



AGENZIA ITALIANA DEL FARMACO

Tutela Ricerca e Sviluppo per la Salute

TRASPARENZA NEL CICLO DI VITA DEL FARMACO

Luca Li Bassi

Il Panorama attuale

- Asimmetria informativa fra soggetti pubblici e privati;
- Dati limitati provenienti da studi clinici;
- Flussi di finanziamento per R&S non chiari, carenti e spesso assenti;
- Mancanza di informazioni sulla disponibilità e rimborsabilità dei farmaci;
- Mancanza di dati facilmente accessibili sui brevetti e scadenza dei relativi diritti di proprietà intellettuale;
- Prezzi elevati e accesso iniquo;
- Responsabilità delle istituzioni in materia di spesa pubblica.

Verso una maggiore trasparenza

- 1988. December 21. EU Directive on transparency on pricing of medicinal products.
- 2015. Resolution 2071 (2015) of the Council of Europe: Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?
- 2016. February 18. Joint NGO, member of EU parliament submission to UN SG HLP on A2M.
- 2016. May 3. Expert Panel on effective ways of investing in Health (EXPH) Report on Access to Health Services in the European Union.
- 2018. January 17. EU Report on Innovative Payment Models for High-Cost Innovative Medicines.
- 2018. July. EURIPID guidance document on external reference 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 its impacts.
- 2018. The OECD Report on Drug Pricing.

Proposta Italiana di Risoluzione all'OMS (1/2/2019)

- Raccogliere e analizzare i dati sui risultati degli studi clinici e sugli effetti avversi dei farmaci e delle altre tecnologie sanitarie;
- Fornire ai governi un forum per la condivisione di informazioni su prezzi dei farmaci, ricavi, costi di ricerca e sviluppo, investimenti del settore pubblico e sussidi per la ricerca e lo sviluppo, costi di marketing e altre informazioni correlate;
- Fornire informazioni cruciali sul panorama brevettuale, comprese informazioni sulle controversie relative alla validità e/o rilevanza dei brevetti dichiarati;
- Intraprendere ulteriori azioni attraverso riunioni e forum al fine di favorire ulteriori progressi in materia.

Media Interest

Médecins Sans Frontières On Drug Prices – You Can't Negotiate Blindfolded
27/02/2019 by [Elaine Ruth Fletcher](#)

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Italy's Draft WHO resolution: Improving the transparency of markets for drugs, vaccines and other health-related technologies
Posted on February 16, 2019 by K&I Staff

STAT+
Italy proposes the WHO set international standards for drug-pricing transparency

By ED SILVERMAN @Pharmdot / FEBRUARY 14, 2019

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14 February 2019
DRUG PRICING — ITALY EYES GLOBAL TRANSPARENCY PUSH: With the backing of 5Stars Health Minister Giulia Grillo, Italy is poised to become a new champion of the international campaign for drug pricing transparency.

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BECKER'S **HOSPITAL REVIEW**
Will the WHO set international standards for drug pricing transparency? Italy wants it to
Alia Paavola - Friday, February 15th, 2019 Print | Email
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Civil Society Interest

March 6, 2019

Open letter to WHO member states

On 1 February 2019, Italy submitted a draft resolution on transparency to the World Health Organization (WHO). This resolution is to be discussed in May 2019, at the 72nd session of the World Health Assembly (WHA).

The title of the proposed resolution is "Improving the transparency of markets for drugs, vaccines and other health-related technologies," and it sets out a number of measures designed to achieve this objective .

There are deplorable asymmetries of access to information about many aspects of the innovation and supply chain for medicines, vaccines and other health technologies. The lack of information creates confusion about basic facts related to prices, research and development costs and other aspects of the value chain for medicines, vaccines and health technologies.

The resolution would create a work program for the WHO and norms for governments to cooperate in improving the transparency of various aspects of these technologies.

This is a critical time for governments to consider reforms in pricing and incentives for innovation for health technologies. The transparency measures proposed in the resolution will ensure that consideration of such reforms will be based upon the best possible evidence.

We urge your government to support the resolution.

Open letter supporting Italy's proposed resolution on Improving the transparency of markets for drugs, vaccines and other health-related technologies

Signed by:

83 Organizations

20 Individuals