3

PRIVATE SECTOR ENGAGEMENT AND ACCOUNTABILITIES

Private sector engagement in health takes many forms. Companies provide services, medicines, and technologies that save lives, as well as the food that underpins our daily nourishment. Many industries also affect the underlying social determinants of health as employers, by advancing women's economic empowerment; through their impact on the environment; or by shaping societal values through media and advertising.

The essential needs of people living in poverty—of women, children and adolescents—cannot be subordinated to profit margins and financial interests.

Many express scepticism about the very notion of business engagement in health. Distrust abounds and there are very good reasons for this. Health is not a commodity. The human right to health is fundamental. The essential needs of people living in poverty—of women, children and adolescents—cannot be subordinated to profit margins and financial interests. Purchasing health coverage or paying for services is not comparable to buying auto insurance or other commercial goods. If businesses are to engage in health, they must abide by ethical and legal standards, including in relation to human rights, labour and the environment.

Today, the participation of the private sector in health is a reality. The question, therefore, is not *if*, but *how* they should engage. This is where accountability comes in.

This chapter looks at what is needed, in practice, to protect the right to health of women, children and adolescents. It reviews the forms of accountability governing the for-profit sector's involvement as health service providers and health insurance companies; the role of the pharmaceutical industry and access to essential medicines; and the food industry and the impacts it has on rising obesity and the NCDs. The IAP found, however, that the literature often does not distinguish the for-profit health sector from the broader private sector (which includes non-governmental and faith-based organizations, as well as charities). This in itself points to large gaps in the information needed for enhancing this sector's accountability. Due to these data limitations, "private sector" in the following sections refers to the category broadly, including for-profit entities.

Today, the participation of the private sector in health is a reality. The question, therefore, is not if, but how they should engage. This is where accountability comes in.

Incentives under the 2030 Agenda: What's in it for me?

Corporations and businesses, large and small, are increasingly recognizing the compelling business case for engaging in health. Supporting community health is good for workers' health and productivity, and therefore for business. It enhances a company's institutional image and reputation; helps to capture and sustain customer loyalty and gain new markets; and provides companies with a competitive edge for attracting employees—especially young workers who are socially conscientious. Brand and reputation represent a huge share of companies' market capital, especially in today's mass-media world where bad—as well as good—corporate behaviour can be immediately exposed and disseminated.

But private sector actors face challenges for engaging in women's, children's and adolescents' health. These include a lack of know-how; the scarcity of dedicated institutional brokers to connect business with health investment opportunities; the lack of a common language between the uninitiated business community, on the one hand, and health and development practitioners on the other; bureaucratic inefficiencies and the diverse requirements for partnering with United Nations and other institutions; mistrust of the private sector by civil society, local communities and other stakeholders; and lack of policy, legislative and regulatory measures to level the playing field (which puts do-gooders practicing genuine self-regulation at risk of losing out when others don't play by the same rules).

Alignment with international legal standards, including human rights

Gradually, companies are committing to social development goals. Standards have evolved that encourage this alignment. These include the UN Guiding Principles on Business and Human Rights; the UN Global Compact 10 Principles; the OECD Guidelines for Multinational Enterprises; the Human Rights Council resolutions on business accountability and remedies; and related work by treaty bodies and the Office of the High Commissioner for Human Rights, among others discussed in this report. A working group was also established by the Human Rights Council to elaborate a treaty on transnational corporations and human rights. The Guiding Principles on Business and Children's Rights, together with the recommendations of the Committee on the Rights of the Child, bring added specificity on protections for children and adolescents. UNICEF's Children's Rights and Business Atlas offers practical guidance for businesses on how to go about implementing these principles.

Businesses engaging in the context of universal health coverage must be aligned with one central objective: improving people's health.

Performance against these and other international human rights standards and inter-governmental agreements, however, shows a mixed picture. Although across the SDGs there are numerous instances where business leadership is moving in the right direction, there are still too many cases of private sector actors undermining human rights and the aspirations of the 2030 Agenda. This often includes the very principles these businesses purport to stand for in their public relations campaigns.

Businesses engaging in the context of universal health coverage must be aligned with one central objective: improving people's health. They may also reap rewards and some profits. Political leadership and corporate will, together with much trust-building among civil society and other stakeholders, can help to ensure that both of these objectives are achieved.

3.1. Accountability, its promises and challenges

The private sector is largely assumed to offer key advantages, and often does; these include cost-effectiveness and efficiency; and know-how in problem-solving, addressing bottlenecks and going to scale. But because states are the primary answerable parties, accountability frameworks, including for the SDGs, are often developed with only the public sector in mind. The World Bank and the World Health Organization position governmental accountability as a pillar of UHC. Private sector accountability, however, has been largely absent from policy-makers' mindsets and actions—and the sector is absent in global monitoring of UHC.

States have an obligation to ensure private sector entities operating within their boundaries or under their effective control are held to the same standards as the public sector—for their participation in service delivery and for ensuring effective price regulation, for example. They must also make sure that they are subjected to independent review and oversight. Furthermore, protecting the right to health and other related rights means addressing threats to public health resulting from the actions of state as well as non-state actors, such as marketing of unhealthy foods and exposure to contaminants.

If we take seriously that health is a human right, the social and institutional arrangements that support its universal and effective enjoyment must be put in place. In this view, health systems cannot be reduced to marketplaces. Rather, we must acknowledge that they function as "core social institutions". They are part of the social contract in democratic societies, and are expected to be just and fair in ensuring equitable access to health goods and services, regardless of people's ability to pay.

Health status is deeply influenced by underlying social, political and legal determinants, and by unequal power dynamics; these factors particularly affect population groups discriminated against on the basis of their income, race, ethnicity, gender, age, migrant, disability, HIV, LGBTQI or other status. The oversight role of the judiciary is, thus, indispensable in ensuring that executive branches of government fulfil their obligations to safeguard equitable health service delivery and financing; to carry out effective private sector regulation; and to step in when needed to provide remedies that can catalyse improved performance and protect the right to health, a hallmark of the IAP's accountability framework.

Health systems cannot be reduced to marketplaces.

Challenges for accountability

The complexity and range of private sector actors in health makes it especially challenging to track and synthesize related accountability issues. The challenges include the diverse ways in which the private sector engages in health; the contexts businesses operate in, from the local to national and global levels; the specific health issues they address; and the diverse forms of accountability that apply. The lack of common definitions and limited understanding of—and experience with—many aspects of private sector accountability make matters more difficult. In addition, the issues about which people care most, such as quality of care and equity, often receive limited attention in monitoring.

When it comes to regulating the private sector, both companies and governments face challenges. Private sector actors can be reluctant to accept external regulation. Many commit to self-regulation as part of their business plans, but participatory monitoring with community involvement, external evaluations and independent accountability are often lacking. Governments are challenged in striking the right balance, since overregulation can turn away private sector engagement when it results in high costs for companies. They may be reluctant to impose regulations fearing that companies might take their business and CSR initiatives—and the prospects of boosting the local economy and employment—elsewhere.

With transnational corporations, accountability challenges are compounded because they operate within multiple and sometimes overlapping jurisdictional boundaries, and have long supply chains with many actors and transactions along the way. Companies and multinationals may also provide health services to their workers without standards, oversight or grievance mechanisms in place to ensure quality or compliance with clinical guidelines and human rights standards. The ILO is considering developing a new convention on violence and harassment and the IAP welcomes this initiative, as it would provide the opportunity to put related services and accountability standards in place for working women and older adolescents.

Governments have an obligation to regulate businesses' existing workplace services and incentivize others to provide them, especially to address the sexual and reproductive health and rights of millions of low-income women employed across global supply chains. The countries that exert effective control over transnational corporations headquartered or managed within their borders must also do their part to ensure that these companies are complying with all relevant national and international standards.

Checks and balances for good outcomes

Various forms of accountability apply to the private sector—from legally binding ones with powers of enforcement, to voluntary measures, social accountability and consumer pressures—with varying degrees of effectiveness and authority. Standards that are cross-cutting to private sector activity include compliance with taxation laws and regulations; protection of workers' rights, health and occupational safety; advancement of gender equality (including in relation to sexual harassment in the workplace); supporting the availability, accessibility, acceptability and quality of health facilities, goods and services; environmental protection

PANEL 2. TYPOLOGY OF MEASURES AND MECHANISMS FOR PRIVATE SECTOR ACCOUNTABILITY

Legislation, regulation and government regulatory functions	Legislation and regulations, such as health insurance laws that mandate minimum coverage for sexual, reproductive, maternal, newborn, child and adolescent health; requirements for licenses, certification and accreditation; and authority for government regulators to inspect, audit, and impose penalties. Relevant legislation also encompasses: • public health laws, such as prohibitions against alcohol and tobacco advertising, food labelling • criminal laws and sanctions for falsified medicines • laws on prevention of sexual and gender-based violence and harassment in the work-place • taxes on bad foods; subsidies and incentives for healthy food markets • enabling new forms of corporations (such as social enterprises) to incentivize the pursuit of social objectives.
Heath finance systems	National public and private health finance approaches that set coverage minimums, maximum out-of-pocket payments and co-payments, quality standards, and accreditation requirements for health insurance (such as URAC in the United States).
Contract law	Contracts between donors, governments, health providers or insurance entities, with clear objectives—such as the supply of services to poor women and rural areas, or compliance with quality standards—and consequences for failure to comply.
Judicial review	Administrative, constitutional and other forms of redress, such as the Brazilian Supreme Court sanctions on food industry marketing to children.
Review by non-judicial bodies	Administrative and other non-court review mechanisms, such as review of cases and complaints by hospital complaint boards, ministry of health internal review bodies, national human rights institutions, alternative dispute resolution mechanisms and other informal justice systems.
Human rights reviews	Human rights reviews by regional and international human rights treaty bodies, which sometimes have been translated into national human rights bodies or courts; human rights impact assessments.
Self-governance and quasi- regulatory	Internationally accepted guidelines and standards, such as the UN Global Compact 10 Principles, the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, and the UN Guiding Principles on Business and Human Rights, on Children's Rights, or those of the International Standards Organization (ISO), the Joint Commission International or the Codex Alimentarius. Corporate social responsibility standards. Standards set by professional associations, and disciplinary and supervisory oversight by health professional and industry associations.
Data, indices and transparency	Assessments and external evaluations, voluntary or mandatory and made publicly accessible, such as the Indices on Access to Medicine and to Nutrition. National statistics and health information systems. Open government meetings and records; participatory decision-making involving affected communities and stakeholders during PPP negotiations; procurement transparency (for example, in Georgia).
Political/National policies	National policies and health strategies that guide parliamentary and executive branch actions. Formal processes that provide civil society participation in policy-making, such as membership in government committees.
Social accountability and the media	Civil society advocacy, research and documentation, public awareness-raising and campaigning, such as through public rankings of companies or scorecards. The investigative role of the traditional and new media, including social media and hashtag activism (e.g. #MeToo). Socially responsible investing, such as shareholder activism proposing annual meeting resolutions.

Source: Prepared by Michele Forzley for the IAP, 2018.

and sustainability; and having effective complaint and redress mechanisms in place.

Panel 2 presents an illustrative typology of forms of accountability, by categories and with selected examples, which can be applied to the diverse actors in the private sector. These tools can help to achieve one or more elements of the IAP's accountability framework—monitor, review, act and remedy (presented in Panel 1 of the Overview). This accountability framework requires more than voluntary measures. However, by mapping gaps and assessing opportunities for strengthening accountability, policy-makers, legislators, civil society, development cooperation partners and the private sector itself can identify ways in which oversight can be strengthened.

3.2. Delivering health services: From local providers to hospital networks

To ensure the protection of rights to health, all public and private service providers must be regulated, in all countries, and at all levels. While some profit-driven providers and corporations may object, this can also bring benefits for enhancing private sector performance. Governments with weak regulatory and enforcement capacities, and fragile rule of law, will need political leadership and support to overcome the challenges, including from multilateral institutions and the governments that host transnational corporations. The bottom line is that markets will not self-regulate for equity and people's care.

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If left unregulated, providers have too much decision-making power to determine what services and medicines they offer to their clients. This, in turn, influences demand, as clients, especially those less-educated or less empowered, may be unaware of the options available and therefore cannot make informed choices. There are additional risks in settings where countless informal private practitioners operate without medical credentials, promoting ineffective or dangerous cures.

Conflicts of interest are pervasive among both private and public service providers within health systems in many countries. For instance, public officials may sell illicit drugs or leave health posts unattended to earn extra income in for-profit facilities; or providers may accept gifts from pharmaceutical companies in return for promotion of their medical products. Corruption also remains stubbornly ingrained in both rich and poor countries, and among both government and private sector actors. It takes many forms, from influencing elections and distorting public health policies, to bribing health officials in order to secure licenses or skirt regulations. It is estimated that in the health sector, corruption accounts for a major share of the US$ 300 billion in losses every year.

The increasing use of digital technologies for health poses additional challenges for accountability. Digital health can make significant contributions to achieving UHC, for example, by strengthening health information systems and transparency, making preventive information and services available through mobile technologies, or expanding training for providers. But digital health approaches have not been properly evaluated—particularly when it comes to their equity and gender aspects—nor regulated. With artificial intelligence and health-care-delivering robots looming on the horizon, now is the time to think through regulation in the digital age.

Who provides health services?

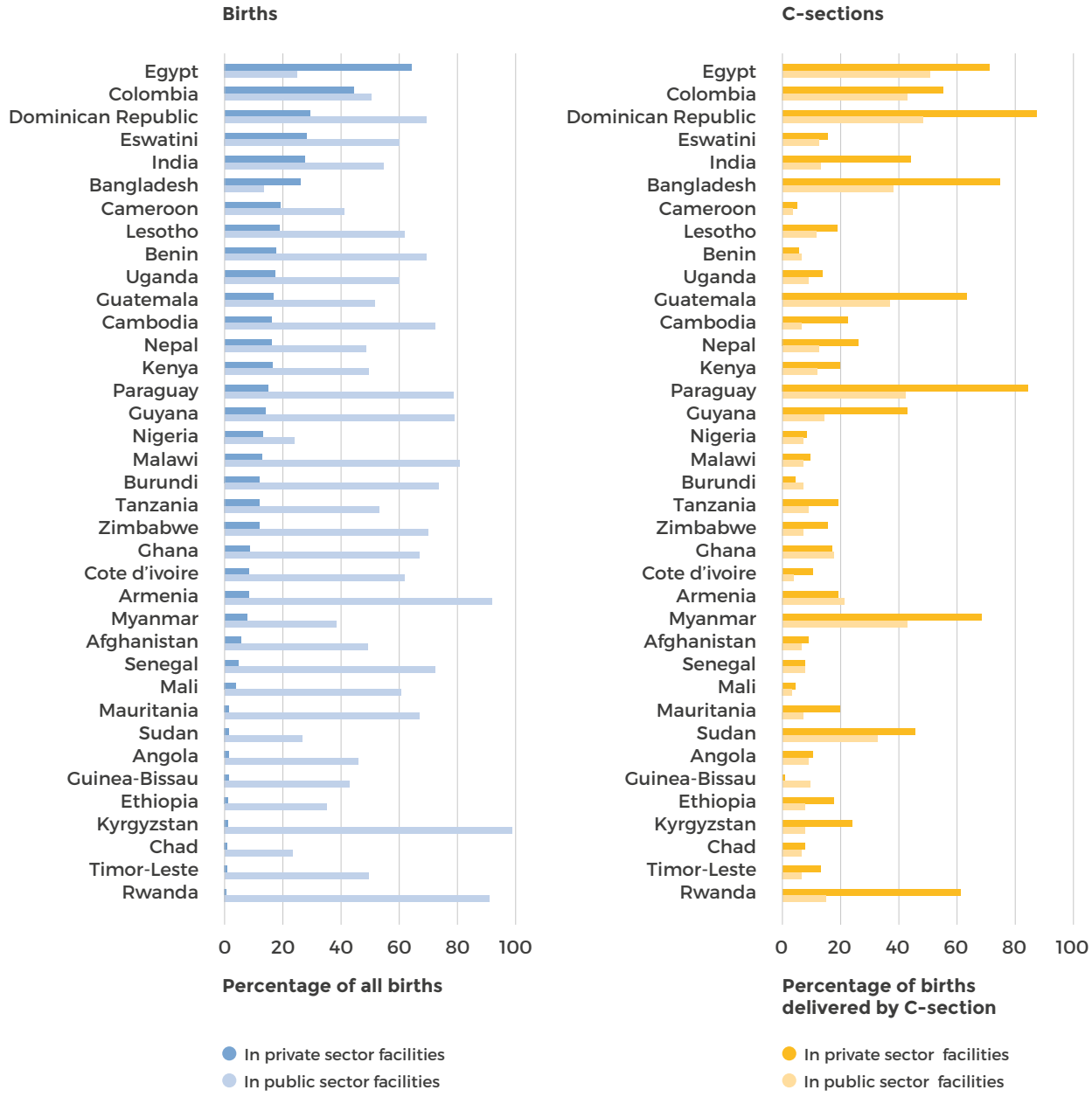
Globally, the private sector provides a significant share of health services. There is great diversity, however, in the public-private service delivery mix across countries. In some—for example, Canada (100%) or Thailand (85%)—nearly all services are run by the public sector. Other countries fall in the other extreme, with the private sector providing most services—for example, the Netherlands, or Georgia (at nearly 100%). The rest fall somewhere in between; in Tanzania, 40% of all primary care visits are to private providers and in several Asian countries, private hospitals account for up to half of all health services.

Recent findings (funded through the Merck for Mothers programme) reveal that in low- and middle-income countries across regions, the private sector covers a large share of sexual and reproductive services for women and adolescent girls: 37% of family planning services, 44% of antenatal care, and 40% of delivery care.

Health system governance models vary too. Most OECD countries have integrated approaches: regardless of whether the services are public or private, regulation and financing mechanisms cover all. This contrasts with the situation in many low- and middle-income countries, where the private and public sectors largely operate in parallel systems. Health insurance schemes also vary across countries—for example, they can be primarily publicly financed, with the private sector only coming in to supplement coverage (for example, in Malta, Rwanda, the United Kingdom); or schemes may be limited to specific categories of beneficiaries (for example, government employees). As consumer demand for choice in providers grows with rising middle-income status (for example, in the People's Republic of China), governments may relax regulations to allow for expansion of the private health-insurance market to supplement public options.

The diversity in the public-private service mix also relates to the delivery of specific services, within and across countries. As Figure 4 shows, more births occur in public facilities than in private ones, with the exception of Egypt and Bangladesh. The proportion of births in private facilities varies widely, from under 1% in Rwanda to over 60% in Egypt. In some countries, births occurring in public and private facilities combined are less than 50% of the total, indicating that home delivery is still common. The percentage of C-sections performed, however, tends to be higher in private facilities—as high as 87% in the Dominican Republic. This reflects the alarming rise of over-medicalization (potentially driven by a range of factors including profit motives) in many low- and middle-income countries. On the other hand, in some countries the low rate of C-sections in both sectors (for example, only 3% in Mali) raises concerns for limited access by women to this vital need.

Figure 4. Births and C-section deliveries in private and public sector facilities



Source: Prepared in 2018 for the IAP by Countdown to 2030 coverage technical working group based at the Johns Hopkins University. Based on DHS and MICS survey data available as of 2014 for 37 low- and middle-income countries, for births and C-section deliveries in the past two years preceding the surveys. Note: Home deliveries are not included.

Achieving universal health coverage

Half or more of the world's population lacks access to quality essential health services. Almost 100 million people fall into extreme poverty every year as a result of out-of-pocket health expenditures and 800 million spend 10% or more of their household budgets on health care. Experts consider that the gaps between the haves and have-nots may actually increase unless equity is put at the forefront of national decision-making. It is no surprise that the latest global stocktaking on the state of UHC concluded that progress is "too slow".

Grappling with accountability will be essential for directing and aligning private sector contributions to achieve UHC. This means ensuring responsiveness to what UHC stands for: equitable access for all to quality essential services, without this resulting in financial ruin or impoverishment. The privatization of health services in many countries; ballooning health care needs; the high costs to public budgets of service provision; and the fact that many people are without even minimally acceptable conditions of access have made it all the more urgent to ensure that checks and balances are in place. Service costs for users (even when covered by health insurance) are of major concern in many countries, posing high-risk barriers for people's health and compounding inequitable service provision and cycles of poverty.

Figure 5 shows how, in sub-Saharan Africa where the private sector is a major source of health care, the richer segments of the population access established hospitals, pharmacies and medical doctors, while those living in poverty are more likely to rely on informal, often unregulated health care providers.

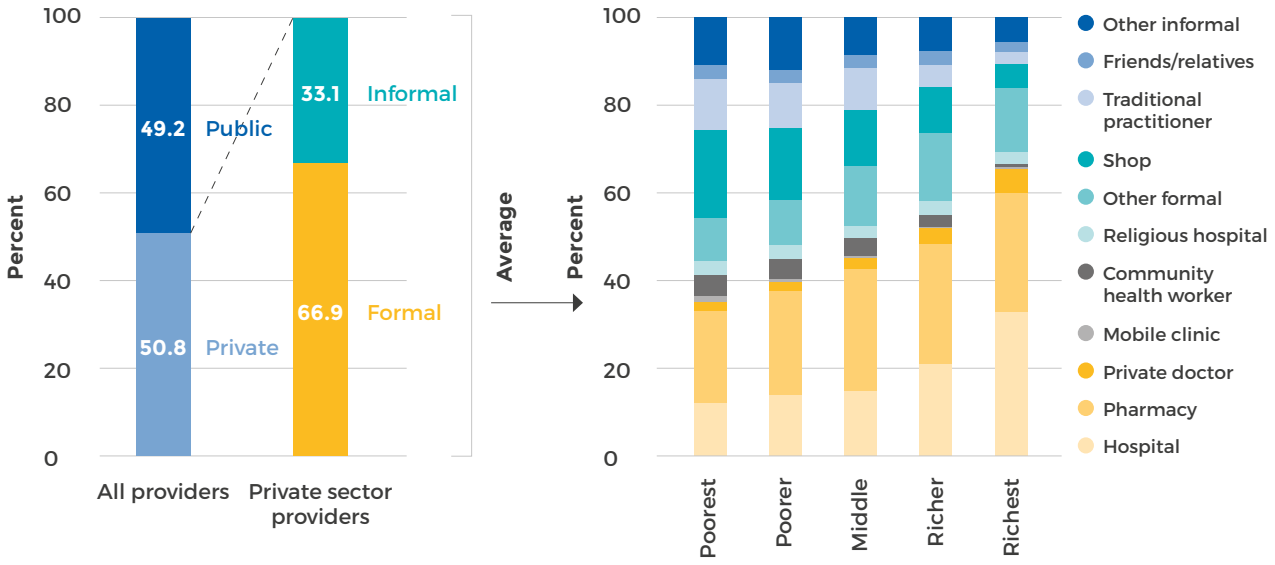
Private sector accountability within national health systems

In many settings, there are serious challenges associated with strategically engaging the private sector while closing equity gaps and upholding standards of quality performance.

To begin with, many governments do not have adequate registries of and data on private sector providers and facilities in their countries; only six of 45 countries in Africa reported having them. Even where registries exist, informal health providers are rarely included, although in some countries they outnumber formal practitioners. In addition, public health officials are not always held accountable for monitoring private sector services because their funding source is not government budgets.

Corporate commercial hospitals have expanded as demand from wealthier segments of society for high-level care and specialized services increases. Some operate as hospital networks within and across countries: examples include Apollo, based in India; the Netcare Group in South Africa; and

Figure 5. Source of health care by wealth quintile and type of service provider for households in sub-Saharan Africa



Source: Analysis of DHS surveys; Montagu 2010 in International Finance Corporation. Healthy partnerships: How governments can engage the private sector to improve health in Africa. World Bank; 2011.

Aster DM, which operates in the Middle East, Far East and India. While these hospitals and clinics fill an important niche in health needs, large segments of the population are often unable to access or afford them. Furthermore, many private sector clinics and hospitals are largely unregulated, offering poor quality of care and overcharging patients. Human rights violations and unethical practices are a major concern, particularly in relation to maternity care; there are cases of families being forced to sell their assets to pay for services, or of at-risk women being discharged to avoid deaths occurring at the facilities. Some of these establishments have been penalized by the courts for egregious violations and neglect.

Knowledge about quality of care is limited, particularly in low- and middle-income countries; there are diverse measurement frameworks and implementation of standards is fragmented (see Panel 3). A new typology developed by researchers from the London School of Hygiene and Tropical Medicine classifies systems for measuring quality of care in the private sector and identifies levers for encouraging providers' participation to improve performance.

Is the private sector a better provider?

The private sector has demonstrated its ability to deliver high-quality services and good health outcomes in many settings. However, there are cases where providers exploit patients or provide poor care. Some private providers have also been known to condone or practice the distribution of counterfeit drugs, overmedication, exorbitant fees for specialist care and the demand for unnecessary tests.

The evidence does not conclusively indicate that, on the whole, private sector services are of better or lesser quality—or higher cost—than those of the public sector. This depends, rather, on how the overall health system is organized. In some cases, the private sector offers higher quality care and is more attentive to clients' needs—especially in terms of stigmatized conditions and populations (such as people living with HIV, or women and adolescent girls with sexual and reproductive health needs). On the other hand, patient preferences may vary according to age or other factors. For example, in sub-Saharan Africa, young women prefer small private sector

PANEL 3. QUALITY OF CARE IN PRIVATE SECTOR SERVICES FOR WOMEN, CHILDREN AND ADOLESCENTS

The Vriddhi project, funded by USAID and implemented by IPE Global and John Snow India, aims to assist India's Ministry of Health and Family Welfare in designing a private sector engagement strategy for reproductive, maternal, newborn and child health (RMNCH) service delivery. A 2016 assessment of private sector facilities in six states found that there was high variability in levels of compliance with established regulations and standards, including clinical guidelines for ensuring patient safety; a majority of in-patient departments lacked legal registration; and very few facilities had the recommended accreditations or renewals from the National Accreditation Board of Hospitals or the International Organization for Standardization. Only one-third of the facilities provided the full package of RMNCH services.

Source: Based on the John Snow Private Limited, India, submission to the IAP 2018 Call for Evidence.

providers for some contraceptive methods, but may turn to the public sector for others. Sometimes, perceptions that public services are of poor quality are borne out by the facts and people prefer to pay for private providers rather than going to public ones for free.

What works for ensuring accountability?

In the context of health care systems, accountability can be defined as measures that ensure that all individual providers, facilities and institutions entrusted and authorized to deliver health goods and services, including medicines and supplies, are answerable for their actions, whether they belong to the public or private sector. This includes ensuring remedial action and instituting timely improvements when problems are detected; mitigating risks of recurrence; and guaranteeing access to justice and redress for neglect and violations of patients' rights. However, while various conceptual frameworks have been advanced by experts, there is no one-size-fits-all approach to accountability because of the very large variance among private sector actors and the contexts in which they operate. Furthermore, government efforts to achieve UHC are often affected by actors beyond their borders.

The following sections look at various approaches and their challenges.

Service providers

Procurement of medicines and supplies, and direct contracting of services

—if terms are well defined—can influence private sector performance by building in incentives, agreed standards, oversight mechanisms and penalties for non-compliance. There is no clear evidence, however, that the quality of outcomes from contracted services in low- and middle-income countries is better or worse than that of publicly provided services; the evidence is mixed in high-income countries. Financial or tax incentives, training, social marketing schemes (that increase demand for services) or offers of subsidies are other approaches that provide incentives for improving performance.

Financial mechanisms,

such as vouchers and performance-based funding, can enhance accountability, but their effectiveness depends on how private sector service delivery is structured and regulated. Vouchers that allow people to access vaccines, sexual and reproductive health, or other services at free or subsidized prices can serve as a quality-control mechanism, allowing governments to monitor private sector participation and discontinue it in cases of poor performance. However, evidence of their effects on improving the quality of care is limited. Similarly, pay-for-performance approaches have had mixed results: they have had limited effectiveness in improving maternal and child health, quality of care and in reducing out-of-pocket costs, although they have been found to improve the clinical knowledge and availability of trained providers.

Accreditation, licensing and certification

are common measures used to align private sector services with quality standards. Many professional organizations—representing general practitioners, hospitals, midwives and other providers—license or certify their members, promoting professional development based on good-practice standards. Depending on the country and legal framework, they may also regulate medical professionals and, in some contexts, investigate malpractice claims. Generally, accreditation by independent organisations (usually an NGO, involving peer reviews) and regulation by government are considered to work best in promoting private sector accountability. While accreditation may be mandated or voluntary, it involves built-in standards, market-entry criteria, inspections, and sanctions in the case of violations. Accreditation is well-established in high-income countries and increasingly so in middle-income countries, where it can be a requirement for participation in national health insurance schemes (for example, in Brazil, Ghana, Kenya, Malaysia, the Philippines and Thailand).

Various accreditation bodies and relevant standards, both national and international, have evolved; they include the International Organization for Standards and the Joint

Commission International, which accredits children's and maternity hospitals. Some specialize in accrediting multinational hospital chains; for example, Accreditation Canada does so globally for ambulatory, child, youth and family care, as well as for obstetrics, based on the standards of the Health Standards Organization. Even in the absence of regulatory requirements for accreditation, providers will often seek out the seal of approval from these highly reputed organizations to provide a competitive edge in gaining clients. However, international accreditation is often too costly or too demanding for many facilities in low- and middle-income countries.

Accreditation has been shown to improve health care provision, but implementation of the associated standards of care by private facilities varies. Accreditation by a health insurance company is sometimes required before a service provider can participate in an insurance scheme, offering a potent financial incentive for compliance with the set standards. This type of accreditation can be more effective in fostering improvements than accreditation by a national organization.

Maternal death surveillance and response systems

are in place in many countries and are considered best practice. Nonetheless, success is reliant on government leadership, provider engagement and institutionalization, among other factors. It is important that these reviews include stillbirths and neonatal deaths; in 2015, out of 71 high-burden countries, 51 had systems for maternal death notification yet only 17 had similar policies for stillbirths and neonatal deaths. Research specific to for-profit services is hard to come by and private facilities may not always disclose the cause of death: in East and Southern Africa, for example, deaths due to early pregnancy among adolescent girls are under-reported.

Social accountability mechanisms

have proven their potential for promoting improvements in health service delivery and quality of care in a range of countries and settings, including rural and impoverished areas. These approaches enable clients and communities to rate service providers, expose grievances and exert consumer pressure for improved performance. The mechanisms include the use of scorecards, social audits, digital technologies, Internet platforms and the radio. Many hospitals and facilities also include community feedback on performance as part of their accountability frameworks.

Patients' rights charters

have been introduced in various countries in response to neglect and abuses in health care. They emphasize the rights of vulnerable groups—for instance, rights to information, informed consent, confidentiality, transparency regarding costs, access to treatment, a second medical opinion and redress, among others. Charters have historically been adopted voluntarily, especially by non-profit organizations, and those developed by the public sector typically have not covered the private sector. Implementation varies: in many countries, service users are not aware of the charters and providers ignore them. Without the backing of oversight mechanisms, patients' rights charters on their own may not be effective; this is especially true if they are not widely disseminated to inform clients of their rights. Cases such as that of Mexico City—where a public information campaign followed a new law allowing abortion—are rare.

Health insurance companies

Health insurance is critical for achieving UHC. When private sector services are not covered and regulated by the public sector, the poorest are the least able to afford out-of-pocket costs and face the greatest risks of financial hardship. In many countries, even when services are supposedly free at the point of service delivery, it is not uncommon for providers, both public and private, to charge fees under the table. With 33% of global health expenditures funded out-of-pocket—a figure that rises to 38% and 43% in low-income and low-middle income countries, respectively—effective regulation to ensure that insurance schemes offer equitable, quality access for those most in need is all the more pressing.

Evidence on what works in promoting the accountability of private health-insurance companies is limited; it rarely differentiates among public and for-profit schemes, and even less among specific groups, such as children and adolescents. While health insurance is generally associated with improved use of maternal health services—including skilled attendance at birth and delivering at a facility—its effects on quality of maternal health care and on outcomes for women and newborns is understudied. There is also the problem of narrow packages that cherry-pick among the services covered, especially in women's sexual and reproductive health.

Lack of public access to easily understood information about health coverage entitlements poses major barriers to users' understanding of their insurance benefits—including with regard to very basic issues, such as what services are covered and for how much. Information about entitlements under insurance schemes, both public and private, may be publicly available in many countries, but it can be too general or too confusing for consumers. One notable exception is the United States' 2014 Affordable Care Act, a multi-payer system with a mix of public and private sector coverage. It details the package of minimum coverage mandated at the federal level—including maternal and newborn care, contraception, breastfeeding and pediatric services, breast and cervical cancer screening for women, and immunization and depression screening for children. While challenges to the law since its adoption have resulted in substantial changes, the minimum mandated services remain.

Regulation by national or sub-national authorities

is the most common mechanism of accountability for health insurance schemes, including private companies. Governments that set clear standards and obligations can monitor compliance to protect clients from arbitrary or exorbitant charges and ensure that they receive, in a timely fashion, the entitlements and reimbursements they are due. However, as with service delivery, regulatory and legal frameworks for insurance schemes vary greatly across countries, as do powers of enforcement. To protect clients, appeal procedures are required in some countries—such as Germany, Switzerland, the United Kingdom (UK), the United States of America (USA) and the United Arab Emirates—to resolve pricing and reimbursement issues. While less common in low- and middle-income countries, remedy mechanisms are also evolving there.

Thailand's experience (Panel 4) demonstrates how a national insurance scheme, overseen by a strong regulatory agency, can deliver for women's and children's health, using strategic purchasing and contracting to ensure clear service standards and cost requirements.

PANEL 4. EQUITY THROUGH REGULATION AND STRATEGIC PURCHASING: THE THAILAND EXPERIENCE

In Thailand, the National Health Security Office ensures accountability through active purchasing of services to provide a comprehensive benefits package, including services for women and children. The services are offered by private and public providers, representing 15% and 85% of providers, respectively. In addition, the Office maintains a 24/7 complaint line and a conflict resolution system. A decade after the launch of this strategic purchasing approach, babies and women (aged 20 to 30) are healthier. This is attributed to having reduced the financial barriers to accessing services among those who were previously uninsured, particularly the poorest members of society, women and young children. This system has been credited with "erasing the equity gap in infant health".

Fostering healthy competition among insurance companies can incentivize good performance when provider networks offer competitive quality of care, enabling them to attract more customers. On the other hand, it can produce quality-skimping to cut costs, such as by not offering services that would be medically advisable, but are considered extra. Insurers themselves can hold health providers accountable through their role in accrediting services, establishing the quality standards that constitute the requirements for participation and reimbursement. Detailed contracts with hospitals, clinics, laboratories and other providers can specify the prices and types of services covered, with complaint mechanisms attached. Likewise external organizations can encourage accountability; for example, URAC in the United States, a non-profit organization legally-mandated to provide Health Network Accreditation to insurance companies, monitors compliance with its standards and requirements, which include mechanisms for self-monitoring, dispute resolution, quality assurance and protection of patients' confidentiality and informed consent.

Accountable Care Organizations provide a mechanism for self-regulation and may be a promising approach for improving quality, affordability and efficiency. Networks of service providers work together with health insurance plans to provide integrated health care while ensuring financial savings. Early results for Cigna in the United States are promising in terms of quality and of some cost factors, although not in the scope of services covered.

What makes health services accountability mechanisms effective?

An effective accountability strategy must foster and test over time an ecosystem of measures for improving health-system performance and governance, tailored to the specific context in which it will be applied and involving a broad range of stakeholders, under principles of equitable service provision. No single mechanism will work in isolation; rather, a combination of government-imposed, self-instituted and citizen-led accountability measures needs to be put in place, facilitated by access to information and transparent reporting.

Many countries need to catch up on regulating the private sector after years of its largely unregulated growth. While private sector stewardship in health is most common in high-income countries, some low- and middle-income countries have also embarked on this trajectory. Afghanistan, for example, launched a stewardship initiative in 2008. In Indonesia, the Expanding Maternal and Neonatal Survival Program deployed a range of measures to strengthen governance of both public and private sector hospitals, as well as community health centres. These measures include clarification of roles, community feedback and convening of public fora, with an emphasis on the providers' social, professional and personal accountability. Early results signal improved quality of care.

The pace and scale of change needed to fill crucial accountability gaps requires fast-tracked leadership from both governments and the private sector, as well as civil society and other actors.

Countries also need to review their existing governance mechanisms, making improvements where needed and adapting to changes in health system developments. The Government of Malta, for instance, in anticipation of expanded private sector provision of hospital services, is applying its concept of clinical governance for ensuring patient-centric care across the whole health system—in line with the country's Charter for Patient Rights and Responsibilities. To underpin stepped up regulation, various initiatives have emerged in support of capacity-building for governments, as well as for the private sector. The pace and scale of change needed to fill crucial accountability gaps requires fast-tracked leadership from both governments and the private sector, as well as civil society and other actors.

3.3. The pharmaceutical industry

The majority of pharmaceutical companies in the world—across the full supply chain—are private sector; they include research companies, manufacturers, exporters, importers and distributors, ranging from the international level through to local retail supply chains and small drug stores. Only a few governments, such as China, Sri Lanka and Thailand, are medicine manufacturers. The role of the pharmaceutical industry in providing universal access to high-quality, affordable, essential medicines—in the context of universal health coverage and SDG target 3.8—is, therefore, indispensable.

Today, 2 billion people lack access to essential medicines, making this one of the most urgent global public health priorities

But today, 2 billion people lack access to essential medicines, making this one of the most urgent global public health priorities. Despite significant progress in immunization rates over the past decades, inequities remain pronounced and the costs of new medicines keep rising. The poor bear the brunt of fractured health systems and persistent market failures: up to 90% of the population in developing countries purchases medicines with out-of-pocket payments, making medicines the largest family budget item after food. For half of all households in low- and middle-income countries, medicines represent 100% of the resources spent on health. In addition, it is particularly alarming that as many as one in ten medical products circulating in low- and middle-income countries are either substandard or falsified.

The availability of medicines, vaccines and equipment for non-communicable diseases is especially poor. For example, in South-East Asia less than 10% of health facilities have a complete array of essential medicines for treating non-communicable diseases. The supply chain in many countries continues to underperform, leading to stock-outs and the inability to deliver quality, uninterrupted supply. On top of these and many other obstacles, countries face continuously emerging challenges to public health, such as anti-microbial resistance and opioid abuse.

The pharmaceutical market is significant: it represented US$ 1.1 trillion in global trade in 2016. The generic drug market is projected to rise to US$ 500 billion by 2021, driven by so-called pharmerging countries; this term refers to the emerging markets in developing countries for both branded and generic drugs. Spending on medicines in these countries has rapidly increased, opening up a growing area of investment for multinational companies. Local production of medicines is also expected to increase, for instance, under the Pharmaceutical Manufacturing Business Plan of the African Union. All this calls for a concomitant increase in regulation and oversight.

Making medicines accessible

Decision-making around research and development of medicines and technologies is central to ensuring equitable access, especially to treat diseases that disproportionately affect the developing world or small patient populations, as well as mothers and children. In 2016, pharmaceutical companies spent US$ 5.6 billion in research and development for drugs and vaccines targeting the developing world. Governments fund an estimated 30% of total research and development globally—and as much as 60% for diseases predominantly burdening low- and middle-income countries—but may fail to set the pricing conditions attached to their financing to ensure optimal return for the public good on those public investments. The challenge is striking the right balance, ensuring fair pricing that is affordable for national budgets and at the same time satisfying the industry's needs for incentives and profit margins. In this regard, it is important to note that the investments pharmaceutical companies make in search of new cures often end up in failure.

Developing safe, effective, new treatments at affordable prices is a complex, costly operation (for example, getting doses and treatments right for young children). If these investments are properly shaped by actors on all sides, negotiating in good faith in line with public health objectives, major cost-savings can be made for health systems in the long-term, while improving equitable access and people's well-being. For example, preventing and managing the risks of NCDs can help to cut the staggering costs of hospital admissions and care once serious chronic conditions present themselves. Many in the industry, however, use well-known tactics to prolong and maximize profits (extending patents and monopolies, blocking manufacturing of generics, etc.); middlemen and hedge fund investors may also hike prices once medicines are on the market.

Efforts to delink the costs of research and development from end-line prices of medicines have intensified as a means of expanding access to essential medicines, but the volume and pace of progress on this front is still limited. High prices for much-needed medicines make them inaccessible to many countries and population groups, including children. The prices of medicines and health products increase across global chains of production, distribution, marketing and retail, but in many countries mark-ups remain unregulated. While some pharmaceutical companies are gradually converging with the aspirations of the SDGs and aligning with needs-based motives, many actors in the industry are not. The challenge, in the context of aggressive competition for markets and profits, is to align the industry as a whole with public health priorities.

Trade negotiations have been the object of bitter deliberations in the struggle to advance universal access to medicines. Pharmaceutical companies sometimes exert undue influence or claim that they cannot afford to lower prices to produce medicines given the high level of investments. Meanwhile, industry profit margins continue to increase—by as much as 20% in recent years for leading USA-based multinational pharmaceutical companies.

Companies and governments have sometimes threatened countries with retaliation when taking advantage of The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities under the Doha Declaration, which allows countries to legally produce and/or import generic versions of patented medicines to expand access to essential medicines for their populations. Recent evidence finds, nonetheless, that 89 countries across all income levels have availed themselves of the TRIPS flexibilities since their adoption in 2001.

History shows what can be achieved. In 1996, Brazil established HIV/AIDS treatment as a legal right and guaranteed free, universal access to antiretroviral drugs (ARVs)—the first developing country to do so. Local manufacture of generics began in the early 1990s. Throughout the 2000s, the government proactively negotiated the prices of treatment and used threats of issuing compulsory licenses to lower prices. Between 2001 and 2005, it is estimated that using the TRIPS flexibilities saved the country some US $1.2 billion on ARV costs. In South Africa, early in the millennium, the government refused to back down from developing ARV generics to ensure access to life-saving treatment for its population, despite threats of lawsuits by pharmaceutical companies. Medication prices dropped as public pressure on the pharmaceutical industry grew and the initiative was hailed a success. Likewise, in India, manufacturing of ARV generics began in 1991, with more companies entering the market since and reducing prices through competition. Today, India is a well-known pioneer in the production of generics, supplying 80% of HIV medicines for Africa. These landmark developments began changing the reality of living with HIV and AIDS, rendering it the chronic, manageable condition that it is today.

The advance market commitment (AMC) model, launched by Gavi and partners in 2009, has drastically cut prices and expanded immunization in resource-poor countries. At the time, the very high prices of pneumococcal vaccines meant that the vaccine would not be available to children in low- and middle-income countries for many years after those

in high-income countries. AMC incentivizes pharmaceutical companies to invest in research and development and to expand production capacity by guaranteeing the price of vaccines through advance donor commitments. In exchange, companies agree to sell them to Gavi at considerably reduced prices for use in low- and middle-income countries. This has resulted in many children's lives being saved.

While some pharmaceutical companies are gradually converging with the aspirations of the SDGs, the challenge, in the context of aggressive competition for markets and profits, is to align the industry as a whole with public health priorities.

However, as countries move to middle-income status they lose eligibility for such schemes, as well as donor support. They can face challenges in sustaining immunization programmes, and be hard-pressed to afford the high costs of introducing new vaccines and medicines. To mitigate these risks, efforts have been underway to assist countries in preparing for the transition to self-financing. Nonetheless, further solutions are needed to ensure long-term affordable pricing of vaccines and medicines, and the sustainability of immunization programmes. The manufacturers of the pneumococcal vaccine agreed in 2016 to drop prices for children in humanitarian contexts, who are especially susceptible to dying from pneumonia, yet it remains out of reach for too many living in developing countries.

The WHO and other stakeholders have launched various global plans and initiatives to address the costs of medicines and price gouging, and to expand access to treatments. These include the Fair Pricing Forum, UNITAID (focused on HIV, tuberculosis and malaria) and PAHO's revolving Fund, among others. The challenges of securing affordable, equitable access to medicines are exemplified by the case of hepatitis C. As of 2016, an estimated 69 million people with hepatitis C were untreated, due in good measure to the exorbitant prices of treatment; these prices are out of reach for developing countries, and even wealthy countries have rationed treatment. In 2017, Medicins sans Frontiers, with UNITAID support, secured generic hepatitis C treatment at greatly reduced prices through the Access Campaign for some of the countries where it operates. Governments in countries such as Brazil and the Ukraine have also pushed back on granting patents and in 2017, Malaysia issued a compulsory license.

Stepping up under the SDGs

Pharmaceutical companies are responding to calls for accelerating progress under the SDGs. Multinational companies have undertaken a range of initiatives to expand access to medicines in low- and middle-income countries, including price reductions, special pricing agreements, training in procurement and supply chain management, financing, and donations of medicines and equipment for ministries of health, among others. These actions often have the dual purpose of enhancing their CSR while securing a foothold in emerging markets. Several initiatives, including PPPs, focus on women's, children's and adolescents' health; they include those listed in the World Health Partnerships Directory of the International Federation of Pharmaceutical Manufacturers (IFPMA). The IFPMA also supports Access Accelerated, which involves over 20 biopharmaceutical companies in developing affordable care for NCDs.

Product development partnerships have expanded in recent years, bringing together the public, private, academic, and philanthropic sectors to pool funding and knowledge behind developing new medicines and related supplies as global public goods (for example, the Medicines for Malaria Venture and the International Partnership for Microbicides). These partnerships are gaining importance and are facilitating technology transfer and local production, especially in emerging markets such as Brazil or Indonesia. An example of a win-win public-private sector partnership in Argentina is showcased in Panel 5.

PANEL 5. A WIN-WIN MODEL FOR PUBLIC HEALTH: SINERGIUM BIOTECH S.A.

Sinergium Biotech S.A. was born in response to the 2009 influenza pandemic, when most vaccines were produced in high-income countries. Argentina, as many other low- and middle-income countries, faced supply shortages. With 100% private investment and through a partnership with a multinational for technology transfer (Novartis at the time, now Seqirus/CSL), Sinergium established a new production facility for flu vaccines. In order to provide free vaccines to all at-risk groups, the government granted Sinergium exclusivity for a number of years to sell its production to the Ministry of Health.

Today, Sinergium's alliances with multinational companies is enabling the company to manufacture other vaccines as well, such as the pneumococcal vaccine (with Pfizer) and the HPV vaccine (with MSD). Argentina is among the countries in the world that have the technology to produce influenza vaccines and is one of the more than 50 members of the Developing Countries Vaccine Manufacturing Network, focused on producing quality vaccines in developing countries.

The Government of Argentina established clear requirements in the contract with Sinergium, including setting annual targets in line with public immunization plans, providing vaccination cards, constructing cold chambers at provincial levels, and supplying computers to vaccination centres for registration and follow-up of those vaccinated, among others. Sinergium's good collaboration with regulators is ongoing. The company has also established links with medical associations and civil society organizations to raise public awareness on HPV, HIV and sexual and reproductive health; foster scientific research; and develop training tools for the medical community.

This experience shows how pharmaceutical companies that exemplify corporate citizenship, and constructive partnership with government regulators, can work for global public health.

Source: Sinergium submission to the IAP 2018 Call for Evidence.

Forms of accountability, challenges and gaps

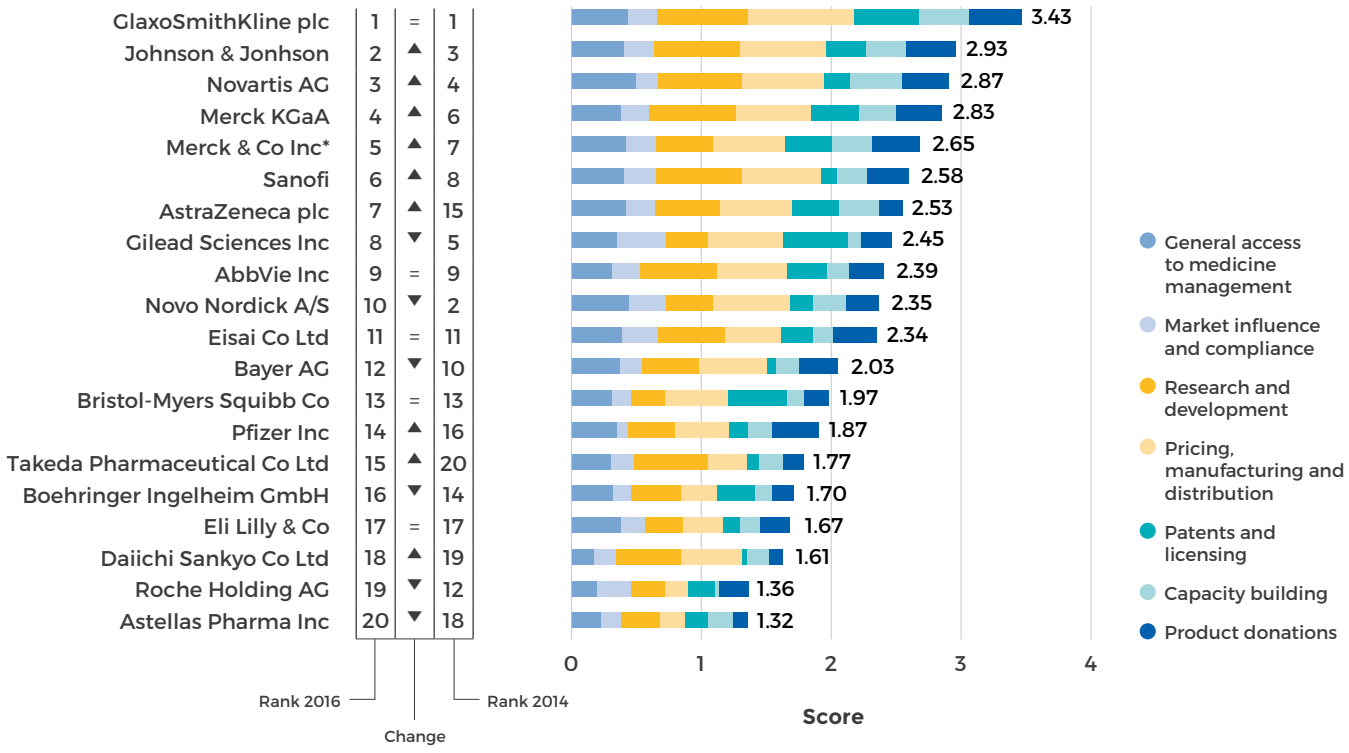
Government regulators, the private sector, or both working together have a primary responsibility to ensure that effective accountability systems with measurable monitoring frameworks are in place to support universal access to essential medicines. Access to medicines is determined by a range of factors that need to be taken into account in establishing these systems, including policies on medicines, pricing and intellectual property rights; public procurement systems and health financing; the effectiveness of regulation; and the existence of corruption (including illicit pricing and political influence), among others. Policies and regulations must extend to generic medicines, and to pharmacies—a primary source of care—including on safety and pricing issues.

Access is also influenced by socio-cultural and gender factors, particularly in relation to sexual and reproductive health. To overcome the barriers and facilitate access by women and adolescent girls to reproductive health commodities, some countries no longer require prescriptions for selected contraceptives, making them available over the counter through legislation (scheduling) and standards for administration of products—such as oral and emergency contraceptives, as well as injectables—by trained pharmacists and drug outlet staff.

Self-governance practices, commonly followed by pharmaceutical companies engaged in CSR in the developing world, include self-monitoring and public reporting; internal policies (for example, on anti-corruption); and codes of conduct regarding social, health and ethical principles (such as responsible pricing). The IFPMA, for example, has its own code of conduct and ethical principles. Brazil's INTERFARMA, the national industry association, actively works on the regulatory environment; it issues detailed guidance on managing conflicts of interest in its Code of Conduct, as do many other national industry associations. However, compliance and internal enforcement of these codes and policies varies across industry actors. Non-disclosure and lack of transparency—such as on costs and investments—are common gaps. Self-governance is not enough. Accountability requires independent review and the existence of effective remedy.

Indices and public rankings incentivize companies to improve over time by pointing them to concrete areas of their operations where course-corrections should be made. The Access to Medicine Index is the leading independent assessment of pharmaceutical companies' performance in improving access to medicines, ranking 20 of the world's largest pharmaceutical companies—including some EWEC commitment-makers. The Index covers seven areas of corporate activity, including research and development, pricing, compliance and capacity building (see Figure 6). It is based on self-reported data from companies, which are cross-checked through research using publicly available sources, as well as through external validation and consultations. The latest findings, from 2016, show that while pharmaceutical companies are becoming more sophisticated in getting their products to poor people and are addressing global health priorities,

Figure 6. A race to the top? Access to Medicine Index overall ranking



Source: Access to Medicine Index, 2016. Five is the maximum score.

good practice is limited to a narrow range of products and countries. In terms of affordable and equitable pricing, only 5% of the companies' products satisfied the Index criteria. In 2017, the Access to Medicine Foundation issued the first Access to Vaccines Index, ranking the so-called big-eight vaccine companies on their efforts to improve immunisation coverage, including pricing sensitivity in line with ability to pay, among other issues.

Social accountability and human rights reviews can, similarly, shape practices by putting pressure on pharmaceutical companies to manage reputational risks in the face of public opinion. In the UK, for example, public and media pressure prompted a retail chain to lower its inflated prices for a generic version of emergency contraception. However, social accountability, like self-governance, is insufficient on its own; it requires going beyond—to effective regulation.

The frailty of regulatory systems does not relieve the business sector from its responsibilities to public health.

Legislation and regulation by governments is ultimately the key for ensuring accountability. All legally licensed operations and all other legitimate players in the pharmaceutical industry supply chain—from manufacturers to distributors, exporters and importers, retail chains and local pharmacies—fall under the regulatory system established by the relevant government agencies. This includes legislative, policy, judicial and contractual mechanisms that can be leveraged to ensure equitable access to essential medicines—for example, legislating pricing transparency for consumers and decision-makers, fixing price ceilings, or directing distribution of pharmacies. Governments have also taken the initiative to enhance collaboration and regulatory frameworks at the regional level, such as CARICOM's Caribbean Pharmaceutical Policy; work is also underway in Eastern Mediterranean countries, including to improve implementation of codes of conduct, establish independent complaints mechanisms, and engage civil society.

Countries, especially those with low institutional capacities, commonly face regulatory challenges. Governments are blind-sided when they lack adequate procurement and regulatory capacities to undertake thorough assessment before granting patents, licenses and market authorization for medicines; and also when they lack access to crucial information for sound decision-making on patents awarded, clinical trial results and prices companies charge for the same products in other countries. These challenges are compounded by the expansion of industry-led initiatives, which has outpaced the ability of developing country governments to effectively engage in their development, implementation and monitoring. In 2018, the WHO issued a policy brief to support governments in assessing industry-led initiatives, including ensuring compliance with national laws and regulations.

Regulators must establish clear rules and standards around promotion and advertising, clinical trials, competition, Internet sales, licensing, and storage, distribution and transport of medicines, among others. The key steps towards effective regulation include ensuring due diligence prior to accepting projects; and establishing clear contractual agreements, including monitoring, evaluation and public disclosure requirements. Taking these steps helps to avert problems governments may run into—such as use of scarce resources for duplicative efforts; accepting drug donations that are not appropriate for country needs or have short expiration periods that end up costing governments to dispose of them; and conflicts of interest arising from, for example, industry tactics to influence doctors' prescription practices by offering training and travels, or decisions concerning what medicines are included in national lists or for reimbursements.

Weak regulatory and enforcement systems remain a major obstacle to securing universal, equitable access to safe, effective, quality essential medicines and related supplies for the populations most in need. While in-country regulatory capacities desperately need strengthening, regulation of transnational pharmaceutical companies in their home countries is also essential. The frailty of regulatory

systems, however, does not relieve the business sector from its responsibilities to public health, as affirmed in the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines. Ultimately, independent monitoring and external regulation are critical to validate compliance with public health objectives and standards. Improved efforts are also needed to track the CSR and PPP initiatives of multinational pharmaceutical companies, as well as their public health effects in developing countries, and to review how these initiatives are coordinated and aligned with national health systems.

3.4. The food industry and big business impacts on health

Beyond the role of the private sector in health-care delivery, a myriad of global industries impact on the well-being of women, children and adolescents. They shape and influence underlying determinants of health–from the air we breathe and the water we drink, to the food we eat. They improve public health when their operations work to curb pollutants and chemicals; protect land and aquifers; and treat their workers right. But there are also many adverse impacts. The fashion industry, for instance, is one of the largest polluters in the world, in addition to paying notoriously low wages for labour. Advertising and the media play a role in eating disorders among adolescents, which have become a global problem. The lack of gun control (as witnessed with the mass shootings and in schools in the United States) is yet another example of how big business influences people's health—and their very survival.

A major influencer of public health and nutrition is the food industry—the focus of this section. We chose this industry, with an emphasis on sugary drinks and junk food, not only because food is a basic necessity, but also because of the urgent need to address the alarming rise of obesity and non-communicable diseases (NCDs) around the world.

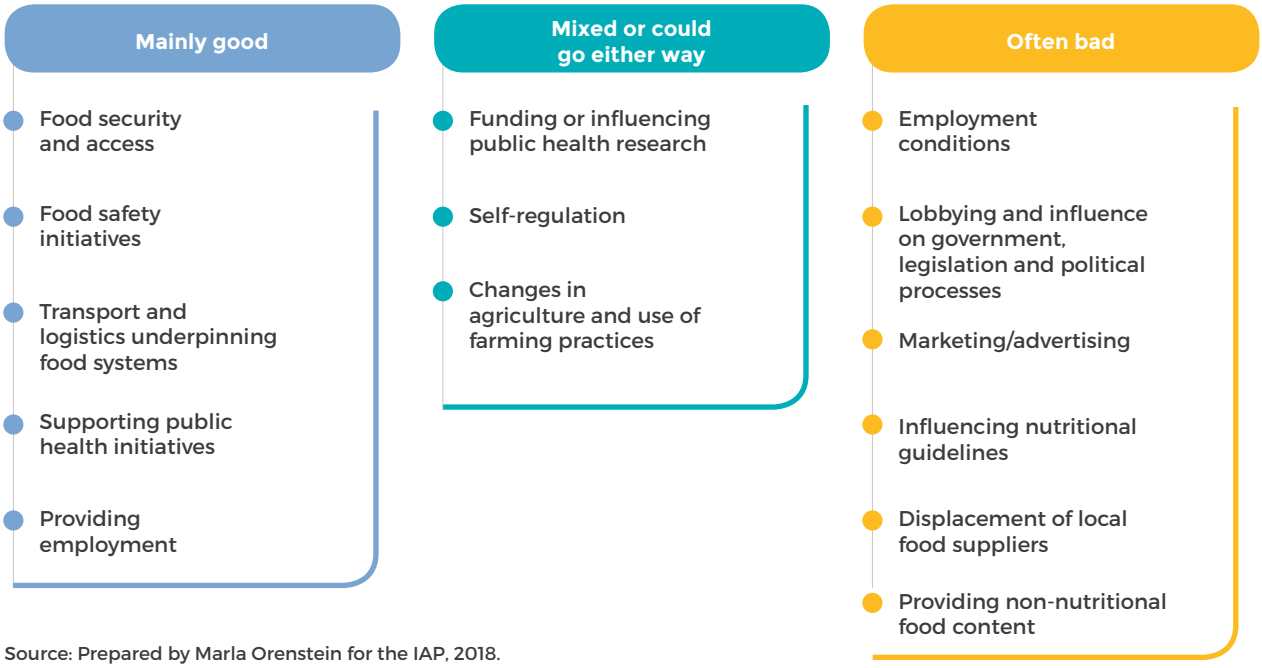
Tackling food industry accountability

The food and beverage industry is enormous, multi-faceted and diverse, comprising all organizations involved in producing, packaging, distributing and marketing foods and beverages. The size of the industry and the complexity of players involved—from small farmers to huge multinational corporations—requires tailored accountability measures across national and global production and supply chains.

We depend on the food industry for the nourishment that sustains us, and for ensuring its nutritious content and safety. Increased public awareness and consumer demand have provided incentives for companies to create new lines of healthier foodstuffs, but too many companies still operate in ways that undermine public health. And while various transnational corporations have committed, through voluntary actions, to minimizing unhealthy food and improving the nutritional value of their products in high-income countries, this may not be the case across the board in low and middle-income countries. Figure 7 illustrates ways in which the food industry influences public health, from the very good and essential to the harmful. It also reflects where public policy and regulatory measures are particularly needed to align industry action with public health.

By comparison to other industries that promote unhealthy consumption patterns (such as tobacco and alcohol), monitoring and regulation of the food industry is lagging. A binding international convention has helped to rein in tobacco companies and has contributed to significant drops in smoking rates in countries where there has been compliance. Standards and national legislation also exist in many countries when it comes to alcohol consumption, including restriction of sales to minors and curtailing times for purchase. Nothing comparable is available when it comes to the impact of the food and sugary beverage industries on obesity and other NCDs, with some notable exceptions—mainly the standards restricting the promotion of breast-milk substitutes and promoting food safety, discussed below.

Figure 7. The good, the bad and the in-between: How the food industry influences public health



Source: Prepared by Marla Orenstein for the IAP, 2018.

Breast-milk substitutes

Breast milk is a unique and nutritious food that boosts infants' healthy growth and development. Aggressive marketing of baby formula and other substitutes contributes to depriving infants of the benefits of breast milk and thereby increases their health risks. In response to concerns for declining breastfeeding and rising child mortality in developing countries, the International Code of Marketing of Breast-milk Substitutes was adopted in 1981. The Code outlines if and how products can be promoted and marketed, to enable mothers to make informed choices free of commercial influences and biased information. Though voluntary in nature, the Code's strong language and clarity, the adoption of its provisions in a growing number of countries and the global mobilization of monitoring efforts have served to sustain pressure to improve business practices. In line with the Code, many countries are also taking measures to support breastfeeding among women. Peru, for example, passed a law in 2016 mandating the public and private sectors to provide breastfeeding spaces, including in banks and shopping malls.

However, lapses in monitoring and enforcement are not uncommon and violations of the Code occur in high-income as well as low- and middle-income countries. Sanctions are relatively few and penalties often too small in comparison to the huge budgets of the companies involved (the industry made some US$ 40 billion in global sales of milk formula in 2013 alone). Conflicts of interest, and public sponsorship and other marketing tactics abound—including misleading women to believe formula is more nutritious.

Even in countries where the Code has been integrated into national legislation, inadequate regulations and weak monitoring render those provisions ineffective. Companies' internal policies have also been found to be sub-standard and inconsistent with the Code. Nearly 40 years since the Code was adopted, aggressive promotion of breast-milk substitutes remains a major barrier to increases in breastfeeding. As sales drop in higher-income countries, low- and middle-income countries—and poorer, less-educated women—are increasingly targeted. Getting accountability right could have priceless rewards: worldwide, the lives of over 820 000

children under five could be saved each year if breastfeeding were universal; this could also generate US$ 300 billion in economic savings.

Big business and NCDs

NCDs, such as cardiovascular diseases, cancer, diabetes and chronic lung diseases, cause 70% of all deaths worldwide—almost 40 million every year—particularly affecting poor and excluded communities. Over three-quarters of NCD deaths occur in low- and middle-income countries—that is, the countries with the health systems least able to cope, and where too many people already lack access to essential services. Globally, more than half a million deaths that occur every year are associated with intake of trans fats. In addition, excess sugars are linked to obesity, illness and death from NCDs, and many people living with NCDs and chronic conditions require treatment and care. The financial burden of NCDs is huge, estimated to cost US$ 47 trillion to the global economy through 2030. Additional health risks regularly emerge, such as the growing threat of antibiotic-resistant bacteria or the potential risks of the use of antibiotics in animal husbandry—banned by the European Union years ago—further burdening health systems.

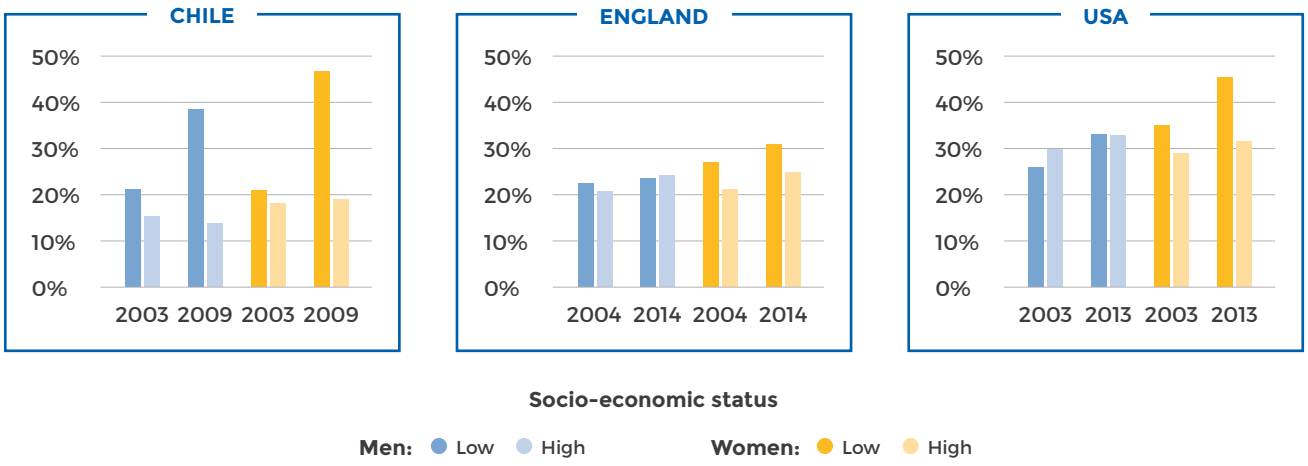
Though NCDs result from a complex combination of factors, such as environment, genetics and behaviour, the risks can be mitigated. Many factors linked to NCDs (for example, tobacco use, exposure to second-hand smoke, unhealthy diet, physical inactivity and harmful use of alcohol) begin during adolescence—a critical time for prevention. Women, children and adolescents are particularly at-risk because of their low socio-economic, legal and political status. Women face higher risks of maternal mortality associated with obesity and high cholesterol which in turn, affects their newborns: in 2015, high blood glucose in pregnancy affected some 21 million live births.

The obesity epidemic

Alarmingly, some two billion adults in the world are overweight or obese. In some countries, the proportion of overweight women is much higher than men. The epidemic is growing alarmingly fast: there has been a tenfold increase in obesity among children and adolescents over the past 40 years. The vast majority of overweight or obese children live in developing countries, where the rate of increase has been more than 30% higher than that of developed countries. Obesity not only increases the risks of diabetes in childhood, but also the likelihood of remaining obese through adulthood, with serious health problems later in life, including diabetes and heart disease.

Obesity and the intake of unhealthy foods affect all countries and are strongly linked to poverty. In OECD countries, low-income groups and

Figure 8. Trends in obesity, by gender and socio-economic status



Source: Prepared by OECD for the IAP, 2018. Based on national survey data. Socio-economic status is defined based on income levels for England and the USA, and on educational levels for Chile.

women are especially affected. Women with less education are up to three times more prone to being overweight than those with higher education in some countries. As Figure 8 shows for three countries, the differences based on gender and socio-economic status are significant, and are increasing in some countries. The increases in obesity among lower-status groups are particularly marked in the case of Chile, among both women and men, as well as among women in the United States.

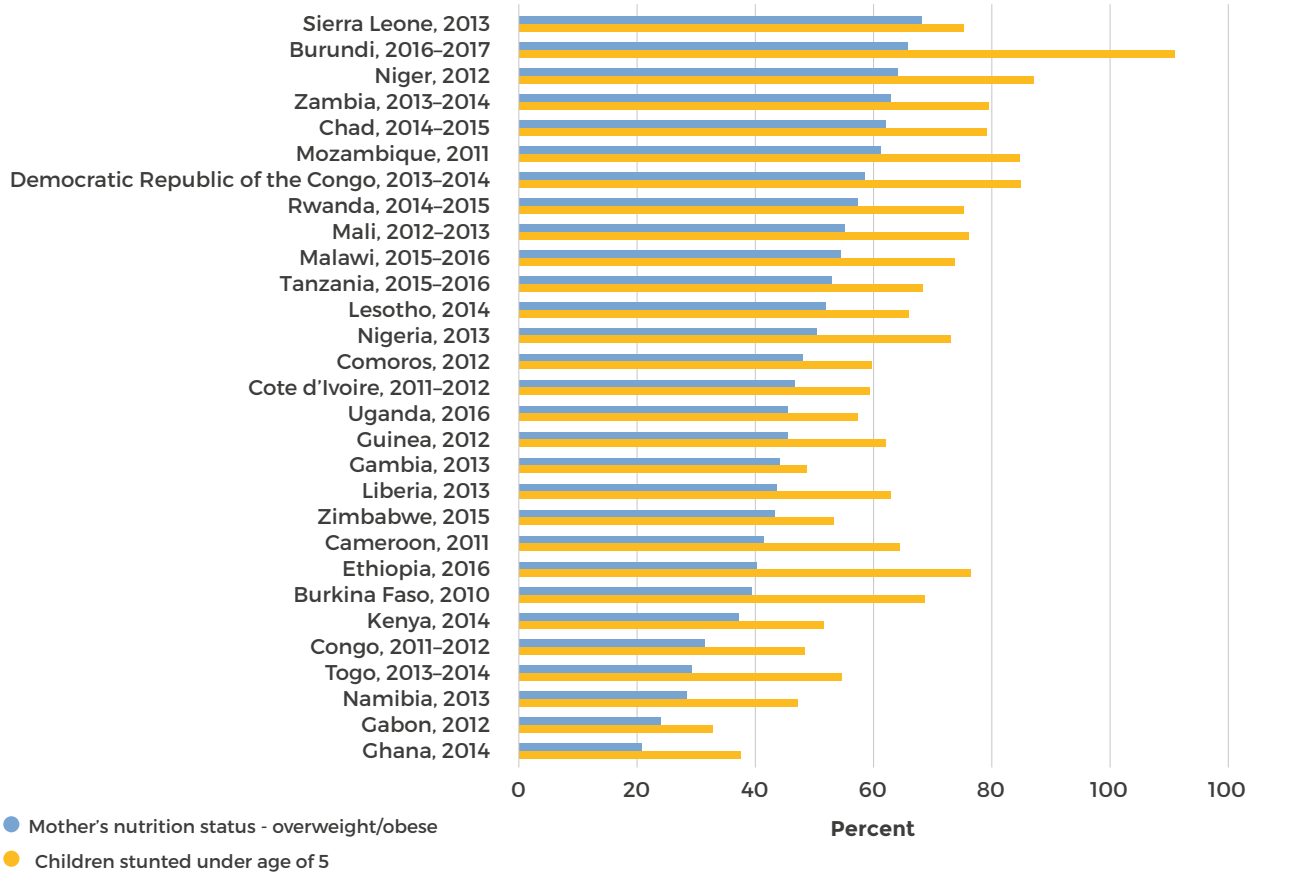
In addition, the paradox of a double burden has emerged within countries, communities and households where, for example, anaemia in girls and women, or child stunting, co-exists with high rates of maternal obesity and overweight (see Figure 9); or at the individual level, among individuals who have micronutrient deficiencies despite high caloric intake. In sub-Saharan Africa—where countries are torn by conflicts and severe drought, and impoverished populations face threats of hunger and famines—increasing overweight and obesity rates among children are linked to cheap imports of food and to urbanization.

Being overweight or obese is a factor in many NCDs, such as diabetes, cancer, and cardiovascular and respiratory disease. The financial costs of obesity are staggering as well: the global obesity epidemic is currently estimated to cost US$ 2 trillion annually, or 3% of GDP. This makes strengthening the accountability of the food industry and transnational corporations, which serve as "vectors for the global spread of NCD risks", all the more urgent.

The rising tide of non-communicable diseases

Why have NCDs risen so fast? While there is no easy answer, they have increased in tandem with the globalization of food processing, distribution and

Figure 9. Under one roof: the obesity-stunting conundrum



Source: Prepared by Marla Orenstein for the IAP, 2018. Based on latest data available for 29 sub-Saharan African countries from DHS surveys, 2010-2017.

marketing, and the trade of unhealthy products. In many developing countries, this has translated into a shift from fresh produce in open markets to supermarkets stocked with processed, unhealthy foods produced by large multinationals. Shifts in the locus of power for decision-making mirror this trend—away from national governments, local producers and farmers, to traders, retailers and international conglomerates.

These trends also exacerbate inequalities: fresh produce and healthy options become financially out-of-reach for low-income households; but inexpensive, non-nutritious, high-calorie foods are accessible almost everywhere. As with tobacco, producing unhealthy foods is hugely profitable for companies given the low production costs and other advantages offered by long-lasting, packaged goods. This creates perverse incentives for businesses to aggressively seek out new markets, especially in low- and middle-income countries, where consumption of unhealthy commodities is rising fastest and is projected to continue.

Policy-makers have adopted international agreements to tackle the fast rise of NCDs, namely the 2011 UN Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases and its follow-up reviews, SDG Target 3.4, and the Montevideo Roadmap 2018-2030 on NCDs as a Sustainable Development Priority (which also calls for private sector accountability). However, limited progress has been made in implementing these agreements. In 2018, to accelerate the global response, the WHO launched the High-Level Commission on NCDs; it proposes solutions, building on recommended cost-effective "best buys".

Aggressive marketing and tactics

The food industry landscape is riddled with power-shaping tactics, conflicts of interest and unethical practices—from aggressive marketing and outright bribery to more nuanced tactics that distort policy-making and scientific research, and derail regulatory efforts that could protect public health. Lobbying by corporations in trade negotiations compounds the global challenge of addressing malnutrition. Equipped with sizable budgets, companies apply tactics learned from the worst offenders, such as the tobacco industry, driving consumer behaviour in ways that perpetuate harm.

Over the past decade in the United States, the food and beverage industry spent, on average, close to US$ 30 million each year on lobbying; since 2009 it has spent US$ 107 million to fight taxes on sodas and warning labels alone. Also in the United States, US$ 2 billion per year was spent on marketing food and beverages to children between 2006 and 2009, targeting those as young as two years old. One major beverage company spent US$ 4 billion worldwide in advertising in 2017. With some US$ 350 billion per year in global sales of carbonated soft drinks, the beverage industry has a lot of incentive to derail regulatory efforts.

Marketing to children

The onslaught of aggressive marketing targeting children is a critical concern. Consumption of unhealthy foods and beverages shapes their eating preferences, beginning with added sugars in breast-milk substitutes. Children are more susceptible to marketing, lured by playful cartoons and similar promotional tactics that provide businesses with potentially life-long, loyal customers for their products.

Several industry-driven initiatives have arisen to address childhood obesity, improve nutrition and curb advertising of fast foods, as well as PPPs, such as the EPODE network. But while very welcome, these initiatives on their own are not enough to combat the large scale of the problem. Industry-led efforts are not always accompanied by independent validation to assess whether companies are staying true to their public pledges. Furthermore, some companies put the onus on individuals for their unhealthy consumption habits to deflect attention from their own responsibilities for public health.

In studies in the United States, the overwhelming majority of foods marketed to children were found to be of poor nutritional quality; three-quarters of the advertised foods comprised fast foods and sweets, in particular breakfast cereals and carbonated beverages. Advertising was also found to specifically target black and

Hispanic youth, who face higher risks of obesity and related diseases. In the UK, one study found that the food industry spent nearly 30 times more on advertising junk foods than the amount spent by the government to promote healthy eating. In China, a study on food industry advertising on television channels that are popular with children found that 25.5% of all advertisements were for food, of which 48.1% were for unhealthy foods.

In 2010, WHO Member States adopted recommendations on marketing foods and non-alcoholic beverages high in saturated fats, trans fats, sugars or salt to children and adolescents. Their implementation is limited, however, and meaningful monitoring and enforcement are lacking. In the absence of effective accountability systems, the standards on ending inappropriate promotion of foods to infants and young children, endorsed by the World Health Assembly in 2016, may meet with the same fate.

Overall, as with the International Code of Marketing of Breast-milk Substitutes, voluntary frameworks largely rely on industry self-regulation, which is too often driven by profit interests rather than by concern for protecting children's rights to nutrition and health. Fast food restaurants are especially notorious: in the United States, a study from 2013 found that only 3% of kids'-meal combinations met the industry's own nutritional standards. The WHO Commission on Childhood Obesity calls on states to actively engage the industry in transparent partnerships, with clear accountability mechanisms in place to align their activity with public health priorities and standards. Under legally binding international conventions and human rights standards, governments have an obligation to ensure that legislation and regulations curb marketing of unhealthy foods to children, including in schools.

International codes of practice to keep food safe

Food safety and packaging are well covered by existing laws and accountability regimes, notably the long-standing Codex Alimentarius initiated by the WHO and FAO in 1963. This collection of thousands of international standards for international food trade ensures safety and quality. The Codex Commission proceedings, in which most countries in the world participate, actively engage industry representatives—who have a voice, but no vote.

While the Codex is not legally binding, it is very effective: incentives for compliance by both governments and the industry are built in. Codex standards are a leading reference point for settling World Trade Organization disputes—thus powerfully dissuading potential violators. Companies face very damaging reputational risks and plummeting sales of their products if scandals arising from loose compliance result in public health emergencies or massive product recalls. Such was a recent case in South Africa, where an outbreak of listeria (an infection that can be lethal, caused by contaminated food), prompted public outcry and a class-action lawsuit against a major food company that is pending court ruling. Because pregnant women are particularly vulnerable to listeria and can pass it on during gestation, some 40% of the fatalities were newborns.

The Codex holds up as a very positive accountability system—and a very rare one when it comes to the food industry. It has increased food safety globally by mediating and guiding public health and industry interests for improved outcomes. However, its scope is narrow and does not comprehensively address the harms of industry conduct.

Where to on food industry accountability?

The gaps in independent monitoring and accountability of the food and beverage industry contrast sharply with the auditing companies routinely undergo of their financial, environmental and social welfare performance. The challenge of balancing public health concerns with for-profit motives is becoming even more acute as the industry increasingly becomes involved in public-private partnerships to reduce obesity. Moreover, small and medium-sized food producers that share the commitment to improving nutrition do not always receive the technical assistance and support they need.

A combination of voluntary standards, strict regulatory measures and legislation (both in countries where corporations operate and where they are headquartered), and consumer demand for healthier products serve as key levers for shaping industry alignment with public health. Building constructive dialogue across stakeholders, including civil society, is also essential to overcome the polarization that has been fuelled by years of industry breaches of existing standards, such as those pertaining to tobacco and breast-milk substitutes.

Legislation and judicial enforcement are increasingly utilized by countries to govern the food industry in order to address rising obesity and NCDs among women, children and adolescents. In Brazil, for example, in response to the influence of food and beverage industry donations on regulatory efforts, the Supreme Court banned corporate contributions to parliamentarians during elections as unconstitutional.

Bold new measures are needed to govern food industry conduct. This can level the playing field, ensuring that all those in the industry doing good can do more, and that others can be brought in line with the protection of women's, children's and adolescents' health.

Fiscal policies, such as taxation of sugary foods and drinks, are effective, much in the same way increasing tobacco prices deters smoking; this is one reason why the WHO issued its recommendation of a 20% tax on sugary drinks in 2016. Soda taxes are increasingly being implemented in a range of countries, including among OECD members. Norway, for example, has taxed added sugar since 1922, and hiked the tax significantly in 2018. Mexico's 2014 tax on sweetened beverages reduced consumption by over 7% within two years.

Public rankings of food companies, as with pharmaceutical companies, incentivize improvements in policies and practices to support better nutrition. The Access to Nutrition Index, developed by a non-profit organization based in the Netherlands together with industry and other stakeholders, ranks 25 leading global food and beverage manufacturers on their nutrition-related commitments. The 2018 report shows that, while some companies are making improvements—such as new policies, or commitments to address undernutrition—progress is too slow, particularly in providing affordable, healthy foods for people living in poverty. Fewer than a third of the products analysed were found to be healthy. All companies were in need of improving responsible marketing, especially aimed at children. A nutrition index dedicated to tracking performance of the leading companies involved in the production and marketing of breast-milk substitutes is also available.

Self-regulation and voluntary codes of practice have resulted in some achievements in some countries, particularly around reducing dietary salt, limiting marketing to children, and improving menu labelling, as well as the beverages made available in schools. Self-regulation has benefits: it conserves government resources, and is less adversarial and more flexible—and can be timelier—than government regulation. But self-regulation is meaningless when companies publicly commit to promoting nutrition, which enhances their reputation, but in effect do the opposite. And as noted elsewhere, lack of external validation and evaluations undermines the credibility of industry self-regulation.

Clear principles and international standards

The current global landscape of food industry accountability is fragmented and limited. States have an obligation to protect people's rights to health and adequate food under international human rights laws and treaties that have been ratified by most countries in the world. Bold new measures are needed to comprehensively govern food industry conduct and ensure that it aligns with public health. This can level the playing field, ensuring that all those in the industry doing good can do more, and that others can be brought in line with the protection of women's, children's and adolescents' health.