.e. the possibility to delay the implementation of the provisions on patents until 2005.[111]

At the end of the transition period, a range of actors increasingly expressed concerns about the effects of patent protections on human rights, on public health, and particularly on access to medicines, especially for middle-income countries.[112] [113] [114] [115] [116]

Aware of the potentially adverse effects of harmonising patent protection, WTO members, especially LMICs, strongly advocated for safeguards in the WTO TRIPS Agreement, called TRIPS flexibilities, which aim to allow countries to counter these potentially adverse effects and help meet their human rights obligations. Among the TRIPS flexibilities are compulsory licences[117] and parallel imports.[118] However, it was only in November 2001, at the occasion of the WTO Ministerial Conference in Doha (Qatar), and following intense pressure from LMICs and civil society against the backdrop of the HIV/AIDS crisis, that these flexibilities were reaffirmed and specified in the Doha Declaration on TRIPS Agreement and Public Health[119].

The power conferred by a patent is considerable and can lead to situations where the patent impedes progress.

Box 3.2

THE WTO TRIPS AGREEMENT AND THE HIV/AIDS CRISIS[120]

The HIV/AIDS crisis of the 1990s was the first major international public health emergency in the era of new international patent rules, and immediately highlighted the practical difficulties of implementing the WTO TRIPS Agreement in a manner supportive of human rights, and in particular of public health.

The TRIPS Agreement gave each member state the right to adopt measures *"necessary to protect public health".*[121] However there was enormous uncertainty about the scope of these measures. At that time countries like South Africa faced tremendous challenges in ensuring access to medicines due to the very high HIV-rate, affecting nearly a fifth of the population, and the staggeringly high prices for newer HIV/AIDS-treatments, which were all patented with an annual price tag of USD 10,000 to USD 15,000 per treatment, way out of the reach of the vast majority of South African patients. Given the emergency of the situation, the South African government decided to modify its Medicines Act to include provisions to increase access to lower-priced medicines. This move provoked a fierce reaction from the pharma industry, culminating in 1998 with a group of 39 pharmaceutical companies suing the South African government for alleged non-compliance of its Medicines Act with the TRIPS Agreement. The companies eventually backed down in 2001 after a massive public outcry, a move described in a UK newspaper as a humiliating PR disaster.

The high price of HIV/AIDS medicines and the staggering loss of lives cruelly highlighted the relationship between patent protection and public health in the post-TRIPS Agreement era.

3.3 – A PROFIT- VS. NEEDS-DRIVEN INNOVATION SYSTEM

Today's global system of innovation relies primarily on patents. The global patent system has been criticised regularly because patent-based monopolies concentrate on profits rather than needs. In fact, R & D is driven by profit. This is particularly problematic in an area of public interest such as health because the dependence on market incentives creates gaps in certain research areas (see for example the debate about neglected tropical diseases or about antibiotics), and the resulting high prices create barriers to access.[122] [123] [124]

Indeed, this market-driven approach to R & D means that innovation tends to focus on diseases affecting wealthy patients. As a result, there is little or no R & D for medicines with limited economic potential, either because patients are too few or too poor. And when a therapeutic breakthrough does occur, the medicines are frequently too expensive and therefore out of reach for the majority of patients.

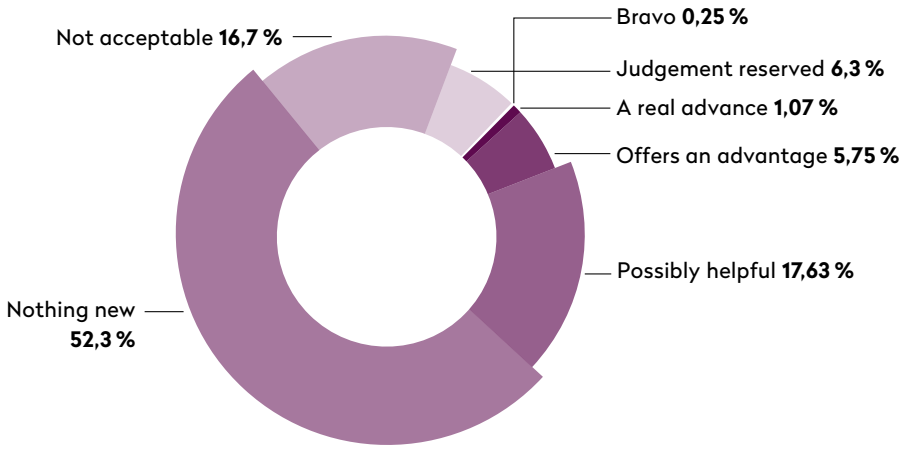
Profit-driven innovation is therefore leading to research and access gaps created by skyrocketing prices[125] [126] [127] which exclude those who cannot afford to pay and, all too often, those who are most in need.

The profit-driven innovation system also leads to severe shortages, even of medicines with proven efficacy, caused by prices falling below a certain threshold. Companies do not have any market incentive to supply drugs or to improve them when there is little or no profit to make.[128] In these cases, companies regularly decide to withdraw important medicines from the market, forcing doctors to prescribe 'newer' drugs, which are also often much more expensive.[129]

3.4 – WHY PATENTS ARE, PARADOXICALLY, STIFLING INNOVATION

Pharmaceutical companies claim that there would be no R & D without patents because patents allow them to recoup their huge investments. Indeed, to justify the monopoly and pricing power conferred by patents, pharmaceutical companies assert that theirs is a risky industry, with a high rate of research failure and, therefore, a strong possibility of losses on their invest-

Figure 6 – PRESCRIRE'S RATING OF NEW PRODUCTS AND INDICATIONS OVER THE PAST 10 YEARS IN FRANCE



Source: La revue Prescrire

PRESCRIRE RATING	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Bravo	0	0	0	0	0	0	1	0	0	0
A real advance	0	0	1	0	1	0	2	3	1	1
Offers an advantage	6	3	3	3	3	6	5	5	5	9
Possibly helpful	25	14	22	13	14	12	15	15	9	18
Nothing new	57	62	49	53	42	48	35	43	56	45
Not acceptable	23	19	19	16	15	15	19	15	16	15
Judgement reserved	9	6	3	7	7	9	10	6	5	4
TOTAL	120	104	97	92	82	90	87	87	92	92

ments.[130] As a result, they seek areas with lower risks of investment loss where profits can be maximized, instead of focusing on areas where innovations are truly needed.

Rather than facilitating innovation and triggering investments in R&D, the patent system incentivises pharmaceutical companies to find ways to secure their revenues and extend their monopolies at a minimum cost and risk. This has the consequence of stifling innovation.

Indeed, pharmaceutical companies pursue controversial strategies, such as trying to secure additional indications, rather than finding truly new innovations:[131] they reformulate a widely prescribed drug whose patent is coming to an end so they can increase the price, rather than extending the indication of the existing drug to other diseases for which it has been proven to be efficient (e.g. Rituxan and Ocrevus from Roche).[132]

Real innovation seems, therefore, to be more the exception than the rule.

La Revue Prescrire, a renowned, independent French medical journal, carries out each year an in-depth analysis of all medicines approved in France during a fiscal year, and categorises them according to their therapeutic value. [133] None of the 92 new drugs approved in 2017 was given the highest ranking ("bravo"), only 1 was considered "a real advance", 9 were considered as "offering an advantage", and 18 were "possibly helpful". 45 medicines added nothing new to the existing pharmacopoeia, while 15 represented a potential public health risk and 4 could not be rated ("judgment reserved"). It means that, out of 92 new drugs, 60 (or 65 %) have either no added value or do more harm than good.[134] An even worse picture emerged in 2016, with 72 out of 92 drugs (78 %) categorised as nothing new or having a negative therapeutic value.[135]

The results of Prescrire's ratings over the period 2008–2017 are displayed in figure 6 (average, expressed in %).

The German Institute for Quality and Efficiency in Health Care (IQWiG), an independent scientific institute tasked with assessing medical interventions and providing recommendations to the German health authorities, regularly provides similar analyses. From 2011 to September 2015 (see figure 7), out of the 117 assessments conducted by IQWiG, 66 new medicines or indications (56 %) did not provide any added value. Only 19 new medicines or indications (16 %) offered a major or a considerable added benefit.[136]

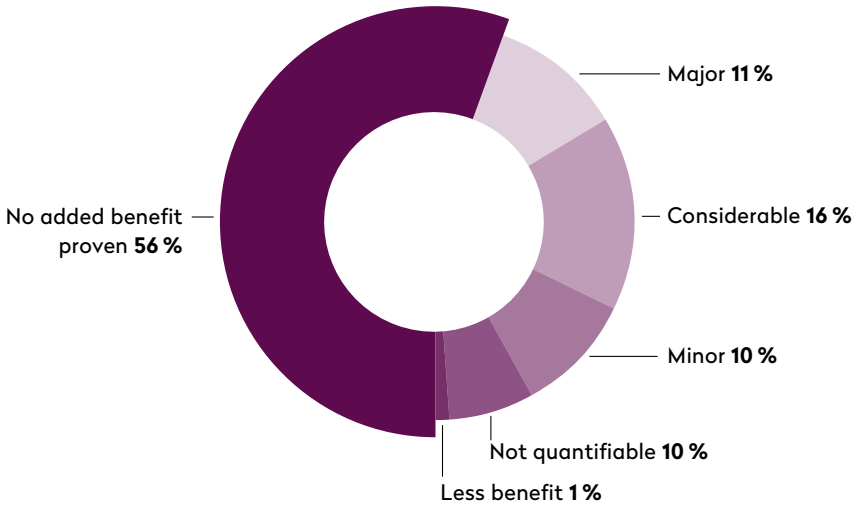
3.5 – PROFIT-DRIVEN VALUE-BASED PRICING: A DANGEROUS JUSTIFICATION

Aware that R&D costs can not really justify the skyrocketing prices of certain 'new' medicines, and facing growing criticism of their lack of transparency, pharmaceutical companies are increasingly applying a value-based pricing strategy, and are striving to change the narrative around the prices of medicines. As claimed by Thomas Cueni, Director General at the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), one of the pharmaceutical lobbies, *"Companies should be paid for the therapeutic value of their drugs to society and patients rather than the cost of research and development or manufacturing"*.[137]

This new pricing strategy separates prices from the cost of R&D. It implies that the more 'value' a medicine brings, the more expensive it should be, regardless of the R&D and manufacturing costs. It is designed to justify high drug prices and generate maximum profit on the back of social security systems. In 2014, the Federal Council itself recognised that such an unprecedented pricing policy has a serious impact on social insurance systems financed by taxes and premiums.[138]

Implicit in this approach is the practice of using the price of existing standards of care as a benchmark to determine the price

Figure 7 – IQWIG'S ASSESSMENTS OF NEW MEDICINES OR INDICATIONS IN GERMANY BETWEEN 2011 AND 2015



Source: IQWiG, September 2015

of new medicines: pharmaceutical companies are likely to use today's controversial prices of existing drugs as a benchmark to set the prices of newly approved medicines, [139] [140] leading to continuous price increases.

Box 3.3

EXAMPLE OF PHARMACEUTICAL COMPANIES POSITIONS ON VALUE-BASED PRICING

ROCHE[141]

*"The prices of our products reflect the **benefits they deliver to patients, their families, payers and societies,** as well as the costs required to sustain innovation and to continue to meet patient needs into the future. [...] We believe value has many components – in addition to direct healthcare costs and patient outcomes, this includes **benefits to caregivers and society,** as well as **improvements in efficiency of healthcare delivery, avoiding unnecessary treatments and procedures, and improving drug administration and compliance in treatment**"* (emphasis added).

GILEAD (ON PRICING OF HEPATITIS C DRUGS) [142]

*"The price of Gilead's hepatitis C treatments reflects the **significant clinical, economic and public health value** that Sovaldi and Harvoni offer to **patients, their families and healthcare systems,** and is comparable to, or in many cases less than, the cost of older, less effective regimens. Gilead's medicines are also cost-effective over the long term. By quickly curing a vast majority of patients, Gilead's hepatitis C treatments **may lessen the frequency of healthcare visits and hospitalizations, and lower the need for medications to manage side effects and complications**"* (emphasis added).

While it may be fair to pay more for a medicine that brings true benefits and limited side effects than for a medicine proven to bring limited benefits and adverse side effects, the value of a medicine to patients and societies should not be used to justify high drug prices.

The purpose of a life-saving drug is to save life, and its value lies in this function. But how are pharmaceutical companies, consumers and governments supposed to evaluate the price of a human life? How do we evaluate the benefits to families, consumers and healthcare systems and translate this into monetary terms? And who decides on what constitutes 'value'? Following this logic, the costs of life-saving antibiotics in the case of a patient with a sepsis should be staggeringly high. But antibiotics today are standard medicines, produced in large and cost-effective quantities.

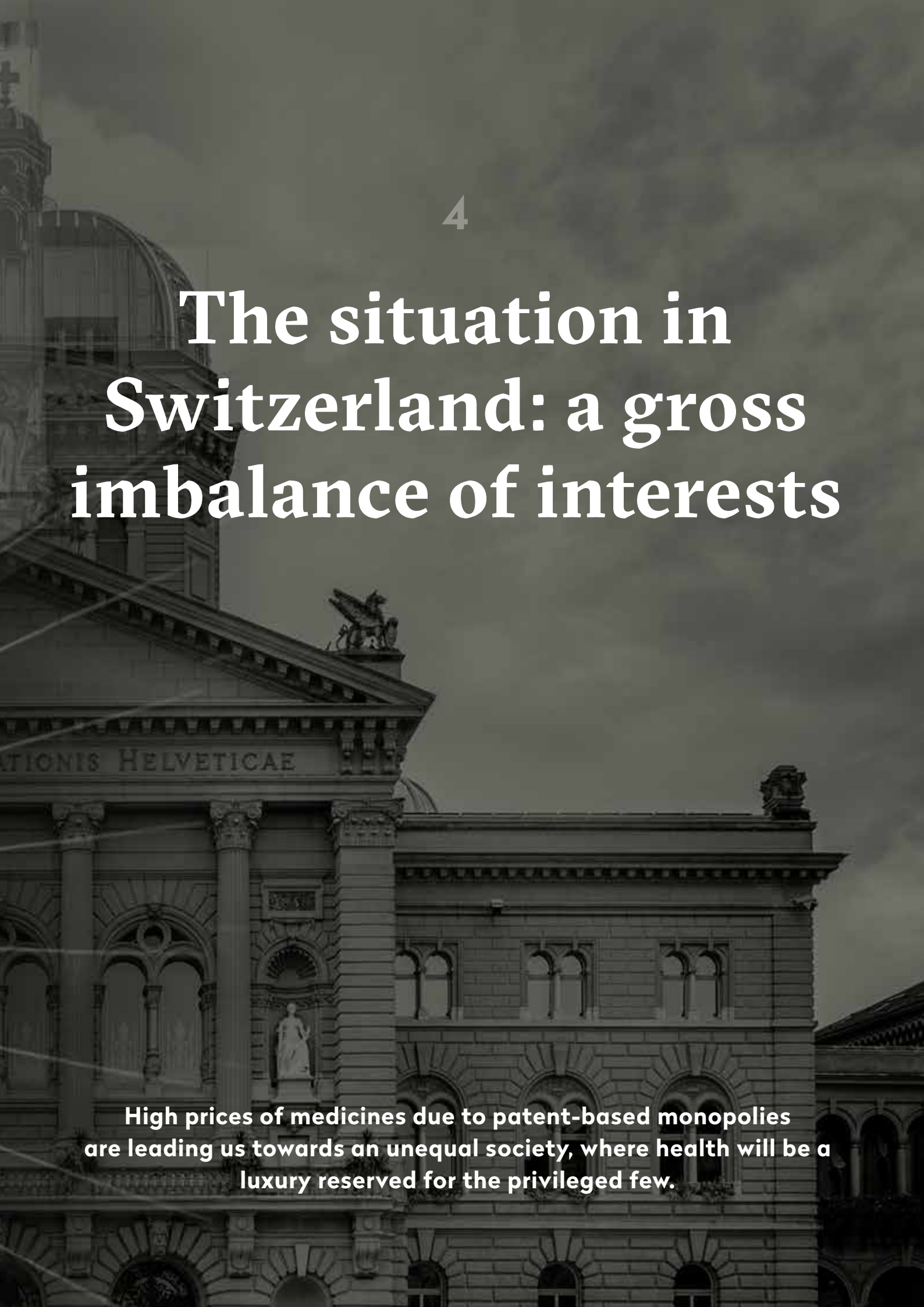
According to Mary-Paul Kieny, former WHO Assistant Director General for health systems and innovation, this approach is *"very dangerous"*. Applied to other products, *"you can say if an airbag can save my life, why isn't the cost of an airbag what I would be willing to pay for my life? And that would be a lot"*. [143] And how would we react if other strategic industries, like the water or food industries, started to apply this logic?

> The price of new treatments, including cancer, has nothing more to do with the R & D costs incurred, but is set according to what the pharmaceutical companies believe governments and patients are willing to pay.

The recent expansion of this strategy confirms that the price of new treatments, including cancer, has nothing more to do with the R & D costs incurred, but is set according to what the pharmaceutical companies believe governments and patients (in other words, the market) are willing to pay.[144] This amount can be quite high as patients with incurable cancer types are often desperate to obtain a new treatment, even if very costly and even if only extending life by a few months (see section 2.4.2). The willingness to pay for an additional year of good health (QALY) can be very high according to US studies.[145] [146] As an illustration, the addition of Perjeta (a breast cancer drug discussed in the next chapter) to the trastuzumab-docetaxel combination therapy in the metastatic setting results in an additional 1.81 life-years and 0.62 QALYs, at an astounding cost of USD 472,668 per QALY gained.[147]

4

The situation in Switzerland: a gross imbalance of interests



High prices of medicines due to patent-based monopolies are leading us towards an unequal society, where health will be a luxury reserved for the privileged few.

The Swiss government relies on a two-pronged approach to safeguard public interest in health. On the one hand pharmaceutical companies are enabled to make profits on the medicines they develop through being granted a monopoly under the patent system. According to the government, this should contribute directly to Switzerland's economic prosperity, and indirectly to positive health outcomes, as ill health is considered both a cause and consequence of poverty.

On the other hand, our insurance model bases health coverage on the principle of public-private solidarity to ensure that patients have access to affordable healthcare by not having to pay the full costs. This insurance model also guarantees a source of steady revenue for pharmaceutical companies, which are heavily dependent on the system[148]. However, the resources of our health coverage system are finite and already stretched to their limits, with medicine expenditure accounting for more than 20 % of the costs covered by the mandatory health insurance system (see section 2.4.3). The sustainability of the system requires that all stakeholders act in good faith and respect its spirit and purpose. Unjustifiably high prices or undue pressure may affect the system's efficiency and viability, and lead to rationing decisions.

Public Eye considers that, with regards the high prices of medicines, especially cancer treatments, the required balance between the private interests of pharmaceutical companies and the public interest of society has been disrupted. The breast cancer drug, Perjeta, manufactured by the Swiss giant Roche, is a good illustration of this imbalance and of the negative effects of patent-based monopolies, as discussed in the section 6.

With regards the high prices of medicines, especially cancer treatments, the required balance between the private interests of pharmaceutical companies and the public interest of society has been disrupted.

4.1 – IS SWITZERLAND DESTINED TO PAY HIGH DRUG PRICES?

Swiss authorities often claim they are unable to prevent increases in patented drug prices, as if it were fate. They claim not to have the legal tools to stop these trends and that the Confederation cannot directly influence the pricing policies of companies.[149]

Further, due to a Federal Tribunal practice, only pharmaceutical companies can contest the prices of the medicines registered on the List of Specialties (LS).[150] Those directly affected by the prices, i.e. the patients, insurers and pharmacists, have no recourse to do so.[151]

Box 4.1

THE SWISS REIMBURSEMENT SYSTEM OF MEDICINES IN A NUTSHELL

In Switzerland, the mandatory health insurance system (or basic health package) only reimburses medicines that are registered on the List of Specialties (LS) and prescribed for authorised indications. The LS is established by the Federal Office for Public Health (FOPH).

To be registered on the LS, a medicine must be authorised by Swissmedic, the Swiss Agency for Therapeutic Products, and must meet legal criteria, such as efficacy, adequacy and economic efficiency (EAE evaluation). Those conditions must be analysed by the FOPH for reimbursement and be reviewed every three years. The request for the admission of a medicine onto the LS is submitted to the FOPH, and each modification of a medicine or its price should be subject to a new request of admission.

In general, the FOPH decides to admit a medicine on the LS at the request of the holder of the market approval and after consultation with the Federal Commission of Medicines (FCM), which is composed of different interest groups – i.e. industry, insurers, patients, doctors, hospitals, pharmacists, federal and cantonal authorities. The FCM examines whether the medicine meets the criteria of efficacy, adequacy and economic efficiency. The FCM then formulates a recommendation to the attention of the FOPH, which also assesses these criteria, especially the economic efficiency, and makes a final decision.

In principle, in order to decide on the maximum public price, the FOPH has to conduct, inter alia, two comparative assessments:
- A comparison with prices of the medicine in referenced countries (geographic comparison);
- A comparison with other medicines used to treat the same disease (therapeutic comparison).

Since March 2017, those two comparisons have equal importance.

Inclusion on the LS is thus an important step as it sets the conditions and level of reimbursement for the product under the mandatory health insurance system. Reimbursement for a medicine on the LS is guaranteed, assuming all conditions spelt out in the so-called "limitatio" are met. Reimbursements for medicines not on the LS are considered under a separate legislative framework[152] and are the sole decision of each health insurer. Therefore, the decision whether to include a drug on the LS has major implications for access to medicines in Switzerland.

As a result, today's system is largely geared towards pharmaceutical companies' interests and undermines the ability of Swiss authorities to effectively control and maintain medicine prices at an affordable level. The inefficiency of the price control system, combined with the questionable pricing strategies of pharmaceutical companies, is jeopardising the sustainability of the health system.

In the face of supply side resistance, authorities tend to divert their attention to the demand side – the patients – which can lead, and has already led, to steady increases in insurance premiums, as well as controversial rationing decisions. Both adversely affect the principle of universal health coverage. For example, the Federal Office of Public Health (FOPH) recently recognised that it will increasingly have to deal with situations in which drugs must, due to their very high price, be included on the LS in a targeted or staggered manner in order to balance efficiency and costs.[153] As previously outlined in the case of the highly expensive antivirals for the treatment of Hepatitis C, Switzerland is not immune to rationing decisions in response to high prices.

4.2 – THE PRESENT PRICE CONTROL MECHANISM IS TOOTHLESS

In response to criticisms about the cost of medicines (especially compared to foreign prices), pricing mechanisms and the lack of transparency in the pharmaceutical industry[154] [155], the Swiss authorities have made laudable efforts since 2009 to lower the prices of reimbursable medicines to sustainable levels[156]. Although they have succeeded in reducing the prices of certain medicines, they have faced strong opposition, and have been unable to stop the overall trend of rising drug prices. Pharmaceutical companies have systematically and successfully challenged the commendable measures of the FOPH.[157] [158]

In 2015, the Federal Tribunal (FT), in a dispute between pharmaceutical companies and the FOPH regarding price reductions, gave reason to the former and called on the FOPH to conduct and give equal weight to a therapeutic and geographical comparison when setting medicine prices.[159] Unfortunately, the FOPH lacks the resources to conduct therapeutic comparisons, which are far more complex than geographical ones, and has to rely largely on data provided by pharmaceutical companies, which are interested in obtaining the highest possible price. Interpharma, the Swiss lobby of pharmaceutical companies, should have been satisfied with this development, because it corresponded to an earlier demand. But it wishes to go one step further, calling for the therapeutic comparison to be given more weight when setting prices.[160] As a result, the reintroduction of price evaluation cycles for drugs on the LS, which also necessitated an adaptation of the relevant legislation, was delayed; initially foreseen to be reintroduced *"during 2017"*[161], it only started at beginning of 2018.

Frustrated by this situation, health insurers threatened the FOPH with a complaint for being too generous, not resisting pharmaceutical industry demands strongly enough and delaying an effective price review of drugs covered by the mandatory health insurance system.[162] The FOPH has not abandoned the idea of controlling the prices of medicines. However, their actions scrupulously avoid tackling the abusive cost of patent-based monopolies, and it does not question the way in which the predominant model of innovation is increasingly jeopardising the sustainability of our health system.

The high prices of medicines due to patent-based monopolies are leading us towards an unequal society, where health will be a luxury reserved for the privileged few. This is an unbearable evolution that we do not want to see in either Switzerland or elsewhere in the world. High drug prices are not predestined.

4.3 – COMPULSORY LICENSING IN SWITZERLAND: THE ELEPHANT IN THE ROOM

There is a way to control the prices of medicines and take a stand against pharmaceutical companies: the issuance of a compulsory licence. The Swiss Patent Act[163] contains a range of provisions regarding compulsory licenses. Unfortunately, Switzerland has been quick to act on behalf of pharmaceutical companies' interests[164] and has chosen to ignore this important public health safeguard.

A public non-commercial use (or government use) licence is a type of compulsory licence that permits the use of a patent by the government itself, or by a contractor or agent appointed by it. Public non-commercial use licencing appears at the end of article 40e al. 1 PatA, which stipulates that efforts to obtain a contractual licence on appropriate commercial terms within a reasonable period of time *"are not required [...] in cases of public non-commercial use"*. In such a case, a government can issue a compulsory licence without prior negotiations,[165] but is required to inform the patent holder promptly.[166]

A government use licence provides authorities with a legal tool to act boldly to ensure that pharmaceutical companies adopt a more reasonable pricing policy, rather than remain a mere spectator. By allowing competition in a monopoly market, this tool is likely to reduce medicine prices, and restore the balance between public and private interests. Roche recognised that *"open competition between originator medicines and generics or biosimilars supports the financial sustainability of healthcare systems"*.[167]

By allowing competition in a monopoly market, a government use licence is likely to reduce medicine prices, and restore the balance between public and private interests.

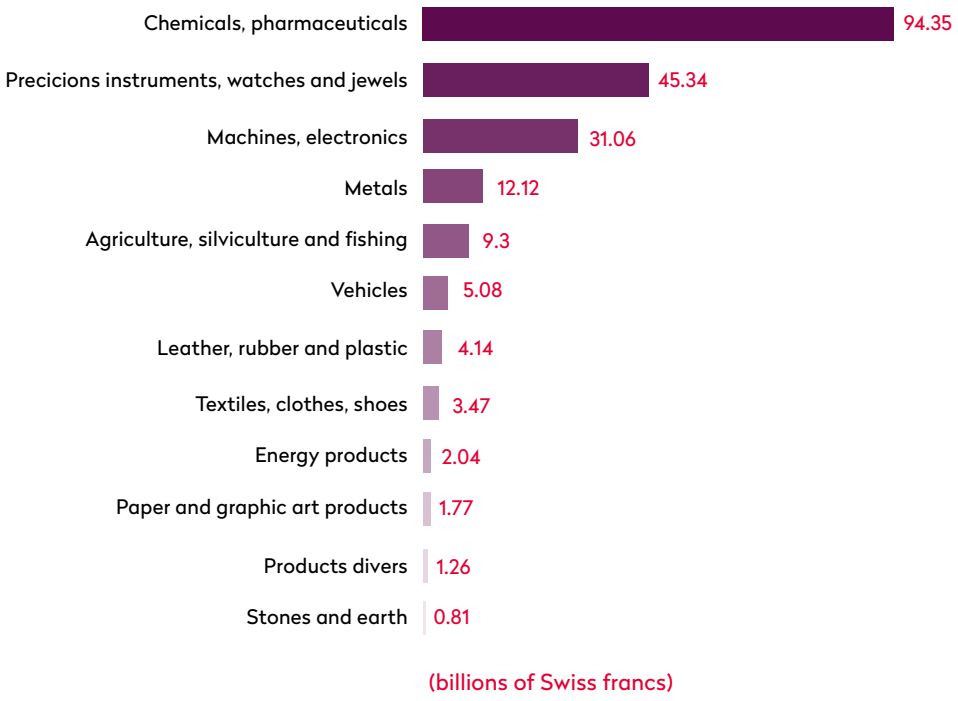
However, the Swiss authorities voluntarily overlook this legal mechanism, even though it could significantly help them in

Swiss authorities voluntarily overlook this legal mechanism, even though it could significantly help them in negotiating the prices of medicines.

negotiating the prices of medicines. This inaction can be explained by Switzerland's great dependence on its pharmaceutical industry. It was estimated that in 2017 more than 45,000 people were employed in the pharmaceutical industry[168] and that 38% of Switzerland's exports were in the pharmaceutical sector (45% when taking into account the whole group of pharmaceutical and chemical products, see figure 8).[169] This equates to around CHF 84 billion and a 15% increase on 2015.[170] However, estimates show that there was only a 1.8% real increase in export volumes in the chemical and pharmaceutical sectors between 2015 and 2016. The growth in exports can therefore be primarily explained by an average price increase for drugs of 9.5%.[171]

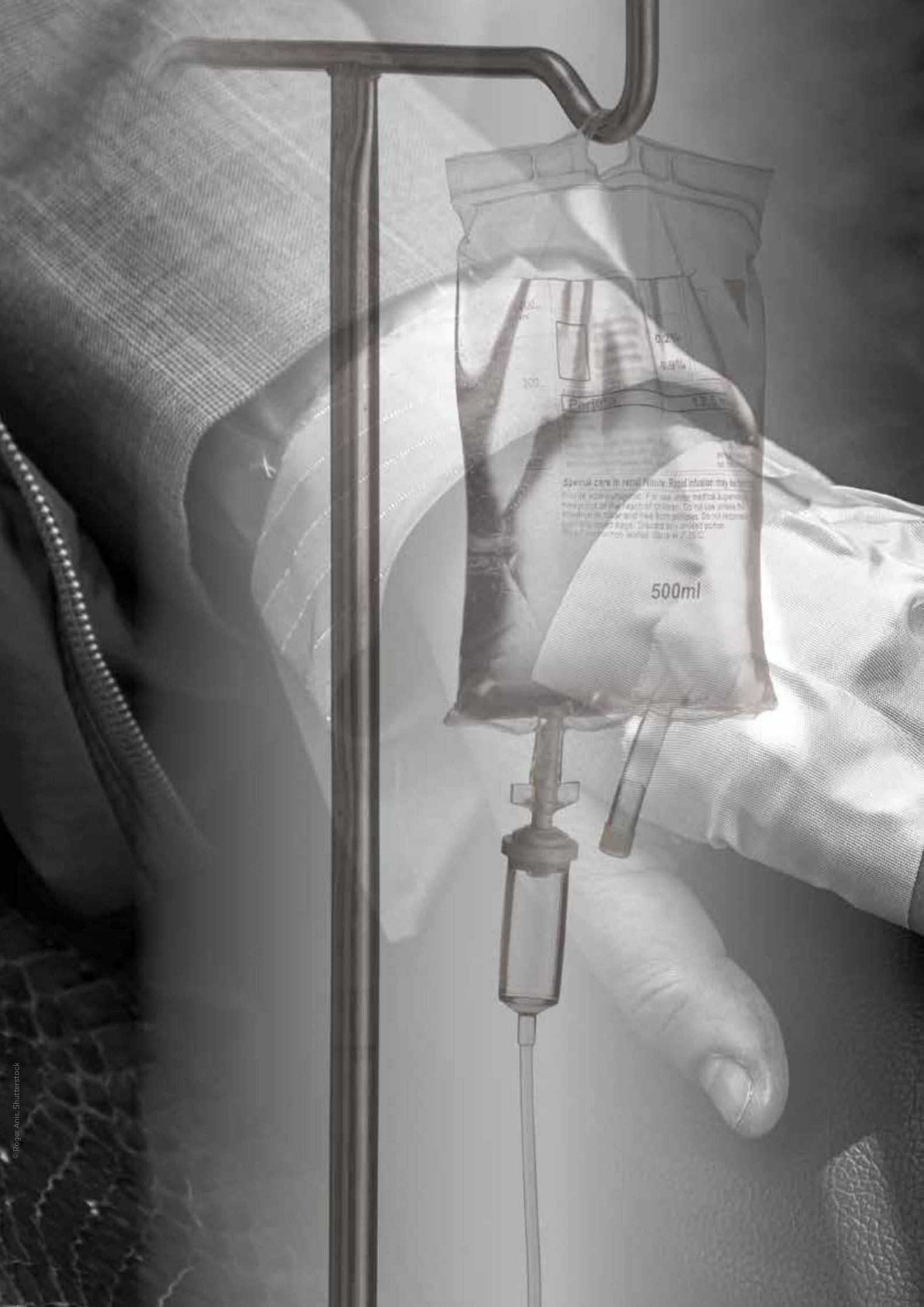
The Federal Patent Court, based in St. Gallen, is the Confederation's first instance in matters dealing with patents. The court rules, inter alia, on litigation over patent validity, patent infringement and actions for issuing a license in respect of patents. [172]

Figure 8: TOTAL SWISS EXPORTS ABROAD IN 2016 BY INDUSTRY



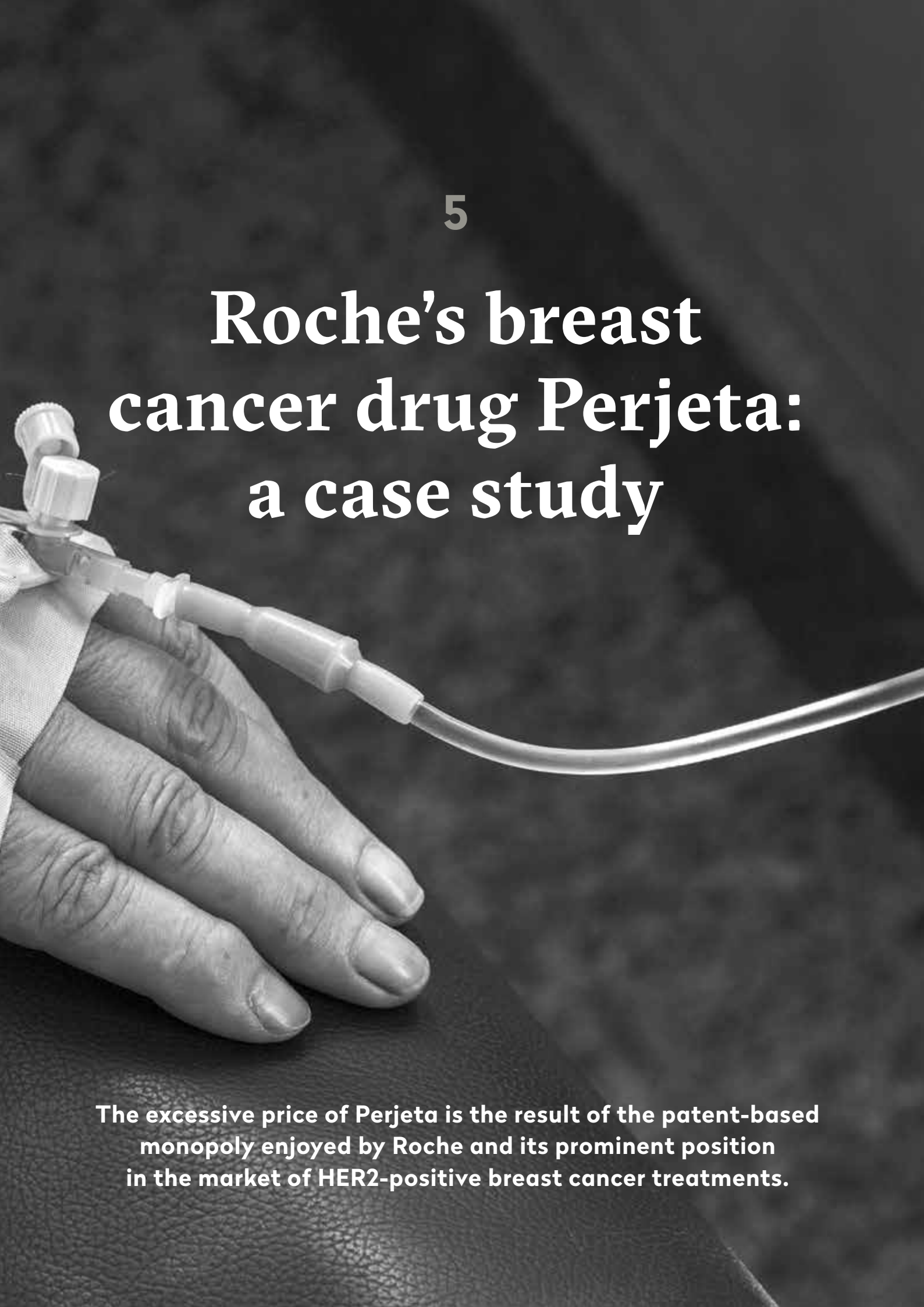
The chemical and pharmaceutical industries represent almost half of the total value of all Swiss exports.

Source: Swissinfo , February 2017



5

Roche's breast cancer drug Perjeta: a case study



The excessive price of Perjeta is the result of the patent-based monopoly enjoyed by Roche and its prominent position in the market of HER2-positive breast cancer treatments.

Estimates in Switzerland show that each year between 2010 and 2014 nearly 6,000 women were diagnosed with a breast cancer.[173] It is the most frequent cancer in women in Switzerland (6,050 per year, or 31.9% of all cancers), and also the deadliest one. From 2008 to 2012, breast cancer caused an average of 1,400 deaths per year, accounting for 19% of all cancer deaths in women. The risk of developing breast cancer is estimated at 12.7%: almost 13 out of 100 women risk suffering from breast cancer over the course of their lives.[174]

HER2-positive breast cancer is a specific type accounting for 15%–20% of all breast cancer cases,[175] [176] or an estimated 900 to 1,200 new cases in Switzerland annually. HER2-positive tumors are less responsive to standard chemotherapy and more aggressive than HER2-negative tumors.

Only two large companies are specifically engaged in the HER2-positive field, and so only a few treatments are available, mostly in combination with chemotherapy: Herceptin® (trastuzumab, Roche), Kadcyla® (trastuzumab emtansine, Roche), Perjeta® (pertuzumab, Roche) and Tyverb® (lapatinib, initially GlaxoSmithKline – now Novartis).

Currently, of the four main medicines approved to treat HER2-positive breast cancer, three are manufactured by F. Hoffmann-La Roche AG. Therefore, patients with HER2-positive breast cancer generally have little choice but to use Roche's treatments.

Perjeta is a biologic drug (monoclonal antibody), first approved in Switzerland in August 2012 for the following indications:

- Treatment of metastatic or locally recurrent HER2-positive breast cancer, unresectable, not pretreated with chemotherapy for metastatic disease.
- Neoadjuvant (use before surgery) treatment of patients with HER2-positive, locally advanced, inflammatory breast cancer or early-stage breast cancer with a high risk of recurrence for breast cancer at an early stage.[177] [178]

According to the "limitatio" decided by the FOPH[179], Perjeta has to be taken in combination with Herceptin and a standard chemotherapy (docetaxel) for the treatment of metastatic HER2-positive breast cancer in order to be reimbursed by the mandatory health insurance.

The second indication (neoadjuvant treatment) was recently included on the List of Specialties (LS) on 1 May, 2018, with a resulting (slight) decrease in price of Perjeta in accordance with the LS regulations.

Roche is also seeking a third indication for adjuvant (in addition to surgery) treatment of HER2-positive early breast cancer in the USA.[180] [181] This indication has not yet been approved by Swissmedic for Switzerland.

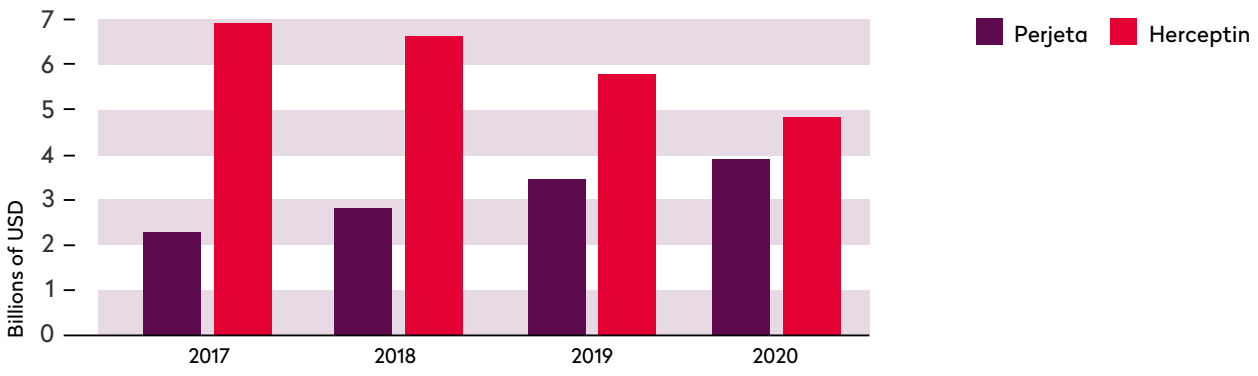
As of today, two indications (metastatic and neoadjuvant treatment) are thus eligible for reimbursement through the LS mechanism (automatic reimbursement if the conditions imposed by the "limitatio" are fulfilled).

For the third indication (adjuvant treatment), an individual request for reimbursement has to be made by the patient or his/her treating physician to the health insurer, a mechanism based on a different legal framework established for specific circumstances (Art. 71a to 71c OAMal).[182] The decision is entirely at the discretion of health insurers on a case-by-case basis.[183]

5.1 – PERJETA® IS PART OF ROCHE'S STRATEGY TO STRENGTHEN THEIR MONOPOLY

In the field of HER2-positive breast cancer, Herceptin, a multi-billion-dollar blockbuster drug from Roche, has been the market leader for many years. Herceptin alone accounted for 84 % of the HER2-positive market in 2013. As a result, Roche was the undeniable global leader in the HER2-positive breast cancer market, capturing 95 % of total HER2-targeted drug sales.[184]

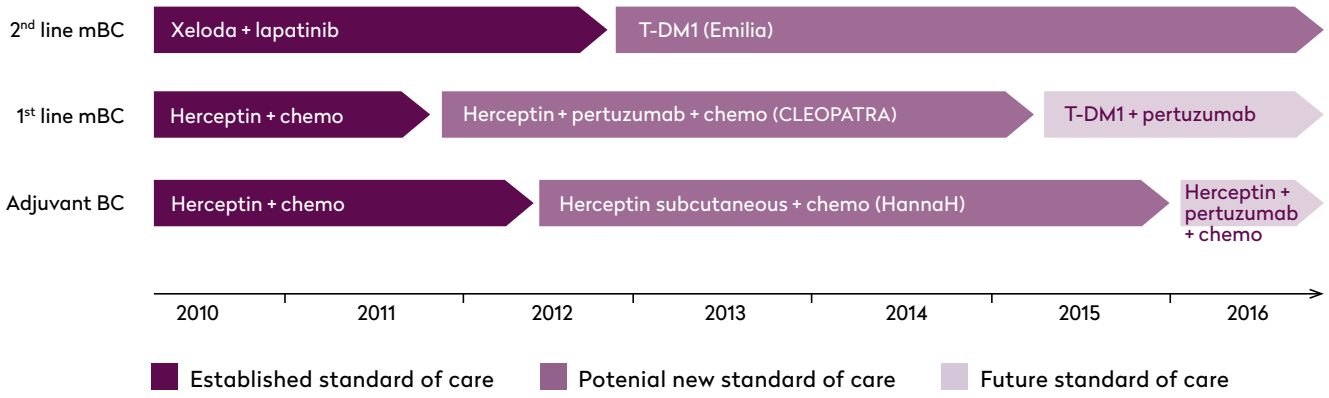
Figure 9 – ROCHE IS COUNTING ON PERJETA FOR GROWTH AS HERCEPTIN FACES COMPETITION



Sales Boost – Roche is counting on Perjeta for growth as Herceptin faces competition

Source: Bloomberg, February 2017

Figure 10 – SECURING GROWTH FOR ROCHE'S HER2 FRANCHISE



Building on the blockbuster Herceptin for metastatic breast cancer (mBC), Roche recently launched two follow-on agents: Kadcyla, an antibody-drug conjugate combining Herceptin and the cytotoxic chemotherapy, DM1; and Perjeta, to be used in conjunction with Herceptin or Kadcyla.

Source: Pharmaceutical Executive , June 2015

Financial analysts believe the company is poised to face decreasing revenues because the patent protection on its blockbuster drug Herceptin is coming to an end (see figure 9).[185] [186] According to media and expert reports, Roche is fighting to maintain its monopoly in the field of HER2-positive breast cancer: one strategy is to try to prevent the entry of Herceptin biosimilars in several markets.[187] [188] [189] [190] But it is also counting on newer follow-on drugs to generate more sales to maintain, or even strengthen, its monopoly in the HER2-positive breast cancer field (see figure 10), thereby counteracting the entry of biosimilars (generics) of its older drug.[191] [192] [193] [194]

Kadcyla and Perjeta are expected to compensate the loss of revenues from Herceptin.[195] [196] In particular, an increased use of Perjeta is expected not only to help protect sales of Herceptin, but also to contribute to higher revenues by extending the duration of treatment.[197]

Financial analysts believe the company is poised to face decreasing revenues because the patent protection on its blockbuster drug Herceptin is coming to an end.

Experts expect that these various strategies will allow Roche to remain the prominent actor in the market of HER2-positive breast cancer treatments,[198] and that future patients will continue to have to rely primarily on Roche drugs to treat their disease.

5.2 – THE PRICE OF PERJETA®: A REFLECTION OF ROCHE'S PROMINENT MARKET POSITION

The combination of Perjeta and Herceptin costs at least double what Herceptin costs when used in monotherapy. In 2013, the annual treatment cost of the combination was estimated by some authors to reach as much as CHF 208,000[199] [200], or CHF 160, 000 if the pay-back discounts imposed on Roche by the "limitatio" were taken into account (see box 5.1). With the expiry of the patent on Herceptin in Europe in 2014, and the recent extension of indication regarding Perjeta, the prices are now somewhat lower. Public Eye's own calculations, based on the current public prices of both products (as of 01.05.2018) show that an annual combined treatment today costs close to CHF 110,000, or CHF 101,600 with the pay-back discount.[201]

While more expensive, the combination treatment is reportedly more effective than monotherapy for metastatic breast cancers. Although the benefits have not tripled (as the price has), studies have shown that patients who were given Perjeta on top of Herceptin and chemotherapy lived on average 16 months longer than those on Herceptin and chemotherapy alone: a median overall survival time of 56 versus 40 months which, according to commentators, is 'unprecedented' in the field of metastatic breast cancer.[202]

This should be reason enough to ensure that the Perjeta-Herceptin Combo is easily and globally accessible to all women

suffering from HER2-positive breast cancer. However, the high price of Perjeta – the result of its patent-based monopoly – is making access and scaling-up of the treatment extremely challenging, even in a rich country like Switzerland.

Perjeta, with a current public price of nearly CHF 60,000, is by far not the only, and even not the most expensive, cancer medicine entitled to reimbursement under Switzerland's mandatory health insurance scheme. However, given the frequency of breast cancer, the high cost of the combination therapy has substantial financial implications for Switzerland's health insurance system. According to the annual incidence of HER2-positive breast cancer cases (900–1,200 per year, 15–20 % of all breast cancers), the costs are estimated at over CHF 130 million, or 22 % of the total annual expenditure on all cancer drugs in 2016 in Switzerland (CHF 605 million) – for only one subtype of breast cancer disease (see section 2.4.3 for more details).

5.3 – PERJETA CANNOT BE CONSIDERED COST-EFFECTIVE AT ITS CURRENT PRICE

Perjeta has had a turbulent regulatory history since its launch, both in Switzerland (see box 5.1) and other European countries. For example, the UK's National Health Service had long considered that it was not cost effective and rejected it for reimbursement. Only following years of negotiations was a (secret) price deal finally struck in February 2018 between the UK health authorities and Roche.[203]

> The regulatory history of Perjeta illustrates perfectly the pricing power of a large pharmaceutical company in a monopoly situation.

Public Eye considers that the excessive price of Perjeta is the result of the patent-based monopoly enjoyed by Roche and its prominent position in the market of HER2-positive breast cancer treatments.

This unique position has allowed, and continues to allow, Roche to impose its controversial prices on the authorities. Despite tough and lengthy negotiations, FOPH's attempts to lower the price of Perjeta failed. It would have been politically difficult to deny the reimbursement of a drug that brings hope and prolongs patients' lives. But the company was granted the inclusion of the drug at a high public price. Roche also succeeded in maintaining its practice of a "showcase" price (see box), a practice that is legally questionable and has been considered "subject to caution" by a parliamentary review,[210] because it allows the company to influence prices in countries that use Swiss prices as a benchmark.

Box 5.1

PERJETA, A CHAOTIC REGULATORY HISTORY IN SWITZERLAND

Following its marketing approval by Swissmedic in August 2012, Perjeta was provisionally included on the List of Specialties (LS) in March 2013.

The inclusion of Perjeta in 2013 was provisional, pending an EAE evaluation by the FCM (see box section 5.1). Nevertheless, it already included a "limitatio" decided upon by the FOPH that contained an unusual kickback mechanism: Roche had to pay the health insurer back CHF 1,600 per pack of Perjeta. The Swiss price supervisor, Stefan Meierhans, believed that Roche suggested this rebate to the FOPH to avoid reducing the public (or 'showcase') price of CHF 3,782 per pack, which is used in other countries for external reference pricing[204]. This decision was unusual because "limitatio" is intended to be used to restrict the use of a drug to specific medical indications or patient groups, and it has been widely criticised, including by a parliamentary commission which called it *"an adventurous deal"* relying on an *"obviously unprecedented use of a limitatio"*[205]. It has even been considered *"illegal"* by established experts.[206]

Perjeta was suddenly withdrawn from the LS in August 2014 because FOPH and Roche could not agree on the price of the preparation. Reasons vary according to media reports: some say FOPH decided to de-list the drug to stop legitimising a highly inflated public price[207], others (actually the majority) blame Roche for withdrawing Perjeta from the LS as a reaction to imposed price reductions that were 20 % below those prevailing in neighbouring countries. [208] [209]

As a result, Perjeta was no longer automatically reimbursed by the mandatory health insurance as of 1 November, 2014. From then on, patients needing the treatment had to, with the help of their treating oncologists, negotiate individually with their health insurer to secure reimbursement under the special scheme mentioned above – with no guarantee of success as the decision rests entirely with each health insurance company.

It was only after several months of negotiations that the FOPH officially included Perjeta on the LS again in June, 2015. Surprisingly, the public price was very similar to the initial one – CHF 3,762.75, i.e. only CHF 20 lower than the public price that had resulted in the drug being withdrawn from the LS. But even more surprising than the controversial pay-back mechanism still being present in the "limitatio" was the fact that it had been drastically reduced from CHF 1,600 to CHF 737.

The final price deal was therefore worse than the first one, and is a perfect illustration of the pricing power of a pharmaceutical company – in this case Roche – and the political impotence of authorities to impose substantial price reductions.

The regulatory history of Perjeta illustrates perfectly the pricing power of a large pharmaceutical company in a monopoly situation – the FOPH could do little but cave in to Roche's claims and include the drug on the LS at the price demanded by the company. It highlights the relative weakness of authorities in such circumstances, and proves that, at least in this context, the FOPH was unable to fulfil its obligations to act in the public interest. It also signals to other pharmaceutical companies that they will be able to dictate high prices in similar situations. It clearly reflects the gross imbalance between public and private interests.

According to Public Eye's research, Perjeta is protected by patents until at least 2029, giving Roche more than an additional decade of monopoly over the Perjeta-Herceptin Combo (a treatment of reference) in the field of HER2-positive breast cancer, even though Herceptin's patents expired in Europe (including Switzerland) in 2014. This comes at a high cost, both for the individual and society.

Roche has already profited enormously from Herceptin, and continues to remunerate its shareholders handsomely[211]. Its next blockbuster, Perjeta, is expected to bring additional billions in revenue. In a press release of 26 April 2018 regarding its financial results over the first quarter, Roche mentions "Ocrevus and Perjeta" among the main drivers of the 7% increase of sales within its Pharmaceutical Division. As expressed by a pharmaceutical sector specialist, commenting on a complaint filed by Roche to block the introduction of a biosimilar version of the drug in the USA, *"Herceptin is a remarkable drug, but after enjoying 19 years as a monopoly and USD 70 billion in sales, one might think enough is enough, as regards the rewards to the Roche shareholders"*. [212]

"Herceptin is a remarkable drug, but after enjoying 19 years as a monopoly and USD 70 billion in sales, one might think enough is enough, as regards the rewards to the Roche shareholders".

© Michael Kupferschmidt / Keystone

6

Compulsory licensing is an efficient solution

Compulsory licensing is a tool that has helped countries to ensure access to medicines by reducing the prices of highly expensive medicines without adverse economic consequences.

As described in previous chapters, exorbitant medicine prices threatens both the sustainability of our health system and the principle of universal health coverage in Switzerland. It also exacerbates problems with access to medicines in markets where Swiss pharmaceutical companies are active.

While the benefits of Perjeta are real, the price of the combined Herceptin-Perjeta treatment, which has more than doubled compared to the standard of care (Herceptin and chemotherapy), is very difficult to justify and, according to us, is unsustainable.

The sound balance required by the patent system between public and private interest has been disrupted. The Federal Council has a special responsibility to restore it. Public Eye considers that a compulsory license is justified in the case of Perjeta because the sustainability of the health system, the principle of universal health coverage and public interest override the interest of the patent holder in retaining its monopoly on its highly priced drug.

6.1 – COMPULSORY LICENSING IS A LEGITIMATE TOOL TO PROTECT AND PROMOTE PUBLIC HEALTH

Compulsory licensing refers to a government allowing a third party to use a patented product or process without the consent of the patent owner.[213] The patent owner retains rights over the patent, including the right to be paid for copies of the products made under the compulsory licence. [214] It is a legal[215] tool available to countries to protect public health, in particular to reduce the prices of highly expensive medicines for reasons of public interest.

Compulsory licensing should not be confused with contractual or voluntary licensing, whereby a licence is granted by the patent holder voluntarily to a third party to exploit the invention in exchange for remuneration.

Compulsory licensing is one of the public health safeguards, or TRIPS flexibilities, provided for by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[216] in order to create competition in a patent-monopoly situation, particularly when abusive, *"to protect public health"*.[217] It is considered an efficient but highly-sensitive tool to ensure affordable access to life-saving medicines, and has thus attracted a lot of political attention internationally.

Table 2 – DEBUNKING SOME MYTHS ABOUT COMPULSORY LICENSING

MYTH	REALITY
Only to be used in national emergency or other extreme urgency circumstances.	Emergency situations may only have the potential to shorten the procedure.
Limited to a certain number of diseases, such as HIV/AIDS or communicable diseases with epidemic potential.	Compulsory licensing is not limited to one disease or to a category of diseases.
Limited to poor countries.	Each WTO Member has the right to issue a compulsory licence.
A last resort tool.	Expropriation is the last resort tool.
Compulsory licensing equals expropriation.	The patent holder remains the owner, and keeps the right to exploit the invention and receive an adequate remuneration.
An arbitrary tool.	Compulsory licences are provided for by most national patent legislations and by international law under the TRIPS.
Deterring incentives to innovate or to invest in R&D.	There is no evidence that compulsory licensing reduces investments in R&D or has potential negative effects on foreign direct investment.
The low use of TRIPS flexibilities, especially compulsory licensing, shows that there is no problem with prices of medicines linked to patents.	From 2001 to 2016, there were 100 instances of compulsory licences or public non-commercial use licences by 89 countries.
The systematic use of compulsory licensing may affect R&D and investments.	Compulsory licences have never been used in a systematic way.
IP is not the problem. Compulsory licensing is therefore pointless.	In some middle-income countries, medicines are sometimes more expensive than in developed countries because of the pricing strategy of patent holders.

Some countries and pharmaceutical companies falsely claim that compulsory licences are tools that should be used only in exceptional circumstances.[218] [219] [220] However, contrary to many beliefs and misunderstandings, compulsory licensing is not restricted to situations of national emergency or other circumstances of extreme urgency, as is clearly reflected in an official WTO webpage.[221] Countries are free to determine the grounds upon which a compulsory licence is issued.[222] Some of the misleading statements surrounding compulsory licensing are summarised in table 2.

It is important to stress that compulsory licensing does not equal expropriation. On the contrary, under a compulsory licence, the patent holder remains the owner[223] and continues to hold the right to exploit the invention[224], with the rights attached to the patent (except to exclude the licensee benefitting from the compulsory license).[225] Moreover, compulsory licences are limited in their scope and duration to the purpose for which they were authorised[226] and are predominantly granted to supply a domestic market.[227] Above all, the patent owner receives regular adequate remuneration, in the form of royalties, as if it had voluntarily licensed its invention.[228]

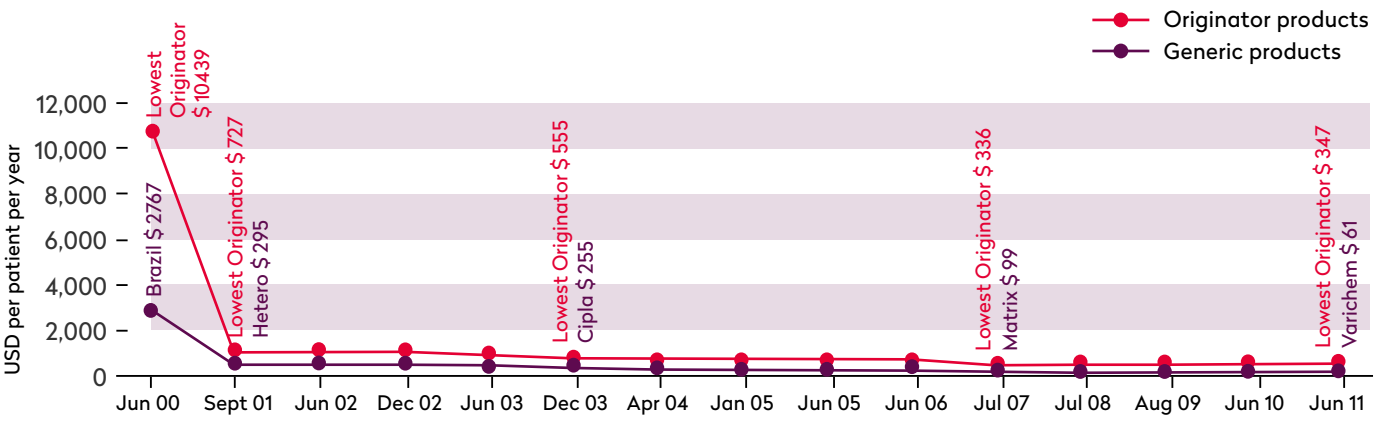
Finally, compulsory licensing is not simply imposed on the patent holder. Except for cases of national emergencies or of public non-commercial use, this mechanism requires that the licensee makes sincere attempts to find an agreement under fair terms and within a reasonable period of time, prior to requesting permission for a compulsory licence.[229]

6.2 – COMPULSORY LICENSING IS A WIDELY RECOGNISED TOOL

Almost all States have provisions on compulsory licensing in their legislation. For example, in France, the law provides that a compulsory licence (or "licence d'office") may be issued in cases where a medicine is available "in insufficient quantity or quality" or at abnormally high prices, or when the patent is used under conditions contrary to the interest of public health, or constituting practices are declared to be anti-competitive.[230] The UK provides for the use of a patented invention in the services of the Crown without the consent of the patent holder.[231] The Belgian government has also enacted broad provisions allowing the authorities to grant compulsory licences in the interest of public health.[232] In Europe more generally, most countries have included the possibility to issue compulsory licences in their respective laws to safeguard the sound balance between the interests of the patent holder and the public.[233] [234]

Moreover, a range of institutional actors have recommended the use of compulsory licensing in order to safeguard access to affordable medicines and reduce the burden of monopoly-based patents on public health budgets. The United Nations Secretary General's High Level Panel on Access to Medicines, formed by stakeholders from various backgrounds including the pharmaceutical industry, recommended the use of TRIPS flexibilities and legislation to facilitate the issuance of compulsory licences.[235] The Lancet Commission on Essential Medicines Policies also recommended the use of compulsory licences in the absence of any voluntary agreement, especially for essential medicines.[236] The European Parliament has recently adopted a resolution that recommended the consideration of using compulsory licensing,[237]

Figure 11 – IMPACT OF GENERIC COMPETITION ON PRICE REDUCTIONS



Competition among multiple generic pharmaceutical manufacturers in countries where medicines were not patented, especially India, is what brought the cost of HIV/AIDS treatment down by 99 % over the past decade. The fall in the price of first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP), since 2000.

Source:
MSF Access Campaign, July 2012

and the Dutch government has taken a strong position in favour of using compulsory licensing.[238] Even the OECD, in one of its latest reports, mentioned compulsory licensing as a means to reduce high-priced medicines.[239]

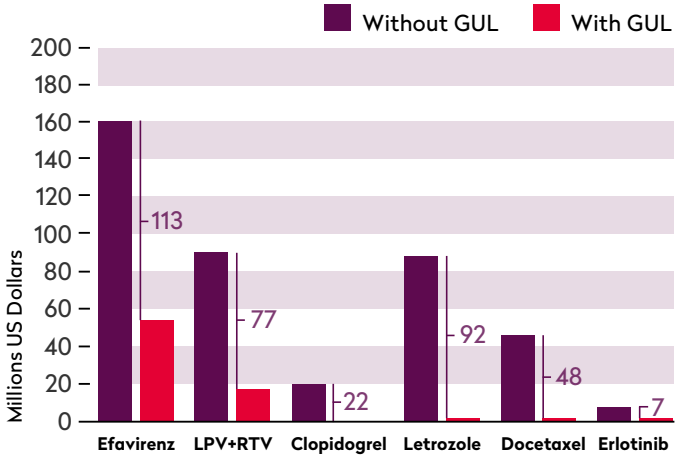
Finally, contrary to many beliefs, and despite several attempts to prevent it, the use of TRIPS flexibilities, including compulsory licensing, has been a frequent practice since 2001 for countries wanting to gain access to lower-priced generic medicines. Unfortunately this fact has been underreported.[240]

Pharmaceutical companies holding patents have also used this legal mechanism. In 2016 the German courts awarded a compulsory licence on a HIV medicine in a case involving two pharmaceutical companies (Shionogi & Company Ltd and Merck & Co).[241] Roche also used this mechanism in 2000–2001 to seek a compulsory licence in Germany on patents for a diagnostic test involving HIV and Hepatitis C Virus held by Chiron.[242]

6.3 – GENERIC COMPETITION HAS A PROVEN TRACK RECORD IN PROMOTING PUBLIC HEALTH

A compulsory licence is an effective means of encouraging pharmaceutical companies to adopt reasonable pricing strategies. By allowing competition from generic manufacturers, a compulsory licence leads to a decrease in prices.

Figure 12 – USE OF COMPULSORY LICENSES – THE EXAMPLE OF THAILAND



GUL = Government use license

Source: Thai Ministry of Public Health, "Price reductions from 2007–2012", cited in UNCTAD, "Use of Compulsory Licenses – Selected National Experiences", Power Point Presentation.

As underlined earlier (see section 3.2), during the HIV/AIDS pandemic in the late 1990s, only highly expensive patented drugs were available on the market, at a price tag of around USD 10,000. Many countries, especially LMICs, struggled to get access to these drugs.

However, thanks to competition from Indian generic manufacturers it was possible to dramatically reduce the prices for antiretroviral therapies (ARVs). In 1996, for example, Brazilian authorities implemented a broad access programme to HIV/AIDS treatments. Such universal access was possible because there were no patents on drugs in Brazil: the drugs could be produced locally and sold at much lower prices. The production of ARVs in Brazil, combined with the broad access programme, made it possible for Indian-based companies to start producing and exporting Active Pharmaceutical Ingredients (APIs) in large volumes, resulting in large economies of scale. Consequently, the price of the WHO-recommended first-line treatment of ARV combination lamivudine/nevirapine/stavudine dropped from USD 15,000 to USD 66 per patient per year (twice-a-day fixed dose combination).[243] This significantly helped the country to increase access to these life-saving medicines (see figure 11).

Experience also shows that compulsory licensing is a tool that has helped countries to ensure access to medicines by reducing the prices of highly expensive medicines without adverse economic consequences.[244] In Thailand, the use of compulsory licences resulted in a significant reduction of over USD 350 million in government expenditure due to the dramatic decrease of drug prices (see figure 12), therefore allowing 85,000 additional patients to have access to lifesaving medicines.[245] [246]

Other countries in Latin America[247], such as Ecuador, or in Asia, such as Malaysia and Indonesia[248] have issued compulsory licences, allowing them to save significant public resources and ensure access by their population to affordable medicines. High-income countries have used it as well, as we will see in the next section.

6.4 – PHARMACEUTICAL COMPANIES RESPOND TO THE RISK OF COMPULSORY LICENSING

Experience demonstrates that the decision to issue, or the mere notification of a compulsory licence, encourages pharmaceutical companies to adopt dramatic price decreases and engage in licensing agreements, and empowers the authorities to negotiate more reasonable prices, all of which result in broadened access.[249] [250] [251]

In 2001, Canada and the US announced their intention to issue a compulsory licence on Ciprofloxacin after the anthrax attacks in the US.[252] According to press reports, Bayer was concerned about the precedence this could create and so decided to offer price discounts and promised to supply the market sufficiently.[253]

The same year, facing intransigence from Roche regarding the price of its antiretroviral drug Viracept® (nelfinavir),[254] Brazil announced its intention to issue a compulsory licence. A few days later, Roche announced an agreement with Brazil to cut the price of the drug.[255]

In 2004, Kenya decided to issue a compulsory licence on some antiretroviral drugs for HIV/AIDS.[256] Later, Glaxo Smith

Kline (GSK) and Boehringer Ingelheim (BI) decided to grant voluntary licences to Kenyan-based generic companies.[257] [258]

In 2005, Taiwan, facing growing concerns about the avian flu, decided to issue a compulsory licence on Tamiflu® (oseltamivir), but said that it would only be used in case stockpiles of the patented drug ran dry.[259] Roche therefore decided to make voluntary licences available in the country.[260]

In September 2017, Malaysia issued a government use licence (GUL) to import or produce a generic version of Sovaldi (sofosbuvir), one of the antivirals used for the treatment of hepatitis C. Before the move, a full course of treatment (3 months) used to cost MYR 300,000 (CHF 74,000 at the current exchange rate). Following the GUL, the Malaysian government expects that a treatment with generics will cost only MYR 1,000 (CHF 250).[261] Soon after the GUL had been announced, Gilead, the US manufacturer of Sovaldi, offered to include Malaysia in its voluntary licence scheme to attempt to dissuade them from issuing a compulsory license. However, as Gilead was not willing to go below MYR 50,000 (CHF 12,000) the Malaysian government proceeded with the GUL.[262]

The mere intention to issue a compulsory license leads to a reaction from the pharmaceutical companies.

Recently the Italian government raised the prospect of utilising compulsory licences during negotiations with US drug company Gilead over the high price of Hepatitis C treatment sofosbuvir (Sovaldi).[263] There are other examples of European countries resorting to compulsory licences. For instance, Italy granted compulsory licences in 2005 on the grounds that Merck had been misusing its market strength in relation to a number of antibiotics containing the active compounds imipenem and cilastin, and in 2006 against GlaxoSmithKline for its refusal to provide a licence for sumatriptan, used for treating migraines. In 2007 Italy demanded that Merck should issue licences free of charge for finasteride, a drug used for treating, among other diseases, prostate cancer. France imposed compulsory licences in 2004 for diagnostic tests for breast cancer, a decision based on French law, which allows for compulsory licences when medical products are insufficiently available to the population or only available at unacceptably high prices.[264]

In conclusion, these cases and a number of studies on the use of compulsory licences[265] [266] confirm that the mere notification or intention to issue a compulsory license leads to a reaction from the pharmaceutical companies, in some cases with offers to significantly reduce prices. It also confirms that the high profit margin of pharmaceutical companies allows for significant negotiating room.

6.5 – SWITZERLAND IS TORN BETWEEN THE PROMOTION OF HUMAN RIGHTS AND ITS FINANCIAL INTERESTS

Despite regular statements in favor of access to affordable medicines and human rights, the Swiss authorities regularly denigrate the use of TRIPS flexibilities in international fora, or put pressure on LMICs to dissuade them from using compulsory licensing to reduce the burden of high drug prices.

In January 2008, the Thai government, faced with the growing burden of cancer, decided to issue a government use licence (GUL) on four highly priced cancer drugs (Novartis' letrozole and imatinib mesylate, Sanofi's docetaxel and Roche's erlotinib). In February 2008, Switzerland sent an "Aide Mémoire"[267] to try to dissuade the Thai government from doing so. The US and the European Union also expressed concerns about it. Thailand resisted the pressure and finally issued the GUL. Despite the threats, the policy resulted in very positive outcomes in terms of public health.[268]

In 2016, Colombia issued a Declaration of Public Interest (DPI),[269] a step towards issuing a compulsory licence, to make Novartis blockbuster leukemia drug Glivec® (imatinib mesylate)[270] more affordable. Facing pressure from Novartis, Switzerland and the United States, Colombia eventually stepped back and limited its decision to a price decrease of the drug.[271] In particular, the Swiss State Secretariat for Economic Affairs (SECO) warned against the issuance of a DPI, indicating that bilateral relations could suffer if a compulsory licence was issued.[272] The US threatened Colombia with economic retaliations, and sent a clear message that they would reconsider funding of the peace process with the FARC in the event of a compulsory licence being issued.[273] In a nutshell, they made Colombia choose between peace and public health. As for Novartis, it threatened Colombia with an international investment arbitration procedure and filed two complaints at the Consejo de Estado (Colombian Supreme Court) against the DPI and the price reduction decision.[274] A letter from Novartis' former CEO, Joe Jimenez, to the President of Colombia was further evidence of the Swiss company's aggressive lobbying to avoid a DPI.[275]

However, Switzerland not only pressures other countries to prevent their recourse to legitimate mechanisms that might affect Switzerland's financial interests. It also pressures countries to adopt, generally in great secrecy, free trade agreements (FTAs) aimed at imposing stricter intellectual property requirements on LMICs than those required by international standards (so-called TRIPS-plus provisions).[276] [277] The aim of such agreements is to deter countries seeking to protect public health from using TRIPS flexibilities.

Switzerland and other HICs also insist on the adoption of so-called Investor-State Dispute Settlement (ISDS) measures through FTAs or Bilateral Investment Treaties (BITs). ISDS are designed to allow transnational companies to sue a state for taking measures that affect their investments. As a result, countries are reluctant to use measures like TRIPS flexibilities to protect public health for fear that a pharmaceutical company will sue them, resulting in heavy sanctions. As seen above in the Colombian context, Novartis threatened the government with an ISDS measure.[278]

© Stephen Eleringmann/Steph/laif

The current pharmaceutical pricing model, reliant on patent-based monopolies, undermines universal health coverage.

7

Our demands

Public Eye considers that the current pharmaceutical pricing model, reliant on patent-based monopolies, works against the public interest by threatening the sustainability of our health system and undermining the principle of universal health coverage. We believe that every person should have access at all times to quality, safe, efficacious and affordable medicines – regardless of where he or she lives.

Although compulsory licensing is a legitimate legal option to reduce unjustifiably high prices of medicines and their burden on health budgets, the Swiss authorities overlook it, presumably for fear of offending one of Switzerland's most powerful industries. In doing so, Switzerland deprives itself of a valuable tool to safeguard public interest, while undermining the sovereign right of other countries that wish to use compulsory licensing to protect their public health and promote universal health coverage. Public Eye considers that all countries have the right to development, and that Switzerland should not adopt positions that are detrimental to human rights, including the right to health.

High medicine prices are not predestined. We hope that through this report and its related campaign, Public Eye is able to show the Swiss authorities a way forward in dealing efficiently with excessive medicine prices.

FOLLOWING ARE PUBLIC EYE'S DEMANDS TO THE FEDERAL COUNCIL:

- Public Eye urges the Federal Council to adopt a stronger stance towards pharmaceutical companies regarding the unjustifiably high prices of (cancer) medicines.
- Public Eye urges the Federal Council to unambiguously recognise and utilise the government use licence where public interest dictates, as provided for by the Swiss Patent Act, especially in the case of excessive pricing of cancer treatments.
- Public Eye urges the Federal Council, SECO, the Federal Institute of Intellectual Property and any other entity representing the Swiss government to refrain from spreading misleading information about compulsory licensing and exercising diplomatic pressure on countries wanting to take legitimate legal measures, such as compulsory licensing, to protect public health.
- Public Eye urges the Federal Council to amend the Swiss Health Foreign Policy[279], adopted in 2012, so as to recognise that all countries have the right to fully apply the TRIPS flexibilities as deemed appropriate, and not, as wrongly stated, only in "emergency situations".[280]
- Public Eye urges the Federal Council and SECO to refrain from imposing on low- and middle-income countries intellectual property (IP) provisions that go beyond the WTO TRIPS Agreement (TRIPS plus provisions) and bear in mind that IP protections may undermine development and adversely affect human rights, especially access to lifesaving medicines.

Endnotes

1 See this report on access to medicines: UN High Level Panel on Access to Medicines, 2016, "Report of the United Nations Secretary General's High Level Panel on Access to medicines: Promoting innovation and access to health technologies" (accessed 26.7.2017).

2 UNITAID, 2016, "Ensuring that Essential Medicines are also Affordable Medicines: Challenges and Options", WHO (accessed 26.7.2017).

3 Consultative Expert Working Group on Research and Development: Coordinating and financing, 2012, "Research and Development to meet health needs in developing countries: Strengthening global financing and coordination" (accessed 26.7.2017)

4 Commission on intellectual property rights, innovation and public health, 2006, "Public Health, Innovation and Intellectual Property Rights" (accessed 27.07.2017)

5 Mostly in the US, Switzerland, Germany, UK, Japan and France.

6 WHO, 2004, The World Medicines Situation, p. 3 (accessed 18.9.2017)

7 See: Michael Christel, June 2017, "Pharm Exec's Top 50 Companies 2017", *Pharmaceutical executive* (accessed 14.3.2018)

8 WHO, 2004, The World Medicines Situation, p. 3 (accessed 18.9.2017)

9 European Federation of Pharmaceutical Industries and Associations (EFPIA), 2009 update, "The Pharmaceutical Industry in Figures", Key data, p. 3. (accessed 26.2.2018)

10 IMS health, 2011, "Le marché pharmaceutique dans le monde et en France: bilan 2010 et persective", Presentation intelligence.360 (accessed 14.3.2018)

11 Statista, "Projected growth of the world pharmaceutical market by regional group between 2017 and 2021" (accessed 1.2.2018)

12 See Ellen 't Hoen for OXFAM, 2014, "Access to Cancer Treatment: a study of medicine pricing issues with recommendations for improving access to cancer medication". (accessed 8.9.2017)

13 Daniel A. Goldstein, Jonathon Clark et al., 2017, "A global comparison of the cost of patented cancer drugs in relation to global differences in wealth", *Oncotarget,* 8(42): 71548-71555 (accessed 7.3.2018)

14 *"In developing countries, up to two-thirds of expenditure on medicines is individually financed through out-of-pocket payments, which are primarily responsible for catastrophic health expenditures, annually pushing approximately 100 million people, mostly in developing countries, into poverty".* See: UN Human Rights Council, 2013, "Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines". (accessed 7.7.2017)

15 The Financial Times, Cancer pill costs soar as drug companies retain pricing power, 30 April 2017 (accessed 06.04.2018)

16 WHO and the World Bank, 2017, "Tracking Universal Health Coverage: 2017 Global Monitoring Report" (accessed 14.3.2018)

17 Some country delegations mentioned the figure during the debate: UN OHCHR, March 2017, "Human Rights Council holds panel discussion on access to medicines" (accessed 14.3.2017)

18 United Nations Office at Geneva, 2017, "Human Rights Council holds panel discussion on enhancing capacity building in public health" (accessed 14.3.2018)

19 See also: Catherine Saez, June 2017, "Human Rights Council speakers: Right to health underlies all other rights, access to medicines key" (accessed 14.3.2018)

20 WTO, WIPO, WHO, 2013, "Promoting access to medical technologies and innovation, Intersections between public health, intellectual property and trade" (accessed 27.09.2017)

21 WTO, WIPO, WHO, 2013, "Promoting access to medical technologies and innovation, Intersections between public health, intellectual property and trade" (accessed 27.09.2017)

22 UN Human Rights Council, 2013, "Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines". (accessed 7.7.2017)

23 Ellen t'hoen, "Access to Cancer Treatment: a study of medicine pricing issues with recommendations for improving access to cancer medication". (accessed 8.9.2017)

24 Global Task Force on Expanded Access to Cancer Care and Control, 2011, "Closing the Cancer Divide: A blueprint to expand access in low and middle income countries".

25 UN Human Rights Council, 2013, "Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines". (accessed 7.7.2017)

26 With chemotherapy and associated transfusion requirements

27 Global Task Force on Expanded Access to Cancer Care and Control, 2011, "Closing the Cancer Divide: A blueprint to expand access in low and middle income countries".

28 WHO website, June 2017, "Keynote address at the Human Rights Council panel on promoting the right to health through enhancing capacity-building in public health" (accessed 14.3.2017)

29 Y. T. Bazargani, A. de Boer et al., 2014, "Selection of oncology medicines in low- and middle-income countries", *Annals of Oncology 25,* 270–276 (accessed 7.3.2018)

30 Global Task Force on Expanded Access to Cancer Care and Control, 2011, "Closing the Cancer Divide: A blueprint to expand access in low and middle income countries".

31 American Society for Clinical Oncology, May 2016, "WHO expands Cancer Essential Medicines List" (accessed 7.3.2018)

32 Margaret Ewen, Marjolein Zweekhorst, et al., 2017, "Baseline assessment of WHO's target for both availability and affordability of essential medicines to treat non-communicable diseases", *PLOS One* (accessed 7.3.2018)

33 Global Task Force on Expanded Access to Cancer Care and Control, "Closing the Cancer Divide: A blueprint to expand access in low and middle income countries".

34 Daniel A. Goldstein, Jonathon Clark et al., 2017, "A global comparison of the cost of patented cancer drugs in relation to global differences in wealth", *Oncotarget,* 8(42): 71548-71555 (accessed 7.3.2018)

35 See also the disparities within Europe: N. Cherny, R. Sullivan, et al., 2016, "ESMO European Consortium Study on the availability, out-of-pocket costs and accessibility or antineoplastic medicines in Europe", *Annals of Oncology,* Volume 27, Issue 8, pp. 1423–1448.

36 Lois Rogers, December 2017, "Why is the NHS agreeing sky high prices for life saving drugs – then refusing to pay for them?", *Daily Mail* (accessed 17.1.2018)

37 Sarah Boseley, April 2017, Gamechanging cancer drugs rejected for use on NHS, *The Guardian* (accessed 26.1.2018).

38 Iain Wither, September 2017, "War on drugs: big pharma fights NHS bill curb", *The Telegraph* (accessed 26.1.2018)

39 In France: Michasle Rivasi, October 2014, "Prix du médicament: un scandale nommé Sovaldi", *Rue89* (accessed 26.1.2018).

40 In UK: Sarah Boseley, July 2016, "NHS 'abandoning' thousands by rationing hepatitis C drugs", *The Guardian* (acccessed 7.9.2017).

41 In Belgium: Jean Delwaide, October 2014, "L'hépatite C est médicalement vaincue mais

le problème se trouve ailleurs", *RTBF* (accessed 7.9.2017).
42 In Italy: Robert Galbraith, January 2015, "Italian Government urged to end access delays to Gilead Sovaldi in hepatitis C", *APM Health Europe* (accessed 7.9.2017)
43 In Spain: David Hammerstein, January 2014, "High priced hepatitis C treatments spark massive public outcry and political debate in Spain", *The Commons Network* (accessed 7.9.2017)
44 The fact that access to medicines is a global concern has been recognized by the "Report of the United Nations Secretary General's High Level Panel on Access to medicines: Promoting innovation and access to health technologies".
45 BBC, Pharmaceutical industry gets high on fat profits, 6 November 2014 (accessed 06.04.2018)
46 Helsana Assurance, 2017, "Helsana-Arzneimittelreport Ausgabe 2017" (accessed 7.2.2018)
47 OFSP, 2016, "Statistique de l'Assurance Maladie Obligatoire 2016", Tableau XLSX, T 2.17. (accessed 8.3.2018)
48 Helsana Assurance, 2017, "Helsana-Arzneimittelreport Ausgabe 2017" (accessed 7.2.2018)
49 See for example the position of the price supervisor: Price Supervising, "Médicaments", Swiss Confederation (accessed 18.9.2017)
50 See: Philipp Bruggmann, interviewed by Rita Flubacher, "Die 28 Tabletten kosten so viel wie ein Mittelklassewagen", *Tages Anzeiger,* 7 August 2014 (accessed 18.9 2017). The decision to lift the limitations on the reimbursement of Hepatitis C drugs was decided in September 2017: OFSP, 2017, "Remboursement sans restriction des nouveaux médicaments pour toutes les personnes concernées" (accessed 19.9.2017).
51 For example: One of the main measures envisaged was to introduce a triennial review of the conditions of admission of the medicines registered on the List of Specialties (LS). That is why in 2009 the Federal Council decided to adapt the legislation, *inter alia* to allow a reduction in health-related costs. It adopted the new art. 65d OAMal, which provides that the FOPH will have to carry out a triennial review of the conditions of admission of all the medicines registered in the LS.
52 Ferlay J, Soerjomataram I, Ervik M et al., 2013, "Cancer Incidence and Mortality Worldwide", GLOBOCAN 2012 v1.0, IARC CancerBase No. 11, Lyon, France: International Agency for Research on Cancer (accessed 29.8.2017)
53 Nature, 2018, Cancer's cost conundrum, 8 March 2018 (accessed 6.4.2018)
54 WHO Webpage, 2018, "Cancer", (accessed 29.8.2017)
55 Swiss Confederation Webpage, "Cancer" (accessed 29.8.2017)
56 Swiss Confederation, "Le cancer en Suisse, rapport 2015", OFS, NICER, RSCE, 2015
57 Swiss Confederation, "Le cancer en Suisse, rapport 2015", OFS, NICER, RSCE, 2015
58 Of the 12 drugs approved by the FDA for various cancer indications in 2012, 11 were priced above USD 100,000 per year. See: CML experts, 2013, "The price of drugs for Chronic Myeloid Leukemia is a reflection of the unsustainable prices of cancer drugs: from the perspective of a large group of CML experts", *Blood Journal* (accessed 27.9.2017)
59 IMS Institute for healthcare Informatics, 2016, "Global Oncology Trend Report, A review of 2015 and outlook to 2020" (accessed 26.11.2017)
60 IMS Institute for healthcare informatics, 2016, "Global Oncology Trend Report, A review of 2015 and outlook to 2020"
61 CML experts, 2013, "The price of drugs for Chronic Myeloid Leukemia is a reflection of the unsustainable prices of cancer drugs: from the perspective of a large group of CML experts", *Blood Journal* (accessed 27.9.2017)
62 IMS Consulting Group, 2015, Pricing & Market Access Outlook, 2015/2016 Edition, p. 36 (accessed 6.4.2018)
63 Nicola Davis, "Over half of new cancer drugs 'show no benefits' for survival or wellbeing", *The Guardian* (accessed 18.9.2017).
64 Sham Mailankody and Vinay Prasad, 2014, "Comparative Effectiveness Questions in Oncology", *NEJM* (accessed 15.9.2017)
65 Howard D. et al., 2015, "Pricing in the Market for Anticancer Drugs", *Journal of Economic Perspectives,* vol. 29, n° 1, pp. 139–162 (accessed 14.11.2017)
66 Light DW and Kantarjian H., 2013, "Market Spiral Pricing of Cancer Drugs", *Cancer,* Nov 15;119(22):3900-2 (accessed 14.11.2017)
67 See for example this retrospective study: Davis C, Naci H et al., 2017, "Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009–13" (accessed 15.9.2017)
68 Organisation de Coopération et de Développement Economique (OCDE), 2015, "Panorama de la santé 2015: les indicateurs de l'OCDE", Paris, p. 46 (accessed 26.11.2017)
69 Organization for Economic Co-operation and Development (OECD), 2017, "New Health Technologies: Managing Access, Value and Sustainability", *OECD publishing,* Paris, p. 13.
70 Davis C, Naci H et al., 2017, "Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009–13" (accessed 15.9.2017)
71 Kumar H. et al., 2016, "An Appraisal of Clinically Meaningful Outcomes Guidelines for Oncology Clinical Trials", JAMA Oncol. 2016;2(9):1238-1240 (accessed 6.4.2018)
72 Fojo T. et al, 2014, "Unintended Consequences of Expensive Cancer Therapeutics: The Pursuit of Marginal Indications and a Me-Too Mentality That Stifles Innovation and Creativity", *JAMA Otolaryngol Head Neck Surg.* 2014;140(12):1225–1236 (accessed 6.4.2018)
73 Ibid
74 Howard D. et al., 2015, "Pricing in the Market for Anticancer Drugs", *Journal of Economic Perspectives,* vol. 29, n° 1, pp. 139–162 (accessed 14.11.2017)
75 The Economist, 2014, Hard Pills to Swallow, 4 January 2014 (accessed 6.4.2018)
76 Solange Peters, Roger von Moos et al., 2015, "Est-ce raisonnable que je prescrive un traitement à 150'000 FRS à mon patient ?", *Revue Médicale Suisse* (accessed 23.9.2017)
77 Pascal Schmuck, April 2013, "Des médecins dénoncent des traitements trop chers", *Tribune de Genève* (accessed 24.7.2017).
78 Alexandre Richard, November 2016, "Campagne choc de Médecins du Monde contre le prix des médicaments", *Radio Télévision Suisse* (accessed 7.8.2017).
79 Von I. Strassheim, August 2015, "Krankenkassen schlagen wegen Krebsmittel Alarm", *20 Minuten* (accessed 26.9.2017).
80 David Eugen, 2006, "06.3438 | Des médicaments trop chers pour le traitement du cancer", *Assemblée Fédérale* (accessed 28.09.2017)
81 Marie Nicollier, "Ce traitement pourrait pourtant me sauver la vie", *Tribune de Genève,* 20 June 2016 (accessed 28.9.2017)
82 Helsana Assurance, 2013, "Oncologie, Statistiques des medicaments 2013" (accessed 26.9.2017)
83 Helsana Assurance, 2016, "Helsana-Arzneimittelreport Ausgabe 2016" (accessed 26.9.2017)
84 Sonntagszeitung, Krebsmittel sind unnötig teuer, 30 September 2017 (accessed 7.4.2018)
85 Translated from German: Helsana Assurance, 2017, "Helsana-Arzneimittelreport Ausgabe 2017" (accessed 7.2.2018)
86 Translated from German: Helsana Assurance, 2017, "Helsana-Arzneimittelreport Ausgabe 2017" (accessed 7.2.2018)
87 ATS/NXP, December 2017, "Payer 475'000 fr. pour un cancer est 'justifié'", *Tribune de Genève* (accessed 7.1.2018)
88 Tufts Center for the Study of Drug Development, November 18, 2014, "Cost to develop and Win Marketing Approval for a New Drug is USD 2.6 billion" (accessed 15.9.2017)
89 Half of the amount calculated corresponds to the estimated cost of opportunity: the idea is that the investments made in drugs that failed were not allocated to other kinds of investments and should therefore be considered as a cost. The opportunity cost was assessed at 10.6 % per year, in spite of the fact that bonds issued by pharmaceutical companies often pay only 1 to 5 %. In addition, the Tufts Center is largely funded by pharmaceutical companies and the study is based on confidential data supplied by pharmaceutical companies. See: Jerry Avorn, M.D, 2015, "The 2.6 billion Pill – Methodologic and policy considerations", *New England Journal of Medicine.*
90 Médecins Sans Frontières (MSF), November 18, 2014, "R & D cost estimates: MSF response to Tufts CSDD study on cost to develop a new drug" (accessed 15.9.2017).
91 See also: Roger Collier, 2009, "Drug development costs estimates hard to swallow" or Médecins Sans Frontières (MSF), November 18, 2014, "R & D cost estimates: MSF response to Tufts CSDD study on cost to develop a new drug" (accessed 15.9.2017).
92 Ben Hirschler, 2013, "GlaxoSmithKline Boss says new drugs can be cheaper" (accessed 28.10.2017)
93 Drugs for Neglected Diseases initiative (DNDi), 2014, "An innovative approach to R & D for Neglected Patients. Ten Years of experience and lessons learned by DNDi", pp. 18 and 20 (accessed 15.9.2017).
94 See also: Médecins Sans Frontières (MSF), November 18, 2014, "R & D cost estimates: MSF response to Tufts CSDD study on cost to develop a new drug" (accessed 15.9.2017).

95 Vinay Prasad and Sham Mailankody, November 2017, "Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval", *The JAMA network* (accessed 15.9.2017)
96 See: Steve Morgan et al., 2011, "The Cost of drug development: A systematic review", *Health policy 100,* 4-17 (accessed 17.9.2017).
97 When the Uruguay Round launched in 1986 (which led to the adoption of the TRIPS Agreement), 49 of the 98 members of the Paris Convention excluded pharmaceutical processes and 22 excluded chemical processes. France (until 1960), Switzerland (until 1977), Italy (until 1978), Sweden (until 1978) and Spain (until 1992) excluded pharmaceutical products from patentability. See: World Intellectual Property Organisation, Negotiating Group on Trade-Related aspects of Intellectual Property rights, including Trade Counterfeit goods, "Existence, scope and form of generally internationally accepted and applied standards/norms for the protection of intellectual property", Note prepared at the international Bureau of WIPO, Revision 15 September 1988 (original published 5 May 1988).
98 See also: Graham Dutfield, July 2003, "Intellectual Property Rights and the life science industries: A Twentieth Century History", Hampshire, England, Ashgate Publishing.
99 Dominique S. Ritter, 2004, "Switzerland's Patent History", Volume 14 issue 2, Article 3 (accessed 19.10.2017).
100 See also: Graham Dutfield, "Intellectual Property Rights and the Life Science Industries: A Twentieth Century History".
101 Berne Declaration, The Relationship Between Patents and Development – the View of the Swiss Industry, Compilation by François Meienberg of the position of Swiss industrialists at the end of the 19th century (accessed 6.4.2018)
102 For some elements of the history of the Indian generic industry: William Greene, 2007, "The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market", *US International Trade Commission* (accessed 19.10.2017).
103 Waning B. et al., 2010, A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries, *Journal of the International AIDS Society 2010,* 13:35 (accessed 6.4.2018)
104 World Intellectual Property Organization (WIPO), Frequently Asked Questions: Patents (accessed 6.4.2018)
105 See for example the position of MSF Access Campaign: MSF Access Campaign, "The impact of patents on access to medicines" (accessed 30.9.2017).
106 See also: UN High Level Panel on Access to Medicines, "Report of the United Nations Secretary General's High Level Panel on Access to medicines: Promoting innovation and access to health technologies"
107 World Trade Organization, 1994, Trade-Related Aspects of Intellectual Property Rights (accessed 6.4.2018)
108 World Trade Organisation (WTO), July 2016, "Members and Observers" (accessed 19.10.2017)
109 *WTO Agreement on Trade-Related aspects of Intellectual Property rights (TRIPS),* 1995, Article 33.
110 See *TRIPs, 1995,* Art. 27.
111 See *TRIPs, 1995,* Article 65.1, 65.2 and 65.4.
112 German Velasquez and Pascale Boulet, 1997, "Part I: Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement", *WHO,* p. 4
113 Indigenous peoples' statement on the trade-related aspects of Intellectual Property rights, 1999, "No to patenting of life!" (accessed 9.11.2017).
114 Some 135 public interest international and national non-governmental groups from 35 countries, including the Green Group of the European Parliament, wrote to US President Bill Clinton expressing deep concern over his administration's consistent opposition at the WTO, WIPO and elsewhere to reform the WTO's TRIPS Agreement to promote equity and sustainable development: See Third-World Network, 2000, "NGOs tell Clinton their concern over his stance on TRIPs" (accessed 22.5.2016).
115 See also: Public Eye (former La Déclaration de Berne), 2001, "Les ONG exigent une réforme fondamentale de l'accord TRIPS" (accessed 22.5.2016).
116 See this public report: Public Eye (Former Declaration de Berne), Action Aid et al., 2001, "Les ADPIC en jugement, l'impact du régime des brevets de l'OMC sur les agriculteurs du monde, les pauvres et les pays en développement" (accessed 19.10.2017).
117 See *TRIPS, 1995,* Article 31
118 See *TRIPS, 1995* Article 6
119 World Trade Organization, Declaration on the TRIPS Agreement and Public Health, Doha WTO Ministerial Conference, WT/MIN(01)/DEC/2, 20 November 2001 (accessed 21.03.2018)
120 Adapted from Ellen 't Hoen, Private Patents and Public Health, Health Action International, Amsterdam, 2016 accessed 6.4.2018)
121 See *TRIPS, 1995,* Article 8.1
122 WHO Commission on intellectual property rights, innovation and public health, 2006, "Public Health, Innovation and Intellectual Property Rights" (accessed 27.07.2017).
123 See also: Consultative Expert Working Group on Research and Development: Coordinating and financing, 2012, "Research and Development to meet health needs in developing countries: Strengthening global financing and coordination" (accessed 26.7.2017).
124 See also: UN High Level Panel on Access to Medicines, 2016, "Report of the United Nations Secretary General's High Level Panel on Access to medicines: Promoting innovation and access to health technologies" (accessed 26.7.2017).
125 See for example: Ellen 't Hoen, Private Patents and Public Health, Health Action International, 2016.
126 See Public Eye's position: Public Eye (former Déclaration de Berne), "Introduction" (accessed 19.9.2017)
127 Ellen 't Hoen, 2009, "The Global Politics of Pharmaceutical Monopoly Power" (accessed 19.9.2017)
128 See for example: Mandy L. Gatesman, Pharm D. and al., November 3 2011, "The Shortage of Essential Chemotherapy drugs in the United States", *NEJM* 2011; 365:1653-1655 (accessed 20.9.2017)
129 Keerthi Gogineni and Katherine L. Schuman, 2013, "Survey of oncologists about shortages of cancer drugs", *NEJM* 2013;369:2463-2464 (accessed 20.9.2017)
130 Tufts Center for the Study of Drug Development, November 18, 2014, "Cost to develop and Win Marketing Approval for a New Drug is USD 2.6 billion" (accessed 15.9.2017)
131 Andrew Lo et al., 2014, "Unintended consequences of expensive cancer therapeutics – the pursuit of marginal indications and a me-too mentality that stifles innovation and creativity", *JAMA Otalaryngol Head Neck Surg,* The John Conley Lecture, 140(12):1225-1236 (accessed 21.9.2017)
132 Naomi Kresge, "How Roche tweaked an aging drug to keep profits rolling in", *Bloomberg,* 23 August 2017 (accessed 21.9.2017).
133 Prescrire, 2018, Prescrire's ratings system: new drugs and indications, at a glance (accessed 6.4.2018)
134 Prescrire, 2018, Drugs in 2017: a brief review, Rev Prescrire 2018; 38 (412): 145-146
135 Prescrire, Février 2017, "L'année 2016 du Médicament: un système qui favorise l'imitation plutôt que la recherche de réels progrès", *La Revue Prescrire,* Tome 37 n° 400, 132–136 (accessed 20.9.2017).
136 Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG), 2015, Auf den Punkt gebracht: Zahlen und Fakten aus dem IQWiG 2015 (Schwerpunkt AMNOG) (accessed 6.4.2018)
137 See Thomas B. Cueni, interviewed by John Zarocostas, December 2017, "Perspectives on access to medicines and IP rights", *WIPO Magazine* (accessed 12.1.2018).
138 Steiert Jean François, "14.3933 | Les nouvelles therapies contre l'hépatite C vont-elles faire exploser les coûts?", Federal Assembly, (accessed 13.2.2018).
139 Novartis President, for example, justified the price of the new treatment Kymriah® by comparing the cost of highly expensive biologic treatments: "Le président de Novartis Jörg Reinhardt défend le coût du nouveau médicament contre la leucémie Kymriah qui s'élève à 475 000 francs. Une seule prise suffit, contrairement aux thérapies standard coûtant annuellement 100 000 francs, fait-il valoir". See ATS/NXP, December 2017, "Payer 475'000 fr. pour un cancer est 'justifié'", *Tribune de Genève* (accessed 7.1.2018)
140 In the Sovaldi case, the Committee on Finance United States Senate determined that at no time did Gilead pay attention to the R&D costs when setting the price of its medicines, rather considering other factors including the costs for the existing standards of care for HCV treatment and setting a high baseline for the next wave of HCV drugs. See: Committee on Finance United States Senate, December 2015, "The prices of Sovaldi and its impact on the US healthcare system", 114th Congress, 1st Session (accessed 07.08.2017)
141 F. Hoffman La Roche, April 2017, "Roche position on pricing" (accessed 02.02.2018).
142 Gilead Sciences Inc., 2014, "Innovating and expanding access to hepatitis C treatments", *Gilead Sciences Policy position* (accessed 08.08.2018).

143 William New, May 2017, "WHO official: Medicines should not be priced at the value of a life", *IP Watch* (accessed 20.6.2017)
144 Prasad V. et al., 2017, The high price of anticancer drugs: origins, implications, barriers, solutions, *Nature Reviews Clinical Oncology* volume 14, pages 381–390 (2017) (accessed 7.4.2018)
145 Hirth R. A. et al. 2000, Willingness to pay for a quality-adjusted life year: in search of a standard, Med Decis Making, 2000 Jul-Sep;20(3):332-42. (accessed 7.4.2018)
146 Howard D. et al., 2015, "Pricing in the Market for Anticancer Drugs", *Journal of Economic Perspectives,* vol. 29, n° 1, pp. 139–162 (accessed 7.4.2018)
147 Durkee BY et al, 2016, Cost-Effectiveness of Pertuzumab in Human Epidermal Growth Factor Receptor 2-Positive Metastatic Breast Cancer, J Clin Oncol 2016 Mar 20; 34(9):902-9 (accessed 23.4.2018)
148 In 2016, the medicines reimbursed by insurers accounted for 83.8 % (4689 million francs) of the turnover of the branch: Interpharma, 2017, "Le marché du médicament en Suisse", p. 24 (accessed 12.1.2018)
149 Fridez Pierre-Alain, March 2015, "15.5005 | Retrait du medicament Perjeta", Federal Assembly (accessed 11.2.2018)
150 Federal Tribunal, 15 July 2009, "9C_766/2008" (accessed 30.11.2017)
151 Alexandra Richard, December 2017, "Le prix des medicaments devrait pouvoir être davantage combattu", *Radio Télévision Suisse* (accessed: 13.02.2018)
152 See Articles 71a and 71b of the Ordonnance sur l'assurance-maladie (OAMal), RS 832.102, status as of 1.1.2018 (accessed 6.4.2018). These legislative texts do not exist in English.
153 Federal Council, July 2015, "Médicaments contre l'hépatite C: conditions pour le remboursement élargies", *Bundesamt für Gesundheit* (accessed 23.11.2017): *"L'OFSP s'attend au cours des prochaines années à devoir face toujours plus souvent à des situations où des médicaments doivent, en raison de leur prix très élevé, être introduits de manière ciblée ou échelonnée dans la liste des spécialités pour obtenir la meilleure adéquation entre efficacité et coûts".*
154 Agences/cab, June 2010, "Monsieur Prix s'attaque au prix des medicaments", *Radio Télévision Suisse* (accessed 23.11.2017).
155 RTS Info, May 2009, "Coûts de la santé: consommateurs et assureurs réclament une baisse massive du prix des médicaments" (accessed 23.11.2017).
156 The prices of medicines was subject to criticism, especially by the Price Supervisor, see: Agences/cab, June 2010, "Monsieur Prix s'attaque au prix des medicaments", Radio Télévision Suisse (accessed 23.11.2017). An urgent debate at the Parliament occurred: RTS Info, June 2006, "Coûts de la santé: Le Conseil National cherche des solutions" (accessed 23.11.2017). The Triennial review of the prices of medicines was introduced in 2009: the Federal Council decided to adapt the legislation, *inter alia* to allow a reduction of the health-related costs. It adopted the new art. 65d OAMal, which provides that the FOPH will have to carry out a triennial review of the conditions of admission of all the medicines registered on the LS.
157 See how Roche and Novartis, but also other pharmaceutical companies have put pressure on the authorities: ATS/NXP, January 2013, "Roche et Novartis gagnent leur bataille", *Tribune de Genève* (accessed 23.11.2017). See also: Natalie Bougeard, "Roche impose le prix d'un medicament malgré la pression des autorités", *Radio Télévision Suisse,* 1 February 2015 (accessed 28.9.2017). See also: ATS, December 2012, "Roche et Novartis recourent contre la baisse du prix de certains medicaments", *Le Temps* (accessed 30.11.2017). See also: Willy Boder, February 2016, "Médicaments: une année d'économies perdue", *Le Temps* (accessed 30.11.2017).
158 In 2013, the pharmaceutical industry filed 16 recourses against the decision of the FOPH to reduce the prices of medicines on the List of Specialties: Arc Info, November 2013, "La Pharma se plaint de la baisse du prix de 500 médicaments" (accessed 30.11.2017).
159 ATS/JGAL, January 2016, "Le système du contrôle du prix des medicaments devra être revu", *Radio Télévision Suisse* (accessed 30.11.2017).
160 ATS/JGAL, January 2016, "Le système du contrôle du prix des medicaments devra être revu", *Radio Télévision Suisse* (accessed 30.11.2017).
161 Bundesamt für Gesundheit (BAG), "Die Preise von Medikamenten sollen auf neue Art und Weise überprüft werden", Medienmitteilung 6.7.2016 (accessed 7.4.2018)
162 Aargauer Zeitung, "Helsana will klagen: Bundesamt für Gesundheit sei mit Pharma zu grosszügig", 27 November 2017 (accessed 7.4.2018)
163 There are a range of provisions on compulsory licensing in the Swiss Patent Act (PatA): Article 36, 37, 38, 40, 40a, 40b, 40c, 40d and 40e PatA
164 ATS, 2015, "Berne accusée d'être la porte-parole de Novartis", *20 minutes* (accessed 8.9.2017)
165 *TRIPS 1995,* Article 31 (b).
166 *TRIPS 1995,* Article 31 (b) *in fine.*
167 F. Hoffman La-Roche, 2017, "Annual Report 2017" (accessed 12.3.2018)
168 Swiss Federal Statistical Office (FSO), "Number of jobs rise for the first time in three years, including in the industrial sector", Press release of 26 February 2018 (accessed 23.4.2018)
169 Federal Customs Administration, "2017: Exports at all-time high", Press release of 30 January 2018 (accessed 23.4.2018)
170 Switzerland Global Enterprise, 2017, "L'industrie pharmaceutique en Suisse" (accessed 10.11.2017)
171 Samuel Jaberg, February 2017, "Export Growth increasingly depends on pharmaceuticals", *Swissinfo* (accessed 7.3.2018).
172 Article 26 al. 1 lit. a) of the Federal Act of 20 March 2009 on the Federal Patent Court (CC 173.41) provides that "1 The Federal Patent Court has exclusive jurisdiction over: a. [...] actions for issuing a license in respect of patents; [...]".
173 Ligue Suisse contre le cancer, 2017, "Le cancer en Suisse: les chiffres" (accessed 19.12.2018)
174 Swiss Confederation, "Le cancer en Suisse, rapport 2015", OFS, NICER, RSCE, 2015
175 Lilian Bringolf, Bernhard Pestalozzi et al., 2016, "Exploring prognostic factors for HER2-positive metastatic breast cancer: a retrospective cohort study in a major Swiss hospital", Swiss Medical Weekly 2016;146:w14393 (accessed 9.11.2017)
176 Rahel Odermatt, Anita Wolfer et al., 2013, "Hormonothérapie dans le cancer du sein: efficacité et effets adverses", Revue Médicale Suisse 2013, Volume 9, pp. 1090–1094 (accessed 9.11.2017)
177 F. Hoffmann La-Roche, July 2015, "Roche's Perjeta regimen approved in Europe for use before surgery in early stage aggressive breast cancer" (accessed 20.11.2017)
178 Compendium, January 2017, "Perjeta" (accessed 20.11.2017)
179 Federal Office of Public Health, Database of the List of Specialties (LS), status as of 01.04.2018 (accessed 6.4.2018)
180 F. Hoffmann La-Roche, September 2017, "FDA grants Priority Review for Roche's Perjeta (pertuzumab) for adjuvant treatment of HER2-positive early breast cancer" (accessed 20.11.2017)
181 F. Hoffmann La-Roche, December 2017, "FDA approves Roche's Perjeta (pertuzumab) for adjuvant treatment of specific type of early breast cancer" (accessed 9.1.2018).
182 See Articles 71a to 71c of the Ordonnance sur l'assurance-maladie (OAMal), RS 832.102, status as of 1.1.2018 (accessed 6.4.2018) These legislative texts do not exist in English.
183 Ibid, Article 71c OAMal
184 GlobalData Pharma Point, September 2014, "HER2-positive breast cancer – Global drug forecast and market analysis to 2023", p. 12 (accessed 11.12.2017)
185 Biosimilars of the Herceptin are already available in the US: Tatum Anderson, December 2017, "Analysis: As biosimilar of Key Cancer Drugs Spreads, Where is the price reduction?", *IP Watch* (accessed 12.12.2017)
186 Trefis Team, October 2017, "Roche's blockbuster oncology drugs losing steam as they approach patent expiry", *Forbes* (accessed 12.12.2017).
187 Generics and biosimilars initative, January 2018, "Roche sues Pfizer over Herceptin biosimilar" (accessed 12.1.2018)
188 Silke Kolotrowitz, February 2014, "Roche bans rivals from comparing copycat drugs to Herceptin", *Reuters* (accessed 12.12.2017).
189 James Love, November 2017, "Roche and the City of Hope claim biosimilar version of trastuzumab will infringe "at least" 40 patents", *Harvard Law* (accessed 1.12.2017)
190 Ed Silverman, June 2016, "Russian drug maker says Roche tried to 'destroy' its ability to sell biosimilars", *Stat News* (accessed 6.12.2017)
191 Tracy Staton, February 2017, "Can Roche's Herceptin-Perjeta combo expand yet again? Check the impending data", *FiercePharma* (accessed 6.12.2017).
192 GlobalData Pharma Point, September 2014, HER2-positive breast cancer – Global drug forecast and market analysis to 2023, p. 12 (accessed 11.12.2017).
193 Kevin M. Nelson and Patrick C. Gallagher, October 2014, "Biosimilars lining up to compete with Herceptin – opportunity knocks", *Journal Expert Opinion on Therapeutic Patents,* Vol. 24 2014, Issue 11 (accessed 11.12.2017)
194 Naomi Kresge and Marthe Fourcade, February 2017, "Roche fights Roche in Bid to preserve USD 9 billion Drug Business", *Bloomberg* (accessed 11.12.2017)

195 Max Nisen, March 2017, "Roche's new drug may protect its old ones", *Bloomberg* (accessed 11.12.2017)
196 GlobalData Pharma Point, September 2014, "HER2-positive breast cancer – Global drug forecast and market analysis to 2023", p. 12 (accessed 11.12.2017)
197 Global Data UK, *HER2-positive breast cancer – global drug forecast and market analysis to 2025,* United Kingdom, 2017 cited in The Centre for Biosimilars Staff, July 2017, "HER2-positive breast cancer market to reach 9.89 billion by 2025" (accessed 7.3.2018)
198 Kevin M. Nelson and Patrick C. Gallagher, "Biosimilars lining up to compete with Herceptin – opportunity knocks", *Journal Expert Opinion on Therapeutic Patents*
199 Infosperber, „Preis-Deal mit Roche ist gesetzwidrig", 3 September 2013 (accessed 7.4.2018)
200 SonntagsZeitung, "Den moralischen Kompass verloren", 16 June 2013 (not available online, 7.4.2018)
201 Calculation based on the public prices of pertuzumab, trastuzumab and docetaxel published on the FOPH List of Specialties database as per 01.05.2018, on the posology recommended by the Swiss Medicines Compendium for each of the medicines, and on the method of calculation of the German Gemeinsame Bundesausschuss for the combined therapy for an annual treatment based on an average female patient of 68kg bodyweight/1.75 m^2 body surface area. The annual treatment cost includes the price of a generic version of docetaxel (Docetaxel Sandoz) (all accessed 7.4.2018)
202 Reuters, 2014, Roche breast cancer drug 'unprecedented' in extending lives, 28 September 2014 (accessed 7.4.2018)
203 The Guardian, "Nice approves life-extending drug for patients with incurable breast cancer", 1 February 2018 (accessed 7.4.2018)
204 Infosperber, „Preis-Deal mit Roche ist gesetzwidrig", 3 September 2013 (accessed 7.4.2018)
205 Commission de gestion du Conseil des Etats, June 2013, Evaluation de l'admission et du réexamen des médicaments dans l'assurance obligatoire des soins (accessed 27.9.2017)
206 Infosperber, „Preis-Deal mit Roche ist gesetzwidrig", 3 September 2013 (accessed 7.4.2018)
207 Infosperber, Bundesrat Berset dürfte Streit mit Roche verlieren, 29 September 2014 (accessed 7.4.2018)
208 Basler Zeitung, Roche und Bund im Streit wegen Brustkrebs-Medikament, 8 August 2014 (accessed 7.4.2018)
209 Natalie Bougeard, "Roche impose le prix d'un medicament malgré la pression des autorités", *Radio Télévision Suisse,* 1 February 2015 (accessed 28.9.2017).
210 Commission de gestion du Conseil des Etats, June 2013, "Evaluation de l'admission et du réexamen des médicaments dans l'assurance obligatoire des soins", p. 26 (accessed 27.9.2017)
211 At its 2017 General Assembly, the shareholders voted in favor of an increase of dividends for the 30th consecutive year: F. Hoffmann La-Roche, March 2017, "Assemblée Générale Roche 2017" (accessed 23.11.2017).
212 Love J., Roche and City of Hope Claim Pfizer Biosimilar Version of Trastuzumab Will Infringe "At Least" 40 Patents, Harvard Blog, 23 November 2017 (accessed 7.4.2018)
213 WTO Webpage, September 2006, "Compulsory licensing of pharmaceuticals and TRIPS" (accessed 24.8.2017).
214 WTO Webpage, September 2006, "Compulsory licensing of pharmaceuticals and TRIPS" (accessed 24.8.2017).
215 Provided by: *TRIPs, 1995,* Article 31.
216 *TRIPs, 1995,* Article 31.
217 *TRIPs, 1995,* Article 8.1.
218 See: Swiss Confederation, Federal Department of Foreign Affairs and Federal Department of Home Affairs, 2012, "Swiss health Foreign Policy" (accessed 09.08.2017): *"The application of TRIPS flexibilities in* ***emergency situations*** *is recognized"* (emphasize added).
219 See also other similar positions in this article: Catherine Saez, June 2017, "TRIPS Council Members: Defining IP Rights and the Public Interest", *IP Watch* (accessed 28.7.2017).
220 See the position of the Swiss Federal Council: Letter from Doris Leuthard, Federal Councilor, in response to Public Eye (former Déclaration de Berne) Letter, 23 May 2008, "Démarches de la Suisse suite aux licences obligatoires en Thaïlande" (accessed 20.8.2017).
221 *"(...) Does there have to be an emergency? Not necessarily. This is a common misunderstanding. The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. However, the Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting compulsory licences (...)".* Excerpt from: WTO Webpage, September 2006, "Compulsory licensing of pharmaceuticals and TRIPS" (accessed 24.8.2017).
222 *Doha Declaration on Public Health and TRIPs,* 2001, §5 (b)
223 Compulsory licenses do no affect the legal status of the patent holder: the patent holder remains the proprietary of the patent.
224 According to *TRIPS 1995,* Article 31(d), compulsory licenses are non exclusive, which means that the licensee does not have the right to prevent the patent holder from making use of its invention.
225 Compulsory licenses give the right to a licensee to exploit the invention without the consent of the patent holder.
226 *TRIPS 1995,* Article 31 (c)
227 *TRIPS 1995,*Article 31 (f)
228 *TRIPS 1995,*Article 31 (h)
229 *TRIPS 1995,*Article 31 (b)
230 *Code de la Santé Publique 2018,* Article L613-16.
231 UK Government, Intellectual Property Office, April 2007, "Section 55: Use of patented inventions for services of the crown" (accessed 9.11.2017).
232 J. Debrulle, L. De Cort, and al., 2007, *La licence obligatoire belge pour raison de santé publique, in G. van Overwalle, ed., Gene Patents and Public Health,* Brussels: Bruylant.
233 Association of patent law firms, September 2006, "Compulsory licensing provisions across Europe" (accessed 27.9.2017).
234 See also: Esther Van Zimmeren and Geertrui Van Overwalle, 2011, "A Paper Tiger? Compulsory License Regimes for Public Health in Europe", *International review of Intellectual Property and Competition Law* (accessed 27.09.2017)
235 UN High Level Panel on Access to Medicines, "Report of the United Nations Secretary General's High Level Panel on Access to medicines: Promoting innovation and access to health technologies" (accessed 26.7.2017).
236 Wirtz VJ, Hogerzeil HV and al., 2017, "Essential Medicines for universal health coverage", *The Lancet;* 389-10067: pp. 403–476 (accessed 2.2.2018)
237 European Parliament, "Resolution of 2 March, EU options for improving access to medicines". 2017; 2016/2057 (INI).
238 Liliane Ploumen and Edith Schippers, November 2016, "Better Life Through medicine – Let's leave no one behind", *The Lancet* (accessed 2.2.2018).
239 Organization for Economic Co-operation and Development (OECD), 2017, "New Health Technologies: Managing Access, Value and Sustainability", *OECD publishing,* Paris, p. 36
240 Ellen FM 't Hoen, Jacquelyn Veraldi, et al., 2018, "Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016", Bulletin World Health Organization 2018;96:185-193.
241 Ulrich Worm, 2017, "German Federal Patent Court Determines License Fee for a Compulsory License under HIV Drug Patent", All About IP Blog, 18 December 2017 (accessed 26.4.2018)
242 Knowledge Ecology International, 2007, Recent examples of the use of compulsory licenses on patents, KEI Research Note 2007:2, 6 May 2007 (accessed 26.4.2018)
243 See Ellen't Hoen, *Private Patents and Public Health,* Health Action International, Amsterdam, 2016.
244 For an illustration in the case of Thailand, see: Ellen't Hoen, *Private Patents and Public Health,* Health Action International, Amsterdam, 2016, pp. 66–67.
245 See for example: Yamabhai et al., 2011, "Government use licenses in Thailand: an assessement of the health and economic impacts", *Globalization and Health 2011,* 7:28 (accessed 14.9.2017)
246 See also: Adun Mohara, Inthira Yamabhai and al., 2012, "Impact of the introduction of government use licenses on the drug expenditure on seven medicines in Thailand", *Value in Health 15,* S95-99 (accessed 14.9.2017)
247 See Carlos Correa, February 2013, "The use of compulsory licenses in Latin America", *South Bulletin 71* (accessed 14.9.2017)
248 See for example: Siraprapha Khim Rungpry, November 2013, "Compulsory licensing issues and trends in Asia", *Future Science,* Pharmaceutical patent analyst, Vol. 2 n° 6 (accessed 15.9.2017).
249 See among other examples: Ellen't Hoen, *Private Patents and Public Health,* Health Action International, Amsterdam, 2016, pp. 71–73
250 Reed Beall and Randall Kuhn, 2012, "Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: a database analysis", *PLOS Medicine 9,* n° 1 (2011):

e1001154.doi:10.1371/journal.pmed.1001154 (accessed 9.9.2017)

251 S. Tunsarawuth, November 2007, "Indonesia Mulls Compulsory Licenses on Three More HIV/AIDS Drugs", *IP Watch* (accessed 20.2.2018).

252 See: James Packard Love, 2007, "Recent examples of compulsory licenses on patents", *Knowledge Ecology International,* KEI Reseaerch Note 2.

253 Amy Harmon and Robert Pear, 2001, "A Nation Challenged: The Treatment; Canada overrides patent for Cipro to treat anthrax", *The New York Times* (accessed 31.01.2018).

254 See: Official Note from the Brazilian Ministry of Health, 2001, "Ministry of Health announces compulsory licensing of Nelfinavir patent", Consumer Project on Technology (New name: Knowledge Ecology International) (accessed 22.12.2017)

255 Jennifer L. Rich, 2001, "Roche reaches accord on drug with Brazil", *The New York Times* (accessed 22.12.2017)

256 See: Paul Garwood, 2007, "Kenyan Parliament rejects bid to remove government's compulsory licensing flexibilities", *IP Watch* (accessed 20.9.2017): "Kenya has never issued a compulsory license, but came close to in 2004 before German pharmaceutical major Boehringer Ingelheim agreed to enter into a voluntary license agreement with Kenyan drug firm Cosmos to produce generic versions of its patented anti-AIDS drug nevirapine".

257 https://khn.org/morning-breakout/dr00025890/

258 Patrick L. Osewe, Yvonne K. Nkrumah et al., 2008, "Improving access to HIV/AIDS medicines in Africa", The World Bank, Washington DC, pp. 33–34 (accessed 29.1.2018).

259 International Centre for Trade and Sustainable Development, 2005, "Taiwan issues compulsory license for Tamiflu" (accessed 24.1.2018).

260 Tove Iren S. Gerhardsen, 2005, "Roche seeks deals on bird flu drug as compulsory licenses loom", *IP Watch* (accessed 29.1.2017)

261 The Star Online, Free Hepatitis C treatment for all, 20 March 2018 (accessed 7.4.2018)

262 Rahman F., 2017, "Inside views: Malaysia inclusion in Gilead voluntary licence – A product of compulsory licence pressure", Intellectual Property Watch (accessed 24.8.2017)

263 Hepatitis C Education & prevention Society (hepcbc), 2017, "Italian Medicine's Agency (AIFA) Issues Ultimatum to Gilead", 21 February 2017 (accessed 26.4.2018)

264 Raad voor Volksgezondheid en Samenleving (RVS), 2017, "Development of new medicines: Better, faster, cheaper", 9 November 2017 (accessed 26.4.2018)

265 Reed Beall and Randall Kuhn, 2012, "Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: a database analysis", *PLOS Medicine 9,* n° 1 (2011): e1001154.doi:10.1371/journal.pmed.1001154 (accessed 9.9.2017)

266 Ellen FM 't Hoen, Jacquelyn Veraldi, et al., 2018, "Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016", Bulletin World Health Organization 2018;96:185-193.

267 Aide Mémoire sent by the Swiss Confederation to the Government of Thailand, 2008, "Compulsory licenses in Thailand on pharmaceuticals under patent protection, Aide Mémoire" (accessed 10.11.2017)

268 Adun Mohara, Inthira Yamabhai and al., 2012, "Impact of the introduction of government use licenses on the drug expenditure on seven medicines in Thailand", *Value in Health 15,* S95-99 (accessed 14.9.2017). See also: Yamabhai et al., 2011, "Government use licenses in Thailand: an assessement of the health and economic impacts", *Globalization and Health 2011*, 7:28 (accessed 14.9.2017).

269 KEI Staff, June 2016, "Colombia issues Public Interest Declaration To Lower Price of Glivec", *Knowledge Ecology International* (accessed 14.9.2017)

270 Public Eye, April 2016, "Licence obligatoire contre Novartis: La Colombie résiste à la pression suisse" (accessed 9.11.2017).

271 See a summary from WIPO of the pressure exerted on Colombia, especially by the US and Switzerland: See: Secretariat Standing Committee on the Law of Patents, June 2017, "Constraints faced by developing countries and least developed countries (LDCs) in making full use of patent flexibilities and their impact on access to affordable especially essential medicines for public health purposes in those countries", *World Intellectual Property Organization (WIPO),* SCP/26/5 (accessed 19.8.2017). See also: Secretariat Standing Committee on the Law of Patents, November 2017, "Constraints faced by developing countries and least developed countries (LDCs) in making full use of patent flexibilities and their impact on access to affordable especially essential medicines for public health purposes in those countries: supplement to document SCP/26/5", *World Intellectual Property Organization (WIPO),* SCP/27/6 (accessed 26.1.2018)

272 SECO, Patent of Imatinib/Glivec: Closing arguments, letter to the Colombian Ministry of Health, 26 May 2015 (accessed 7.4.2018)

273 Zach Carter, November 2016, "Colombia fears U.S. may reject peace plan to protect pharma profits", *Huffington Post* (accessed 12.1.2018).

274 Public Eye (former Déclaration de Berne), April 2017, "Licence obligatoire en Colombie: des documents attestent du lobbying agressif de Novartis" (accessed 7.8.2017).

275 Public Eye, Glivec in Colombia: new leaked letter from Novartis attests to pressure at highest level, 5 February 2018 (accessed 7.4.2018)

276 See MSF on TRIPS-plus provisions: MSF Access, July 2011, "TRIPs, TRIPs Plus and Doha" (accessed 7.8.2017). See also: Catherine Saez, August 2014, "Médecins Sans Frontières warns about IP inclusion in Asian FTA", *IP Watch* (accessed 7.8.2017) and Elise de Geyter, May 2017, Brief: MSF Warns Of Threats To Public Health In Asian Trade Agreement IP Proposals, Intellectual Property Watch (accessed 7.8.2017)

277 See more recently the negotiations of a Free Trade Agreement between the EFTA and India: MSF Access, May 2017, "MSF response on the India-EFTA free trade agreement negotiations in Liechtenstein this week" (accessed 7.8.2017)

278 Zoe Williams, November 2016, "Investigation: As Colombia pushes for cancer drug price-cut and considers compulsory licensing, Novartis responds with quiet filing of an investment treaty notice", *ISDS Platform* (accessed 24.8.2017)

279 Federal Office of Public Health (FOPH), 2012, Swiss Health Foreign Policy (accessed 7.4.2018)

280 This interpretation is in full conformity with *TRIPs 1995,* Article 31, which recognizes that a compulsory license may be issued *"[w]here the law of the Members allows […]".* This is also confirmed by the §5 b. of the Doha Declaration on TRIPs and Public Health (2001), which states that ***"[e]ach member** has the right to grant compulsory licenses and the **freedom to determine the grounds** upon which such licenses are granted"* (emphasis added).

Access to lifesaving medicines is no longer confined to developing countries – it has become a global issue. Even high-income economies like Switzerland struggle to guarantee universal coverage, with cancer treatments frequently costing well over CHF 100,000 per patient per year.

Monopolies conferred by patents are the root cause of these escalating drug prices as they provide pharmaceutical companies with market exclusivity and extraordinary pricing power. Governmental price control mechanisms are toothless in trying to curb this inflationary trend, pushing governments to implement controversial reimbursement limitations or even rationing decisions. Today's pharmaceutical business model jeopardises the sustainability of public health systems and the right to health.

Yet high medicine prices are not predestined and political solutions exist. A compulsory license can efficiently drive excessive drug prices down by creating competition in a patent-monopoly situation. However, Switzerland has so far overlooked this important public health safeguard, and even exercised undue diplomatic pressure to discourage other countries from using this legal instrument.

This Public Eye report analyses the situation in Switzerland regarding the escalating prices of cancer medicines and calls on the Swiss authorities to use compulsory licences whenever the balance between public and private interests is broken.

Avenue Charles-Dickens 4
CH-1006 Lausanne
Phone +41 (0)21 620 03 03
Fax +41 (0)21 620 03 00
contact@publiceye.ch

Dienerstrasse 12
Postfach | CH-8021 Zurich
Phone +41 (0)44 2 777 999
Fax +41 (0)44 2 777 991
kontakt@publiceye.ch

www.publiceye.ch | @PublicEyeSuisse | @PublicEyeSuisse | @publiceye.ch

Public Eye