ESSENTIAL MEDICINES AND HEALTH PRODUCTS

EMP Policy Brief Series No. 2.0

RESPONDING TO INDUSTRY INITIATIVES TO INCREASE ACCESS TO MEDICINES AND OTHER HEALTH TECHNOLOGIES IN COUNTRIES

KEY POINTS

The number and scope of activities carried out by industry[1] to facilitate access to medicines and other health technologies[2] and strengthen health systems in low- and middle-income countries is increasing.

Despite the proliferation of industry initiatives[3], no global framework or guidelines exist to guide their development, implementation and regulation.

Careful consideration is required to ensure public health interests remain at the centre of all access initiatives.

This policy brief aims to outline the types of initiatives that are taking place in countries that involve industry, the risks and benefits for the health system and guiding principles for governments.

WHAT IS THE ISSUE?

In recent years, there has been an increase in the number and scope of activities carried out by pharmaceutical and medical device companies to facilitate access to medicines and other health technologies and strengthen health systems in low- and middle-income countries. These initiatives follow a call for more commitment from the private and public sectors to contribute to Universal Health Coverage *(1,2)*.

Despite the proliferation of these initiatives, no global framework or guidelines exist to guide governments in their development, implementation and regulation. Thus, the challenges for governments working with industry are: 1) ensuring public accountability; 2) sharing and managing risks; 3) monitoring and evaluating performance; 4) ensuring good governance; and 5) long-term sustainability *(4)*.

This policy brief was therefore designed for governments to highlight potential risks and benefits of these initiatives and to provide guidance to effectively respond to industry initiatives related to medicines and other health products.

1 The term "industry" refers to private companies that discover, develop, produce and market medicines and other health technologies.

2 The term "health technologies" refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives.

3 Industry initiatives include partnerships, collaborative relationships and contractual agreements between companies that discover, develop, produce and market medicines and other health technologies and national authorities.

World Health Organization

TYPES OF INDUSTRY INITIATIVES TO INCREASE ACCESS

Pharmaceutical and medical device companies lead a variety of initiatives that aim to improve access to medicines and other health technologies. These initiatives can be categorized as: access initiatives; health systems strengthening and capacity building initiatives; and financing of Ministry of Health activities (Table 1). Access initiatives generally focus on provision of medicines or medical devices through donation, reduced prices or special discounts. Health system strengthening and capacity building initiatives help provide resources required to strengthen institutions and workforce capacity, typically to improve access to pharmaceuticals and medical devices. Financing of activities which fall under the mandate of the government is another approach that is used.

TABLE 1. EXAMPLES OF INDUSTRY LED INITIATIVES

ACCESS INITIATIVES	HEALTH SYSTEM STRENGTHENING AND CAPACITY BUILDING	FINANCING OF MINISTRY OF HEALTH ACTIVITIES
Donations of medicines, equipment or consumables Often provided in response to an emergency situation, but can also be provided in response to a need for long-term aid or to assist national health systems in the provision of health-care delivery.	**Procurement and supply chain strengthening** Typically involves the provision of training on procurement and supply chain management or of software management tools.	**Community-based health promotion activity** Financing of awareness programmes on disease prevention, diagnosis, treatment and care.
Special arrangements in exchange for a purchase These include low-cost equipment leasing and equipment donations often with an agreement to purchase consumables from the company for a fixed period of time.	**National regulatory authority capacity** Includes training on, for example market authorization or quality control.	**Disease screening and follow up care** Financing the cost of diagnostic tests for disease screening and then provision of follow-up care or referrals for follow-up care.
Price reductions These include temporary price reductions, loyalty or rebate programmes and tiered pricing.	**Healthcare professional training** Includes providing courses for physicians and nurses and sponsoring continuing medical education. It may also include training of technical staff on the use and maintenance of medical devices.	**Steering committees and dialogue platforms** Initiating, convening and financing of steering committees and policy dialogue platforms.
	Infrastructure Typically include investments in hospitals, laboratories and diagnostic units, for example.	

Given the financial and technical limitations that exist in many countries, these initiatives are attractive sources of funding, resources and expertise that can help address institutional weaknesses and infrastructure gaps in exchange for tax, marketing, regulatory or other benefits *(3,4)*. Many pharmaceutical and medical device companies view these initiatives as a way to improve their corporate social responsibility in addition to developing their businesses in emerging markets *(5,6)*.

POTENTIAL BENEFITS OF INDUSTRY INITIATIVES TO INCREASE ACCESS

INCREASED AVAILABILITY OF MEDICINES AND OTHER HEALTH TECHNOLOGIES

Access initiatives can contribute to saving lives and improving patient well-being when countries are facing challenges in providing access to medicines and other health technologies. For example, in Botswana, Sri Lanka, Uganda and Zambia, private sector initiatives that involved the donation of medicines for HIV/AIDS contributed to the prevention and spread of the disease *(7)*.

INCREASED QUALITY AND ACCESSIBILITY OF CARE THROUGH HEALTHCARE WORKFORCE CAPACITY STRENGTHENING

Industry initiatives help governments fill important gaps in health service delivery by training healthcare workers and thus increasing the capacity and quality of care *(8)*. These initiatives can also help tackle diseases that are underfunded, and increase the availability of care and technologies to larger populations, especially in remote and underfunded areas. For example, the private sector's involvement in the Directly Observed Treatment Short-Course (DOTS) program in Bangladesh helped train more than 2,000 village doctors on how to effectively detect, diagnose and treat tuberculosis, expanding healthcare coverage to 26 million people in rural areas *(8)*. Another example is the 2015 partnership between the Kenyan government and GE Health, which modernized the country's radiology infrastructure through the deployment of 585 units of diagnostic imaging equipment with a long-term servicing contract and training for healthcare workers *(9)*.

INCREASED FUNDING FOR MINISTRIES OF HEALTH

Industry initiatives can provide needed funding for activities planned by Ministries of Health and which are important for improving health outcomes. For example, pharmaceutical companies have supported governments by utilizing their considerable resources and commercial techniques to promote and distribute products such as vaccines, contraceptives and insecticide-treated bed nets *(8,10)*.

POTENTIAL RISKS OF INDUSTRY INITIATIVES TO INCREASE ACCESS

ADDITIONAL COSTS FOR COUNTRIES

Poorly implemented initiatives can create burdens for recipient countries, wasting money, human resources and time and can have long-term implications on the healthcare system and the environment *(11)*. For example, if a medicine or medical device being donated is inappropriate (quantity too high, expiration too short, product not needed), the cost to the government for disposal can be high. Unsafe disposal of medicines and medical devices can result in medical waste leaching into the soil and water supply, creating additional risks to the health of the environment.

Industry initiatives can run the risk of becoming vertical programs with limited integration into existing health system infrastructure *(3)*. This can potentially overwhelm or divert health workforce and other resources from other health care priorities *(3,7)*. For example, donations and discounted products may increase availability, but they may also require additional government resources such as training on the use of the product, the purchasing of concomitant

treatments and ancillary products like syringes for injectable medicines, or consumables for medical devices. For donated medical equipment, the burden increases when there are no consumables, spare parts or trained staff to maintain the equipment *(12)*. If these resources are unavailable the products become useless.

DUPLICATION AND UNSUSTAINABILITY

Without proper coordination and oversight, industry initiatives can create duplications in health sector activities, further overwhelming and diverting resources away from where they are most needed. New initiatives must therefore be coordinated with already existing programs.

Concerns about the sustainability of and dependency on industry initiatives also exist, as these initiatives can have unclear or short-term timelines and lack clear transition plans for continuity and sustainability *(3)*. Therefore, when making use of such contributions, a transition plan should be discussed and agreed upon upfront. Governments must have transitioning plans to minimize the interruption of the health care services and pharmaceutical products being provided through these initiatives.

LONG-TERM IMPACT ON AFFORDABILITY OF MEDICINES AND OTHER HEALTH PRODUCTS

Industry initiatives can have long term effects on countries' pharmaceutical markets. For example, medicine donations or special procurement agreements can delay the entry of generic medicines into the market by reducing the size of the residual market of a medicine *(13)*. This decreases incentives to invest in the development of generic equivalents and increases the cost of market entry for generic companies *(11, 14)*.

Rebates, loyalty programmes and coupons provide short term savings, but they can also increase healthcare costs in the long-term. The can create a sense of loyalty among physicians and patients, reducing the use and uptake of generic equivalents and increasing the likelihood that insurers will raise coverage rates for all patients to offset increased expenditures on medicines *(14, 15)*.

INCREASED UNDUE INFLUENCE

Industry involvement in the training of health workers can introduce undue influence on doctors' prescribing practices and regulatory and procurement decisions when there is a lack of oversight. Analyses of private sector sponsorships of healthcare professional capacity building and training have found that these sponsorships can influence healthcare workers *(16, 17)*. When capacity building programmes involve travel, accommodation and meals, the risk of influencing the participant is even greater *(18)*. Careful management of conflict of interest should therefore be an essential part of these programmes to mitigate these risks.

These initiatives can also negatively influence prescribing practices in a more indirect way. For example, when donations bypass national policies and regulations, they can weaken adherence to national selection and prescribing guidelines and contribute to irrational prescribing *(14)*. In addition, rebate and royalty programs increase the likelihood of patients developing a sense of loyalty to a brand name product and may decrease doctor's willingness to prescribe a generic equivalent *(15)*.

WEAKENED PUBLIC ACCOUNTABILITY

Industry initiatives can weaken the public sector by transferring the responsibility of providing health and pharmaceutical care from the public to the private sector, eroding social safety nets *(19)*. This can create ambiguity about who is responsible for what and challenges for governments on how industry partners will be monitored, evaluated and sanctioned in the case of underperformance *(3)*. Without proper governance mechanisms to minimize conflicts of interest, and clear responsibilities for all stakeholders involved, the likelihood of these risks increases.

HOW CAN GOVERNMENTS RESPOND?

The following checklist outlines the key considerations to be taken into account when evaluating proposals for access initiatives from medicines and medical device companies.

1 ALIGNMENT WITH COUNTRIES' NATIONAL HEALTH AND DEVELOPMENT PLANS, NEEDS, CAPACITY, LAWS AND POLICIES

- The initiative serves a public health need.
- The policy objective is clear.
- The initiative can be implemented under existing legislation and it adheres to national regulations, procurement procedures, treatment guidelines, and standards of care, quality and safety requirements, remuneration scales and hiring practices.
- The initiative aligns with health strategic plans and the general development agenda.
- The initiative is suitable for the existing infrastructure, capacity, environment and local context.
- Additional government resources (infrastructure, human resources or funding) that are required have been identified and are available.
- The initiative does not divert resources away from other public health priorities.
- The initiative has been compared to other approaches/initiatives/programmes as has been found to be the most suitable.

2 STRONG MECHANISMS TO ENSURE FINANCIAL, PERFORMANCE, AND PUBLIC ACCOUNTABILITY

- Roles and responsibilities for all stakeholders involved are clear.
- The mechanisms for how the initiative will be carried out are clear.
- Those responsible for overseeing and monitoring the initiative have been identified.
- The process for monitoring and evaluation has been established.
- Allocation, disbursement and utilization of financial resources have been defined.
- Performance targets, outputs and results are defined.
- There is sufficient support for the initiative amongst political parties, unions, and civil society organizations.
- Measures to disclose information to the public, including procurement information, contractual obligations, evaluation criteria, progress reports, fund flows, commitments and timelines have been established.

3 STRONG RISK MANAGEMENT AND MITIGATION STRATEGIES

- Risks have been identified.
- Mitigation strategies for each risk, have been developed.
- Due diligence on industry partner has been conducted (including financial, managerial and implementation capacity assessments).
- Potential conflicts of interest have been identified.

4 CLEAR TRANSITIONING PLANS FOR LONG-TERM SUSTAINABILITY

- The initiative is or will be integrated into the health system.
- A clear transition plan for when the initiative ends has been developed.
- A strategy to ensure sustainability of health gains has been developed.

The Paris Declaration on Aid Effectiveness and the Accra Agenda for Action (20) highlight specific measures which are useful for governments to take into account when considering how to effectively respond to industry proposals to improve access to medicines and health technologies in countries. Specifically, they promote country ownership, alignment with local systems, harmonization with other development initiatives, all while focusing on results and mutual accountability. In line with these principles, and to maximize benefits and minimize the potential risks previously outlined, governments must ensure that all initiatives:

1 ALIGN WITH COUNTRIES' LAWS AND POLICIES, NATIONAL HEALTH AND DEVELOPMENT PLANS, AND COUNTRY NEEDS AND CAPACITY

Governments should develop a set of criteria to assess initiatives based on needs, priorities and local setting. This criteria must include ensuring that initiatives abide by all national regulations, procurement procedures, treatment guidelines, and standards of care, quality and safety requirements, remuneration scales and hiring practices.

Secondly, a strategic analysis should be carried out to ensure that initiatives align with national health plans and other development plans and goals *(8)*.This involves ensuring coherence with other sectors and countries' general development agenda to select initiatives that will yield the greatest health impact and advance national health and development goals *(8)*.

Thirdly, governments must ensure that any proposed initiative is based on country needs, infrastructure, capacity, environment, and local context. Initiatives must be considered within the context of the entire health system and the full package of care, from prevention and diagnosis to treatment and care. This includes analysing what human resources, health system infrastructure and any additional resources may be required to successfully implement the initiative. This will help minimize the risk of introducing initiatives that are not well suited for countries' healthcare systems and that may create additional burdens and challenges for governments. This can be achieved through active consultations between Ministries of Health and local partners to evaluate and prioritize country needs and tailor them to local settings and capacity *(21)*.

Lastly, countries are encouraged to compare proposed initiatives to other alternative approaches rather than directly accepting a single offer. Harmonization and coordination with existing programmes and future initiatives should also take place to avoid duplication.

2 HAVE STRONG MECHANISMS TO ENSURE FINANCIAL, PERFORMANCE, AND PUBLIC ACCOUNTABILITY

Prior to implementation, countries must ensure that initiatives' contractual agreements clearly and explicitly define the roles and responsibilities of all stakeholders involved, along with clear monitoring and evaluation agreements *(21)*.