World Health Assembly May 2019
Debate on transparency in R&D and medicines pricing

A vigorous debate is occurring at the WHA in Geneva over the need for R&D cost transparency leading to availability of medicines at affordable prices. Italy has submitted a resolution that is supported by some, modified by others and opposed by others.

Here are detailed analyses of what is happening.

- Italy submits drug pricing transparency resolution to WHO
- Italy and 11 co-sponsors introduce transparency resolution text to WHA72
- Improving the transparency of markets for medicines, vaccines, and other health-related products and other technologies to be discussed at the 72nd session of the WHA to be held on 20-28 May 2019
- Push for drug pricing transparency strikes a nerve with industry
- Side event: Health Policy Watch: Several Ministers Of Health Speak Up For Drug Market Transparency, Lower Prices At WHA Side Event
- Clinical trials: Roche and Novartis neglect their ethical responsibility in emerging countries

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Italy submits drug pricing transparency resolution to WHO

By Sarah Wheaton and Helen Collis
5/20/19

The Italian government formally submitted late today a new draft of its resolution <https://politico.us8.list-manage.com/track/click?u=e26c1a1c392386a968d02fdbc&id=8e79a1b04c&e=3e3aedc8a6> on medicine cost and pricing transparency for consideration at the World Health Assembly, a health ministry spokeswoman said.

The submission, just ahead of today's deadline, means the resolution will be considered during the discussion about access to medicines at the World Health Organization's annual gathering of all member countries in Geneva.

The latest version shows Italy rejected some attempts by countries to weaken the resolution; for example Germany, Switzerland, Denmark and the U.S. did not want to make public the costs incurred by carrying out clinical trials.

Italy instead leaned towards suggestions by countries including Greece and Ecuador to strengthen the resolution, by including for example, a declaration about enhancing publicly available information on the 'costs throughout the value chain' of medicines, vaccines, cell and gene therapies.
The submission shows Italy is determined to press forward with the transparency initiative, despite initial grumbling from some other EU countries that the government did not go through the normal process of bringing such matters to the Council of the EU first, as well as calls for consideration of the measure to be postponed until next year.

Beyond Italy's original nine cosponsors which included Greece, Portugal, Slovenia and Spain, Tunisia and Egypt signed on to today's version of the resolution.
https://www.swissinfo.ch/eng/business/world-health-assembly_push-for-drug-pricing-transparency-strikes-a-nerve-with-industry/44969974

Italy and 11 co-sponsors introduce transparency resolution text to WHA72

[Copied from Ip-health with thanks]

https://www.keionline.org/30793

Jamie Love: Politico has published a copy of the new draft of the World Health Assembly (WHA) transparency resolution. The Politico account cites the disclosure of clinical trial costs as one area for transparency that is strongly opposed by the pharmaceutical industry (and governments responsive to the pharma industry lobbies).

Over all, the newest version of the resolution contains several changes, following informal negotiations on the text, but is still quite strong -- in some areas stronger than the previous version, and in others more nuanced and flexible for governments.

Negotiations on the text will continue through the week. In the several days, a number of countries have announced support for the proposal, in whole or in part. Today there was a side event sponsored by the Republic of Korea, Italy and 14 other countries, where the transparency resolution was discussed extensively, by governments, often by Ministers, in a positive light. The side event was held in a large room, but ran out of chairs, and many participants, if they could get in at all, had to stand.

Civil society activists in France appear to have had considerable influence on the French position, and some of the most aggressive opponents of a restitution on transparency have moderated their opposition, or announced they support a resolution on transparency, at this WHA. The US has been more constructive than expected earlier. Germany and the UK are among the strongest opponents of the resolution, and some countries still see anything dealing with R&D cost transparency as a threat to drug company interests.

This is just the opening of the negotiations, and the pharma lobby against transparency is quite strong, well funded, and well organized, working closely with several governments to weaken, delay or block the resolution, or elements of the transparency proposals.

Disclosure of clinical trial costs, the major R&D cost factor and one that is straightforward to assign to specific products, remains a major area of controversy, and drug companies are concerned that if the actual costs are disclosed, their narratives about massive R&D costs will undermined, by facts.

The drug companies have sought to raise, through government delegations responsive to drug company lobbies, a number of process related manoeuvers designed to bog the progress down with proposed bad faith amendments, procedural hurdles, and perhaps to extend the negotiations into the weekend, when many countries will no longer have subject matter experts available. At the same time, the civil society lobby on behalf of robust transparency has been impressive in its energy, breadth and strength.

Jamie

From IP health continued:

Improving the transparency of markets for medicines, vaccines, and other health-related products and other technologies to be discussed at the 72nd session of the WHA to be held on 20-28 May 2019

Draft resolution proposed by Italy, Greece, Egypt, Malaysia, Portugal, Serbia, Slovenia, South Africa, Spain, Tunisia, Turkey, Uganda Provisional Agenda Item 11.7

VERSION 20 May 2019 The Seventy-Second World Health Assembly

1. Having considered the Report by the Director-General on Access to medicines and vaccines (document A72/17) and its annex 'Draft Road Map for access to medicines, vaccines, and other health products'[illegible] and the Report by the Director-General on Medicines vaccines and health products, Cancer medicines (document EB144/18), pursuant to resolution WHA70.12;

2. Recognizing that improving access to health-related products and other technologies is a multi-dimensional challenge that requires action at, and adequate knowledge of, their entire value chain and life cycle, from research and development to quality assurance, regulatory capacity, supply chain management and use;

3. Recognizing the critical role played by health products and services innovation in bringing new treatments and value to patients and healthcare systems around the world;

4. Concerned about the high prices for some medicines, vaccines, cell and gene therapies, diagnostic tests and other health-related products and services, and the inequitable access within and among Member States as well as the financial hardships associated with high prices which can impede progress toward Universal Health Coverage.

5. Recognizing that publicly-available data on prices and costs are scarce and that the availability of price and cost information is important for facilitating Member States' efforts towards the introduction of and affordable access to new medicines, vaccines, cell and gene therapies, diagnostic tests and other health-related products and services

6. Seeking to enhance the publicly available information on the actual prices applied in different sectors, in different countries, recognizing differences in health systems and differential pricing systems;

7. Commending the productive discussions at the last Fair Pricing Forum in South Africa regarding the promotion of greater transparency around prices of medicines, vaccines, cell and gene therapies, diagnostic tests and other health technologies, especially through sharing of information in order to stimulate the development of healthy and competitive global markets;

8. Noting the importance of both public and private sector funding for research and development of medicines, vaccines, cell and gene therapies, diagnostic tests, and other health technologies, and seeking to improve the level of information about them, in accordance with national legislations, concerning the allocation of investments and the costs for research and development, including costs incurred for conducting the clinical trials involving human subjects in order to obtain marketing approval, reimbursement or coverage for products or services;

9. Seeking to progressively enhance the publicly available information on the costs throughout the value chain of medicines, vaccines, cell and gene therapies and diagnostic tests and other health products and services and the patent landscape of medical technologies, while welcoming recent initiatives to achieve this goal;

10. Noting the latest Declaration of Helsinki, which promotes making publicly available the results of clinical trials, including negative and inconclusive as well as positive results, and noting that public access to complete and comprehensive data on clinical trials is important for promoting the advancement in science and successful treatment of patients, provided the need for protection of personal patient information;

11. Agreeing that policies that influence the pricing of health products and services or the appropriate rewards for successful research outcomes should consider and can be better evaluated when there is reliable, transparent and sufficiently detailed data on the costs of R&D inputs (including information on the role of public funding and subsidies), and the medical benefits and added therapeutic value of products;

12. Seeking to have better evidence of the units sold and reaching patients in different markets in order to evaluate the efficacy of health systems and the impact of the variety of barriers to access health related products and services.

1. URGES Member States, within the context of their own legal system and practice, to:

Opt 1.1. Undertake measures to publicly share information on prices and reimbursement cost of medicines, vaccines, cell and gene-based therapies and other health technologies;

Opt 1.2. Require the dissemination of results and costs from human subject clinical trials regardless of outcome or whether the results will support an application for marketing approval, while also taking appropriate steps to promote patient confidentiality;

Opt 1.3. Require the following information be made public for medicines, vaccines cell and gene-based therapies and other relevant technologies;

a) Annual Reports on sales revenues, prices and units sold,

b) Annual Reports on marketing costs incurred for each registered product or procedure,

c) The costs directly associated with each clinical trial used to support the marketing authorization of a product or procedure, separately, and

d) All grants, tax credits or any other public sector subsidies and incentives relating to the initial regulatory approval and annually on the subsequent development of a product or service;

Opt 1.4. Improve the transparency of the patent landscape of medical technologies, including but not limited to biologic drugs, vaccines and cell and gene therapies and diagnostic tests.

Opt 1.5. Report to the WHA 73 on the use of generic and/or biosimilar products and health services, and the policies and information that governments have used to enable early market entry, substitution and uptake of such products and services, including in particular those recommended by WHO in its guidelines.

Opt 1.6. Collaborate on the production of and open dissemination of research and know-how regarding the developing, manufacturing and supply of medicines, vaccines, cell and gene therapies and diagnostic tests, and help build national capacities of especially the LMIC countries and for diseases that primarily affect them, supported by WHO.

2. REQUESTS the WHO Director-General to:

Opt 2.1. Support Member States by providing tools and, upon their request, guidance, in collecting and analysing information on prices, costs and clinical trials outcome data for relevant policy development and implementation towards Universal Health Coverage (UHC);

Opt 2.2 Support Member States, especially the LMIC countries, in partnership with relevant stakeholders, to promote access to research and the know-how to manufacture and otherwise provide generic medicines, medicines, vaccines, cell and gene therapies, diagnostic tests and other products and services.

Opt 2.3 Collect and analyse clinical trial data with regard to medicines and the procurement prices of medicines and vaccines from national and international agencies.

Opt 2.4 Propose a model/concept for the possible creation of a web-based tool for national governments to share information, where appropriate, on medicines prices, revenues, units sold, patent landscapes, R&D costs, the public sector investments and subsidies for R&D, marketing costs, and other related information, on a voluntary basis.

Opt 2.5. Create a forum for relevant experts and stakeholders, consistent with FENSA, to develop, suitable options for alternative incentive frameworks to patent or regulatory monopolies for new medicines and vaccines that could better serve the need of Member States to attain Universal Health Coverage and the need to adequately reward innovation, utilizing information from expanded transparency of markets health-related innovations.

Opt 2.6 Create a biennial forum on the transparency of markets for medicines, vaccines and diagnostics, to evaluate progress toward the progressive expansion of transparency,

Opt 2.7 Continue its efforts to periodically convene a Fair Pricing Forum with all relevant stakeholders to discuss affordability and transparency of prices and costs relating to health-related products and services.

Opt 2.8 Formalize the biennial Fair Pricing Forum which creates a critical opportunity to discuss transparency of markets for medicines, vaccines, cell and gene therapies and diagnostics, and to evaluate progress toward the progressive expansion of transparency.

Opt 2.9 Provide a report to the 146th session of the Executive Board on the measures that are needed for the WHO Global Observatory on Health R&D to enhance the reporting on pre-clinical investments in R&D by both the public and the private sectors.

Opt 2.10 Submit a report to the EB 146 and EB 147 on progress in implementing this resolution.

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Push for drug pricing transparency strikes a nerve with industry

By Jessica Davis Plüss

<https://www.swissinfo.ch/eng/profiles-swissinfo/jessica-davis-pluess>

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Ahead of the World Health Assembly in Geneva, an Italian draft resolution to end secrecy around drug pricing has already ruffled feathers among some governments and industry players. Could Italy be on to something?

The resolution <http://www.salute.gov.it/imgs/C_17_notizie_3670_listaFile_itemName_1_file.pdf> proposed by Italy's Minister of Health Giulia Grillo in February urges the World Health Organization (WHO) and governments to boost transparency in four areas: drug prices, R&D costs, clinical trial data, and patent information.

Arriving late in the typical resolution submission process, a frenzied review of the text revealed sharp divisions among governments. It quickly gained widespread support from many NGOs and struck a nerve with some in the pharmaceutical industry.

The fact that documents from closed-door sessions were made open-source by some media helped draw attention to the debate.

But another reason the resolution is creating such buzz is that it shines a spotlight on the well-kept secrets around how drug prices are determined.

This raises uncomfortable questions about which governments are benefiting from special deals and how companies might be profiting from high drug prices.

Switzerland has a stake in the discussions as a WHO member state but also as home to some of the largest pharmaceutical companies, including Roche and Novartis. Why now?

Access to medicines has long been considered a developing country issue of vaccines and basic medicines. But the rise in chronic diseases and expensive life-saving treatments is bringing the access debate to rich countries worried about the burden on healthcare budgets.

The sense of urgency is growing as people wrestle with the shock of a $475,000 cancer drug. Or a $4 million (CHF4 million) drug to treat spinal muscular atrophy.

Supporters of the resolution argue that transparency is essential to determine a fair price for medicines and ultimately make them more affordable. A recent OECD report on the industry reinforced this, stating that, 'R&D costs and pricing structures are often opaque, raising legitimate questions about the value offered by some increasingly costly new treatments.'

WHO's definition of a fair drug price

A 'fair' price is one that is affordable for health systems and patients and that at the same time provides sufficient market incentive for industry to invest in innovation and the production of medicines.

While transparency has been discussed in global health circles for years, Swiss Global Health Ambassador Nora Kronig told swissinfo.ch that seeing transparency as a way to improve access to medicines is a new development.

"This has become more important to member states as they face the huge challenge of rare diseases and expensive treatments for diseases like cancer," she said.

In Switzerland, the cost of medicine per person has increased by 13% in just three years to CHF814 in 2017. The costs are largely driven by oncology and expensive combination therapies, explained the Federal Office of Public Health (FOPH) at a press conference earlier this month. The FOPH estimates that nearly half of the 90 or so requests for approval last year were for treatments exceeding CHF100,000 ($99,097) per person per year.

Late last year, the Federal Council (executive body) proposed a cost containment programme recognizing the gravity of the situation.

Debates on the topic are not only raging in Switzerland. In February, seven executives of top pharmaceutical companies were grilled in a 3-hour US congressional hearing about skyrocketing drug prices. Lowering drug prices has become one of the rare issues on which a deeply divided US government agrees.

Even investors are sounding the alarm. At the Novartis annual general meeting a few days after the Senate hearing, Swiss shareholder group Actares said insurance systems are being 'taken hostage' by high prices for life-saving drugs.

Sticking points

Kronig strongly supports transparency on prices at an international level.

Switzerland sets drug prices based on a comparison to nine other countries and negotiations with individual manufacturers. But it is common knowledge that many countries receive special discounts from companies on certain drugs. Kronig says 'this means that the basket of prices we use for comparison is wrong. In a sense, we lose because we are the only ones that are transparent.'

But the industry is pushing back, arguing that transparency could have unintended consequences. Both Roche and Novartis referred swissinfo.ch to the International Federation of Pharmaceutical Manufacturers and Associations (IPFMA) for industry perspective.

Director General of IFPMA Thomas Cueni argues that 'requiring the disclosure of confidential discounts and other commercial pricing arrangements would not benefit patients, but rather would impose new burdens on companies, could undermine differential pricing that benefits poorer countries, and disrupt market competition.'

Some recent research also expresses concern that price transparency, particularly for on-patent medicines, could slow the diffusion of these products to poorer countries.

How transparent is Switzerland?

Based on the Freedom of Information Act that came into force in 2006, any Swiss citizens can request access to any public documents. There are some exceptions in cases of ongoing diplomatic negotiations, personal privacy, and national security. When it comes to drug pricing, Kronig explains, 'we are one of the only countries that are fully transparent about prices. There are no secret deals.' In the face of difficult negotiations with pharmaceutical companies, the FOPH recently introduced discounts, which it says is in place for about 20 or so treatments. In effect, this means there are two prices for certain drugs.

This double price list drew criticism from some NGOs for the lack of transparency after it was revealed by the Swiss public television programme Runds a few months ago. Although the information about the discount price is available, some NGOs argue that it is difficult to find and calculate. There is even greater debate on other aspects of the resolution. Kronig explains that 'transparency is an important part of building trust but there are a few cases where it can be counterproductive. We have to ask if transparency will help or hinder access?' Cueni points out that transparency on R&D costs could discourage the introduction of innovative treatments and delay patient access to critically-needed and life-saving new medicines.

To Kronig, there isn't enough clarity on what impact revealing R&D costs could have on innovation. And right now, she explains R&D costs are not factors Switzerland considers in price negotiations.

Patrick Durisch of the NGO Public Eye sees it differently. 'How can any authority, not just the Swiss, set a price without knowing how much has been invested? What were the R&D costs? These are still

considered a trade secret. Even the FOPH whose task is to set the price, does not know how much the R&D costs are. How do you want to set a fair price?' Is there such a thing as a fair price?

What is a fair price for drugs has become the question shadowing the discussions on transparency. Companies have typically defended high prices by pointing to much needed investments in research and development. But more research from the WHO, Switzerland and elsewhere shows that prices are disconnected from costs and that drug company profits continue to rise. Companies like Novartis and Roche have even said that costs are not the best way to determine prices. With new gene therapy treatments that cure diseases with a single treatment, they are calling for a shift to a value-based model based on patient outcomes and savings to hospitals and health systems.

Cueni backs this up saying that focusing narrowly on R&D costs and other inputs, does not say anything about the value that medicines provide to patients and health care systems. But, this model is unlikely to simplify calculations when faced with the uncomfortable question of how much a life is worth. Durisch says: 'Imagine if we used value-based pricing for all goods. How much would you value a life vest or an airbag? How much is a life?'

Durisch believes that value-based pricing is a strategy of the pharmaceutical industry to avoid unveiling their real investment cost.

'There are no limits [with value-based pricing] because basically every patient suffering from a deadly disease is ready to pay a lot for a medicine. You are just taking patients hostage. You are taking the government hostage.'

The fate of Italy's resolution may be decided next week but whatever the outcome, it is unlikely that the topic will fade away anytime soon.

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Side event: Health Policy Watch: Several Ministers Of Health Speak Up For Drug Market Transparency, Lower Prices At WHA Side Event

https://www.healthpolicy-watch.org/several-ministers-of-health-speak-up-for-drug-market-transparency-lower-prices-at-wha-side-event/

Several Ministers Of Health Speak Up For Drug Market Transparency, Lower Prices At WHA Side Event
20/05/2019 by Catherine Saez

The room holding the high-level side event on transparency of pharmaceutical product markets was overflowing today with dozens of people standing to hear the speakers - many of them ministers of health, reflecting the importance of the topic at the 72nd World Health Assembly.

Member state organisers and co-sponsors of the event, representing diverse levels of economic development, all made a call for a change of game, more transparency in the pharmaceutical market, and the end of forced confidentiality of price negotiations between countries and drug companies.

The side event, 'Access to medicines, vaccines and health products: A multi-dimensional approach for ensuring transparency of markets, affordable and quality products to achieve Universal Health Coverage was organised by Italy and South Korea, and co-sponsored by Costa-Rica, Greece, Indonesia, Italy, Mexico, Mongolia, Netherlands, Portugal, Republic of Korea, Saudi Arabia, Spain, and Vietnam. It was held on the first day of the 72nd World Health Assembly (WHA), taking place from 20-28 May.

The topic is controversial and is the subject of a draft resolution proposed by Italy, Greece, Malaysia, Portugal, Serbia, Slovenia, South Africa, Spain, Turkey, and Uganda. The draft resolution has not yet been tabled. Civil society groups drew attention to alleged efforts by some developed countries to bar the resolution.

Intense discussions between WHO member states have been ongoing prior to the WHA. Knowledge Ecology International provided a comparison between the original proposal from 29 April, and the ones from 7 and 10 May.

Speakers at the side event underlined high prices, the secrecy around research and development costs, and the negotiated prices obtained by countries. They all called for a collaborative efforts to tackle those issues.

Differential Pricing: Cyprus Denounces 'Unethical Practices'

A representative of the Cyprus Ministry of Health in the audience gave a vibrant account of what he described as 'unethical practices' by the pharmaceutical industry. He gave two examples where he said Cyprus, with no negotiating power, and a small population of 800,000, was being asked to pay prices vastly superior to those awarded to other countries. He gave the example of a medicine to treat an orphan neurological condition, for which 800,000 euros per patient was the price set by the manufacturer of the product.

According to him, a study conducted in Cyprus examined all products approved by the European Medical Agency (EMA) since 2011, and showed that industry mostly waits about four years before releasing newly EMA-approved products in Cyprus, reserving those products to richer northern European countries first.

Lucas Li Bassi, director of the Italian Medicines Agency, said it would be interesting to see whether differential pricing is actually occurring according to countries' gross domestic product (GDP), giving the example of a pneumococcal vaccine which was charged twice as much in Lebanon as in Greece. He called for better information leading to better policy decisions. Countries are the biggest investors of the pharmaceutical industry, he said and 'should be able to shape the market.'

Valuable New Treatments Unaffordable, Older Ones Unavailable

Treatments for previously untreatable or fatal conditions have become available, however due to some pharmaceutical monopolies driving high prices, people are prevented from accessing those medicines, said Neunghoo Park, Minister of Health and Welfare of South Korea. He called for collaboration among countries and noted that the promotion of better health should be central, and the ultimate goal of pursuing innovation in drugs.

Armando Bartolazzi, Italy's Undersecretary for Health also remarked on the increasing number of valuable, but unaffordable, medicines. Transparency, he said, is recognised as a solution to address this challenge. The lack of information does not allow public actors to know if resources are allocated in the best way, he said, adding that tax payers currently pay multiple times for products when research has been conducted with public funds. He explained that 'few clinical trials are in line with European Union law,' which requests that clinical trials be registered before they start and that summary results be reported within specific timelines. It also requires that results should be disclosed regardless of the fact that they might be negative, neutral or inconclusive. This disclosure would help further research and avoid the duplication of trials, he said.

Bartolazzi also commented on new products and said that not all products 'are truly innovative,' but simply serve to preserve market exclusivity.

Bruno Bruins, Minister of Health, Welfare and Sport of the Netherlands talked about shortages of previously accessible medicines. Some antibiotics, he said, are manufactured in a single manufacturing site, calling the situation 'worrying.' He, too, reflected on the expensive prices of new medicines, and called for increased collaboration between countries. A joint approach would improve health technology assessment, prices, and negotiating power, he said. Countries should be more transparent on the price they are willing to pay, he added, and innovation should be encouraged and rewarded, 'but not at any cost,' he said.

Marta Temido, Minister of Health of Portugal, argued that the spread of chronic diseases and an aging population will drive up healthcare expenditure in the years to come. As health systems are 'pressured to adopt new drugs' she said, the need for evidence-based decisions and transparency are key.

For Sarangeral Davaajantsan, Mongolian Minister of Health, the price of medicines would decrease if transparency was legalised, as it might create competition between suppliers.

'We cannot continue business as usual,' said Faustino Blanco, Secretary General for Health and Consumer Affairs at the Ministry of Health of Spain.

Countries have a justified concern about the inequality of the price of medicines and the true value added of new products, he said, underlining the essential role of a dynamic competition.

Strategies to Tackle High Prices Fall Short, Non-Disclosure Clauses Harmfu

Soonman Kwon Seoul of the National University of Public Health of Korea also underlined the lack of bargaining power of many countries and the lack of information on R&D costs. High prices, he said, represent a 'huge impediment' for universal coverage, even in high income country settings, threatening the sustainability of many health systems.

Multinational pharmaceutical companies, he said, threaten to withdraw some products from the market as a strategy to increase prices. He listed different ways governments tried to address the issue of high prices, including managed entry agreements, health technology assessments, external reference pricing, pooled procurement, and compulsory licensing.

Confidential rebates and discounts keep the list prices high, he said, impairing the effectiveness of external reference pricing.

Giannis Baskozos, secretary general of Public Health at the Ministry of Health of Greece said the issue of affordability and transparency should remain high on the political agenda.

For Nikolaos Raptis, advisor to the Minister of Health of Greece, the non-disclosure clauses that countries have to sign is a way for the pharmaceutical industry to 'divide and conquer.'

In the audience, a speaker from South Africa called countries to follow the South African example. The country enforced a law preventing those non-disclosure contracts, and requiring some compulsory information from pharmaceutical companies, such as the price of the active ingredients in their formulation. Transparency does not mean the information has to be disclosed to the public, he added.

CLINICAL TRIALS: ROCHE AND NOVARTIS NEGLECT THEIR ETHICAL RESPONSIBILITY IN EMERGING COUNTRIES

Zurich / Lausanne, 20 May 2019

Only the wealthy part of the population benefits when Roche or Novartis test new anti-cancer drugs in Mexico or Ukraine, for these essential treatments sometimes cost more in these countries than they do in Switzerland.

That is the conclusion of a public eye investigation, conducted in the five emerging countries that serve as the Switzerland-based giants' favourite 'laboratories' for their clinical trials. Pharma companies must change these scandalous pricing policies to guarantee access to medicine for all.

International ethical standards as the Helsinki Declaration clearly state that in the countries where clinical trials take place, the vulnerable members of those societies should be able to benefit from the treatments that they have helped to develop. To check whether this principle is respected by Roche and Novartis, Public Eye studied 22 medicines tested in South Africa, Colombia, Mexico, Thailand and/or Ukraine.

The results
(https://www.publiceye.ch/fileadmin/doc/Medikamente/2019_PublicEye_PostTrialAccess_Report.pdf) show progress in terms of bringing them to market: between 86% and 100% of these treatments are officially available in these countries. But they are sold at such exorbitant prices that they are unaffordable and thus inaccessible to most patients.

The investigation reveals serious problems in relation to access to nearly all of the 22 drugs studied, none of which are covered by state healthcare due to their high cost. Roche's anti-breast cancer drug Perjeta (pertuzumab) provides a good example of the impact of pharma companies' irresponsible pricing policies. In Switzerland, the excessively high price of the drug - set after bitter negotiations with the Federal Office of Public Health - threatens the principle of universal coverage of healthcare, as revealed by Public Eye's campaign for affordable drugs (https://www.publiceye.ch/en/topics/medicines/affordabledrugs). In emerging countries,

Perjeta is almost as expensive: it costs nearly $56,000 a year in Ukraine and Mexico, which would take someone earning the minimum wage in these countries over 30 years to earn.

In contrast to their claims, Roche and Novartis do not respect their responsibilities to provide access to treatment following trials. They must review their pricing policies, factoring in the local economic context.

Transparency is another essential part of restraining the unbridled power of pharma companies and guaranteeing access to medicines for all. A resolution introduced by Italy calling for full transparency of research and development costs as well as the true prices charged in each country will provoke heated discussion at the World Health Assembly (WHA), which opens in Geneva today.

Responding to the influence of the pharma lobby, numerous EU countries are exerting pressure for the initiative to be buried. If Switzerland, as home country of two of the world's largest pharmaceutical companies, were to support the resolution it would send a strong political message in favour of defending the public interest.

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