OPACITY IN NET MEDICINES PRICING

FROM THE GLOBAL HEALTH ISSUE TO THE LOCAL EXPERIENCE: THE CASE OF NO ES SANO

NO ES SANO

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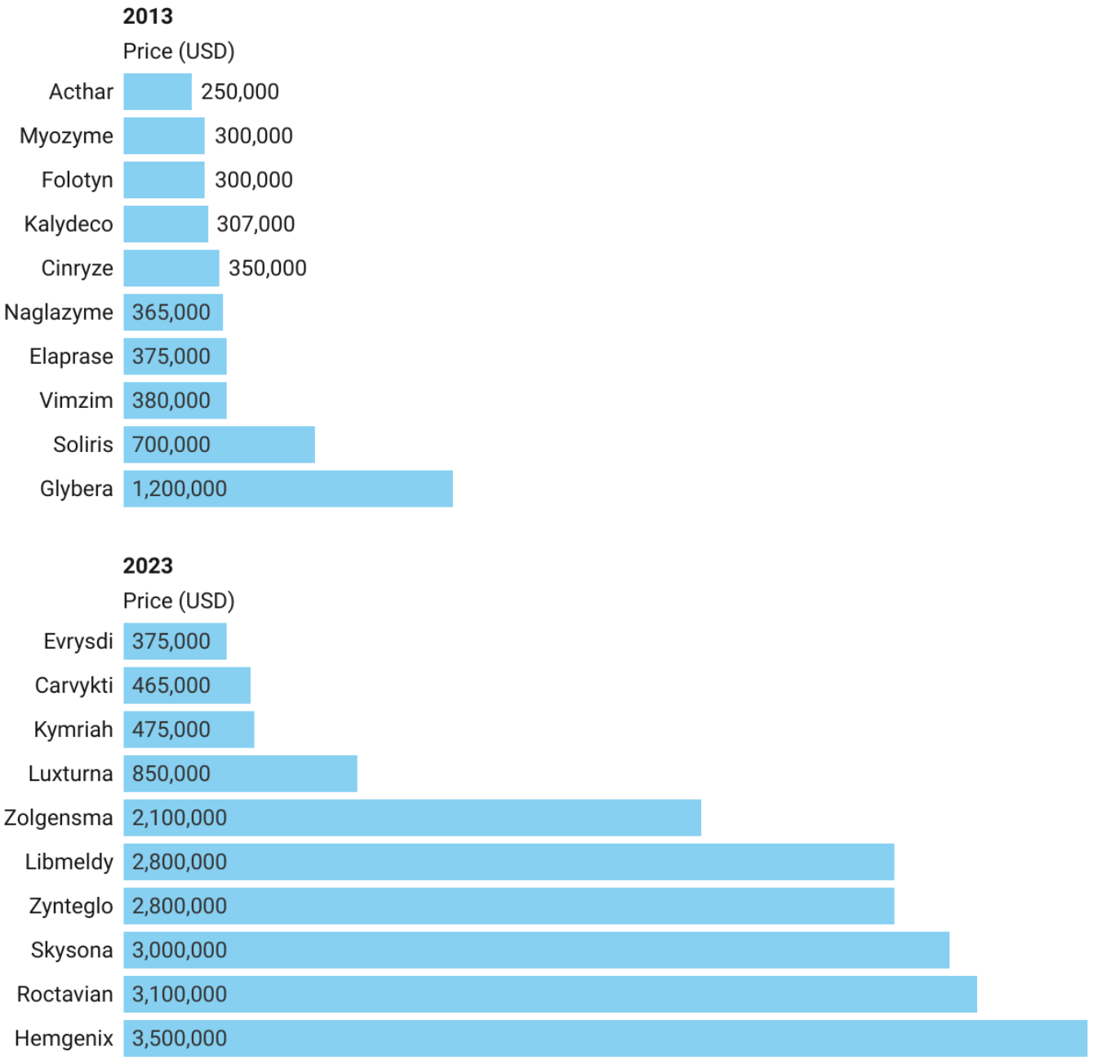
INTRODUCTION

Ensuring equitable access to affordable medicines is a fundamental right that is becoming increasingly difficult to fulfill globally (1). The sustainability of health systems is being challenged globally by the dramatic increase in prices in the last years. It is important to highlight the word “globally”, since this is not just an issue in low- and middle-income countries (LMIC). For instance, affording the new gene therapy priced at over $3 million in the US (3), will be challenging for high-income countries, while creating immense difficulties in LMICs to access it (4). Countries like Norway had to reject new medicines due to high prices (2). To further illustrate the price spiral we are living in, the most expensive drug from 2013 will not make it in the top 5 in 2023 (Figure 1).

Figure 1: Comparison of most expensive drugs 2013 Vs. 2023



Own elaboration. Source: (2,41)

Where is the price limit for new drugs? Global medicine spending is expected to reach $2.3Tn by 2028(5). In Oncology, the largest therapeutic area in terms of spending, the median annual cost for new medicines has more than tripled in the last decade, reaching nearly $300,000(6). As pharmaceutical companies keep demanding ever-higher prices for new drugs, civil society, patients and governments highlight the “unfair” nature of the system.(1,7,8)

BUT HOW DO WE ESTABLISH WHAT IS FAIR?

Transparency is a key element to addressing this challenge. However, there is a significant lack of reliable data in the pharmaceutical ecosystem: from clinical trial data, patent expiry dates, research and development costs (R&D) to the real prices of medicines (9,10). Opacity is the cornerstone of pharmaceutical monopolies, allowing companies to charge increasingly artificially higher prices that generate revenues that far exceed costs of Research and Development (R&D) (11,12).

This situation persists despite governments agreeing to greater transparency in pharmaceutical markets through the 72nd World Health Assembly Transparency Resolution (13). One of the measures proposed in this resolution was the public sharing of net prices, defined as “the amount received by manufacturers after subtraction of all rebates, discounts, and other incentives” (13). Why did the World Health Assembly conclude that net price transparency could increase access to medicines?

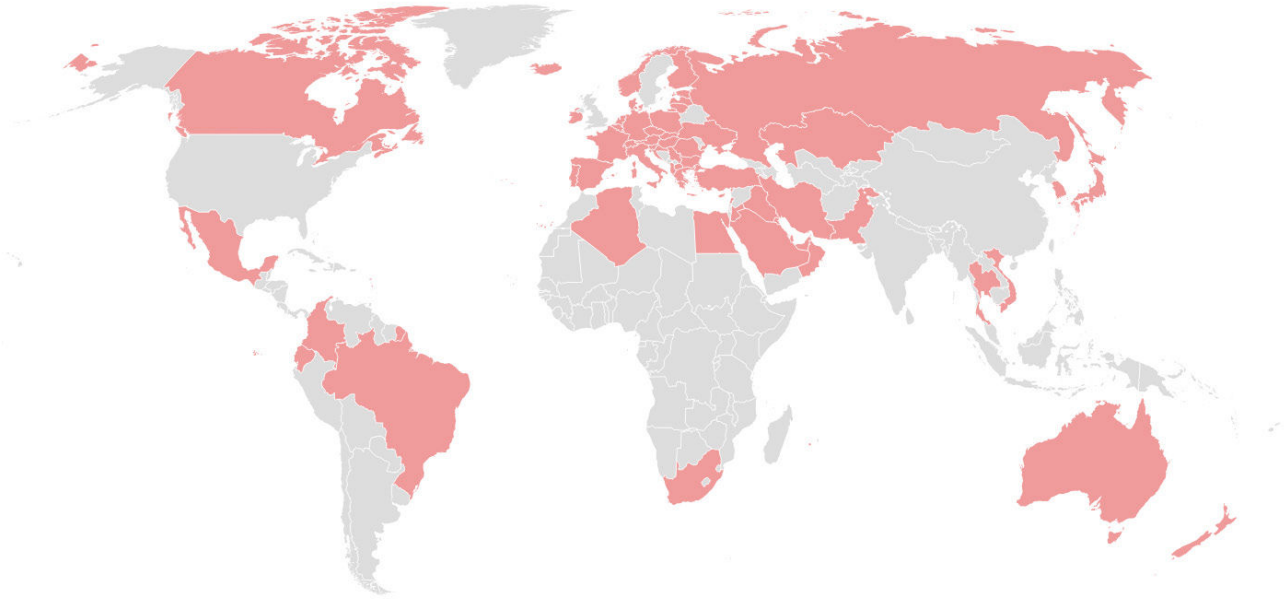
HOW DOES LACK OF TRANSPARENCY CONTRIBUTE TO ARTIFICIALLY HIGH PRICES?

Governments and medicine purchasers often rely on published official prices (list prices) in other countries as benchmarks to set the prices they will pay (Figure 2). This practice, known as external reference pricing(2), favors that pharmaceutical companies provide confidential discounts with the objective to ensure that referenced prices across countries remain as high as possible (14). By maintaining net prices secret through non-disclosure agreements (NDAs) (10), companies prevent countries from demanding the lowest available reference price. Given the interconnectedness of international reference pricing, high list prices in high-income countries like Spain, influence pricing in countries of all income levels (see Figure 3), contributing to the unaffordability of lifesaving health technologies.

This problem is further amplified by pharmaceutical companies' strategy to prioritize launches in markets where prices are higher, such as those where prices are set freely, while delaying market access in less lucrative markets, as it has been recognized by the pharmaceutical companies themselves(15). By doing this, companies set international reference prices that are as high as possible for the subsequent cross-country comparisons. Evidence collected from European countries over 20 years found that that delayed market launch was inversely correlated with the country income status, with poorer countries accessing later medication needed by their citizens (16).

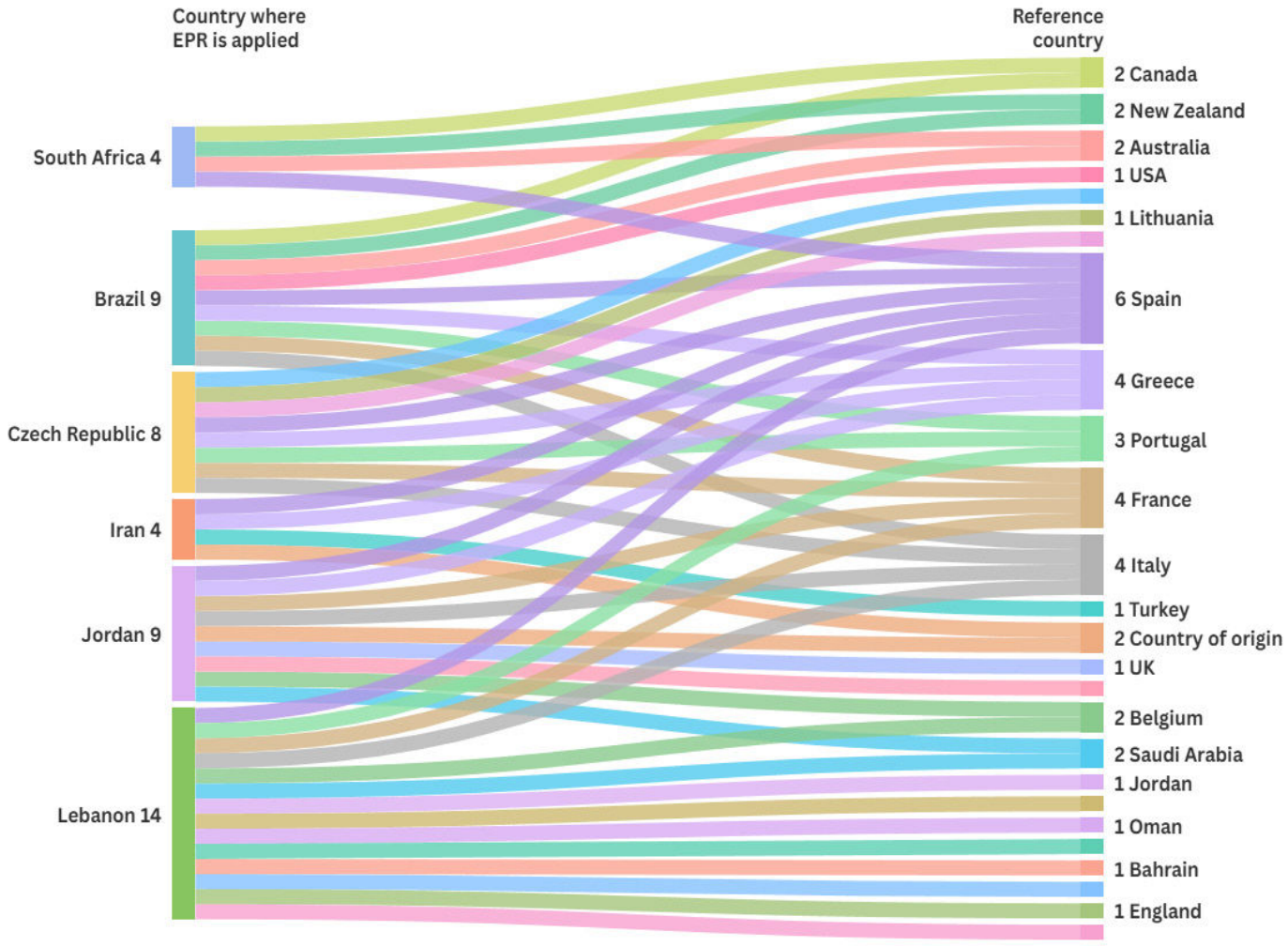
Another consequence is market withdrawals. If the system is rewarding and promoting high prices as the main incentive for innovation, companies that do not see their expectations on profitability met, will withdraw their products from the market. This has been the case in Europe with advanced therapy medicinal products (ATMPs): as of mid-2023, 7 out of 25 approved ATMPs in Europe were withdrawn from the market, mainly for commercial reasons (17).

Figure 2: Countries where EPR is commonly applied



Own elaboration, not exhaustive but based on a rapid literature review. Sources: (4,42–45)

Figure 3: Examples of international reference pricing.



Own elaboration. Sources: (43)

WHO BENEFITS FROM THIS SYSTEM?

Pharmaceutical companies justify the use of confidential discounts as a means to guarantee global access to affordable medicines, supporting a system where poorer countries pay less, and richer countries pay more (18). In their view, net price transparency would lead to a price convergence that would increase prices in lower-income countries. Through the signature of NDAs, decision-makers are told they have secured the best deal possible, achieving the most favorable conditions in return for not disclosing them. Whether this is true or not, it is very difficult to prove as data remains confidential, becoming an act of faith for medicine purchasers. However, it's clear that not everyone can make the best deal—someone is forcibly getting a bad deal.

Who might be then getting a bad deal? One has to agree with the pharmaceutical lobby in one aspect: prices for the same medicine are different depending on which country is buying. However, this variation does not seem to be related with countries' income status, as they claim. As some of the evidence that manages to work around the confidentiality walls suggests, wealthier countries with greater purchasing and negotiation power can often negotiate cheaper prices than poorer countries. Evidence published on the actual costs of expensive cancer drugs suggested that there countries with similar income status showed unjustified price discrepancies and found that richer European countries tended to pay less than less wealthy countries(19).

Another study examining hospital discounts across five European countries found that Norway, with its coordinated purchasing strategy for public hospitals and transparent pricing, secured the most advantageous deals compared to hospitals from other countries, that received minimal or no discounts, and there was little difference in pricing between them(20). Recently, a journalistic investigation by Investigate Europe found that cystic fibrosis drugs like Kaftrio, Kalydeco, Orkambi and Symkevi were priced higher for poorer countries(21).

This is not only observed within Europe. For example, Pfizer's pneumococcal vaccine (PCV13) was priced higher in Tunisia and Morocco than in France (10), South Africa had to pay twice as much for the AstraZeneca COVID-19 vaccine as countries in the European Union(22) and the US is paying less than UNICEF to purchase mpox vaccines. These cases show the global inequities in medicine pricing, where less wealthy nations often bear a heavier financial burden(23).

Contrary to the pharmaceutical industry's argument, opacity does not increase access to medicines. It creates an ecosystem defined by information asymmetry with only one winner: pharmaceutical companies, who maintain negotiation leverage to maximize profits. Everyone else, both governments and the public, are left with misleading and incomplete information, highly-priced innovative medicines and sicker societies. The lack of transparency creates a double effect with negative implications for the common good. On one hand, it traps governments in a form of a prisoner's dilemma, believing their deal is better than their neighbors, and fearing that increased transparency and cooperation would raise their price, lead to litigation over the non-disclosure agreements or even blackmailing from companies (18).

On the other hand, it prevents both governments and corporations from being held accountable by the public: governments for the use of public resources and corporations for setting artificial high prices without objective criteria.

Civil Society Organizations (CSOs) have become relevant actors fighting to expand price transparency in the pharmaceutical sector. Through campaigning, advocacy and making use of transparency regulations, CSOs have aimed to shed light on the levels of public expenditure on pharmaceuticals, with the intention to increase public accountability on governments and companies. The following section showcases NO ES SANO's experience in Spain to expand access to medicine price information through the use of litigation.

THE SPANISH LAWSUIT: WHY AND HOW IT HAPPENED

Since 2019, NO ES SANO (NES), a civil society and consumer organization's coalition, has actively pursued transparency around medicine net prices and pricing process. The coalition advocates for greater transparency in the pharmaceutical market, public interest conditions for public investment, and alternative innovation models since 2015. Regarding net prices, it advocates for medicine net prices and pricing process to be transparent and accessible by the public, and to determine prices based on verifiable criteria (such as transparent R&D and manufacturing costs). To achieve this, the coalition has conducted investigations on the issue (24) and has utilized the transparency mechanisms established in the Spanish Transparency Law.

How does transparency work in Spain? The 2013 Transparency Law regulates the transparency of public sector information, recognizing the right to access public information(25). The Transparency Portal allows the public to request information online. The Administration must respond within 30 days, with an option to appeal to the Transparency Council. This body decides whether the administration should provide the requested information. The appeal leads to a Transparency Council Resolution, which can be further appealed in court.

'Transparency, access to public information and the rules of good governance must be the basic pillars of every political action. Only when the action of public authorities is subjected to scrutiny, when citizens can know how decisions affecting them are made, how public funds are managed, and under what criteria our institutions act, will we be able to speak of the outset of a process in which the public authorities begin to respond to a society that is critical, exacting and demands that public authorities enable participation. Countries with higher levels of transparency and rules of good governance have stronger institutions, which foster economic growth and social development. In these countries, citizens can judge, more accurately and using better criteria, the capacity of their public authorities and decide accordingly. Better supervision of public activity contributes to the necessary democratic regeneration, promotes the State's efficiency and effectiveness and fosters economic growth"

19/2013 Transparency Law Preamble. (25)

This law is applied to all information stemming from the public budget or managed by administrative bodies, including acts, decisions, and supporting documentation. Additionally, The Medicines Act (Royal Legislative Decree 1/2015), lays down the general principle of maximum transparency in the decisions of the health authorities regarding medicinal products, despite limiting it by considering confidential the technical, economic, and financial information provided by companies to the Ministry of Health during the pricing negotiations.

The coalition's journey on transparency has not been easy, and here we provide a chronology of the actions:

2019

No es Sano submitted a request for access to information addressed to the Ministry of Health (MoH) to obtain the unpublished list price of Kymriah® (tisagenlecleucel) - the first CAR-T therapy for the treatment of refractory B-cell acute lymphoblastic leukemia and for the indication of diffuse large B-cell lymphoma - as well as "the concrete, objective criteria under which this therapy is approved, as well as the economic conditions of the agreement"

The MoH sent us a letter with the price, which amounted to 320,000 euros in Spain. However, in the case of the criteria and conditions, it provided generic and incomplete information that did not respond to NES request.

As a consequence, the coalition filed a complaint to the Transparency Council for the Ministry's response. This complaint was upheld by the Council, who urged the government to provide the information, establishing an important milestone for pricing transparency in Spain:

> *"However, [the Ministry of Health] should be requested to make a more detailed and specific effort so that the complainant can promote an informed public debate on the problems of the current system of R&D and medical innovation and its impact on access to medicines and on the sustainability of health systems, inside and outside our country, a purpose that is in line with the spirit of the [Transparency Law], of knowing how the public authorities make decisions that affect citizens, especially on the issue of public health and its funding, which is of marked social interest."*
>
> *"We understand, therefore, that the issues raised by the complainant [...] are directly related to the purpose and ratio iuris of the [Transparency Law]. And this without failing to remember that we are dealing with a right of constitutional anchorage that must be highlighted as a value intrinsic to the concept of democracy [...] whose protection and guarantee, therefore, must take this nature into account."*
>
> *Transparency Council - Resolution 079/2019. (26)*

The pharmaceutical company decided to take the case to court to stop the process, filing an administrative appeal against the resolution of the Transparency Council.

2020

In Judgment No. 42/2020 of the Central Contentious-Administrative Court No. 1(26), the judge attributed a formal defect in the Kymriah process, arguing that the Ministry should have given the company a hearing to present its allegations. In this way, the judge urged the Ministry to backtrack and give Novartis a hearing before accepting or denying No es Sano's request. Thus, the process was blocked.

2022

Salud por Derecho, on behalf of the No es Sano campaign, requested the Ministry of Health access to the net price and impact on the health budget of three highly-priced medicines – remdesivir (Veklury®), onasemnogene abeparvovec (Zolgensma®) and lanadelumab (Takhzyro®).

The Ministry, after hearing the companies' concerns and noting their opposition to grant access to the information, refused the publication of this information, considering that the disclosure of the requested data would go against the limits established by law (namely the protection of commercial interests, intellectual and industrial property and the duty of confidentiality). More specifically, the MoH argued that revealing the net price would mean disclosing the information of the entire administrative file that contained all technical, economic or financial aspects provided by the company in the negotiation process, following the same rationale as pharmaceutical companies.

"Many countries, including Spain, avoid publishing these prices as a measure to protect national interests, since only by maintaining the secrecy of these prices can they ensure that they obtain better conditions. In other words, giving third parties access to the prices of medicines financed in Spain would mean a loss of credibility for our Administration, and would entail a negotiating disadvantage when it comes to obtaining more competitive prices."

Ministry of Health – Response to access request
Remdesivir case - Resolution 0052/2023(27)

"It also argues that this system, which allows the Ministry of Health to make products available at a reasonable price, would be unfeasible if the company were not guaranteed absolute confidentiality, backed by a regulation with the status of law, of the data and information it provides and works with until the administrative resolution is reached, which also contains the economic conditions for the approval of the medicine, which are closely linked to the information provided by the laboratory."

Pharmaceutical company - Opposition to access to information
Remdesivir case - Resolution 0052/2023(27)

After the refusal, No es Sano filed a complaint with the Transparency Council, rejecting the argument of the Ministry of Health. Although both the Ministry and the companies claimed the price was confidential, this is not was the law says.

According to the law, confidentiality covers 'technical, economic, and financial aspects' provided by the laboratories during negotiation, not the price itself, which appears in the contract for the acquisition of medicines and is set by the administration, not the company (28). The Transparency Law requires that all contracts be made public, indicating the object, duration, amount, and award(25).

The arguments used by the coalition in favor of greater transparency were summarized as it follows:

"a) [...] the prices of medicines must be set in a reasoned manner and in accordance with objective criteria: the legally-required motivation and objectivity [to approve these therapies] can only be contrasted and evaluated with the due level of transparency.

b) [...] application of the harm test1 and the public interest of dissemination test: existence of an overriding public interest

c) Unfair negotiation: asymmetry in the information available to the CIPM [Inter-ministerial price commission] and the company during price-setting negotiations: there will be no fair and affordable prices as long as there are no fair negotiations and fair negotiations are not possible as long as there is no transparency."

No es Sano complaint - Remdesivir case Resolution 0052/2023(27)

2023

The Transparency Council upheld NES' complaints in all three cases via Resolutions 0052/2023(27), 0023/2023(29) and 0204/2023(30) which puts an end to the administrative pathway.

> *"However, it should be pointed out that, in this case, what is requested is not the full dossiers or the information provided by the laboratory regarding its contributions or formulas for considering one price or another to be more appropriate, possibly affecting its commercial interests, but only the financing price approved by the National Health System [...] In other words, what is requested is the price finally set by the Administration, without reference to the prices recommended by the laboratory, as well as the final conditions under which the medicine will be financed, and therefore, it is clear that, insofar as it involves the use of public resources, there is an interest in the public knowing about it."*
>
> *Transparency Council – Resolution 0052/2023(27)*

The Ministry of Health and the pharmaceutical companies filed a contentious-administrative appeal against the Council's resolution, starting the judiciary pathway. Salud por Derecho and the Consumers and Users Organization (OCU), on behalf of NES, are intervening parties.

2024

The cases on onasemnogene abeparvovec (Zolgensma®) and lanadelumab (Takhzyro®) are pending judgement. For remdesivir, the Court has dismissed the appeal filed by the Ministry of Health and supports the position of NES and the Transparency Council.

> *"Among the limits to the right of access to information are the following: '(h) Economic and commercial interests; (i) Economic and monetary policy; (j) Professional secrecy and intellectual and industrial property; and (k) The guarantee of confidentiality or secrecy required in decision-making processes'. In the present case, none of these limits can be considered to have been breached. Firstly, with regard to the protection of economic and*

commercial interests, the only information requested in the present case is that relating to the express resolution issued [...] In other words, it is requested to know the price of the medicine set by the Administration, and the final conditions under which it will be financed, but not other aspects on the basis of which the price has been determined, as these aspects would reveal economic and commercial interests, as they are directly related to the competitive position of the company or to its production processes."

Ruling no. 2/2024, of 8 January 2024, of the Central Contentious-Administrative Court no. 4(27)

Whereas this ruling is final, the pharmaceutical company's appeal has not yet been judged, as the case has been processed before the Higher National Court. An important milestone here is that the Ministry of Health, for the first time, has not appealed the sentence and has committed to comply with the judgement without further delay. In this sense, the pharmaceutical companies are now alone in their appeal in favor of opacity.

2025

The fight for transparency, however, continues. The No Es Sano campaign is requesting access to the price and the criteria for setting it for the antiretroviral drug Sunleca (lenacapavir). The Ministry once again denies access to information on Sunleca, citing confidentiality and the protection of commercial interests.

WHAT IS IT EXPECTED TO HAPPEN IN THE FUTURE REGARDING THE TRANSPARENCY CASES?

The judicialization of the right to information on medicines' net prices has delivered mixed results in Spain. The bad news is that the National High Court has ruled twice against net price transparency, one of which is a final ruling. The good news is that there are four firs-instance court rulings concluding otherwise and urging to make real prices publicly transparent. Given the difference between rulings on the same topic, the Supreme Court may have to establish jurisprudence on the issue.

The Ministry of Health, while not appealing the sentences anymore, which is a necessary first step, has not announced any measure to proactively disclose the price of medicines without a court ruling. However, they have committed to advanced in the transparency area on a number of national pharmaceutical legislative texts, such as the disclosure of R&D and production costs as part of the Health Technology Assessment(31).

WHY IS THIS ACTION IMPORTANT FOR PATIENTS AND ACCESS?

Opacity leads to blind negotiations that result in worse outcomes for payers, resulting in higher prices. Higher prices make it more challenging to finance these drugs, increasing the risk of non-availability or delayed market launch(32). Additionally, it affects reference prices used elsewhere as benchmarks, leading to higher prices globally. In that sense, transparency actions at national level would benefit not only patients at that level, but globally.

Moreover, it is about focusing on the fair pricing of medicines and the objective reasons that lead to a final price: How are prices really set? How much did the R&D actually cost? Are high prices an effective way of rewarding innovation? (33) Are we incentivizing innovation or "maximizing shareholder value" (34)?

High prices ultimately mean that patients who need these medicines may not access them when needed, either because they are unavailable or because their availability threatens the sustainability of health systems. In other words, by overspending on certain medicines, we reduce the resources available for other potential health improvements. This not only affects other health outcomes but also impacts other patients and the overall public health.

CONCLUSION

Knowing how much we pay for medicines as a society, and its impact on the public budget is of utmost public interest for five reasons:

1. Transparency is necessary for fair negotiations, and fair negotiations are needed for fair prices. It is a matter of fighting against information asymmetry, increasing the negotiation capacity of purchasers, and demanding corporate accountability to reduce prices.

2. Transparency is crucial for good governance and accountability. Opacity in public contracts is not only bad for patients, it is bad for democracy.

3. Transparency is essential for global health. Lifting the veil on net prices so that they can be used as reference prices for countries with less negotiation capacity improves access for patients globally.

4. Transparency is lacking throughout the entire lifecycle by design. We cannot discuss fair prices without transparency in R&D costs, clinical trial data, and public support received. We aim to obtain media attention to bring this issue to the political agenda, as a necessary step towards greater transparency in the system.

5. Transparency by design. It is not sustainable, nor desirable, that citizens and civil society is forced to go through costly judicial process to obtain transparency. We need a proactive approach by the Administration to make effective the right to information through active advertising policies (35).

RECOMMENDATIONS

Transparency as a condition for public support: whenever a pharmaceutical company receives public support, conditions should be included to align public and private interests. Therefore, any financial support should require net price-transparency. This should include also indirect financial support, such as tax incentives, that are frequently used to promote R&D (36).

While this can be done at national level, it is important to encourage this action internationally. For instance, at EU level, all incentives from regulatory data protection, market protection, orphan designation market exclusivity, PRIME schemes and intellectual property protection, should be linked to greater transparency (37).

At international level, negotiations to incorporate pro-transparency measures as part of the Pandemic Accord are ongoing, and it is imperative that the EU and other high-income countries stop opposing these measures (38).

Transparency in national price and reimbursement systems: action at national level is as important as regional collaboration to effectively move towards greater transparency. In Spain, it is essential to shed light on the meetings where pricing decisions are made, through the publication of the meeting minutes. Furthermore, the public should have access to real, net prices, as well as the signature of any type of managed entry agreement (e.g., risk-sharing agreement, or patient access schemes).

While full public net price transparency is the desired outcome, there is a range of policy options that can serve as intermediate steps towards that end. For instance, it would be a zero-cost option to flag in EURIPID, a list price databased accessible by governments in Europe, the prices that are not real and have received any form of discount (9). Countries like Austria and Australia have taken this step for medicines that benefit from a managed entry agreement (39).

Italy requests pharmaceutical companies sharing the net price data in other European countries prior to start negotiating for pricing and reimbursement, as well as the type of risk-sharing agreement, and information subject to confidential agreements. While this option would primarily benefit the country of implementation, it is a policy tool to be considered in line with WHA72.8 (40).

Collaborative platforms like the Valetta Declaration, the Beneluxa Initiative, or the Baltic Procurement Initiative might represent important spaces to share net prices between countries. Moreover, joint tenders, such as the ones carried out by the Baltic Initiative, net prices have been made available to the public, without negative consequences reported (14).

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