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Right to health foundation

# DRIVING TRANSPARENCY IN THE PHARMACEUTICAL MARKET

## ACTIONS FOR THE SPANISH MINISTRY OF HEALTH

### CONTEXT

Five years after the adoption of World Health Assembly Resolution WHA 72.8 on transparency in pharmaceutical markets, challenges persist in the availability of information on prices, research and development (R&D) costs, and reimbursement mechanisms, among others. The opacity in these areas affects equity in access to medicines, hinders global health objectives, and calls into question the very concept of democracy.

The Ministry of Health plays a key role in implementing this resolution by advancing regulatory measures that ensure greater accountability and fairness in the pharmaceutical market. Below are a series of concrete actions to strengthen transparency and improve decision-making in drug pricing and access.

### 1. TRANSPARENCY IN PRICING AND R&D COSTS

**PROBLEM**

There is complete opacity regarding the final price paid for medicines, both among the general public and across different countries, distorting global price references and making accountability impossible. Likewise, the real cost of developing a drug remains unknown, making it impossible to assess whether the price paid is fair.

**SOLUTIONS**

- Implement all necessary measures to make net drug prices public, preferably through coordinated regional and global efforts. Promote, at the European level,

a review of the EU Transparency Directive on drug pricing[1] to ensure transparency in pricing procedures, net prices, and price types resulting from risk-sharing agreements.

- Explore the launch of a pilot mechanism for sharing net prices among countries at a global level, following the OECD proposal (1).

- Encourage international collaboration among hospitals to share net prices through networks such as the European Fair Pricing Network. Promote the creation of similar national mechanisms to share hospital-level net drug prices, preferably disaggregated, following initiatives like the Dutch Hospital Benchmark (2).

- Include a clear indication in the EURIPID database regarding which prices have been subject to discounts and confidentiality agreements, replicating models from Austria and Australia (3).

- Require pharmaceutical companies to disclose net prices in other European countries before negotiating price and reimbursement, as well as the type of risk-sharing agreement and information subject to confidentiality agreements, following Italy's example (4,5).

- Require pharmaceutical companies to report all direct and indirect funding—whether public, private, or philanthropic—in a disaggregated manner by development phase, within the framework of the upcoming RDL on Technology Assessment and the future Medicines Law. This follows examples from Italy and France (4,6) and aligns with the European Parliament's proposal in the negotiation of EU legislation (Article 57 of the Directive) (7).

- Condition all industry incentives—such as regulatory and market data protection, orphan drug exclusivity, PRIME schemes, and/or intellectual property protection—on greater transparency, as proposed in the European Parliament's amendment (1242-1244) for the creation of a new Article 84a (8).

- Prevent the Draft Medicines Law from contradicting the Transparency Law and the resolutions of the Council for Transparency and Good Governance. Only economic or financial information provided during the negotiation process will be considered confidential, but not the final price or reimbursement mechanisms established by the Administration and included in the public contract.

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1 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

## 2. TRANSPARENCY AND ACCESSIBILITY OF INFORMATION

**PROBLEM**

Information on the pricing and reimbursement process is scarce, and the available data is in formats that are difficult to use.

**SOLUTIONS**

- Continue initiatives such as publishing reports on drug financing decisions (9), improving transparency in the methodological foundations used to set prices and reimbursements, including detailed reports and final recommendations.

- Ensure that key information about the pricing process and outcome is accessible in reusable formats (CSV). Currently, the BIFIMED database does not include all relevant data, such as list prices, and the financing conditions lack clarity.

## 3. TRANSPARENCIA EN ENSAYOS CLÍNICOS

**PROBLEM**

The contribution of the public sector to clinical trials is unknown, and there is a lack of implementation of best practices by public trial funders.

**SOLUTIONS**

- Ensure the implementation of policies for the registration and reporting of clinical trials. This will improve transparency, prevent redundancies and resource waste, enhance health technology assessment processes, and ensure patient safety. The Carlos III Health Institute failed to comply with the 11 WHO-recommended best practices in clinical trial transparency (10), according to an independent investigation (11).

- Evaluate the implications of using public resources in clinical trials, quantifying the inputs provided by the public system following the "Transparency CORE" methodology (12).

## 4. TRANSPARENCY IN MONOPOLY DURATION

**PROBLEM**

Although patent documents are usually available, it is not easy to identify a definitive expiration date for the entire protection period. Additionally, there are other protections unrelated to the patent itself.

**SOLUTIONS**

- Require pharmaceutical companies to disclose and make public the maximum duration of all exclusivity periods benefiting a pharmaceutical product under evaluation and financing, including regulatory, market, or intellectual property protections. This should be published in an accessible manner with a single final expiration date, as highlighted in the Oslo Medicines Initiative (13). Examples to build upon include Italy (5), Germany (13), and, as a successful operability case, the Medicines Patent Pool database, Medspal (14).

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