Subject: **Call for Contributions - OHCHR analytical study on key challenges in ensuring access to medicines, vaccines and other health products (HRC resolution 50/13)**

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This is a joint-submission from the **International Federation of Gynecology and Obstetrics (FIGO)** and the **East, Central, Southern Africa College of Obstetrics & Gynecology (ECSACOG) Community of Practice** which comprises of 10 national member societies of obstetricians and gynaecologists (OBGYNS) from *Ethiopia, Kenya, Malawi, Mozambique, Rwanda, South Sudan, Tanzania Uganda, Zambia and Zimbabwe.*

FIGO brings together more than 130+ OBGYN member societies from all over the world. FIGO's vision is that women and girls of the world achieve the highest possible standards of physical, mental, reproductive and sexual health and wellbeing throughout their lives. FIGO leads on global programme activities, with a particular focus on sub-Saharan Africa and South East Asia. FIGO advocates on a global stage, especially in relation to the Sustainable Development Goals (SDGs) pertaining to strengthening reproductive, maternal, newborn, child and adolescent health and non-communicable diseases (SDG3) and deepening gender equality (SDG5).

ECSACOG is dedicated to transforming healthcare in East, Central, and Southern Africa by training specialist obstetricians and gynaecologists. ESCACOG is a collegiate training institution with a profound mission to elevate healthcare standards in the region and address the unique reproductive and sexual health needs of our population.

(a) **What are the major obstacles at the national, regional and international levels to ensure equitable access to medicines, vaccines and other health products?** Some of the major obstacles include:

Intellectual Property Rights

- **Global Patent System**: Stringent patent laws and global patent systems can hinder access to affordable generic medicines, making it difficult for countries, especially low-income ones, to produce or import cost-effective drugs.
- **TRIPS Agreement**: The Agreement on Trade-Related Aspects of Intellectual Property Rights can pose challenges, as it sets minimum standards for intellectual property protection, potentially limiting the production and distribution of generic drugs.
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Market Dynamics

- **Market Monopolies:** Limited competition and market monopolies by pharmaceutical companies can result in high prices for medicines, limiting accessibility for lower-income populations
- **Lack of Incentives:** Pharmaceutical companies may be more inclined to focus on high-profit markets rather than investing in research and development for diseases that predominantly affect low-income countries.
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Regulatory Barriers

- **Stringent Regulatory Processes:** Cumbersome and time-consuming regulatory processes can delay the approval and distribution of essential health products, affecting timely access to medicines and vaccines.
- **Quality Standards**: Overly strict quality standards may impede the importation of generic drugs, even if they meet international quality and safety requirements.

Infrastructure and Distribution Challenges

- **Logistical Issues:** Weak healthcare infrastructure, inadequate transportation systems, and poor distribution networks can hinder the effective delivery of health products to remote or underserved areas.
- **Storage and Cold Chain Requirements**: Some vaccines and medicines require specific storage conditions, posing challenges for regions with limited infrastructure for maintaining cold chains.

Financial Barriers

- **Affordability:** Limited financial resources in some countries make it difficult to purchase and distribute essential health products, contributing to disparities in access.
- **Healthcare Financing**: Inadequate healthcare financing and insurance systems can result in out-of-pocket expenses for individuals, creating barriers to accessing necessary health products.

Global Health Governance

- **Global Health Inequities:** Power imbalances and inequities in global health governance can influence resource allocation and decision-making, impacting access to health products for certain regions or populations.
- Coordination Challenges: Lack of effective coordination and collaboration among countries, international organizations, and non-governmental organizations can lead to inefficiencies in addressing health crises.

Emergency Response and Preparedness

- Pandemic Preparedness: In the face of global health emergencies, rapid response mechanisms and equitable distribution plans may be lacking, leading to disparities in access to life-saving interventions.
- Due to the lack of recognition of SRH medicines – i.e. Misoprostol and Mifepristone as emergency drugs, there is inadequate distribution of SRHR medicines during times of crisis (includes pandemics) which can impact the supply and quality of the product[1].
- Response to SRHR services and needs is frequently sidelined during emergency response.[2]
- WHO usually provides guidelines on management of some diseases and it gives evidence-based management. But, it takes a long time for a countries to accept and adopt these guidelines. While, it's within their right to adopt/adapt or reject the guidelines, it is critical to strengthen buy-in and ownership of best practice guidelines that country teams are more involved in the creation of such guidelines.

National Level

i. **Economic Disparities:** Limited financial resources in some countries hinder their ability to purchase and distribute essential health products.
ii. **Healthcare Infrastructure:** Inadequate healthcare infrastructure in certain regions can impede the efficient distribution and delivery of medicines and vaccines.
iii. **Regulatory Barriers**: Stringent regulatory frameworks can slow down the approval process for new medications and vaccines, delaying their availability to the public.
iv. **Intellectual Property Rights**: Stringent intellectual property protections may limit generic production, keeping prices high and reducing accessibility.
v. **Corruption:** Corruption in healthcare systems can lead to diversion of resources and hinder the fair distribution of health products.

[1] https://www.spdc.pt/images/FIGO_Statement_Abortifacient_Product_Quality_EN.pdf

[2] https://www.ippf.org/resource/advocacy-good-practices-lessons-learned-ensuring-sexual-reproductive-safety-during-covid and https://www.unfpa.org/sites/default/files/resource-pdf/COVID-19_impact_brief_for_UNFPA_24_April_2020_1.pdf

vi. **Lack of commitment by governments**: Inadequate political translating also into financial commitment by governments to purchase essential health product and instead delegating the responsibility to implementing partners which is not sustainable.[3]

vii. **WHO Model List of Essential Medicines**-The absence of certain medications like SRH medications on the essential drug list can hinder access to and emergency refills for medications during stock-outs.[4]

Regional Level

i. **Supply Chain Challenges:** Weak supply chain management can result in delays and inefficiencies in the distribution of health products across regions.

ii. **Logistical Issues:** Geographic and logistical challenges, especially in remote areas, can hinder the timely delivery of medicines and vaccines.

iii. **Fragmented Health Systems:** Lack of coordination and integration between different regional health systems can lead to gaps in coverage and access.

iv. **Disease Burden Variability:** Varied disease burdens across regions may result in unequal prioritization of health products, leaving certain areas underserved.

v. **Equity:**-Unequal distributions between regions due to lack of awareness, financial stability of the region and political commitment of the specific region[5]

International Level

i. **Global Health Governance:** Limited global governance mechanisms can hinder the coordination of efforts to address health inequities on a broader scale.

ii. **Trade Barriers:** Trade restrictions and tariffs can affect the flow of health products across borders, impacting availability and affordability.

iii. **Global Intellectual Property Regime:** The global intellectual property regime may contribute to monopolies and high prices, limiting access for countries with fewer resources.

iv. **Unequal Research and Development:** Concentration of research and development efforts in wealthier countries may result in neglect of diseases that predominantly affect low-income regions.

v. **Pandemic Preparedness:** Lack of a coordinated international response mechanism can lead to delays in providing health products during global health crises.

(b) Please elaborate on the specific barriers, if any, that women and girls, older persons, children, persons living in poverty, or other persons or groups in situations of vulnerability or marginalization face in accessing medicines, vaccines and other health products.

Women and Girls

Gender Inequality: Deep-rooted gender inequalities result in women having less access to healthcare resources, including medicines and vaccines, and women/girls with intersectional marginalised identities face further barriers eg women/girls living in poverty, rural areas, transgender women/girls, and those women/girls with black, ethnic and

[3] https://thinkwell.global/wp-content/uploads/2021/05/Health-Purchasing-Factsheet_Uganda.pdf

[4] https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.02

[5] https://www.undp.org/sites/g/files/zskgke326/files/2023-02/UNDP-Inequality-in-Access-to-Essential-Health-and-Medicine-COVID19-Vaccines-2021.pdf

minority women identities are at the highest risk of having their access to health services includes medicine denied. More than 600 million women and girls live in conflict affected countries in 2022[6] and Events of political violence targeting women increased by 50 per cent in conflict-affected countries between 2020 and 2022.[7] Women's and girls access to healthcare is often overlooked in decision-making forums. There were only 44 women health ministers in 2020.[8] As was evident during the covid pandemic many governments were slow to respond to the impact of specific needs of domestic violence victims/survivors[9] and the impact of school closures and how this led to the rise of gender based violence includes FGM and sexual violence and early marriage for some girls living in Sub-Sahran girls.[10]

- **Reproductive Health Products:** Women may face challenges in accessing reproductive health products, such as contraceptives and maternal health medications.
- **Sociocultural Barriers:** Sociocultural norms and practices may limit women's autonomy in making healthcare decisions, affecting their access to essential health products.
- **Inadequate supportive structures in health facilities** to ease access to SRHR services for women and girls and young people.

Older Persons

- **Ageism:** Discrimination based on age (ageism) can lead to older persons being overlooked in healthcare priorities, affecting their access to medicines and vaccines.
- **Polypharmacy Issues:** Older individuals often have multiple health conditions, requiring multiple medications, leading to potential challenges in medication management.
- **Limited Vaccine Prioritization:** In some cases, older persons may not be prioritized for certain vaccines, leaving them more vulnerable to preventable diseases.
- **Financial instability**- Lack of access to (affordable) health insurance by older persons is a barrier to accessing essential medications and health services
- **Physical barriers:** In many countries especially in LMIC, accessing these medicines and health products is limited by the distance travelled to the nearest health facility, which may be difficult for older persons due to a poor transport network as well.[11]

Children

- **Pediatric Formulations:** Limited availability of child-friendly formulations for medicines and vaccines can make administration challenging for children.
- **Vaccine Hesitancy:** In some communities, vaccine hesitancy can impact the uptake of essential vaccines, leaving children susceptible to preventable diseases.

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[6] https://www.figo.org/resources/figo-statements/supporting-access-safe-abortion-conflict-and-humanitarian-settings and see Protecting the health and rights of women and newborns during conflict and crisis https://www.figo.org/resources/figo-statements/protecting-health-and-rights-women-girls-and-newborns-during-conflict-and-crisis

[7] https://www.unwomen.org/en/news-stories/press-release/2023/10/press-release-women-are-increasingly-at-risk-in-conflict-and-underrepresented-in-peace-processes-according-to-a-un-report#:~:text=New%20York%20%E2%80%94%20More%20than%20600,USD%202.2%20trillion%20in%202022.

[8] https://www.womenpoliticalleaders.org/women-health-ministers-courageous-and-ambitious-leaders-during-the-covid-19-pandemic/

[9] https://www.womensaid.org.uk/wp-content/uploads/2021/11/Shadow_Pandemic_Report_FINAL.pdf see also https://www.figo.org/news/covid-19-lockdowns-leading-rise-violence-against-women-and-girls

[10] https://girlseducationchallenge.org/media/1fgipm4r/emerging_findings_southern_africa.pdf

[11] https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-019-7437-2

- **Parental Awareness and Education:** Lack of parental awareness and education about the importance of vaccinations may contribute to under-vaccination in children.

Persons Living in Poverty

i. **Financial Barriers:** Individuals living in poverty may struggle to afford the cost of medicines and healthcare services, leading to delayed or inadequate treatment.
ii. **Limited Access to Healthcare Facilities:** Geographical and economic barriers may restrict access to healthcare facilities, making it difficult for individuals in poverty to obtain necessary health products.
iii. **Inadequate Health Insurance:** Lack of comprehensive health insurance coverage can be a significant barrier, limiting the ability of individuals in poverty to access essential health services.

Persons or Groups in Situations of Vulnerability or Marginalization

iv. **Discrimination and Stigma:** Individuals facing discrimination or stigma may avoid seeking healthcare, impacting their access to medicines and vaccines.
v. **Displacement and Refugee Status:** Displaced populations, including refugees, often face challenges in accessing healthcare services, including essential health products.
vi. **Language and Cultural Barriers:** Language and cultural differences can create communication barriers, affecting the understanding and utilization of health products.
vii. **Limited Representation in Research:** Underrepresentation of certain groups in clinical trials may result in a lack of data on the safety and efficacy of health products for specific populations.

(c) Are there any legal or regulatory challenges that impact the accessibility and affordability of medicines, vaccines and other health products?

Intellectual Property Rights (IPR)

- **Patent Protection:** Strong patent protection can lead to monopolies, limiting the entry of generic versions and keeping prices high.
- **Data Exclusivity:** Regulations that grant exclusive rights to the data generated during the clinical trial period can delay the entry of generic medicines.
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Regulatory Approval Processes

- **Lengthy Approval Timelines:** Lengthy and complex regulatory approval processes can delay the introduction of new medicines and vaccines, impacting timely access.
- **Harmonization Issues:** Lack of harmonization in regulatory standards across countries can hinder the simultaneous approval of health products in multiple markets.

Price Controls and Transparency

- **Lack of Price Controls:** The absence of effective price controls can result in unaffordable prices for essential medicines and vaccines.
- **Limited Price Transparency:** Lack of transparency in pricing structures can make it challenging to assess whether prices are fair and reasonable.
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Parallel Importation and Trade Agreements

- **Restrictions on Parallel Importation:** Restrictions on parallel importation can limit the ability of countries to access lower-priced medicines from other markets.
- **Trade Agreements Impacting Access:** Trade agreements may include provisions that affect the affordability of medicines, such as extended patent protection periods.

Compulsory Licensing and Access to Medicines

- **Limited Use of Compulsory Licensing:** Some countries may face legal or political challenges in issuing compulsory licenses, which allow the production of generic versions of patented medicines to enhance affordability.
- **Barriers to Generic Entry:** Legal and regulatory barriers may impede the timely entry of generic medicines into the market, reducing competition.

Regulation of Biological Products

- **Complex Regulatory Pathways:** Biological products, including vaccines, often face complex regulatory pathways, contributing to delays and increased costs.
- **Biosimilar Approvals:** Stringent requirements for biosimilar approvals may limit competition and affordability in the biopharmaceutical market.

Orphan Drug Designation - Orphan Drug Incentives: While orphan drug designation is intended to encourage the development of treatments for rare diseases, it may lead to high prices due to limited market competition.

Regulation of Clinical Trials - Stringent Requirements: Overly stringent regulatory requirements for clinical trials may lead to increased costs, hindering research and development efforts for new health products.

(d) Please elaborate on the impact of research and development models for pharmaceuticals and other health technologies, including emerging digital technologies, on the access to medicines, vaccines and other health products? The impact of research and development (R&D) models for pharmaceuticals and other health technologies, including emerging digital technologies, plays a crucial role in determining the accessibility, affordability, and availability of medicines, vaccines, and other health products.

Traditional R&D Models for Pharmaceuticals

i. **High Costs and Pricing:** Traditional R&D models often involve high research and development costs. Pharmaceutical companies may set higher prices for drugs to recover these costs and generate profits, potentially limiting affordability.
ii. **Focus on Blockbuster Drugs:** Profit-driven R&D may lead to a focus on developing blockbuster drugs that target widespread diseases, potentially neglecting the research on medicines for less prevalent conditions.
iii. **Intellectual Property Protection:** Stringent intellectual property rights can create monopolies, limiting generic competition and keeping drug prices elevated for extended periods.
iv. **Limited Research for Neglected Diseases:** Neglected tropical diseases and diseases primarily affecting low-income populations may receive less attention due to lower profit potential, resulting in limited research efforts.

Impact of Emerging Digital Technologies

i. **Advancements in Drug Discovery:** Digital technologies, such as artificial intelligence and machine learning, can accelerate drug discovery processes, potentially reducing R&D costs and time.
ii. **Personalized Medicine:** Digital technologies enable the development of personalized medicine, tailoring treatments based on individual patient characteristics. While this can enhance efficacy, it may also increase costs.
iii. **Remote Healthcare Delivery:** Telemedicine and digital health platforms can improve access to healthcare services, including the prescription and delivery of medicines, especially in remote or underserved areas.
iv. **Real-world Data and Evidence:** Digital technologies facilitate the collection of real-world data, contributing to post-market surveillance and a better understanding of a product's performance in diverse populations.

Access Implications

i. **Innovation vs. Access Balancing Act:** While innovation is critical for developing new and effective health products, there is a need to balance this with ensuring that innovations are accessible and affordable, especially for essential medicines.
ii. **Global Collaboration:** Collaboration between pharmaceutical companies, governments, international organizations, and public-private partnerships can help address access issues. Initiatives like open-access drug development can promote sharing of knowledge and resources.
iii. **Technology Transfer:** Transferring technology and knowledge to regions with limited R&D capabilities can enhance local capacity for pharmaceutical production, contributing to increased access.
iv. **Open Science Initiatives:** Open science initiatives, where research findings and data are shared openly, can foster collaborative efforts and speed up the development of treatments and vaccines, potentially improving accessibility.

Policy Considerations

i. **Balancing Incentives and Access:** Policymakers must strike a balance between providing incentives for innovation and implementing policies that ensure equitable access to health products
ii. **Regulatory Pathways for Digital Technologies**: Establishing clear regulatory pathways for emerging digital health technologies is crucial to ensure their safety, efficacy, and accessibility.
iii. **Global Health Funding Models:** Exploring alternative funding models, such as public-private partnerships and innovative financing mechanisms, can address funding challenges in R&D while ensuring broad access.

(e) From your perspective, what are the main challenges in terms of international cooperation, partnerships and collaboration to ensure access to medicines, vaccines and other health products? These challenges often stem from diverse factors such as geopolitical considerations, economic disparities, regulatory complexities, and differing national priorities.

Examples of key challenges:

- **Global Economic Disparities:** Economic disparities between high-income and low-income countries can hinder collaborative efforts. Limited resources in some nations may impede their ability to contribute financially to international initiative.
- **Intellectual Property Rights and Trade Agreements:** Disparities in intellectual property rights and the influence of trade agreements may create obstacles to the global sharing of medical technologies and hinder the production of affordable generic drugs.
- **Nationalism and Protectionism:** Nationalistic tendencies and protectionist policies can restrict the free flow of medicines and vaccines across borders, limiting the effectiveness of international collaboration.
- **Differing Regulatory Standards:** Variations in regulatory standards and approval processes across countries can slow down the deployment of health products globally, leading to delays in access.
- **Lack of Coordination and Information Sharing:** Inadequate coordination and information sharing between countries, organizations, and stakeholders can result in duplicative efforts, inefficiencies, and suboptimal resource allocation.
- **Limited Capacity in Low-Income Countries:** Low-income countries may lack the infrastructure, technical expertise, and resources needed to actively participate in international collaborations and benefit from technological advancements.
- **Political Instability:** Political instability and conflicts in certain regions can disrupt international cooperation and hinder the equitable distribution of health products.
- **Global Health Governance Gaps:** Gaps in global health governance may lead to fragmented efforts and a lack of a unified response, particularly in addressing emerging health threats.

- **Vaccine Nationalism:** The phenomenon of "vaccine nationalism," where countries prioritize their domestic populations over global needs, can result in uneven distribution of vaccines and hinder efforts for global immunization.
- **Inequality in Research and Development:** Disparities in research and development funding and infrastructure may lead to an unequal focus on health issues that predominantly affect certain regions or populations.
- **Funding Challenges:** Limited funding for international health initiatives and a lack of sustainable financing mechanisms can impede long-term collaborative efforts.
- **Ethical and Cultural Considerations:** Ethical and cultural considerations may vary between regions, impacting the acceptance and implementation of certain health interventions and products.

(f) What impact, if any, does the existing intellectual property rights (IPR) regime have on access to medicines, vaccines and other health products. How can global efforts better address intellectual property rights and technology transfer issues to enhance access to medicines, vaccines and other health products?

Impact of Existing IPR Regime

Positive Impacts: Incentives for Innovation: IPR provides innovators with exclusive rights to their inventions, offering financial incentives for research and development in the pharmaceutical and healthcare sectors.

Encouragement of Investment: Strong IPR protection encourages investment in the development of new and advanced medicines, vaccines, and technologies.

Negative Impacts: Monopolies and High Prices: Strict IPR regimes, especially in the form of patents, can grant companies monopolies on certain drugs, leading to high prices that may hinder access, particularly in low-income countries.

Delayed Access: Patent exclusivity delays the entry of generic versions of medicines into the market, limiting competition and keeping prices high for an extended period.

Technology Transfer Challenges: Stringent IPR can hinder technology transfer, preventing the manufacturing of generic versions of patented medicines in low-income countries.

Strategies to Enhance Access

Use of TRIPS Flexibilities

- **Compulsory Licensing:** Countries can use compulsory licensing provisions allowed under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement to produce or import generic versions of patented medicines, promoting affordability**.**
- **Parallel Importation:** allows countries to import lower-cost medicines from other countries where they are available at a lower price.
- **Global Access Licensing Agreements:** Encourage pharmaceutical companies to voluntarily enter into global access licensing agreements, allowing manufacturers in low- and middle-income countries to produce and distribute affordable generic versions of patented medicines.
- **Open-Source Initiatives:** Promote open-source platforms and collaborative initiatives where research findings, data, and technologies are shared openly, fostering innovation and facilitating technology transfer.
- **Public-Private Partnerships:** Foster public-private partnerships that prioritize access to medicines, vaccines, and health technologies. Collaborations can ensure that products are developed with affordability and accessibility in mind.
- **Global Health Funding Models:** Explore and implement alternative funding models that prioritize global health needs, providing sustainable financing for research and development while ensuring broad access to resulting health products.

- **Equitable Distribution of Benefits:** Implement mechanisms to ensure that the benefits arising from research and innovation are equitably distributed, especially for diseases that disproportionately affect low-income populations.
- **Technology Transfer Initiatives:** Actively support initiatives that facilitate technology transfer, enabling manufacturers in low-income countries to produce high-quality, affordable medicines and vaccines.
- **Advocacy and Policy Change:** Advocate for policy changes at national and international levels that strike a balance between protecting intellectual property rights and ensuring access to essential health products.

(g) What are the main challenges to ensure the quality, safety and efficacy of medicines and vaccines? Main challenges include:

1. **Counterfeit and Substandard Medicines:** The prevalence of counterfeit and substandard medicines poses a significant challenge. These products may lack the proper active ingredients, have incorrect dosages, or even contain harmful substances.
2. **Global Supply Chain Complexity:** The pharmaceutical supply chain is extensive and global, making it challenging to monitor and control every step of the production process. This complexity increases the risk of quality issues, including contamination or adulteration.
3. **Regulatory Capacity and Oversight:** Insufficient regulatory capacity in some regions can lead to challenges in effectively overseeing and ensuring the quality, safety, and efficacy of medicines and vaccines.
4. **Quality Control Infrastructure:** Some countries may lack well-equipped quality control laboratories, hindering their ability to assess and verify the quality of medicines and vaccines.
5. **Variability in Manufacturing Standards:** Differences in manufacturing standards across countries and regions can result in inconsistencies in the quality of health products.
6. **Emerging Technologies and Complex Products:** Advances in pharmaceutical technologies, such as biologics and gene therapies, introduce complexities in manufacturing and quality control. Regulatory frameworks may need to evolve to address these challenges.
7. **Cold Chain Management:** Vaccines and certain medicines require specific storage conditions, and maintaining an unbroken cold chain can be challenging, particularly in resource-constrained settings.
8. **Post-Market Surveillance:** Weak post-market surveillance systems can lead to delays in detecting and responding to safety concerns or adverse reactions related to medicines and vaccines.
9. **Antimicrobial Resistance:** Overuse or misuse of antibiotics contributes to the rise of antimicrobial resistance, reducing the effectiveness of existing medicines.
10. **Access to Essential Medicines:** Ensuring the quality of medicines can be challenging in settings with limited resources, affecting the availability of essential drugs.
11. **Vaccine Hesitancy:** Public concerns and hesitancy around vaccines can impact vaccination rates, potentially compromising herd immunity and the effectiveness of immunization programs.
12. **Global Health Emergencies:** During pandemics or health emergencies, there may be pressure to expedite the development and deployment of medicines and vaccines, raising concerns about thorough testing and safety measures.
13. **Data Integrity and Transparency:** Ensuring the integrity of data in clinical trials and promoting transparency in reporting results are crucial for accurately assessing the safety and efficacy of medicines and vaccines.
14. **Training and Education:** Insufficient training and education of healthcare professionals and regulatory personnel may lead to challenges in enforcing quality standards and conducting effective oversight.
15. **Limited Resources for Regulatory Authorities:** Regulatory authorities in some countries may face resource constraints, limiting their ability to conduct thorough inspections and enforce quality standards.

(h) What obstacles do you see to ensuring the affordability of medicines, vaccines and other health products?

Ensuring the affordability of medicines, vaccines, and other health products is a complex challenge influenced by various factors. Here are key obstacles to achieving affordability:

i. **High Research and Development Costs:** the high costs associated with research and development (R&D) contribute to the pricing of new medicines and vaccines. Companies often seek to recover these expenses, resulting in high initial prices.
ii. **Intellectual Property Protections:** Stringent intellectual property rights, including patents, can grant companies monopolies on certain drugs, limiting competition and keeping prices high for an extended period.
iii. **Lack of Generic Competition:** Delayed entry of generic versions into the market due to patent exclusivity reduces competition, preventing price reductions that typically occur with generic alternatives.
iv. **Biological and Specialty Medicines**: The development and manufacturing complexity of biological and specialty medicines often result in higher prices, making them less affordable for individuals and healthcare systems.
v. **Regulatory Barriers:** Complex and lengthy regulatory approval processes can increase the time and resources required to bring new medicines and vaccines to market, contributing to higher prices.
vi. **Market Dynamics and Limited Competition:** Limited competition in certain therapeutic areas or or specific drugs may result in monopolistic pricing practices, negatively impacting affordability.
vii. **Trade Agreements and Market Access**: Trade agreements may include provisions that impact the pricing and accessibility of health products, potentially limiting the ability of governments to negotiate lower prices.
viii. **Health Insurance Gaps**: Gaps in health insurance coverage leave individuals responsible for a significant portion of medication costs, affecting their ability to afford essential medicines.
ix. **Global Economic Disparities:** Economic disparities between high-income and low-income countries affect purchasing power, limiting access to essential health products in less affluent nations.
x. **Pricing Strategies of Pharmaceutical Companies:** Pricing strategies adopted by pharmaceutical companies, including value-based pricing and reference pricing, can contribute to higher prices and hinder affordability.
xi. **Out-of-Pocket Expenses:** High out-of-pocket expenses for medicines, vaccines, and health products can lead to financial barriers, making it difficult for individuals to afford necessary treatments.
xii. **Supply Chain Costs:** Costs associated with the distribution and supply chain logistics of health products can contribute to their overall pricing.
xiii. **Global Health Emergencies:** During health emergencies, such as pandemics, the urgency of demand can lead to increased prices and challenges in ensuring affordable access.
xiv. **Impact of Currency Fluctuations:** Currency fluctuations can influence the pricing of imported health products, affecting affordability in certain regions.
xv. **Innovative Therapies and Precision Medicine**: The development of innovative therapies and precision medicine approaches may come with higher costs, posing challenges to affordability.

(i) What concrete recommendations would you make to enhance access to medicines, vaccines and other health products?

Enhancing access to medicines, vaccines, and other health products requires a comprehensive and collaborative approach involving various stakeholders. Here are concrete recommendations:

1. Global Collaboration: Strengthen international collaboration and cooperation among governments, pharmaceutical companies, international organizations, and non-governmental organizations to address global health challenges collectively.

2. Affordable Pricing and Fair Market Practices: Encourage fair pricing strategies by pharmaceutical companies, including transparent pricing structures and fair profit margins. Advocate for pricing models that balance profitability with affordability.
3. Use of TRIPS Flexibilities: Promote and utilize the flexibilities allowed under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, including compulsory licensing, to facilitate the production and importation of affordable generic medicines.
4. Global Access Licensing Agreements: Encourage pharmaceutical companies to voluntarily enter into global access licensing agreements, allowing manufacturers in low- and middle-income countries to produce generic versions of patented medicines at affordable prices.
5. Open-Source Initiatives: Support and incentivize open-source initiatives where research findings, data, and technologies are shared openly, fostering innovation and facilitating technology transfer.
6. Technology Transfer: Facilitate technology transfer from innovator companies to manufacturers in low-income countries, enabling local production of essential health products.
7. Equitable Distribution of Benefits: Ensure that international agreements and collaborations include mechanisms to guarantee the equitable distribution of benefits arising from research and innovation.
8. Investment in Research and Development: Explore and implement sustainable funding models to support research and development, with a focus on neglected diseases and health issues that disproportionately affect low-income populations.
9. Public-Private Partnerships: Foster and incentivize public-private partnerships that prioritize access to medicines and vaccines. Collaborate on research and development initiatives that address global health needs.
10. **Capacity Building:** - Invest in building the technical and manufacturing capacity of pharmaceutical industries in low-income countries to enhance their ability to engage in technology transfer and produce high-quality medicines.
11. Regulatory Harmonization: Promote regulatory harmonization and mutual recognition of regulatory approvals to streamline processes for bringing medicines and vaccines to market while ensuring safety and efficacy.
12. Transparency in Clinical Trials: Require transparency in clinical trial data, ensuring that findings are openly accessible to the public and regulatory authorities for independent evaluation.
13. Enhanced Pharmacovigilance: - Strengthen pharmacovigilance systems globally to monitor and address safety concerns related to medicines and vaccines.
14. Addressing Health Inequities: Incorporate strategies to address social determinants of health and health inequities, recognizing that broader societal factors impact access to healthcare.
15. Support for Essential Medicines List: Promote the development and implementation of national essential medicines lists, focusing on ensuring access to the most critical and cost-effective health products.
16. Advocacy and Public Awareness: Encourage advocacy efforts at national and international levels to raise awareness about the importance of equitable access to medicines and vaccines.
17. Emergency Preparedness and Response: Develop and implement mechanisms for rapid and equitable access to health

(j) Please add any other information or data you would like to share that have not been covered above? N/A