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The pharmaceutical industry and equitable access to medicines

RECOMMENDATION 2

To ensure equitable, affordable access to quality essential medicines and related health products for all women, children and adolescents, governments and parliaments should strengthen policies and regulation governing the pharmaceutical industry.

Many factors influence the fact that millions of people around the world lack access to essential vaccines, medicines and diagnostics. High costs—to people's pockets, national budgets and the pharmaceutical industry itself (for research and development)—are among them. The monopolies held by pharmaceutical companies keep out competitors and constrain governments' policy space to negotiate fair prices. This is compounded by global trade and investment rules that traditionally are focused on economic growth, rather than on outcomes for people's health and well-being; and by trade agreements that enhance patent protections beyond the TRIPS requirements, undermining governments' ability to protect public health and regulate prices.

Strengthening the accountability of the pharmaceutical industry to align it with public health should involve a mix of effective self-regulation in compliance with policies, laws and robust internal codes of conduct, alongside policies that offer incentives for companies to delink costs from the end-line prices of medicines. Governments also need to ensure that adequate policies and funding are available to support investments in research and development, create fair-pricing mechanisms, and improve protection from high out-of-pocket costs. The IAP lends its voice—from an equity and right-to-health perspective—to various expert findings and proposals, including from the WHO, civil society, and the UN Secretary-General's High-Level Panel on Access to Medicines.

2.1. Ministries of health and public regulatory and procurement agencies should strengthen the policies and regulations governing the pharmaceutical industry and other actors involved in delivering medicines, in collaboration with ministries of finance and trade, among others.

KEY MEASURES

Undertake national assessments and reviews of progress in ensuring access to essential medicines for women, children and adolescents *through inter-ministerial collaboration and with the participation of civil society. This includes reviewing the implementation and impacts of related policies, legislation and regulations on out-of-pocket costs and fair pricing. Pharmaceutical companies should annually report on their efforts to facilitate equitable, affordable access to essential medicines. They should ensure public transparency regarding their policies and their implementation (including pricing), as well as their lines of accountability.*

Set standards and minimal requirements to regulate pharmacies and drug retail outlets *on quality and safety, as well as on pricing of medicines, including sharing savings from manufacturers' discounts with consumers to reduce out-of-pocket expenditures. This should extend to pharmacy benefit managers. For essential vaccines and medicines, fee-waiver and subsidy programmes for women, children, adolescents and other vulnerable population groups should be established.*

Ensure adherence to standards and transparency in procurement processes, and set clear contractual stipulations when negotiating PPPs with pharmaceutical companies, *including on monitoring and reporting, and with an emphasis on the negotiation of fair prices.*

Make full use of TRIPS flexibilities in trade and investment negotiations, *refusing provisions that restrict governments' ability to protect public health. This should be buttressed by legislation that fully integrates TRIPS flexibilities, including compulsory licensing. Health and human rights impact assessments should be undertaken to inform decision-making, and these should be made publicly available.*

2.2. Parliamentarians should strengthen legislation and oversight to ensure that public and private actors involved in the provision of essential medicines are aligned with rights-to-health and fair-pricing principles.

In considering legislation specific to any industry, existing corporate legislation, as well as any laws that cut across the business sector relating to financial disclosure, investment, trade, competition and others, may warrant revision from a public health perspective and to ensure coherence with new reforms undertaken.

KEY MEASURES

Require transparency on costs across the research and development, production, distribution and marketing of medicines and treatments; *mandate reporting and disclosure by pharmaceutical companies to regulatory and procurement bodies, including prior to granting licenses, contracts or marketing authorization. This includes requiring companies to justify setting high prices for medicines (such as legislation adopted in Vermont, USA). Regulations on market authorization should also be strengthened, including prohibiting unethical marketing practices by pharmaceutical companies and imposing sanctions, such as the suspension of licenses.*

Ensure strict standards and enforce patent legislation from a public health needs perspective *to avoid companies seeking to unduly extend monopolies (such as the regulations adopted in Argentina and India). Patents should only be awarded for innovations in the production of priority medicines (noting that an estimated 70% of medicines currently available are non-essential or duplicative). Mechanisms should be put in place to ensure that ministries of health weigh in on decision-making by patent offices; and for civil society and other third parties to present grounds for opposing patent applications (such as the legislation adopted in India).*

Require pharmaceutical companies to make clinical trial data publicly accessible *in order to ensure the best possible outcomes for people's health and to enable health providers to access the latest findings on the safety, effectiveness and side effects of treatments they prescribe. The European Medicines Agency, for example, adopted a policy in 2014 to this end.*

Leverage financial and other incentives for pharmaceutical companies to invest in research and development aligned with public health priorities. *For example, the priority voucher review programme in the USA fast-tracks regulatory review for treatment of neglected diseases (e.g. tuberculosis, rare pediatric conditions), an approach that could be adapted to essential medicines for women, children and adolescents, taking into account the lessons learned.*

Set standards of conduct for managing conflicts of interest. *Prevent lobbying by pharmaceutical companies against fair pricing regulations, as well as their undue influence on both public officials and for-profit service providers. Require full disclosure of financial expenses and other contributions for political lobbying and to research centres, patient advocacy groups and health professionals, as well as of public funds or tax breaks received by companies.*

Standardize the prices of medicines, including by establishing price controls and caps for out-of-pocket expenses; ensure public awareness of price ceilings and of reimbursements for out-of-pocket costs. *For example, European Union countries reduced prices for consumers by capping prices for generic medicines and setting standards for reimbursements. Similarly, in 2003 Norway set caps on retail prices for a selection of drugs that were subject to generic competition, resulting in lower prices for consumers. This should be done for essential medicines for women, children and adolescents.*