



With the support of the
Erasmus+ Programme
of the European Union

Fighting excessive pharmaceutical prices: evaluating the options

André den Exter

Associate Professor of Health law and Jean Monnet Chair EU Health law

Erasmus University Rotterdam, the Netherlands

Email: denexter@law.eur.nl

Abstract

New treatment options for various cancer therapies appear to be extremely expensive and prices may increase further. The affordability and availability of life-saving medicines is therefore a key issue in the national health policies of all countries. International and European law grant several price-reducing options, including compulsory licensing. Still, countries are reluctant to apply for compulsory licensing and/or other regulatory options to curtail pharmaceutical prices. Why is that? Evaluating the options will support health policy decision-making on safeguarding access to affordable innovative medicines.

Keywords: high-priced medicines, compulsory licensing, mandatory disclosure, competition law, joint procurement

1. Introduction: the race to “CARs”

One of the latest medicinal innovations introduces new treatment options for life-threatening diseases such as leukaemia and other kinds of cancers.¹ These immune therapies use the patient's own gene-edited stem cells (CAR-T cells) to attack cancerous cells and add years to their life. Some of these therapies are developed by hospitals whereas other gene and cell-based therapies have been commercialised by pharmaceutical companies such as Novartis (Yescarta), Gilead (Kyriah). Between 2020 and 2025, the Federal Drug Agency (FDA) expects an increase of more than 200 gene-edited applications per year pending approval.² To

¹ E.g. C. Puig-Sausa, A Ribas, 'Gene editing: Towards the third generation of adoptive T-cell transfer therapies', *Immuno-Oncology Technology* 1 (2019) 19–26; A Ghobadi, 'Chimeric antigen receptor T cell therapy for non-Hodgkin lymphoma', *Current Research in Translational Medicine* 66 (2018) 43–49; L Rein, H Yang, N Chao, 'Applications of Gene Editing Technologies to Cellular Therapies', *Biol Blood Marrow Transplant* 24 (2018) 1537–1545; Y Zhang, W Mu, H Wang, 'Gene editing in T cell therapy', *Journal of Genetics and Genomics* 44 (2017) 415–422.

² Food and Drug Administration. 'Statement from FDA Commissioner Scott Gottlieb, M.D. and Peter Marks, M.D., Ph.D., Director of the Center for Biologics Evaluation and Research on new policies to advance development of safe and effective cell and gene therapies', 15 January 2019. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics>.

use an individual's immune system is challenging but also extremely expensive (Yescarta: USD 373,000, Kyriah: USD 475,000). So far, the therapies do not cure, but postpone death by between several months to a number of years. Apart from the excessive price of treatment, cancer cells may mutate and this limits the effectiveness of the personalised T-cell therapy. Altering the gene-based therapy is a time-consuming process, whereas delay in treatment may decrease the patient's chance of survival. Another complication is that – for unknown reasons – patients may respond differently to the gene-based therapies, and can be differentiated into high and low treatment responders.³ These medical innovations therefore raise fundamental and controversial issues such as who should be treated and based on what criteria? Ultimately, such decisions would restrict and even deny certain patients access to gene-based medicines. Alternatively, governments may consider other (regulatory) mechanisms to reduce the price of these expensive medicines, increasing the accessibility of gene-based medicines to larger groups of patients. But what are these price-restricting options, and are they effective: i.e. reducing excessive prices and improving access to innovative medicines? Unfortunately, apart from anecdotal evidence, reliable studies reviewing the impact of price-reducing measures are largely absent.⁴ Therefore, this paper aims to examine potentially meaningful legal options supporting policymakers' decision-making regarding the safeguarding of access to affordable innovative medicines.

2. Price-reducing initiatives

What options do governments have when they are confronted with excessive prices for gene-based medicines? Almost every European country uses price regulation to curb the growth in pharmaceutical expenditure.⁵ One of the most controversial measures is the compulsory licensing option aimed at both price control and, more importantly, safeguarding the affordability of medicines. Alternative regulatory strategies might be targeted negotiations, challenging unfair pricing by competition authorities, mandatory disclosure of economic data, and facilitating voluntary cross-border purchasing arrangements. These options will now be further examined.

2.1 Compulsory patent licensing

The idea of compulsory patent licensing, or compulsory licensing (CL), was introduced by the Doha Declaration on Public Health, a declaration under the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS Agreement Annex 1 c), allowing patent infringements by countries for reasons of 'national emergency'.⁶

The TRIPS Agreement (1995) was generally regarded as an instrument to protect the exclusive rights of the right holders against any unlawful breaches by third parties. This

³ By using so-called immune biomarkers predicting response to a treatment: A van Belzen, Kesmir, 'Immune biomarkers for predicting response to adoptive cell transfer as cancer treatment', *Immunogenetics* (2019) 71:71–86.

⁴ A rare exception is the study of Beall and others, concluding that compulsory licensing (thereafter) did not result in lower prices for Antiretrovirals compared to international procurement, although the focus was on low-income countries. RF Beall, R Kuhn and A Attaran, 'Compulsory Licensing often did not produce lower prices for Antiretrovirals compared to international procurement', *Health Affairs* 3 (2015) 493-501.

⁵ E.g. tiered pricing, price cuts and parallel trade, but these strategies require a more economic analysis rather than a legal approach.

⁶ WTO member governments adopted the Declaration on the TRIPS Agreement and Public Health by consensus at the WTO's Fourth Ministerial Conference in Doha, Qatar, on 14 November 2001.

exclusivity right to manufacture and sell patented products such as pharmaceuticals grants the pharmaceutical companies a monopoly position. Without competition, this has resulted in pharma's excessive pricing practice, particularly when it concerns cancer and rare diseases.⁷ For developing countries, excessive pricing threatens access to essential medicines (HIV/AIDS, malaria, tuberculosis), and thus raises serious public health concerns. The Doha Declaration recognised the dilemma of respecting property right versus the state's obligation to protect public health, by introducing so-called exceptions or 'patent flexibilities', including Compulsory Licensing (CL).⁸ Originally intended for developing countries, CL can be invoked by developed countries too. This has been confirmed by the Doha Declaration: 'Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'.⁹ Therefore, all countries may trigger CL, as applied by the United States (anthrax crisis in 2001)¹⁰ and Germany (HIV/AIDS),¹¹ when confronted with a national public health emergency. The national emergency situation also justifies the voluntary licence waiver (Art 31b TRIPS).¹²

Then the question remains of what constitutes a situation of national public health emergency. According to the Doha Declaration: 'Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency', and 'it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency'.¹³ Reading the text closely, one may conclude that protecting public health is not limited to infectious diseases.¹⁴ This has been confirmed by the previous section (section 4), stipulating that 'the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'. This reaffirms the flexible use of TRIPS for this purpose. Taking the example of excessive pricing of gene-edited cancer medicines, this could also trigger a public health emergency invoking countries to invoke CL. In case access to affordable (CAR-T) gene therapy is under threat, then countries may consider applying for CL. This is more likely when it concerns life-threatening diseases where no other treatment option than gene therapy is available. Given the increased number of available gene therapies, and thus rising health care costs, the absence of affordable medicines can then be considered as a public health emergency or other circumstances of extreme urgency that justifies the CL

⁷ European Commission, Antitrust: Commission opens Pharma's pricing practices 2017.

⁸ Next to other flexibilities, such as parallel trade and the research exemption. The concept of CL is not mentioned in the TRIPS agreement itself, here it is referred to as 'other use without authorization of the right holder' (Art 31), and only when efforts to obtain a voluntary license have not been successful.

⁹ Declaration on the TRIPS agreement and public health, adopted on 14 November 2001, WT/MIN(01)/DEC/2, par 5 b.

¹⁰ <http://tripsflexibilities.medicineslawandpolicy.org>.

¹¹ Federal Court of Justice (Bundesgerichtshof), 11 July 2017, ECLI:DE:BGH:2017:110717UXZB2.17.0. By contrast, the Federal Court of Justice denied that it was in the public interest to grant a compulsory license (Präluent medicine), case X ZB 2/19 (4 June 2019).

¹² According to TRIPS Art 31 b: 'such use (i.e. CL) may only be permitted if, prior to such use, the *proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms* and conditions and that such efforts have not been successful within a reasonable period of time'. This requirement may be waived by a Member in case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

¹³ Par 5 (c) of the Declaration on the TRIPS agreement and public health, DOHA WTO MINISTERIAL 2001: TRIPS WT/MIN(01)/DEC/2, 20 November 2001, adopted on 14 November 2001.

¹⁴ Also confirmed by Musungu, 'the list of diseases mentioned are only illustrative of some of the obvious cases that can constitute an emergency but in no way denotes an exhaustive list. It is not even an indicative list.' SF Musungu, 'The TRIPS Agreement and Public Health', in: A Yusuf and C Correa (eds), *Intellectual Property and International Trade, The TRIPS Agreement* (3rd edition, Alphen a/d Rijn: Kluwer Law International, 2016) 515.

exception, promoting affordable medicines to the patients in need. One example is Thailand (middle-income country) which successfully invoked a CL for Erlotinib (lung cancer medicine) produced by Roche in 2008.¹⁵ In 2007, the Italian Anti-Competition Authority (AGCM) granted a CL for producing a cheaper version of Finasteride (prostate cancer).¹⁶ A so-called ‘Crown licence’, allowing a generic version of Pertuzumab (breast cancer medicine) under CL is currently pending in the Scottish parliament.¹⁷ By contrast, CL of Spinraza (muscle disease) was denied in Norway due to the lack of production facilities and absence of a public health emergency.¹⁸ This limited number of examples confirms the flexible interpretation of the public health emergency concept, including affordable access to (gene-based) cancer treatment, reviewed on a case-by-case basis.

Apart from CL for domestic use (Art 31 sub f), Art 31 *bis* TRIPS introduces a CL waiver for exporting generic medicines to other countries in need, most likely low-income countries. The export waiver was already decided in the Doha Declaration, but required a separate treaty amendment to prevent political uncertainties.¹⁹

At EU level, Regulation (EC) No. 816/2006 provides the legal basis for EU Member States to grant compulsory licences for export of patented medicines to address a public health problem in the importing country, not necessarily a public health emergency situation.²⁰ Apart from low-income countries, Art 4 (b) of Reg 816/2006 shows that other countries, including EU Member States, may also act as eligible importing countries.²¹ This means that, in case of a public health problem in Member State A (inadequate pharmaceutical capacities or excessively priced innovative cancer medicines), any person may apply for a CL at the competent authority in Member State B to export a patented medicine (e.g. Spinraza). During the verification process (Art 8 Reg), the applicant will provide evidence that efforts to obtain authorisation from the patent holder have remained unsuccessful (Art 9). Then, the competent authority may grant a licence to export the medicine to Member State A. However, the licensee is responsible for adequate remuneration to the patent holder. In case of a public health emergency, this is a maximum of 4% of the total price to be paid by Member State A (Art 9(9)(a)). Although integrated into national law, so far the export flexibility has never been used.²²

A major advantage of Reg 816/2006 is the data exclusivity waiver, meaning that when a compulsory license is granted, the applicant will automatically have access to the originator’s clinical test data in order to manufacture a generic medicine (Art 18(2)). In all other cases, the

¹⁵ <http://tripsflexibilities.medicineslawandpolicy.org>, based on Art 31 TRIPS.

¹⁶ AGCM A364 - MERCK-PRINCIPI ATTIVI, no. 16597, www.agcm.it, quoted by KEI Research Note: Recent European Union Compulsory Licenses, 1 March 2014, p 13.

¹⁷ <http://tripsflexibilities.medicineslawandpolicy.org>, based on Art 31 TRIPS, UK Patents Act 1977 (as amended).

¹⁸ Innstilling til Stortinget, fra helse- og omsorgskomiteen, Dokument 8:138 S (2017–2018), Innst. 285 S (2017–2018).

¹⁹ General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of the General Council of 30 August 2003, 1 September 2003, WT/L/540. The amendment came into force 23 January 2017.

²⁰ Regulation (EC) No. 816/2006 of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems of 17 May 2006, OJ EU L 157, 9 June 2006.

²¹ Art 4 reads: ‘The following are eligible importing countries: ... (b) ‘any member of the WTO, other than the least-developed country members referred to in point (a), that has made a notification to the Council for TRIPS of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way’.

²² European Patent Office (EPO), Compulsory licensing in Europe. A country-by-country overview, Munich 2018. The only example known so far is Canada exporting an HIV medicine to Rwanda (2007) under the Doha Public Health flexibility (IP/N/10/CAN/1) source: www.wto.org, notifications by exporting countries.

non-disclosure clause has to be respected (Directive 2004/27/EC).²³ As a result, EU data exclusivity legislation creates a significant hurdle to effectuate CL, preventing generic competitors from accessing test data to manufacture cheaper medicines.²⁴ Extending the data exclusivity flexibility to all cases of public health interest where CL has been issued could stimulate patients' access to affordable medicines.²⁵ Access to test data is therefore part of the right to health care.

2.2 Pharmacist's exemption

If CL remains controversial, an alternative option is the 'pharmacist's exemption' (also known as 'compounding'), allowing (hospital) pharmacists to prepare a patented medicine for individual patients on a small scale.²⁶ Article 27(e) of the Council Agreement on a Unified Patent Court allows EU Member States to limit pharmaceutical patent rights with: 'the extemporaneous preparation by a pharmacy, for individual cases, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared'.²⁷ Various Member States have incorporated the pharmacist's compounding exception in national patent law.²⁸ Essential is the preparation for the therapeutic needs of a specific patient, or small groups of patients, whose medical requirements cannot be met by industrially manufactured medicines.²⁹ Originally referring to products under the magistral formula rules (marketing authorisation exception),³⁰ national patent law may also extend the patent limitation to hospital pharmacies' preparations for the purpose of curbing excessively priced patented medicines (public health reasons). As long as such (a) 'limited exception[s] do[es] not unreasonably conflict with a normal exploitation of the patent, and do[es] not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties' (Art 30 TRIPS agreement). Since the wording is rather vague and in absence of further indications, compliance with the conditions remains highly uncertain.³¹ Consequently, the liability risk for patent infringement is therefore considerable.

2.3 Excessive pricing challenged by competition authorities: acting as substitute price regulators?

Since (the threat of using) CL is generally considered as the 'nuclear option' to convince pharmaceutical companies to lower their excessive prices, the search for alternative, less

²³ Directive 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (par 8, Art 10). L 136/34, 30 April 2004. There is of course the 'voluntary license' option granting the generic producer access to relevant clinical data, but that option is not applicable here.

²⁴ E 't Hoen, P Boulet, B Baker, 'Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation', *J Pharmaceutical Policy and Practice* 10 (2017) 3.

²⁵ *ibid*, 6.

²⁶ Compounding is the individual preparation of medicines in pharmacies when an equivalent licensed product is unavailable or is unsuitable for use and if the use can be clearly justified clinically and pharmaceutically according to prescriptions. In other words, it is the basis of personalised medicine, source:

<https://www.eahp.eu/practice-and-policy/compounding>.

²⁷ Art 27(e) Council Agreement on a Unified Patent Court (2013/C 175/01) OJ EU C175/9, 20 June 2013.

²⁸ E.g. Belgium IP Act (2014) Art XI.34. § 1; French IP Code Art L613-5(c); German Patent Act §11(3), UK Patent Act (1977) section 60 (5)(c) and most recently (1.1.2019) the amended Dutch Patent Act (1995) Art 53(3).

²⁹ *idem*.

³⁰ See Art 3(1)(2) Directive 2001/83/EC as amended referring to pharmacy preparation under the rules governing medicinal products for human use at European level.

³¹ Although the WTO Panel gave some clarity in the EC-Canada case, interpreting the phrases "limited", "normal exploitation", and "legitimated interests", WT/DS114/R, 17 March 2000, par 7.30-7.71.

drastic measures continues. One of these options includes the use of competition rules. More specifically, reviewing intellectual property rights (patents) under the abuse of dominant position. The use of economic legal tools to challenge unfair prices of medicines is not new. It has been confirmed by Article 8.2 TRIPS:

‘Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.’

whereas European Union competition rules prohibit the abuse of dominant position under Article 102 TFEU as:

‘Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States.

Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions; [...]

This provision, generally being understood as holding a dominant position (monopoly) by developing an innovative medicine or vaccine, is not necessarily problematic, but the misuse of the pharmaceutical company’s market position by setting unreasonable prices or price conditions could be considered as an *abuse* of dominant position and thus breaching competition law. In the *AstraZeneca* case, the European Union Court of Justice (EUCJ) ruled for the first time that misleading patent authorities aimed to exclude generic competitors from the ulcer treatment market is considered an abuse of dominant position.³² Thus, exercising rights of the patent holder may attract both national and European competition legislation. An approach also relevant in cases of fighting unfair or excessive prices of innovative gene-based therapies.

Nevertheless, the European Commission has been reluctant to assess allegedly high prices practised by dominant enterprises under Article 102 TFEU.³³ That position might be correct in a free and competitive market: ‘with no barriers to entry, high prices should normally attract new entrants. The market would self-correct.’³⁴ Still, with the public health interest involved, the Commission cannot stay inactive, particularly since life-saving medicines remain largely inaccessible.

Recalling the Court’s case law on unfair prices, a price is excessive when it has no reasonable relation to the economic value of the product supplied.³⁵ Accordingly, only ‘disproportionate’ or ‘exorbitant’ prices could be in breach of Article 102 TFEU.³⁶ This could be measured by comparing the selling price with the cost of production (cost plus approach), as this would disclose the amount of profit margin. Here, the Court allows competition authorities a certain margin of discretion regarding the economic method to define excessive prices, but each

³² Case C-457/10 P, ECLI:EU:C:2012:770, 6 December 2012.

³³ Opinion A-G Wahl, 6 April 2017, Case C-177/16, ECLI:EU:C:2017:286 request for a preliminary ruling from the Supreme Court Latvia, par 3.

³⁴ *idem*.

³⁵ E.g. Case 27/76 *United Brands*, European Commission, 14 February 1978, ECLI:EU:C:1978:22, par 250-2. 17 July 1997 *GT-Link v DSB*, ECLI:EU:C:1997:376, par 39.

³⁶ Case C-323/93 *Centre d'Insémination de la Crespelle*, 5 October 1994, ECLI:EU:C:1994:368, par 19 and 21, as quoted by A-G Wahl, *supra* note 33.

method has its own weaknesses.³⁷ A-G Wahl correctly concluded that the proper approach is, where possible, to combine several methods to avoid the risk of errors.³⁸ Still, defining the line between reasonable high and unreasonable high price remains difficult.³⁹ Once the excessiveness has been confirmed, it must be determined whether the price is unfair, or can be justified for objective reasons. The ‘fairness test’ requires an analysis of the economic reasons for its pricing policy.⁴⁰ The economic rationale of excessive pricing generally provided is the high cost of research and development (R&D) of new medicines. Research is becoming more expensive and more complex. Also, it can take many years before a new medicine is or is not approved for entering the market. High prices are thus necessary to cover the investment costs and stimulate future innovation. But it is difficult – and often impossible – to get reliable information on actual medicine prices as well as costs of inputs to those prices. Transparency in R&D expenditures and the methodologies underlying the calculations would help to assess whether a medicine price is fair, but these economic parameters remain confidential. Only in cases where there is no rational economic explanation for the high price may these be qualified as abusive under 102 TFEU.⁴¹ In practice, national competition authorities are struggling with pharmaceutical excessive pricing investigations and so far the results are diverse. Leading cases are *Aspen* (Italy),⁴² *CD Pharma* (Denmark)⁴³ and recently *Pfizer/Flynn* (United Kingdom),⁴⁴ followed by the European Commission’s own pan-European investigation into excessive pricing by pharmaceutical company Aspen launched in 2018.⁴⁵ What these excessive pricing situations have in common are the difficulties in terms of data availability and analysis, and identifying appropriate assessment standards.⁴⁶ This has led to the conclusion that the identification of excessive prices is a ‘daunting, if not, impossible task’.⁴⁷ Therefore, one may question whether competition authorities are equipped for that function which is closer to the competences of a price regulator.⁴⁸

³⁷ Wahl, par 251.

³⁸ Par 43. Recently, the UK Competition Appeal Tribunal (CAT) decided in an appeal that a cost plus approach, in isolation, is rather obsolete and an insufficient method to determine the excessiveness of pharmaceutical prices, par 310, and thus confirming A-G Wahl’s mixed approach: *Pfizer and Flynn Pharma* [2018] CAT 11, 7 June 2018.

³⁹ D Chalmers, G Davies and G Monti, *European Union Law* (2nd ed Cambridge: CUP 2010) 1002.

⁴⁰ Wahl par 118.

⁴¹ Wahl, par 131.

⁴² AGCM Decision 29 September 2016 (Aspen), case A-480, upheld in appeal by the Lazio Regional Administrative Tribunal, judgment no. 8948/2017, 26 July 2017, applying a theoretical and single cost plus method (difference between the selling price and costs) to determine the excessiveness, and ruled that Aspen abused its dominant position by charging unfair prices.

⁴³ The Danish competition authority (DCC) *CD Pharma*, press release, 31 January 2018. Using the cost plus method, there was no objective justification for a 2,000% price increase of off-patent medicine Syntocinon.

⁴⁴ In appeal, the CAT overturned the Tribunal’s (CMA) assessment, as it identified ‘important errors in its legal test’ (par 310). CAT highlighted that a finding of abuse through excessive pricing should rely on proper evidence and analysis, ‘taking into account the real world’ (par 318) and ‘using a range of methods for setting a benchmark price and establishing the excess’ (par 443(1)), Judgment [2018] CAT 11, 7 June 2018

⁴⁵ European Commission, ‘Antitrust: Commission opens formal investigation into Aspen Pharma’s pricing practices for cancer medicines’, IP/17/1323.

⁴⁶ OECD DAF/Com 2018, p 6.

⁴⁷ D Evans and J Jorge Padilla, ‘Excessive Prices: Using Economics to Define Administrative Legal Rules’, *J Competition Law and Economics* (2005) 97-122, at 118.

⁴⁸ E.g. B Kianzad, T Minssen, ‘How much is too much? Defining the metes and bounds of excessive pricing in the pharmaceutical sector’, *EPLR* 3 (2018) 15-30, at 16; C Calcagno, A Chapsal, and J White, ‘Economist’s Note. Economics of Excessive Pricing: An Application to the Pharmaceutical Industry’, *J European Competition Law & Practice*, 3 (2019) 166-171, at 171, quoting the CAT in its Flynn/Pfizer judgment, ‘competition authorities

2.4 Price transparency and mandatory disclosure

Greater transparency regarding pharmaceutical prices and costs imposed by law may help competition authorities and price regulators to improve the understanding of price setting, combined with constant monitoring of prices and detailed market knowledge. Recently, the WHO Assembly approved a resolution ‘urging member states to take appropriate measures for public disclosure of economic data on medicine prices’, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives.⁴⁹ As well as supporting research on and monitoring the impact of price transparency on affordability and availability of medicines.⁵⁰ Unlike the original text proposal, the final resolution emphasises the voluntary nature of disclosure of R&D data (par 1.2), which seems not very realistic.⁵¹ Coping with the lack of transparency and information asymmetry, mandatory disclosure to public authorities in price negotiations is required.

2.5 Cross-border collaboration initiatives: solving imbalances in market power

Although important, mandatory disclosure alone will not solve the actual imbalances in market power between national/local procurers and payers vs globally acting pharmaceutical companies. Therefore, collaboration may be considered a more successful avenue. Collaboration between different public payers and purchasers at different levels: regional, national and cross-border level addressing a range of topics, from the exchange of information on medicines and pharmaceutical policies, to joint price negotiations of (selective) medicines.⁵² The underlying idea is that joint collaboration initiatives will help to overcome information asymmetry and enhance the buyers’ bargaining power.⁵³ A good example of multilateral collaboration is the Beneluxa initiative, concluding positive joint reimbursement negotiations on Spinraza, a medicine for Spinal Muscular Atrophy (SMA),⁵⁴ as well as the Velatta Alliance, a number of southern European countries bargaining collectively with the giant pharmaceutical companies.⁵⁵

should be wary of casting themselves in the role of price regulators. Generally, price control is better left to sectoral regulators, where they exist, and operated prospectively; ex post price regulation through the medium of competition law presents many problems’, par 462.

⁴⁹ World Health Organization. Resolution WHA 72.8: Improving the transparency of markets for medicines, vaccines, and other health products. 2019, A72/A/CONF./2 Rev 1, 28 May 2019.

⁵⁰ Idem par 2.3.

⁵¹ As painfully illustrated by the Dutch Pharmaceutical code of conduct (2020) emphasising transparency as core value for all stakeholders but is silent on *price* transparency, <https://www.vereniginginnovatievegeneesmiddelen.nl/>.

⁵² Horizon Scanning aims to highlight important pharmaceutical and medical technology innovations before they reach the market by continuously gathering data and analysing research and literature. This improves insight in expected costs and enables timely decision-making and (joint) price negotiations.

⁵³ S Vogler, V Paris, D Panteli, ‘Ensuring access to medicines: How to redesign pricing, reimbursement and procurement?’ Policy brief 30, European Observatory on Health Systems and Policies (2018) 20-21.

⁵⁴ <https://beneluxa.org>, an initiative of the Health Ministers of Austria, Belgium, Ireland, Luxembourg and the Netherlands. The Spinraza agreement was on joint pricing, and was successfully concluded between Beneluxa partners Belgium and the Netherlands (12 July 2018).

⁵⁵ The Valetta Declaration, signed by the Ministers for Health of Cyprus, Greece, Ireland, Italy, Malta, Portugal, Romania, Spain, Slovenia and Croatia (8-9 May 2017). The cooperation allows for sharing of information about medicinal products, policies, legislative proposals and procedures being adopted by the different participating countries,

<https://www.gov.mt/en/Government/DOI/Press%20Releases/Pages/2019/August/28/pr191795en.aspx> . Other

At EU level, Decision 1082/2013/EU facilitates the joint acquisition of medicines by introducing a joint procurement mechanism, the Joint Procurement Agreement (JPA), for purchasing vaccines and medicines to combat major cross-border health threats.⁵⁶ Based on the Treaty's public health provision (Article 168(5) TFEU), the JPA option is limited to cross-border health threats, transmitted from person to person, and thus excluding non-contagious diseases.⁵⁷ Extending the common purchase procedure to individual health care-related medicines with no direct border crossing health risk would exceed the Union's public health mandate. Therefore, in case of high-priced cancer medicines, the JPA instrument is not feasible.

Instead, EU Member States may – also on a voluntary basis – consider the cross-border public procurement option for high-priced medicines provided by Directive 2014/24/EU.⁵⁸

According to Article 39 of the Directive, 'contracting authorities from different Member States may act jointly in the award of public contracts by using one of the means provided for in this Article'. For this purpose, participating contracting authorities may establish a joint entity entrusted with the procedure to strengthen buyers' bargaining powers (Art 39(5) of the Directive). The large volume of medicines purchased, and thus lower prices, makes this type of acquisition an attractive option for all parties involved. Still, there are several hurdles to cross-border procurement of medicines, particularly since regulations on prices and procurement may differ from country to country. Or, for more opportunistic reasons, individual countries believe they may reach a better result, i.e. a lower price, by confidential price agreements.⁵⁹ Despite these and other political obstacles, voluntary cross-border purchasing arrangements are potentially promising, particularly for small countries.

3. Conclusion

Almost every European country has been confronted with emerging innovative medicines and the increased costs of pharmaceuticals. In the fight against excessive pharmaceutical prices, this paper examined a 'toolbox' of price-reducing measures. Each of these alternatives has its limitations, but cross-border collaboration on (price and cost) negotiation of selective medicines seems the most feasible remedy to create advantages of economies of scale, and thus provide access to affordable new medicines. Triggering CL, transparency and mandatory disclosure of economic costs and criteria, as well as the pharmacy's exemption and competition authorities' price assessments remain highly complex, riskful and/or doubtful in terms of a meaningful impact on affordability. One must even fear the risk of opening

joint negotiations initiatives include the Nordic Pharmaceuticals Forum (2016), Declaration of Sofia (2015), and the Romanian and Bulgarian Initiative (2015).

⁵⁶ Article 5 of the Decision sets the conditions for the joint procurement of medicines, Decision 1082/2013/EU on serious cross-border threats to health and repealing Decision No. 2119/98/EC, OJ L 293/1, 5 November 2013.

⁵⁷ According to Art 3 (g) of the Decision, a serious cross-border threat to health means 'a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection'.

⁵⁸ Directive 2014/24/EU on public procurement, which repeals Directive 2004/18/EC on public works. OJ L 94, 28.3.2014, p 65, 26 February 2014.

⁵⁹ J Aspin and others, 'How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe?', Policy brief 21, European Observatory on Health Systems and Policies (2016) 18.

Pandora's box when, if their property rights are curtailed, pharmaceutical companies withdraw their products from the market.