World Health Organization
REGIONAL OFFICE FOR Europe

EXPERT MEETING ON MARKET TRANSPARENCY TO IMPROVE ACCESS TO HIGH-PRICED INNOVATIVE MEDICINES

18 FEBRUARY 2020, NATIONAL INSTITUTE FOR HEALTH AND DISABILITY INSURANCE, BRUSSELS, BELGIUM

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Abstract

On 18 February 2020, the Health Technologies and Pharmaceuticals Programme within the WHO Division of Health Systems and Public Health convened a high-level informal expert meeting on the situation regarding access to innovative, high-value medicines in Europe. The aim was to propose mechanisms by which the WHO Regional Office for Europe could contribute to implementation of World Health Assembly resolution WHA72.8 in the Region. This was a preliminary event in the lead-up to a high-level meeting originally scheduled to be hosted by the Government of Norway in June 2020 (since postponed to 1–2 March 2021), which will involve the participation of representatives of Member States and stakeholders.

Keywords

ACCESS TO MEDICINES
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Background

Equitable and sustainable access to safe, effective, affordable and quality-assured medicines and health products is critical to achieving universal health coverage and the Sustainable Development Goals – in particular, target 3.8.1. Based on input from the Fair Pricing Forums, WHO's working definition of a "fair" price for medicines is one that is affordable for health systems and patients, and that simultaneously provides sufficient market incentive for industry to invest in innovation and the research and development (R&D) required to produce new effective medicines.

In recent years, rapid scientific advancements have resulted in the production of a number of innovative life-saving and life-changing treatments. These medicines and devices, however, often come with high price tags, and prove inaccessible for people in need. While recognizing and accepting that the pharmaceutical sector is a for-profit industry that accrues substantial costs and risks for R&D, evidence is increasing that the prices of innovative medications and devices far exceed the R&D costs. This has led to questions about whether the profit margins should be considered acceptable. The high and unaffordable prices of these medications – including but not limited to cell and gene therapies – have prompted calls for fair pricing models and increased transparency on the financing of drug development and drug supply, to better understand whether prices are justified. The combination of high prices and the lack of transparency, as well as examples of unscrupulous practice, has eroded stakeholder trust; this must be rebuilt.

Countries have expressed increasing concern about the rising prices of some potentially high-value medicines, including advanced therapy medicinal products, particularly when there is a lack of certainty about the mid- to long-term benefits. These high costs are a significant barrier to access, causing inequities within and among Member States, and leading to unacceptable levels of out-of-pocket expenditure in countries across all income levels.

Within the WHO European Region several country-led partnerships have been developed over recent years in response to the common challenges faced by individual countries in financing and managing access to expensive innovative medicines, vaccines and other health products. In addition to health technology assessment, data collection and financial agreements, countries have explored numerous strategies to mitigate costs, including policy exchanges and collaboration on horizon scanning, price negotiations and pooled procurement. These partnerships include:

- Baltic Partnership Agreement (2012 – Estonia, Latvia, Lithuania);
- Nordic Pharmaceuticals Forum (2015 – Denmark, Iceland, Norway, Sweden);
- Beneluxa Initiative (2015 – Austria, Belgium, Ireland, Luxembourg, Netherlands);
- Romanian and Bulgarian Initiative (2015 – Bulgaria, Romania);
- Sofia Declaration (2016 – Bulgaria, Croatia, Estonia, North Macedonia, Hungary, Latvia, Romania, Serbia, Slovakia, Slovenia);
- Valletta Declaration (2017 – Croatia, Cyprus, Greece, Italy, Ireland, Malta, Portugal, Romania, Slovenia, Spain);

- Fair and Affordable Pricing Initiative (formerly Visegrad+2 Group) (2017 – Czechia, Hungary, Lithuania, Poland and Slovakia, with Latvia as invited guest);
- Spanish and Portuguese Initiative (2017 – Spain, Portugal);
- WGEMA Collaboration (2017 – Denmark, Finland, Iceland, Norway, Sweden);
- FINOSE Collaboration (2018 – Finland, Norway, Sweden).

Introduction

Increased concerns were raised by Member States during the Seventy-second World Health Assembly in May 2019 about better access to effective, innovative and high-priced medicines. This led to the endorsement in resolution WHA72.8 on improving the transparency of markets for medicines, vaccines and other health products[1] of a draft roadmap for expanding access to medicines, vaccines and other health products for 2019–2023.[2] The resolution presents a series of recommendations for Member States and actions for WHO, acknowledging the various national and regional legal frameworks and contexts and noting the importance of differential pricing.

The WHO Regional Office for Europe convened an informal high-level expert meeting in Brussels, Belgium, on 18 February 2020, hosted by the National Institute for Health and Disability Insurance. Its aims were to discuss the situation regarding access to innovative, high-value medicines in Europe and to form proposals for the Regional Office's contribution to implementation of resolution WHA72.8. It would also set up the framework and issues to be addressed during a planned high-level meeting to be hosted by the Norwegian Ministry of Health and Care Services in June 2020 (since postponed to 1–2 March 2021).

Participants of the February 2020 expert meeting included representatives from health ministries, insurance institutions and academia from Austria, Belgium, Malta, Norway, Switzerland and the United Kingdom, as well as European experts from a range of institutional backgrounds and representatives from both the Regional Office and WHO headquarters. The meeting was an opportunity for experts from several countries to convene to discuss potential actions, focusing on the following objectives to achieve better access to effective, innovative, high-priced medicines:

- to review progress since May 2019 on implementing resolution WHA72.8 on market transparency;
- to discuss progress and experience in implementation of the resolution across various initiatives in the WHO European Region that may inspire future action in other countries;
- to identify further potential national and collaborative actions to be taken and the level of support required from WHO to undertake these;
- to identify constraints that are impeding progress;
- to propose the agenda and content for the June 2020 meeting in Oslo, Norway (since postponed to 1–2 March 2021);
- to discuss existing policy and technical reviews produced by the group and identify whether further work should be commissioned to support the following meeting.

[1] Resolution WHA72.8. Improving the transparency of markets for medicines, vaccines, and other health products. In: Seventy-second World Health Assembly, Geneva, 20–28 May 2019. Resolutions and decisions, annexes. Geneva: World Health Organization; 2019:28 (WHA72/2019/REC/1; https://apps.who.int/gb/or/e/e_wha72r1.html, accessed 22 June 2020).

[2] Annex: draft road map for access to medicines, vaccines and other health products, 2019–2023. In: Access to medicines and vaccines: report by the Director-General. Geneva: World Health Organization; 2019: 3–46 (A72/17; https://apps.who.int/iris/handle/10665/328625, accessed 22 June 2020).

Dr Jo De Cock, CEO of the National Institute for Health and Disability Insurance, Belgium, opened the meeting and welcomed participants. Belgium is actively involved on the international stage in promoting transparency in access to medicines, and both the Institute and the Belgian Government generously agreed to host the meeting.

Dr Hans Kluge, WHO Regional Director for Europe, recalled that the mission of the Regional Office is to support Member States in developing their own health policies, health systems and public health programmes, and in preventing and overcoming threats to health. He further set out the importance and challenges surrounding the discussions on high-cost medicines.

Progress on implementing resolution WHA72.8 on market transparency

The session opened with an overview from WHO headquarters of the background, achievements to date and next steps towards implementation of resolution WHA72.8 on market transparency. Among a variety of initiatives and activities, the following are examples of some of the key efforts that are in progress or planned for 2020–2021:

- development of a framework to monitor the impact of price transparency planned for the second quarter of 2020;
- a revision of WHO guidelines on country pharmaceutical pricing policies[3] planned for the third quarter of 2020 (to include evidence-informed recommendations for a number of pricing interventions and their impact on prices of medicines, availability, affordability, quality and safety);
- a feasibility study of an online platform for data and knowledge sharing;
- an updated progress report on access to hepatitis C treatment[4] planned for the end of 2020;
- discussion of resolution WHA72.8 at the 148th session of the WHO Executive Board in 2021;
- the third Fair Pricing Forum scheduled for 2021, with technical working groups in 2020 contributing to the agenda;
- discussion of resolution WHA72.8 on the agenda of the Seventy-fourth World Health Assembly in 2021;
- a transparency webinar hosted by the Beneluxa Initiative in January 2020, focusing on transparency issues in the context of pharmaceutical development;
- a WHO-commissioned *British Medical Journal* series on achieving fair pricing of medicines, including existing evidence and further research needed to balance affordability and innovation of medicines.

[3] WHO guideline on country pharmaceutical pricing policies. Geneva: World Health Organization; 2015 (https://apps.who.int/iris/handle/10665/153920, accessed 23 June 2020).

[4] Progress report on access to hepatitis C treatment: focus on overcoming barriers in low- and middle-income countries. Geneva: World Health Organization; 2018 (https://apps.who.int/iris/handle/10665/260445, accessed 23 June 2020).

Relevant initiatives in the Region

This session included presentations providing a summary of existing initiatives in the Region. Updates were also given on:

- relevant Organisation for Economic Co-operation and Development (OECD) work on improving the information base and promoting transparency in pharmaceutical markets;
- the European Commission Directorate-General for Health and Food Safety's European Union Health Programme 2019 Work Plan;
- the Commission's "Work Programme 2020: promoting our European way of life";
- work commissioned that may inspire future action in other parts of the Region and information gaps identified that should be considered for future work.

The European Observatory on Health Systems and Policies set out a detailed review of the evidence on the effects of price transparency policies on price development. This provided a concise overview of the potential implications of transparency policies, based on identified evidence and expert consultation.

The outline of a planned Health Evidence Network synthesis report on the legislative aspects of implementation of resolution WHA72.8 was also presented. The targeted synthesis question was: "What is the evidence on the mechanisms, factors and tools to implement resolution WHA72.8 on improving the transparency of markets for medicines, vaccines and other health products for Member States?"

The following general information was covered for each of the current initiatives discussed.

- The **Pharmaceutical Pricing and Reimbursement Information (PPRI) network** was established in 2005 to provide a platform for national experts working on relevant issues to exchange information and data and to establish a sustainable reporting system for country information. The PPRI network has produced over 60 country reports focused on more than 27 European countries on issues related to medicines policies for outpatient and hospital sectors. It has also produced integrated country profiles on both the inpatient and outpatient sectors. A platform for network members to ask for information on pharmaceutical policies and situations in other countries within the network is also provided.
- The 2009/2010 **Pharmaceutical Health Information System project** was set up to improve understanding of several key pharmaceutical issues in the inpatient sector: procurement, distribution, pricing, financing and use. Resulting products included a comparative analysis of hospital medicines management in 27 European countries and findings from a case study survey. Recent efforts to conduct a similar project and update these results proved to be unfeasible as many institutions were either unable or unwilling to share relevant information.

- The **EURIPID Collaboration** is a voluntary non-profit collaboration between European countries to develop and maintain a database with information on prices and pricing regulations of pharmaceutical products. The database contains information on official list prices of publicly reimbursed – mainly outpatient – medicinal products. Only those countries that provide data have access to the database.

- The **Beneluxa Initiative** was established in April 2015 with the aim of ensuring access to innovative drugs (which can often be expensive) for all those in need of them. Partners include Austria, Belgium, Ireland, Luxembourg and the Netherlands. Areas of cooperation and practice include horizon scanning, health technology assessment, information sharing and policy exchange on pharmaceutical markets and prices and data for specific diseases, as well as advocacy of the need for evidence on clinical benefits of new medicines.

- The **Nordic Pharmaceutical Forum** was established in 2015 to create an informal space for Nordic collaboration and enable knowledge sharing and work towards common Nordic solutions. This politically backed operational network includes representatives from Denmark, Iceland, Norway and Sweden. Focus areas include horizon scanning, ensuring the security of drug supply, joint procurement of long-existing drugs and joint price negotiations for new, expensive drugs. Recently, the Danish and Norwegian ministries of health signed an agreement to demonstrate their support and aspirations for joint price negotiations on selected medicines.

- The **Valletta Declaration** was formed in 2017 to provide access to the latest services, technologies and medicines to all citizens at affordable prices. The group is made up of 10 European Union (EU) countries, including Croatia, Cyprus, Greece, Ireland, Italy, Malta, Portugal, Romania, Slovenia and Spain. The group has held regular meetings and collaborations for three years. It includes a technical committee with experts from all national entities.

- The **Working Group on Exchange of Information and Experience in Medicines** includes representatives from all five Nordic countries, collaborating on various pharmaceutical issues including horizon scanning, risk-sharing, shortages and transparency.

- The **OECD Expert Group on Pharmaceuticals and Medical Devices** is among the OECD's many projects to explore avenues to increase pharmaceutical expenditure efficiency and prepare to change the market. The pharmaceutical pricing policy project had two main objectives: to add to the information base on pharmaceutical pricing policies in OECD countries and develop a taxonomy and framework for making international comparisons of policies; and to analyse cross-national impacts and implications of policies, particularly with respect to the impacts on pharmaceutical prices paid in other countries and on pharmaceutical R&D.

- **FINOSE** is a collaboration between three Nordic health technology assessment bodies – the Finnish Medicines Agency, the Norwegian Medicines Agency and Sweden's Dental and Pharmaceutical Benefits Agency. It produces joint assessment reports to improve the efficiency of the health technology assessment process.

Key considerations, experience and constraints impeding progress

This expert panel set out to discuss progress on and experience of implementing resolution WHA72.8, and to identify constraints impeding progress from the perspective of development partners, stakeholders and WHO headquarters. The aims were to identify commonalities in priorities and to underscore key challenges faced.

Key questions considered were:

- What is your perspective on the cost of new therapies in your country, particularly for advanced approaches such as cell and gene therapy?
- What impact do prices have on access to medical products in your country?
- What are the most critical changes that must be made?
- What factors influence political support for making those changes?
- What activities have been undertaken to increase market transparency in your country?
- What are the opportunities and barriers to implementation of resolution WHA72.8, particularly regarding greater transparency of the net prices of medicines?
- Have any stakeholder discussions/engagement taken place; if so, what were the results?

The expert panel aimed to explore innovation in practice through country cases and interventions by different actors, and to investigate the system conditions needed to put new processes and resources into practice, reflecting on different approaches and techniques to manage the change process itself. Importantly, discussions centred on both successes and failures of interventions, seeing both as useful sources for lessons learned about facilitators of and barriers to the interventions. The discussion raised the following key points.

Solidarity

The group discussed the dilemmas faced by payers in balancing national budget responsibilities; these have led to confidentiality clauses as opposed to a broader imperative to increase transparency at the national, European and global levels. It was noted that the transparency shown by Switzerland had not been replicated in other countries. Whether full transparency is possible in a system with sovereign states was discussed.

Information asymmetries and negotiation power

In the pharmaceutical arena – and particularly for new developments with minimal and immature evidence bases – large uncertainties exist around the true value, effectiveness, safety and development costs of drugs.

Experts noted that the pharmaceutical industry dominates negotiations in all countries, regardless of country size or income status. Pharmaceutical price negotiations require significant effort and financial resources, for which many countries lack capacity. For small countries, where sales volumes of medical products are lower, negotiating affordable prices is often difficult because the industry presents a case that high prices are required to compensate for launch costs and maintenance of profit levels with low volume. For larger, high-income settings in the WHO European Region, countries have historically been able to afford higher prices than other parts of the world. As a result, in standard negotiation processes, the industry sets high prices as a baseline. These continue to increase with each new launch.

Information asymmetries exist not only between governments and the pharmaceutical industry but also at the point of health care service delivery and across governments. For example, many physicians lack knowledge of the actual costs of the treatments they order for patients. In addition, information provided by national governments is often opaque when it comes to disclosing what they are willing to pay for certain medicines.

To combat these information asymmetries and power imbalances, countries have "teamed up" and created larger units to share information, even if there is no intention to undertake joint negotiation or procurement.

Dealing with uncertainty

While novel medications have many potential benefits, payers often face the challenge of having to pay high prices for products with unproven effectiveness or without demonstrated marginal benefits. This results in payers bearing significant uncertainty in their investments. Conditional licensing, introduced to facilitate rapid patient access to promising medicines in specific circumstances, has enabled certain products to receive preliminary authorization based on immature data at the point of launch. In addition, many of the studies undertaken lack randomization owing to the nature of the diseases they address; are short and lack information on long-term impacts; and are based on surrogate end-points, rather than death or infection rates.

In other investment areas outside the pharmaceutical realm, certainty is rewarded and investors pay lower prices for uncertain buys. Oftentimes, however, this is not the case for pharmaceutical purchases. The industry argues that high prices for these innovative medicines reflect the potential clinical value and the small numbers of eligible patients. Payers typically lack explicit willingness-to-pay criteria on which to base investment decisions. Thus, they often act as passive payers rather than as active buyers who shape the market.

Media attention further complicates this, and politicized stories around refusals to fund drug purchases "at any price" often fuels countries implicitly to pick up the costs associated with uncertainty. These include ownership of the burden to prove the drug's added benefit and the costs associated with management of emerging adverse events. Explicit consideration of the roles and responsibilities of each stakeholder in the negotiation process could enable uncertainty to be acknowledged explicitly and managed, with joint arrangements for further evidence generation and appropriate and transparent

cost-sharing – for example, through pay-for-performance arrangements. Under these financing agreements, patients and professionals are fully informed of a drug's uncertainty and accept that the medicine will no longer be covered if benefits are not demonstrated; likewise, price increases will be justified if the benefits are greater than anticipated.

Increasing role of the media

In recent years, several wide-reaching and emotional news and media stories have criticized governments for not providing tax-paying citizens with the expensive life-saving treatment they need. With the promotion of new "miracle million-dollar cures", these stories are likely to increase, despite great efforts being made to negotiate better prices to manage constrained budgets. Improved systems are required to set priorities to achieve the most health gains possible with the resources available. While this makes rational sense at a population level, the issue becomes very complex for individual patients.

It was also noted that most health systems are currently financed for the near term rather than being provided with increasing budgets to account for increased upfront costs for later health system savings over the life-course. Participants also mentioned that the pharmaceutical industry is starting to be criticized by patients, professionals and the media when negotiations stall.

Other key issues and constraints

The heterogeneity of countries in intercountry voluntary collaborations was noted. Differences exist in approaches and mandates, and the collaborations are resource- and time-intensive, while some pharmaceutical companies have been reluctant to engage.

Organization of the market is an issue: medicines are increasingly targeted at smaller fragments of the population, with high costs due to small population sizes, regardless of the cumulative number of patients across different indications.

In most countries responsibility for providing access to medicines is seen to lie solely with the state, but efforts should be made to increase the accountability of industry, as this is a shared responsibility and is affected by corporate strategy, budgets, evidence, pricing and negotiation.

Potential national and collaborative actions and support required from WHO

The WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Austria, presented a report on cross-country collaborations, published in July 2020. This summarized current EU-level initiatives, outlining progress and experiences and identifying constraints impeding progress. It also set out opportunities, challenges and limitations in current approaches, as well as potential new approaches.

The presentation explored expert interventions and illustrative country cases, evidence and first-hand experiences from practice. As a result, participants suggested several ideas for future collaborations and areas for WHO support. Foremost among these was development of a social contract between stakeholders to address the current challenges, with the ultimate goal of providing access to high-quality, effective, affordable and safe medications for those who need them, while also encouraging

and incentivizing innovation. This was seen as a potential win–win situation. Such a social contract would build coherence by outlining the roles and responsibilities of each stakeholder in the negotiation process to support the process and enable a better dynamic for mutual benefit. The feasibility of a social responsibility index for the industry was also discussed.

Several attendees also discussed ways to improve and strengthen voluntary intercountry collaborations. Ideas included:

- building and strengthening databases for knowledge and information sharing;
- WHO support to design a process for establishing and maintaining these collaborations;
- a platform for enhancing collaboration between voluntary intercountry initiatives to share experiences and lessons learned;
- teaming up to create larger supranational procurement groups, particularly for specialty items with low anticipated volumes in individual countries.

Another action suggested was to develop evidence-based practices and recommendations for investment decisions for medicines, based on financial investor behaviours towards uncertainty. These would be grounded in providing a financial reward for greater certainty and less risky investments.

Final remarks and next steps

A diverse range of topics was explored, and the experiences shared by the experts resonated with related key messages, indicating the relevance and sensitivity of this topic.

Discussion highlights included the following issues that need to be addressed to achieve the goal of better access to effective, innovative and high-priced medicines.

- Health loss caused by unaffordable pricing of medications has economic impacts.
- Medicines are paid for out of public money; it is therefore critical to increase transparency in the interactions between all stakeholders.
- All stakeholders have a role in research, development and access, and there is a need for greater trust and coherence to address the current challenges.
- The current paradigm of measuring value is resulting in unaffordable medicines.
- The current system requires the public sector to be willing to pay more for greater uncertainty.
- Further methodological work is required on how to measure and incentivize value.
- Discussion is also required on how to leverage competition opportunities provided by drugs with similar therapeutic effects.
- A number of potential payment mechanisms should be explored further, including:
  - outcomes-based payments
  - supranational procurement and payment negotiations
  - differential pricing according to income level.
- Further support and development of payer practices are required in order to turn passive payers into more powerful active buyers who shape the market.

Planning the June 2020 high-level meeting

Participants welcomed the proposal to hold the high-level meeting in Oslo, Norway, in June 2020 (since postponed to 1–2 March 2021), hosted by the Norwegian government. Based on the February meeting's discussions, it was agreed that the next meeting would focus on development of greater coherence between stakeholders to facilitate efforts to increase access to high-quality, effective, life-saving treatments for all those who need them. While emphasis would be placed on the importance of transparency and a social contract in order to achieve resolution WHA72.8, a number of other potential topics and workstreams were identified that would merit further discussion:

- defining the value of new medicines: dealing with uncertainties and making investment decisions, including:
  - the impact of multiple high-cost orphan indications on the market;
  - "me-too" drugs and their role in increasing market competition to reduce prices (a me-too drug is structurally very similar to known drugs – the term "me-too" carries a negative connotation, but me-too products may create competition and drive prices down);
  - surrogate clinical trial end-points; short-term versus long-term health impacts;
  - the marginal value of new products and incremental innovation;

- mechanisms for fair pricing: value-based pricing, managed entry agreements and other options;

- the role of governments as price takers or price makers: passive payers or active buyers;

- responsibility- and risk-sharing across industry, government, patients and professionals;

- procurement cooperation;

- negotiating techniques and power: seeking solutions through dialogue.

Potential attendees were also discussed in planning for the next meeting. There was consensus that, as far as possible, the discussions should involve representatives from all stakeholders. Further conversations on funding and feasibility would be held between WHO and the Norwegian meeting organizers.

In line with the Sustainable Development Goals and WHO's European Programme of Work, the next meeting will ensure a strong focus on equity and "leaving no one behind". Access to effective innovative medicines will be considered through three themes:

- achieving greater **unity** between stakeholders on solutions to resolve some of the critical issues that are restricting access for patients in the WHO European Region;

- understanding how **transparency** could be used to build trust and support access;

- ensuring **sustainability** in both industry and health care systems.

Further preparatory work would be undertaken, including engagement with experts and background papers. The European Observatory on Health Systems and Policies would continue its examination of the empirical evidence on the impact of price transparency on prices. Work would also continue on the Health Evidence Network synthesis report on the legal implementation of measures to improve the transparency of markets for medicines, vaccines and other health products.

Annex 1. Agenda

09:30 – 11:00	Welcome and opening remarks – Hans Kluge, WHO Regional Director for Europe, and Jo de Cock, National Institute for Health and Disability Insurance, Belgium
	Introductions
	World Health Assembly resolution WHA72.8 on market transparency
	Support for implementation of resolution WHA72.8 in the WHO European Region Discussion – all participants
11:20 – 12:30	Updates and perspectives from experts in response to the following questions: What is your perspective on the cost of new therapies in your country, particularly for advanced approaches such as cell and gene therapy? What impact do prices have on access to medical products in your country? What are the most critical changes that must be made? What factors influence political support for making those changes? What activities have been undertaken to increase market transparency in your country? What are the opportunities and barriers to implementation of resolution WHA72.8, particularly regarding greater transparency of the net prices of medicines? Have any stakeholder discussions/engagement taken place; if so, what were the results?
	Update from the voluntary intercountry collaborations: Beneluxa Initiative Nordic Pharmaceutical Forum Valletta Declaration Discussion – all participants
13:15 – 14:30	Proposals for future collaboration Role of the WHO Regional Office for Europe Stakeholder engagement Planning the June 2020 meeting Discussion – all participants
14:45 –16:00	Next steps, including meeting outputs

Annex 2. List of participants

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The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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