AGENZIA ITALIANA DEL FARMACO

Tutela Ricerca e Sviluppo per la Salute

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

Federica Mammarella

ESIP Meeting, ROME, 24 Sept 2019

Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 preavious years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	x	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	x	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	x	☐	☐	☐ optional
2. Consultancy for a company	x	☐	☐	☐ optional
3. Strategic advisory role for a company	x	☐	☐	☐ optional
4. Financial interests	x	☐	☐	☐ optional
5. Ownership of a patent	x	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	x	☐	☐	☐ optional
7. Investigator	x	☐	☐	☐ optional
8. Grant or other funding	x	☐	☐	☐ optional
9. Family members interests	x	☐	☐	☐ optional

*Federica Mammarella, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts.

N.B. I am not receiving any compensation

The TRANSPARENCY RESOLUTION

Feb 2019

- Italian call for international action to increase the transparency; Italian submission of a DRAFT WHO Resolution

May 2019

- Approval of the final text of Transparency Resolution during WHA

World Health Organization

SEVENTY-SECOND WORLD HEALTH ASSEMBLY
Agenda item 11.7

A72/A/CONF./2 Rev.1
28 May 2019

Improving the transparency of markets for medicines, vaccines, and other health products (FOOTNOTE)

Draft resolution proposed by Andorra, Brazil, Egypt, Eswatini, Greece, India, Italy, Kenya, Luxembourg, Malaysia, Malta, Portugal, Russian Federation, Serbia, Slovenia, South Africa, Spain, Sri Lanka, Uganda

Steps towards the TRANSPARENCY I

1988, December 21	• EU Directive on transparency on pricing of medicinal products
2008, May 15-16	• Medicines Transparency Alliance launch
2016, February 18	• Joint NGO, member of EU parliament submission to UN SG HLP on A2M
2016, May 3	• Report on Access to Health Services in the European Union
2017, May 11	• Fair Pricing Forum, Amsterdam
2018, January 17	• EU Report on Innovative Payment Models for High-Cost Innovative Medicines

Steps towards the TRANSPARENCY II

2018, May 30	• Vermont Act 193
2018	• The OECD Report on Drug Pricing
2018, December	• WHO Draft RoadMap for access to medicines, vaccines and other health products, 2019-2023
2018, December 18	• WHO Report: Pricing of cancer medicines and other health products
2019, February 5	• State of the Union Address, by USA President

Main issues of cost and prices transparency

- ✓ Limited data from clinical trials
- ✓ Unclear investment flows for research and development
- ✓ Lack of information on patent landscape
- ✓ High prices and unequal access to health
- ✓ Accountability of institutions on public spending

2019, May 29 — Transparency Resolution

- The concern about high prices for some health products
- The need for publicly available information on data across the value chain of health products and on patent landscape
- The need for comparable price information
- The need for more tranparency of both public and private sector funding for health products

AFFORDABLE AND EQUITABLE ACCESS TO HEALTH PRODUCTS

UNIVERSAL HEALTH COVERAGE

“Policies that influence the pricing of health products and that reduce barriers to access can be better formulated and evaluated when there is reliable, comparable, transparent and sufficiently detailed data across the value chain”

Transparency resolution to Member States I

1.1 Take appropriate measures to publicly share information on the net prices of health products;

1.2 Take the necessary steps, as appropriate, to support dissemination of 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;

Transparency resolution to Member States II

1.3 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;

1.4 Facilitate improved public reporting of patent status information and marketing approval status of health products;

1.5 Improve national capacities, including through international cooperation, open and collaborative research for development and production of health products, especially in developing countries and low- and middle-income countries (LMICs), including for diseases that primarily affect them, as well as for product selection and cost-effective procurement, quality assurance, and supply chain management;

Transparency resolution to WHO Director-General I

2.1 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 (UHC);

2.2 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;

Transparency resolution to WHO Director-General II

2.3 Support research on and monitor the impact of price transparency on affordability and availability of health products, including the effect on differential pricing, especially in LMICs and small markets, and provide analysis and support to Member States in this regard as appropriate;

2.4 Analyse the availability of data on inputs throughout the value chain, including on clinical trial data 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 investments, incentives, and subsidies;

Transparency resolution to WHO Director-General III

2.5 Continue WHO's efforts to biennially convene the Fair Pricing Forum with Member States and all relevant stakeholders to discuss affordability and transparency of prices and costs relating to health products;

2.6 Continue supporting the existing efforts for determining patent status of health products and promoting 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;

2.7 Report to the Seventh-fourth World Health Assembly (through EB148) on progress made in implementing this resolution.

First statements

"We addressed one of the most complex and polarising issues in 21st century global health..."

Silvia Paula Valentim Lutucuta
Chair of the WHA Committee

"Landmark agreement"

Tedros Adhanom Ghebreyesus
Director General of WHO

Health Policy Watch
Independent Global Health Reporting

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World Health Assembly Approves Milestone Resolution On Price Transparency

28/05/2019 by Elaine Ruth Fletcher

MEDEV SURVEY on WHO resolution I

The Transparency Resolution will

- facilitate access to health product for patients
- facilitate a more equitable access to health products for patients
- promote competitiveness among pharmaceutical companies
- allow a more affordable and fair pricing of heath products, by stimulating a greater level of competition in the pharmaceutical market

MEDEV SURVEY on WHO resolution II

The Transparency Resolution will

- facilitate the development and implementation of national policies to enhance the transparency of pharmaceutical market.
- promote and facilitate the development and implementation of national policies for a rapid and timely adoption of generics and biosimilars.
- promote and facilitate the development of more cost-effective procurements.

MEDEV SURVEY on WHO resolution III

The Transparency Resolution will

- help to clarify the main determinants for pricing of health products
- support the collaboration of Member States in sharing important information on the life-cycle of health products.
- promote and facilitate the supply-chain management of health products

Comments & suggestions from MEDEV

- The content of the “Transparency resolution” meets one of the main topics of Beneluxa Initiative

Transparency of prices

The members of the Beneluxa Initiative highly value transparency as a key contributor to achieving sustainability of access to medicines. Transparency will assist in improving insight into the inner workings of the pharmaceutical value chain. We strongly support access to data generated by clinical research, including negative and inconclusive outcomes. We welcome a wide debate on these topics and further discussion at international level. The first concrete step should be to create price transparency among countries.

- This resolution is considered a positive result but we should act quickly to realize the aim through concrete programs and actions

- To assess the reasons for dissociation of some Countries

Steps towards the future

2019, August 

Inter-ministerial committee for economic planning Deliberation

•CONSIDERING the **Resolution WHA 72/2019**;

•CONSIDERING that in the first phase of price negotiation of drugs charged to the NHS between AIFA and the pharmaceutical company, updated and adequate criteria should be guaranteed for the continuous evolution of the drug policy, as well as for **complying with the necessary transparency**;

2019, August 

Inter-ministerial committee for economic planning Deliberation

Istance of negotiation

➢ Art 2

The company shall support its instance of negotiation with:

- self-certified information on the medicinal product subject to negotiation regarding marketing information, usage and reimbursement in other countries, and in this case at what price and reimbursement conditions, including any further negotiation agreement; (art. 2, paragraph 2.c)
- self-certified quantification of any public contributions and incentives with the purpose of fostering drug research and development programs; (art. 2, paragraph 2.g)
- any other information that may be useful for the purposes of negotiation, including the patent status of the medicinal product. (art. 2, paragraph 2.j)

2019, August

Inter-ministerial committee for economic planning Deliberation

Negotiation procedure

- Art. 3

When there are no comparative medicinal products, the company presents Economic evaluations according to the indications referred to paragraph 1 of this determination, supplemented by **adequate documentation aimed at justifying the price proposal also depending on the sustained costs relating to R&D and production** (art. 3, paragraph 7)

2019, August

Inter-ministerial committee for economic planning Deliberation

Negotiated Agreement I

➢ Art. 4

The negotiation procedure is finalized through an agreement between AIFA and the pharmaceutical company with the definition of the conditions of reimbursement and **price taking into account the conditions** listed below:

- sales volume;
- poduct availability for the NHS;
- discounts for supplies to the NHS institutions;
- public incentives to drug development and research programs

(art. 4, paragraph1)

2019, August

Inter-ministerial committee for economic planning Deliberation

Negotiated Agreement II

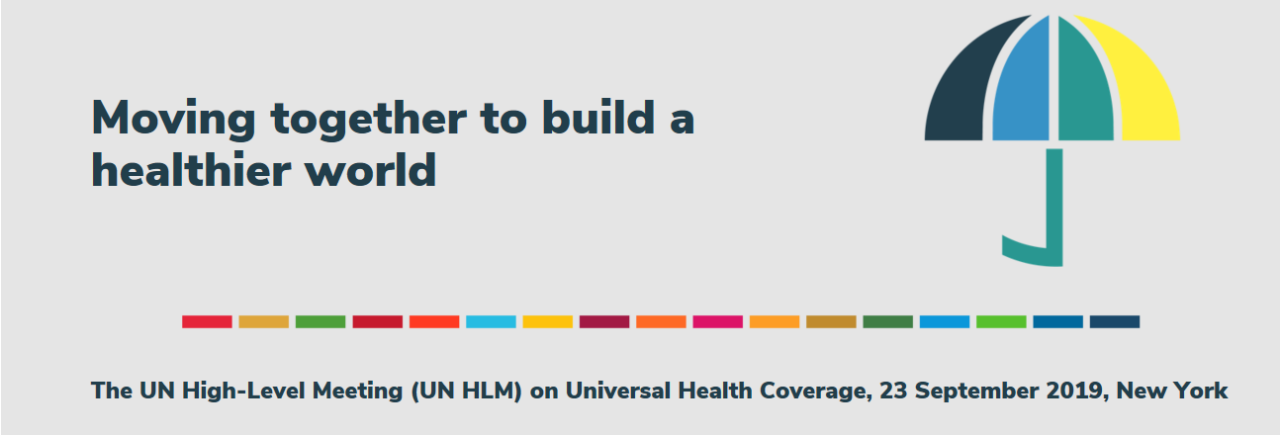
- Art. 4

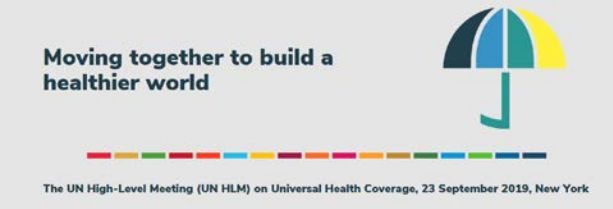
the **obligation that AIFA is annually informed** of the **sales data**, **Turnover, marketing costs** and the **patent status** of the medicine in Italy as well as to report any differences with respect to what was previously defined. (art. 4, paragraph 2.a)

Latest news

2019, September 23

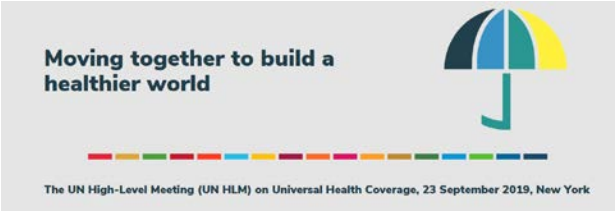
- The UN High-Level Meeting on universal Health Coverage, NY





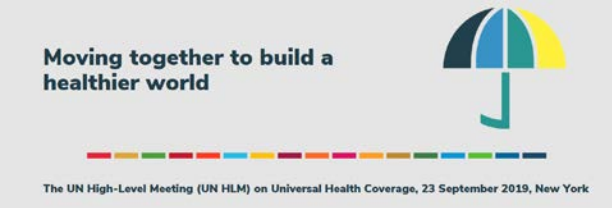
- Art. 50

Improve availability, affordability and efficiency of health products by increasing transparency of prices of medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health technologies across the value chain, including through improved regulations and building constructive engagement and a stronger partnership with relevant stakeholders, including industries, private sector and civil society, in accordance with national and regional legal frameworks and contexts, to address the global concern on high prices of some health products and in this regard encourage WHO to continue its efforts o 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;



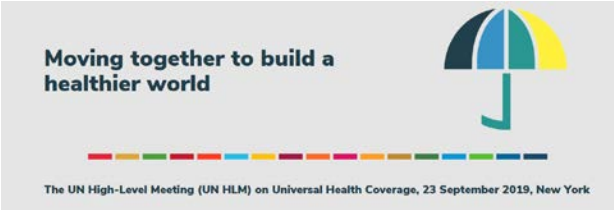
- Art 51

  Promote increased access to affordable, safe, effective and quality medicines, including generics, vaccines, diagnostics and health technologies, reaffirming the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as amended, and also reaffirming the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health, which recognizes that intellectual property rights should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all, and notes the need for appropriate incentives in the development of new health products;



- Art 52

  Explore, encourage and promote a range of innovative incentives and financing mechanisms for health research and development, including a **stronger and transparent partnership between the public and the private sectors as well as the academia**, recognizing the need for increasing public health-driven research and development that is needs-driven and evidence-based, guided by the core principles of safety, affordability, effectiveness, efficiency, **equity** and considered as a shared responsibility, as well as appropriate incentives in the development of new health products and technologies;



- Art 53

  Recognize the important role played by the private sector in research and development of innovative medicines, encourage the use, where appropriate, of alternative financing mechanisms for research and development as a driver of innovation for new medicines and new uses for medicines and continue to **support voluntary initiatives and incentive mechanisms that separate the cost of investment in research and development from the price and volume of sales, facilitate equitable and affordable access to new tools and other results to be gained through research and development**;

Take steps towards TRANSPARENCY

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