ECL: ACCESS TO MEDICINES TASK FORCE

BEHIND THE PRICE TAG:

Transparency and barriers in equitable access to cancer treatment in the European Union

May 2026

The Association of European Cancer Leagues (ECL) is a non-profit umbrella organisation bringing together national and regional cancer societies advocating for improved cancer control and care across Europe. Our vision is a Europe free of cancer.

ABOUT THE ECL ACCESS TO MEDICINES TASK FORCE

This publication was made possible with the support of the ECL Access to Medicines Task Force. Established in 2016, this task force connects cancer control experts who are dedicated to ensuring that cancer patients across Europe have access to safe, effective, and affordable medicines. Central to its mission is promoting accessibility, affordability, availability, and transparency of medicine prices, with an emphasis on sustainability within healthcare systems.

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EXECUTIVE SUMMARY

The European Union's Directive 89/105/EEC on the transparency of measures regulating the prices of medicines for human use and their inclusion in the scope of national health insurance systems i.e. Transparency Directive, adopted in 1989, was designed to ensure that national decisions on the pricing and reimbursement of medicines are taken within clear timelines and according to transparent procedures.

While the Directive established an important procedural framework for Europe's pharmaceutical market, it has remained largely unchanged for more than three decades. Since 1989, the pharmaceutical landscape has evolved considerably, with increasingly complex price systems, confidential discount agreements, and the growing use of high-cost innovative therapies. These developments have exposed the significant limitations in the Directive's ability to ensure true transparency and equitable access to cancer medicines across the European Union (EU).

Today, access to medicines remains uneven across EU countries. As a result of differences in the affordability, availability, and timing of reimbursement decisions, patients – especially those from smaller or lower-income countries – continue to face obstacles in accessing the treatment they urgently need. At the same time, limited transparency regarding price agreements and the true costs of researching and developing medication is keeping both governments and hospitals in the dark, weakening their ability to negotiate fair prices.

Key challenges that the Transparency Directive fails to address:

- The current EU Transparency Directive is outdated and does not sufficiently address net price transparency.
- Confidential net pricing and rebate agreements for medicines hinder equitable access, accountability, and fair competition.
- Research shows that hospitals across the EU are paying vastly different prices for the same cancer medicines. Stark price differences exist not only between countries, but also between hospitals in the same country [1].
- Long timelines for pricing and reimbursement decisions of generics and biosimilars result in higher healthcare spending.
- New treatment modalities bring new uncertainties about pricing and effectiveness.
- Poorly communicated pricing and reimbursement decisions confuse stakeholders and patients.
- There is no regulation on pricing and reimbursement processes for joint procurement of medicines in the EU.
- EU member states are currently not able to request pharmaceutical companies to apply for pricing and reimbursement. This leaves patients across Europe waiting for life-saving treatment.

This report assesses the effectiveness of the Transparency Directive in today's pharmaceutical landscape. Our analysis combines a review of existing literature and policy documents with interviews conducted with key stakeholders, including consumer groups, health insurers, and representatives from the pharmaceutical sector. The findings show broad agreement among health stakeholders that the Directive is outdated and is in urgent need of reform.

As the report shows, previous attempts to revise the Directive have not succeeded. Yet without action to change direction, the Directive risks becoming increasingly disconnected from the realities of the modern pharmaceutical market and the challenges it generates for healthcare systems and patients.

To ensure the Transparency Directive lives up to its potential, the Association of European Cancer Leagues (ECL) therefore proposes five key recommendations:

1. **Improve price transparency of medicines** to promote accountability, fairness, and public trust.

2. **Introduce transparency standards for Managed Entry Agreements** to create clarity on negotiated discounts, avoid longer reimbursement procedures, and improve insights into data collection protocols and outcomes.

3. **Accelerate access to biosimilars and generics** to keep the budgetary impact of medicines within reasonable limits and to free up budgetary space to make new drugs available more quickly.

4. **Improve public communication** by creating clear, easy to understand EU standards for how pricing and reimbursement decisions are published and communicated.

5. **Prioritise evidence quality in reimbursement decisions.**

Transparency in price negotiations should be the rule, not the exception. A comprehensive revision of the Transparency Directive would help ensure patients across Europe have fair and timely access to the cancer medicines they need.

INTRODUCTION

The Transparency Directive (89/105/EEC) aims to make national price-control measures predictable and transparent for pharmaceutical companies and to prevent undue delays in patient access to medicines. Adopted in 1989, the directive was intended to promote transparency, predictability, and timelines in pricing and reimbursement decisions.

More than three decades later, the pharmaceutical landscape has evolved dramatically. Increasingly complex pricing mechanisms, the widespread use of confidential agreements, and the emergence of high-cost, innovative cancer therapies have significantly changed how medicines are priced and accessed. Despite these new challenges, the Transparency Directive has remained largely unchanged, leading to growing concerns that it is no longer fit for purpose [2].

The shortcomings of the Transparency Directive directly affect cancer patients. Unequal access to innovative, high-cost cancer treatments persists across Europe, with delays and affordability issues particularly evident in smaller or lower-income countries [3]. However, high-income countries also face challenges in ensuring the timely availability of new medicines. Limited transparency weakens the effectiveness of pricing mechanisms and contributes to persistent inequalities in access to essential cancer medicines across the EU.

This paper critically examines the gaps in the content and implementation of the Transparency Directive and argues that in its current form, the directive fails to address transparency in the pharmaceutical market. Instead, meaningful reform is needed to promote fair access to medicines for all cancer patients while modernising the EU's approach to pharmaceutical price regulation. As the EU is in the final stage of updating its pharmaceutical framework, there is a timely opportunity to update the Transparency Directive. Europe's rising burden of cancer, mounting fiscal pressures, and renewed momentum for fairness and openness in medicine pricing collectively underline the urgency for reform.

METHODOLOGY

To support the development of this paper, a literature review was conducted, drawing on academic publications, policy papers, and official EU documents referencing the Transparency Directive. The outcomes provided both a historical background and insight into current challenges with implementation.

Based on the literature, a range of relevant stakeholders were identified for qualitative interviews. Additional stakeholders were selected to ensure diverse representation across sectors and included consumer organisations, health insurers, industry representatives, and civil society actors.

Semi-structured interviews explored views on the Transparency Directive's strengths, weaknesses, and relevance today. Topics included compliance with timelines, transparency in pricing and reimbursement, the role of managed entry agreements, and challenges posed by personalised medicines and biosimilars. Stakeholders also shared perspectives on potential revisions and future developments.

Findings from the literature and interviews formed the basis for the analysis and recommendations put forward in this report. The recommendations reflect the views of ECL alone and not of the interviewed stakeholders.

WHAT IS THE EU TRANSPARENCY DIRECTIVE?

The Transparency Directive (89/105/EEC), approved in 1989, aims to make national price-control measures predictable and transparent for pharmaceutical companies and to prevent undue delays in patient access to medicines.

The directive requires EU member states to make pricing and reimbursement decisions within defined timelines, provide clear and objective reasons for those decisions, and publish both the decisions and the criteria applied. If a country fails to do so within 90 days, pharmaceutical companies may market their product at the proposed price. Where pricing and reimbursement approvals are needed sequentially, the overall process should not exceed 180 days. Member states must also allow companies to appeal decisions before a court.

National authorities are required to publish lists of medicines subject to regulated prices or reimbursement status and report key criteria and decisions to the European Commission. Where profitability controls are in place, EU member states must disclose the methods used to define profitability and the permitted profit margins and inform the Commission accordingly.

Although the original 1989 Transparency Directive remains in force today, its perceived effectiveness has diminished over time. Many of its provisions are not fully complied with or are circumvented in practice [4]. Significant implementation challenges persist, including extended timelines due to clock stops, difficulties faced by some countries in meeting deadlines, and a lack of standardised transparency across countries [5].

Additionally, transparency regarding research and development (R&D) costs and net prices remains limited, while confidential pricing agreements further undermine openness and often increase timelines due to lengthy negotiation processes. The directive also fails to address the growing complexity of national pricing mechanisms, reference pricing systems, and clawback systems. Weak enforcement capabilities constrain its effectiveness.

TERM	DEFINITION
Managed Entry Agreements (MEAs)	Agreements between pharmaceutical companies and public authorities that enable access to new medicines while managing uncertainty about their effectiveness or cost. These may involve outcome-based schemes (payment linked to patient results) or financial deals such as discounts or price-volume agreements. Specific agreements on pricing are often confidential in nature.
Reference Pricing	A pricing method where countries compare medicine prices in other countries (external reference pricing) or among similar medicines domestically (internal reference pricing) to determine the price in their country. This helps ensure fair and consistent prices across markets.
Clawback Systems	Policies requiring pharmaceutical companies to repay part of their income when national spending on medicines exceeds a set limit. Clawbacks help control overall costs and protect the sustainability of health budgets.

A MISSED OPPORTUNITY:
The attempt to revise the EU Transparency Directive in 2012

Following a public consultation, the European Commission proposed a comprehensive revision of the Transparency Directive in 2012 [6]. The proposal was scrutinised in detail by the European Parliament and the Council of the European Union between 2012 and 2015, but it was ultimately withdrawn by the Commission due to a lack of consensus between parties.

The revision aimed to modernise the directive, which was already more than two decades old at the time, through several key changes. These included shorter decision-making deadlines (120 days for innovative medicines and 30 days for generics), expanded transparency requirements covering all pricing measures, and the explicit inclusion of the Health Technology Assessment (HTA). The proposal also introduced stronger enforcement mechanisms with penalties for non-compliance, the exclusion of confidential Managed Entry Agreements (MEAs) from transparency obligations, and measures to prevent redundant national reassessments of data already approved by the European Medicines Agency (EMA).

Although there was a general recognition that the Transparency Directive's provisions were outdated and no longer fit for purpose, no further attempts have been made since the withdrawal of the 2012 proposal.

Reactions from key stakeholders to the 2012 revision and subsequent calls to update the Transparency Directive

Patient representatives, consumer groups and NGO's

The *European Patients Forum (EPF)* welcomed tighter time limits on pricing and reimbursement to speed up access to medicines. At the same time, EPF emphasised the need for greater transparency and public access to pricing and reimbursement information. They also emphasised that the directive governs only interactions between pharmaceutical companies and authorities, imposing no obligations towards patients or the public, and called for greater stakeholder involvement [7].

The *Standing Committee of European Doctors (CPME)* advocated for broader access to pricing and reimbursement data throughout the entire lifecycle of medicines, highlighting that information asymmetry can hinder fair price negotiations. They also called for public disclosure of research and development (R&D) and manufacturing costs, market exclusivity incentives, and public investments. Additionally, CPME underlined the need for clearer guidance on managed entry agreements and the adoption of a multidimensional approach to Health Technology Assessment (HTA) [8].

Public health insurers and payers

The *European Social Insurance Platform (ESIP)* expressed cautious support for the revision. They agreed that unwarranted delays for generics should be tackled and proposed a 60-day timeline. However, ESIP questioned whether faster timelines alone would effectively solve delays, noting that additional hurdles for the directive's implementation exist. They also were strongly opposed the inclusion of penalties after delayed reimbursement decisions. ESIP emphasised the importance of maintaining national authority over pricing decisions and sought clearer industry transparency regarding costs and pricing [9].

Pharmaceutical industry

The *European Federation of Pharmaceutical Industries and Associations (EFPIA)* mostly welcomed the 2012 proposal for a revision of the Transparency Directive. Arguments in favour included the inclusion of streamlined timelines and more predictable pricing and reimbursement processes, which EFPIA argued would enable the pharmaceutical industry to better plan market introductions. However, the federation also highlighted that international reference pricing could erode the value of innovation in Europe [10].

Medicines for Europe welcomed the revision, particularly the inclusion of generics under strict 30-day pricing and reimbursement deadlines. The industry group emphasised that faster market entry for generics could help reduce prices and save costs [11]. It also advocated for amending the patent linkage rule, as outlined in Article 14 of the revision proposal, to prevent patent disputes from delaying pricing and reimbursement processes. Medicines for Europe underlined this amendment would allow generics to enter the market once regulatory approval was granted, regardless of ongoing court cases [12, 13].

Parallel importers and exporters of pharmaceuticals

Affordable Medicines Europe strongly supported the revision but called for several key changes. These included bringing all voluntary and secret agreements within the scope of the directive, supported by a clear definition; ensuring that prices resulting from public tenders are transparent and accessible to all market players; extending the directive's scope to cover generic medicines; and limiting pricing and reimbursement decisions for new medicines to a maximum of 60 days [14].

BUILDING MOMENTUM?
A closer look at the 2023 public consultation

Nearly ten years after the failed attempt to revise the Transparency Directive, the European Commission launched a new public survey to support the preparation of a planned study on the functioning of the directive. Key stakeholders, including the Association of European Cancer Leagues (ECL), used this opportunity to highlight the need for several important policy adjustments:

- Clearer guidance and standardised definitions to ensure consistent interpretation and enforcement across EU member states.
- Stronger enforcement mechanisms to guarantee adherence to established deadlines.
- The explicit inclusion of generics, biosimilars, and hospital medicines within transparency requirements.
- Addressing transparency gaps caused by confidential pricing agreements, potentially through mechanisms for controlled disclosure.
- The standardisation and centralisation of reporting systems to enhance EU-wide transparency, for example by strengthening the EURIPID database.
- Better alignment of the directive with new EU-wide HTA procedures to prevent duplication and delays [15].

A recent analysis by Wemos and Health Action International from 2025 also highlights that the current Transparency Directive focuses mainly on procedures and timelines, while failing to ensure real price transparency [16]. The absence of publicly available data on actual prices, R&D costs, and public investments limits member states' ability to assess fair pricing and negotiate effectively. The report therefore calls for binding transparency rules within an updated Transparency Directive to strengthen accountability and support equitable access across the EU.

A 2025 report from the European Court of Auditors furthermore found insufficient price transparency across EU member states [17]. Confidential discounts and inconsistent reporting obscure real medicine prices, fragmenting the internal market and hindering equal access. The Court urged the Commission to improve the application of the Transparency Directive, including by centralising information on pricing and reimbursement, and to prepare for a future revision to strengthen fairness and accountability.

However, following her re-election in 2024, the President of the European Commission, Ursula von der Leyen, did not assign the newly appointed Health Commissioner, Olivér Várhelyi, an explicit mandate to revise the Transparency Directive in his mission letter [18]. This omission indicates that there is currently no political will from the Commission to re-open the dossier.

Nevertheless, pressure to revisit the directive is steadily growing. Rapidly evolving pharmaceutical markets and increased concerns from civil society organisations are all contributing to renewed calls for reform [19, 20, 21].

STAKEHOLDER INTERVIEWS:
Health actors share insights

European cancer leagues, patient organisations, consumer groups, and other health actors have long called for a comprehensive revision of the EU Transparency Directive. Below is a summary of the stakeholders' views on different aspects of transparency and the need for a reform, which were collected through semi-structured interviews with the International Association of Mutual Benefit Societies (AIM)[1], Affordable Medicines Europe (AME), the European Consumer Organisation (BEUC), the European Hematology Association (EHA), and a representative from the pharmaceutical sector who was granted anonymity. A list of interviewees is available in Appendix 1.

General perspectives on the Transparency Directive

The International Association of Mutual Benefit Societies (AIM), Affordable Medicines Europe (AME) and the European Consumer Organisation (BEUC) consider the directive minimally effective. In their view, it provides a basic framework, but no real transparency or equitable access to medicines. They argue that the directive is outdated and poorly suited to address today's pharmaceutical landscape, particularly with regard to managed entry agreements, innovative pricing, and complex therapies. The widespread use of secret price agreements, they note, significantly increases market opacity.

The European Hematology Association (EHA) similarly sees the directive as a basic transparency tool, but one with limited modern relevance.

In contrast, one voice from the pharmaceutical sector emphasised that the directive still works as a clear, minimal, and effective procedural framework.

Perspectives on the need for a revision

AIM, BEUC and AME explicitly call for a comprehensive revision of the Transparency Directive to better reflect market developments and strengthen enforceability.

BEUC highlights that incremental improvements might be necessary, given the current political realities. However, for BEUC, net-price transparency should be the ultimate objective of the reform.

EHA likewise supports a cautious, incremental, and realistic approach.

On the other hand, a voice from the pharmaceutical sector opposes a revision, fearing it would complicate or slow down national access to new medicines and undermine subsidiarity. They stated that the focus should be on national-level implementation rather than on EU-level legislative change.

[1] Opinions expressed by AIM, the International Association for Mutual Benefit societies, reflect the position of its members collectively. However, some of the opinions may not reflect the views of the individual members, nor the views of their respective organisations.

Perspectives on transparency on the pharmaceutical market

AIM, BEUC, and AME all find that there is a significant lack of transparency in the pharmaceutical market. BEUC advocates for incremental improvements, with information-sharing amongst Member States, and public disclosure of net-prices within a given timeframe (possibly retrospective) as an initial step to build public trust. The consumer organisation also calls for harmonised, user-friendly reporting on decision rationales.

EHA underlines that information is often delayed and difficult to understand, arguing that better clarity and explanation of decision-making processes are equally as important as more data availability. AIM and AME find that secret price agreements, procurement opacity and the fact that decision-making processes are rarely disclosed severely limit transparency and harm trust, trade and fair competition across borders.

A representative from the pharmaceutical sector supports procedural transparency, such as public criteria and justifications, but opposes public price disclosure, citing concerns over reference pricing pressures. Instead, they favour differentiated and confidential pricing arrangements.

Perspectives on timelines of pricing and reimbursement decisions

Stakeholders broadly agree that existing timelines are often not met, especially for advanced, novel, or complex therapies. BEUC attributes these delays to a lack of capacity and insufficient national administrative resources.

BEUC further points out that incomplete submissions from pharmaceutical companies could be contributing to prolonged procedures. In addition, pricing and reimbursement decisions for medicines that have been authorised based on more limited evidence on efficacy, and for which the company asks a very high price, may be more challenging.

EHA stresses the challenge of balancing quick decisions and thorough, evidence-based assessments.

AIM calls for greater flexibility and updated rules, while AME advocates for shorter timelines and stronger enforcement, potentially by providing legal tools for stakeholders. A voice from the pharmaceutical sector, however, does consider the formal timelines themselves as the primary problem.

Perspectives on Managed Entry Agreements

AIM and BEUC argue that Managed Entry Agreements (MEAs) worsen opacity and inequity. AIM believes that such agreements delay access and disrupt trust between countries. AME similarly considers MEAs to distort markets by harming fair trade, and that MEAs hamper competition. BEUC advocates for information-sharing amongst EU Member States and, at minimum, for the retrospective publication of pricing-related terms. They support transparency of outcomes. EHA characterises MEAs as opaque and complicated but does not offer a detailed opinion on reform of these agreements.

A representative from the pharmaceutical sector regards MEAs as a useful tool for flexibility, especially when standard procedures fail or in cases of uncertainty. They believe these agreements can enable faster access, if used properly.

Perspectives on personalised and advanced therapies

AIM and BEUC believe that the Transparency Directive is poorly suited to the complexity, evidence requirements and value assessment challenges for personalised and advanced treatments.

BEUC argues the directive does not meet the challenges of modern, complex therapies and new types of evidence. EHA likewise highlights serious shortcomings in the directive's capacity to support personalised and advanced therapies due to the challenges of assessing and communicating their value and public benefit. Although AME does not prioritise this issue, it acknowledges that new medicines are not well covered in the Transparency Directive.

On the contrary, a voice from the pharmaceutical sector believes that the directive is broad and flexible enough to accommodate new therapies and regards existing challenges as local implementation problems, rather than structural weaknesses in the directive itself.

Perspectives on generics and biosimilars

AME argues that clarity on how the directive deals with generics and biosimilars is important, stating that including them in the directive's scope would improve transparency and competition.

A representative from the pharmaceutical sector considers the Directive to have minimal direct impact on generics and biosimilars. They argue that market mechanisms govern uptake and pricing more than the Transparency Directive does.

BEUC and EHA nevertheless recognise that the affordability of medicines is key. AIM views the directive as potentially beneficial for generics in terms of predictability.

EHA indicated that they do not have a defined position on this issue.

A CALL TO ACTION FROM EUROPEAN CANCER LEAGUES

The Association of European Cancer Leagues (ECL), representing national and regional cancer societies, has long called for greater pricing transparency to guarantee equitable access to cancer medicines for all patients across Europe.

While the current EU Transparency Directive promotes openness on reimbursement decisions from member states, it does not sufficiently address transparency of net prices and research and development costs – both of which are essential for accountability and fair access to medicines. As EU member states have so far shown no willingness to reopen the Transparency Directive, ECL has developed five recommendations for alternative pathways and stronger collaborative efforts among EU member states and regional initiatives.

These recommendations reflect ECL's positions and do not represent the views of any organisations interviewed for the purpose of this report.

Recommendation #1: Improve price transparency of medicines

Transparency in government decisions and pharmaceutical pricing promotes accountability, fairness, and public trust, contributing to more equitable health outcomes. Transparent prices help governments and healthcare providers better assess medicine costs, negotiate effectively, and prevent unfair pricing disparities.

While the Transparency Directive requires public health authorities to disclose which cancer drugs are reimbursed and what criteria are used in those reimbursement decisions, it stops short of addressing the transparency of net prices. Enhancing transparency in net pricing would significantly increase government accountability, fiscal sustainability, improve internal market competition, and enhance equitable access for patients by reducing price disparities across EU member states.

ECL shares concerns with consumer and patient organisations about rising drug prices and the political choice of EU member states to keep these prices confidential. This secrecy threatens equal and swift access to new cancer treatments for European citizens.

Industry argues that price transparency could trigger a "downward price spiral" due to external reference pricing, whereby one country's low price is used to cap prices elsewhere. Companies argue that they use differential pricing, supported by confidential pricing agreements, within the EU to offer lower prices to countries with a lower GDP. However, research suggests that differential pricing is not necessarily improving equitable access to oncology drugs and generics. Research by the European Fair Pricing Network (EFPN) suggests that countries with a lower GDP do not necessarily pay less in relation to their GDP [22].

Transparent R&D costs are also needed to inform fair pricing debates. Contrary to industry concerns, empirical evidence indicates transparency of prices and R&D costs does not stifle pharmaceutical innovation; rather, it may lead to price reductions without deterring investment in R&D [23].

Transparent prices are necessary for balanced price negotiations and to escape the prisoner's dilemma in which member states have locked themselves. Transparent prices in the EU would lead to more symmetrical price negotiations, but countries cannot individually move towards more transparency, because it would mean that it must forego confidential discounts that enable access to essential cancer medicines. Coordinated EU-wide action is thus essential to effectively achieve balanced, transparent, and equitable pharmaceutical pricing.

We therefore call for:

- An EU-wide price observatory accessible to designated health officials to foster balanced negotiations, improve competition, reduce inequities, and improve affordability.
- Mandated transparency of pharmaceutical companies' R&D costs to inform fair pricing without harming innovation.
- Guidelines on the implementation of the Transparency Directive to explicitly include contemporary pricing and reimbursement mechanisms, such as Managed Entry Agreements (MEAs) and confidential pricing agreements.

Best practices already exist. One innovative approach is Belgium's parliamentary mechanism, which allows the national Court of Auditors to confidentially access net pricing agreements under specific conditions, providing oversight without immediate public disclosure [24]. This retrospective transparency is important to hold governments accountable for their pharmaceutical spending.

Recommendation #2: Introduce transparency standards for Managed Entry Agreements

Managed Entry Agreements (MEAs) are widely used to enable patient access by managing budgetary uncertainties and reservations on the added benefit of these drugs. However, MEAs come with transparency challenges of their own.

1. MEAs exacerbate transparency challenges by obscuring net prices as they usually include confidential discounts.
2. MEAs can lead to longer reimbursement procedures as negotiations for MEAs often start after standard reimbursement procedures [25].
3. MEAs are often used to deal with uncertainties about clinical benefits and side effects of new drugs [26].
4. Performance-based MEAs often lack transparency regarding data collection protocols and outcomes [27].

We therefore call for:

- The establishment of minimum transparency standards for MEAs by competent authorities. It is essential that the type of financial arrangement, and the products concerned, along with their therapeutic objective, are publicly disclosed.
- Allowing the national Courts of Audit to access confidential annexes to evaluate public financial impact. A good example is a new legislation in Belgium [28].
- The public disclosure of what uncertainties precisely performance-based MEAs are designed to address, including information on the protocols and parties responsible for data collection and on the evidence derived from the data.
- MEAs should not lead to longer reimbursement procedures. Patients are waiting for potentially life-prolonging or lifesaving treatment. Therefore, negotiations should ideally start as soon as possible in the reimbursement process to avoid unnecessary delays.

Recommendation #3: Accelerate access to biosimilars and generics

Swift access to biosimilars and generics is essential to keep the budgetary impact of drugs within reasonable limits and to free up budgetary space to make new drugs quickly accessible [29]. Currently, the Transparency Directive allows a total of 180 days for pricing and reimbursement decisions. Recognising the similarity between generics and biosimilars and their reference drugs, shorter timelines for these medicines are fully justified.

We therefore call for:

- Shorten the current 180-day timeline for pricing and reimbursement decisions to 30 days for generics and biosimilars by issuing implementation guidance.
- Require pharmaceutical companies to apply for reimbursement if asked to do so by member-states to break the cycle of pharmaceutical launch sequencing.

Recommendation #4: Improve public communication

Under the Transparency Directive, national authorities are obliged to publish lists of medicines with regulated prices or reimbursement status and report key criteria and decisions to the European Commission. However, approaches currently differ widely across EU member states, leading to information that is difficult for patients to navigate and understand.

ECL calls for better, clearer, and user-friendly information on pricing and reimbursement decisions. The European Public Assessment Report (EPAR) published by the European Medicines

Agency (EMA), as well as the Good Lay Summary Practice (GLSP) for clinical trial regulation, can be a source of inspiration [30]. This helps make complex concepts and projects more accessible and understandable for patients.

We therefore call for:

- Create clear, easy to understand EU standards for how pricing and reimbursement decisions are published and communicated, drawing on examples from the EMA summaries and Dutch lay summaries by ZINL, so patients can easily find and understand this information.

Recommendation #5: Prioritise evidence quality in reimbursement decisions

The 2012 revision of the Transparency Directive by the Commission proposed even shorter timeliness for pricing and reimbursement decisions. Since then, new treatment modalities and treatment formulations have entered the market. However, due to the uncertainties these treatments come with, evaluating these drugs is becoming increasingly difficult.

Therefore, reducing decision-making timelines alone is insufficient and potentially counter-productive if doing so does not improve treatment for patients. Instead, emphasis should be placed on enhancing the quality of evidence available for health technology assessments (HTAs) and pricing decisions.

If we want to improve and accelerate access to new cancer medicines, it is essential to invest in well-designed clinical research that focuses on patient-relevant outcomes as well as high-quality data collection for HTAs that compare treatment to current standards of care. These efforts must address the information needs of both regulatory authorities and reimbursement bodies.

The EU Regulation on Health Technology Assessment (2021/2282), introducing joint clinical assessments (JCAs) and scientific consultations from 2025 onwards, represents a crucial development in the coordination of information needs of the European Medicines Agency and HTA bodies.

We therefore call for:

- Strengthened evidence generation and aligned regulatory and HTA requirements, rather than a focus solely on shortening decision timelines.
- A focus on robust, patient-centred evidence collection to enable informed and timely access decisions.

FINAL CONCLUSIONS

This report provides an overview of the history and context of the EU Transparency Directive and outlines key challenges in its implementation. Drawing on diverse sources and stakeholder interviews, we conclude the directive is outdated and no longer fits today's complex pharmaceutical environment. While it offers procedural clarity and strict timelines, it lacks meaningful transparency on pricing, reimbursement decisions, and Managed Entry Agreements (MEAs). Implementation is inconsistent, enforcement weak, and confidentiality undermines fair access and competition.

Whereas the majority of health stakeholders agree that the directive is outdated, views diverge on whether to pursue a comprehensive revision. Some health actors strongly support it, while others urge caution, favouring improved national implementation instead. Despite these differences, most stakeholders agree on the need for greater transparency, harmonisation, standardised processes, and alignment with new EU regulations such as the HTA framework.

To conclude, this report shows that a comprehensive revision of the EU Transparency Directive is needed to ensure genuine transparency, strengthen enforcement, and promote a fairer and more sustainable pharmaceutical system for cancer patients across the EU. However, as there is no political will to do so, it puts forward five concrete recommendations for ambitious action by EU institutions and EU member states to move in the right direction.

APPENDIX 1:

List of stakeholders interviewed

- Ancel·la Santos Quintano, Head of Food, Health and Chemicals safety, the European Consumer Organisation (BEUC)
- Robin Doeswijk, Head of European Affairs, the European Hematology Association (EHA)
- Sibylle Reichert, Executive Director, the International Association of Mutual Benefit Societies (AIM)
- Matteo Poidomani, Senior Policy Advisor, Affordable Medicines Europe (AME)

Disclaimer: participation in the interview does not mean that an interviewee agrees with the recommendations concluded in this paper, and any mistakes or omissions in the paper are solely the responsibility of ECL.

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