

WHO Transparency Resolution: WHA 72.8

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Europe: A house divided

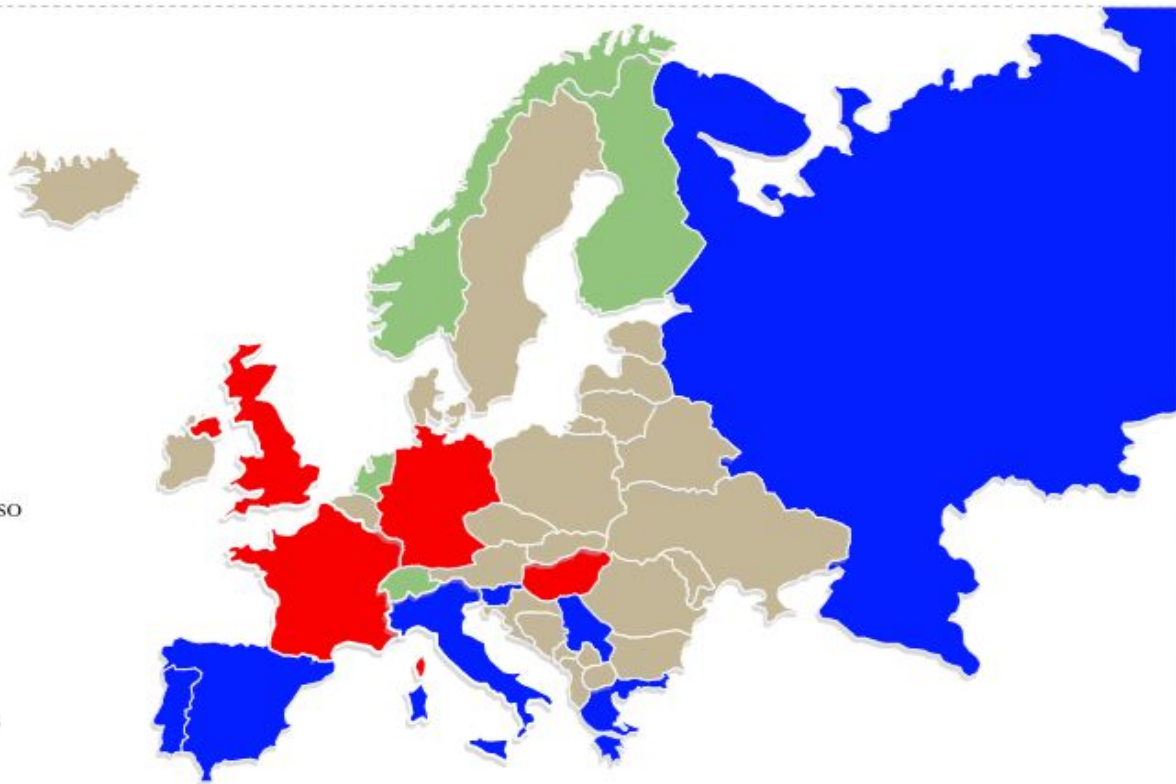
Missing on the map:
Sponsors of the WHO
transparency resolution also
include Andorra,
Luxembourg, and Malta

Legend

Blue: Official co-sponsors

Green: Supportive
countries

Red: Opponents



WHA72.8 Improving the transparency of markets for medicines, vaccines, and other health products.

The 2019 WHA adopted a resolution on transparency

1. Prices
2. Sales revenue (by country)
3. Units sold (by country)
4. Patent landscapes
5. Investments, subsidies
6. Know how

Most controversial element: R&D costs, including in particular, the costs of each clinical trial

Transparency resolution: mandate for member states

1. URGES Member States in accordance with their national and regional legal frameworks and contexts:

- (1) to take appropriate measures to publicly share information on the net prices of health products;
- (2) to take the necessary steps, as appropriate, to support dissemination and enhanced availability of, and access to, aggregated results data and, if already publicly available or voluntarily provided, costs from human subject clinical trials regardless of outcomes or whether the results will support an application for marketing approval, while ensuring patient confidentiality;
- (3) to work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives;
- (4) to facilitate improved public reporting of patent status information and the marketing approval status of health products;
- (5) to improve national capacities, including through international cooperation and open and collaborative research and development and production of health products, especially in developing countries and low- and middle-income countries (LMICs), including health products for the diseases that primarily affect them, as well as for product selection, cost-effective procurement, quality assurance, and supply chain management;

Transparency resolution: mandate for the World Health Organization

2. REQUESTS the Director-General to:

- (1) to continue to support Member States, upon their request, in collecting and analysing information on economic data across the value chain for health products and data for relevant policy development and implementation towards achieving universal health coverage;
- (2) to continue supporting Member States, especially LMICs, in developing and implementing their national policies relevant to the transparency of markets for health products, including national capacities for local production, rapid and timely adoption of generic and biosimilar products, cost-effective procurement, product selection, quality assurance and supply-chain management of health products;
- (3) to support research on and monitor the impact of price transparency on affordability and availability of health products, including its effect on differential pricing, especially in LMICs and small markets, and provide analysis and support to Member States in this regard as appropriate;
- (4) to analyse the availability of data on inputs throughout the value chain, including data on clinical trials and price information, with a view to assessing the feasibility and potential value of establishing a web-based tool to share information relevant to the transparency of markets for health products, including information on investments, incentives, and subsidies;
- (5) to continue WHO's efforts to biennially convene the Fair Pricing Forum with Member States and all relevant stakeholders to discuss the affordability and transparency of prices and costs relating to health products;

Transparency resolution: mandate for the World Health Organization

2. REQUESTS the Director-General to:

(6) to continue supporting existing efforts to determine the patent status of health products and promote publicly available user-friendly patent status information databases for public health actors, in line with the global strategy and plan of action on public health, innovation and intellectual property, and to work with other relevant international organizations and stakeholders to improve international cooperation, avoid duplication of work, and promote relevant initiatives;

(7) to submit a report on progress made to the Seventy-fourth World Health Assembly, through the Executive Board at its 148th session

State practice: Italy's implementation of the WHO transparency resolution

On 1 August 2019, the Italian Minister of Health and the Minister of Economy and Finance unveiled a new price and reimbursement decree which implemented key elements of the WHO transparency resolution.

As noted by Italy at the WHO Regional Committee for Europe (19 September 2019),

“The Decree includes some important aspects related to transparency. In particular, the **pharmaceutical companies seeking reimbursement from the National Health System, are requested to provide information on marketing, sales and reimbursement in other countries, including negotiated prices.** Moreover, **information should be provided with regard to public contributions and incentives received on research and development (R&D) programs, as well as clear and up to date information on the patent status** of the concerned medicinal product. Finally, the pharmaceutical companies, as part of the final agreement for medicines reimbursed by the National Health System, will be **obliged to provide annual reports regarding sales data, revenues and marketing expenses.**”

State practice: United States - S.1801 - Affordable Medications Act

On 12 June 2019, 15 US Senators introduced S.1801, a bill to make medicines more affordable.

S. 1801: Affordable Medications Act

Ms. Smith (for herself, Ms. Klobuchar, Mr. Blumenthal, Mr. Udall, Mr. Brown, Ms. Warren, Mr. Sanders, Ms. Hassan, Mr. Whitehouse, Mr. Merkley, Mr. Reed, Ms. Baldwin, Mr. Booker, Mr. Durbin, and Mrs. Gillibrand) introduced the following bill; which was read twice and referred to the Committee on Finance.

This proposed bill would required applicable manufacturers of approved drugs and biologic products an annual report to the Secretary of Health and Human Services and Congress an annual report detailing the following for each such drug: the total expenditures of the manufacturer on domestic and foreign drug research and development, including an itemized description of—

“(I) basic and preclinical research;

“(II) clinical research, broken out by clinical trial phase;

“(III) development of alternative dosage forms and strengths for the drug molecule or combinations, including the molecule

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“(G) any Federal benefits received by the manufacturer, including the amounts and periods of impact for each such benefit, including tax credits, patent applications that benefited from a Federal grant, patent extensions, exclusivity periods, and other Federal benefits with respect to such drug; and

“(H) the percentage of research and development expenditures on—

“(i) activities conducted by the manufacturer;

“(ii) activities funded by Federal entities; and

“(iii) activities conducted by other entities such as academic institutions or other drug manufacturers;

“(2) executive compensation for the chief executive officer, chief financial officer, and the three other most highly compensated executive officers, including bonuses, paid by such manufacturer, and stock options affiliated with the manufacturer that were offered to or accrued by such officers;

Secrets to success: Active and determined civil society social media campaign

← **Katy Athersuch** 2,957 Tweets Following

Katy Athersuch @Kathersuch · May 27
For the negotiators of the [#transparencyResolution](#) this evening: some food for thought [#WHA72](#) [#NoMoreSecrets](#)



↳ Katy Athersuch Retweeted

Bernie Sanders @SenSanders · May 25
I understand President Trump is blocking a resolution at the [@WHO](#) that would require drug companies to disclose actual R&D costs for pharmaceutical drugs. Nobody should believe Mr. Trump when he talks about taking on Big Pharma.

WHO drug pricing talks may fail to end secrecy, acti...
Governments are working on a drug pricing transparency deal at the World Health Organization'...
REUTERS [reuters.com](#)

Pauline Londeix @londeixp · May 24

Alors qu'on approche des derniers jours de négociations, la France [@FranceONUGeneve](#) se plaint de la procédure sur pour bloquer la résolution sur la transparence. De quoi avez-vous peur [@S_Seydoux](#) [@agnesbuzyn](#) ? [#hontealafrance](#) [@PBenkimoun](#) [@IanBrossat](#) [@PierreSerne](#) [#WHA72](#)



A LA FRANCE
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Repository of information on the WHO transparency negotiations:

<https://www.keionline.org/transparency/wha72>

Negotiations on 72nd World Health Assembly (WHA) resolution on transparency

See <https://keionline.org/transparency> for links to research materials and blogs.

Background Memo on Transparency Norms

2019. February 18. [Note prepared for WHA negotiations on transparency resolution](#)

[Examples of SEC disclosures](#)

Negotiating texts for WHA 72, on transparency.

February 1, 2019. Draft resolution, as [sent to WHO: italy-draft-resolution-transparency-72WHA-.pdf](#)

April 29, 2019. Italy and 10 co-sponsors: Greece, Malaysia, Portugal, Serbia, Slovenia, South Africa, Spain, Turkey, Uganda, share a revised text. [Dif-April29-May7-WHA-Transparency-Resolution.pdf](#)

May 7, 2019. Text with brackets, after first informal negotiation at WHO. [Dif-April29-May7-WHA-Transparency-Resolution.pdf](#)

May 10, 2019. Text with brackets, after second informal negotiation at WHO. [WHA-Resolution_DRAFT_10May1740.](#)

See also table comparing April 29, May 7 and May 10. [Dif-May-10-7-and-April-29-WHA-Transparency-Resolution.pdf](#)

May 20, 2019. Version as introduced on first day of the WHA72: [A72_ACONF2-en](#)

May 22, 2019. Version at end of day on May 22, 2019, published by WHO morning of May 23, 2019. Removed from WHO web page on morning of May 24, 2019, after several countries opposing transparency bitterly objected to having the country positions in the negotiation made public. [A72_ACONF2-en-May22](#)

Resolution A72/A/CONF./2 Rev.1

[Resolution A72/A/CONF./2 Rev.1](#), approved by the 72nd World Health Assembly (WHA)

Resolution WHA72.8

[Official version of resolution WHA72.8](#) adopted by the Seventy-second World Health Assembly on 28 May 2019.