Chapter

Stakeholders in Pharmaceutical Policy Development

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Abstract

Pharmaceutical policy development is a linear and step-wise process that moves from problem statement or agenda setting, to planning and analysis, to definitions and objectives, to policy formulation and statutory approval, to implementation and monitoring, to policy review and evaluation and finally to improvisation. In the process of developing and implementing such a policy framework several stakeholders including national and multi-national drug manufacturers, state and central governments (including all ministries like health, commerce, trade, industry), regulatory authorities, patients, doctors, pharmacists, pharmaceutical traders, insurance agencies, academia, professional associations, NGOs, civil society and consumer groups assume primary importance without whose active involvement the whole process would be inadequate and sometimes even inappropriate leaving huge gaps in their comprehensiveness, inclusiveness and acceptability. This chapter defines the role and describes the importance of these very stakeholders in the process of pharmaceutical policy development and implementation in any settings across the world.

Keywords: academia, civil society, consumer groups, doctors, drug regulators, evaluation and monitoring, NGOs, patients, pharmaceutical industry, pharmaceutical policy development, pharmaceutical traders, pharmacists, policy implementation, professional associations, stakeholders

1. Introduction

Essentially pharmaceutical policy formulation can be viewed from three different perspectives viz., supply chain perspective that includes components like selection, quantification, tendering and procurement, storage and distribution, quality control and use by the patients; industrial perspective that includes components like manufacture, sale, import, export, licensing, pricing, investments, R&D including clinical research, innovation, patents and drug regulatory affairs; rational use perspective that includes components like safety, efficacy and quality of medicines; promotion of accessibility (including availability and affordability), rational prescribing, rational dispensing and rational use of medicines besides provision of cost-effective, timely and efficient centralized procurement and decentralized distribution of drugs. In spite of different perceptions and perspectives about pharmaceutical policy it goes without saying that quality pharmaceutical and healthcare services to patients can

only be ensured in presence of a strong policy framework that caters to all the needs in respect of drug delivery services and incorporates all components required to enforce and implement existing laws in respect of key issues of public importance.

Worldwide, at national levels terms like national drug policy, national medicines policy and national pharmaceutical policy are used synonymously to describe a policy framework for action in relation to import, export, pricing, investments, research and development, industrial licensing and manufacture of drugs and pharmaceuticals though at deeper regional levels these terms more often than not are used to indicate policies required to enforce and ensure effective quality control of drugs; rational prescribing and use of medicines; availability of safe and effective drugs in adequate quantities particularly at government health facilities; improved procurement, storage and distribution practices for drugs and other medical supplies; quality pharmaceutical and healthcare services at hospitals; stringent enforcement of drug related laws; adequate pharmacy and health education, research and training facilities at all academic and healthcare institutions etc.

Thus at regional and state levels focus of pharmaceutical policy development is more upon regulating safe and effective use of good quality drugs, good dispensing and prescribing practices and rational use of medicines by the patients besides their availability at affordable prices to all sections of the society irrespective of their caste, creed, color or religion within one hour walking distance from their place of inhabitation as well as their acceptability as a reliable source of relief from diseases and disorders. WHO defines national medicines policy as a commitment to a goal and a guide for action that expresses and prioritizes the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both public and private sectors, and involves all the main actors in the pharmaceutical field [1].

On paper, the policy development process appears to be a linear process. It is a step-by-step process that moves from problem statement, to definition, to objectives and outcomes. Those objectives and outcomes are developed, analyzed and evaluated into optional solutions and instruments to be deliberated on. A decision is made by elected or government officials. A policy moving forward goes into program design, potential legislative drafting, implementation and planning. The program is implemented, monitored and evaluated. Finally, the process is reviewed and assessed. The problem is that policy development does not happen in a vacuum. The process looks opaque from the outside in, (given policy priorities, urgencies and timelines) the actual policy process does not always follow the theoretical process, and while stakeholder/citizen engagement can happen throughout the policy cycle, it is at the discretion of the policy makers when, how and what impact it will have on the outcome [2].

In the process of developing and implementing a pharmaceutical policy framework several stakeholders including national and multi-national drug manufacturers, state and central governments (including all ministries like health, commerce, trade, industry), regulatory authorities, patients, doctors, pharmacists, pharmaceutical traders, insurance agencies, academia, professional associations, NGOs, civil society and consumer groups assume primary importance without whose active involvement the whole process would be inadequate and sometimes even inappropriate leaving huge gaps in their comprehensiveness, inclusiveness and acceptability.

A national drug policy, presented and printed as an official government statement, is important because it acts as a formal record of aspirations, aims, decisions and commitments. Without such a formal policy document there may be no general

overview of what is needed; as a result, some government measures may conflict with others, because the various goals and responsibilities are not clearly defined and understood. The policy document should be developed through a systematic process of consultation with all interested parties. In this process the objectives must be defined, priorities must be set, strategies must be developed and commitment must be built. The consultations and national discussions preceding the drug policy document are very important, as they create a mechanism to bring all parties together and achieve a sense of collective ownership of the final policy. This is crucial in view of the national effort that will later be necessary to implement the policy. The policy process is just as important as the policy document itself [1].

Role, responsibilities and importance of various stakeholders in pharmaceutical policy development and implementation is described one-by-one as under:

2. Governments

Governments include state and central/federal governments and all its ministries concerned with the manufacture, import, export, investment, licensing, pricing, R&D and quality control of drugs. They are the key stakeholders and in fact pioneer in pharmaceutical policy development, planning, implementation and monitoring. For any new pharmaceutical policy development, initiatives must come from the governments and it is mainly their duty to take all other stakeholders on board for consultation before promulgation of any policy framework. Political will of the government can be the real game-changer in any country for development of effective policies on quality control, procurement, distribution, safe and effective use of medicines alongwith their equitable access, affordability and financial risk protection. Political will of the federal and state governments alone can ensure full transparency and accountability in drug selection, quantification, procurement, tendering, distribution and rational use and for such a will to take shape strong and effective leadership and governance structure is a pre-requisite. Some of the most robust policy documents have eventually turned to be a failure in absence of political will, support and effective leadership of central and state governments. Supportive governments and willing political establishments alone can earmark sufficient budgetary allocations towards healthcare in order to sufficiently meet drug demands and bear all administrative costs besides giving full autonomy to the procurement agencies to follow norms and well-established standards in drug quality and procurement without any kind of government or political interference.

India presents a peculiar example of how different federal ministries govern different aspects of pharmaceuticals and therefore how they need to be consulted and integrated not only for developing an effective policy framework but also for its effective implementation and constant monitoring. In India Ministry of Chemicals and Petrochemicals oversees policy, planning, development and regulatory activities pertaining to the chemicals, petrochemicals and pharmaceuticals sector whereas Ministry of Health and Family Welfare examines pharmaceutical issues within the larger context of public health and the focus of the Ministry of Chemicals and Fertilizers is on the industrial policy. Other ministries that also play a role in the drug regulation process include the Ministry of Environment and Forests, Ministry of Finance, Ministry of Commerce and Industry and the Ministry of Science and Technology. Issues related to industrial policy such as the regulation of patents, drug exports and government support to the industry are governed by the Department

of Industrial Policy and Promotion and Directorate General of Foreign Trade, both under the aegis of Ministry of Commerce and Industry and the Ministry of Chemicals and Fertilizers [3].

3. Drug regulators

Most important organ of the governments that are directly responsible for implementation and execution of the Acts, Ordinances, Rules and Regulations related to clinical trials, manufacture, import, export, licensing, sale, distribution, storage and dispensing of drugs are the drug regulators though they are not at the forefront of pharmaceutical policy development in many countries like India where that task is accomplished directly by the ministries themselves. However for any comprehensive, practicable and robust policy development drug regulators are very important stakeholders for they are the ones who implement policies on ground and are in know-how of the practical difficulties and hurdles in their implementation. Therefore without their consultation no policy document can be considered to be complete in all respects. That is the reason why in spite of being a government functionary drug regulators deserve a special mention as stakeholders in pharmaceutical policy development. On the basis of their past experience and practical knowledge they can be of immense help in giving significant inputs about the gaps, barriers, prospects and challenges towards adoption and implementation of new pharmaceutical policies like for instance universal health coverage policy, drug de-addiction policy, counter-spurious drug policy, effective pharmaceutical pricing policy, generic drug substitution policy, drug recall, disposal and withdrawal policy, drug procurement and medicines management policy etc.

Without the interest and active involvement of drug regulators quality assurance of medicines remains a far-fetched dream particularly in developing countries. This is illustrated by the very fact that India in spite of being a world leader in manufacture and supply of quality generic drugs to the extent that it covers 20–30 percent of the world market and is popularly known as the "pharmacy of developing world" yet a vast section of its own population to the extent of 50–65% was not having access to quality generics as per the World Medicines Situation Report [4]. However, the situation has drastically improved in recent years ever since Govt. of India implemented a whole lot of new Universal Health Coverage Schemes like Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (AB-PMJAY), Pradhan Mantri Jan Aushadhi Yojana (PMJAY) and many others. Unlike previous schemes, AB-PMJAY covers larger population, provides more comprehensive benefit package and incorporates a wider network of hospitals for healthcare delivery. Thus in spite of several universal health coverage policies like *Jan Aushadhi* (people's medicine) scheme, *Rashtiya Swasth Bhima Yojna* (National Health Insurance Scheme) and recently launched *Ayushman Bharat* (Long live India) having been launched in the past by the successive governments of India, quality and effectiveness of generic drugs supplied free of cost at government health facilities continued to remain doubtful and unreliable for a long time thereby affecting the overall success of these government schemes and primarily it was the failure of drug regulators in ensuring fool-proof quality assurance system. Paucity of government drug testing facilities, inadequacy of the drug inspectorate staff, insufficiency of the funds, manpower and equipments at govt. drug testing laboratories, less testing capacity and high testing load resulting into high lead time of testing, unscientific and unsystematic drug coding, sample handling and testing

procedures were some of the issues confronted in the quality assurance system of developing countries where drug regulators have a major role to play as important stakeholders in the pharmaceutical policy development and implementation.

4. Manufacturers

Pharmaceutical industry is the primary target of governments and their drug regulators when it comes to law enforcement and policy implementation. Doctors prescribe, pharmacists dispense and patients consume what manufacturers make available to them through ill or well-regulated markets and pharmaceutical supply chains. Therefore, manufacturers are the first to determine quality of medicines and thereby their effectiveness in alleviating the ailments of common masses. They are also the first to determine the prices of medicines and thereby their access to people living under various strata of the society. Hence manufacturers can play a lead role in ensuring health and well-being of the society by making good quality medicines available, affordable and accessible to all sections across the spectrum. However, it is a well-established fact that pharmaceutical companies are for-profit corporates whose primary goals are to enhance the worth of its share-holders. Therefore, they do not make all the drugs accessible to all the people irrespective of their paying capacity and that turns them into important stakeholders in pharmaceutical policy development because somewhere a balance has to be struck between access and profits, between investments and returns, between innovation and sustainability and between patents and patients.

Social justice in medical care demands that patients belonging to all sections of the society enjoy an equitable access to medicines irrespective of their caste, creed, color, religion, ethnicity, gender or paying capacity as enshrined under the principles governing universal healthcare, however, pharmaceutical corporates need money for research, development and innovation, major chunk of which is made available to them by either the academics or the governments from the tax-payers money as per the available facts and figures. Although the pharmaceutical industry emphasizes how much money it devotes to discovering new drugs, little of that money actually goes into basic research. Data from companies, the United States National Science Foundation, and government reports indicate that companies have been spending only 1.3% of revenues on basic research to discover new molecules, net of taxpayer subsidies [5, 6].

Cases of anti-cancer drugs Sovaldi and Imatinib and directly acting anti-viral drug used in Hepatitis-C, Sofosbuvir can be cited as classic examples of unreasonable and excessive profiteering by pharmaceutical corporates that eventually blocked access to these life-saving medicines in low- and middle-income countries and led to a spate of litigations following invoking of compulsory licensing provisions by the countries like India. Therefore, for any successful and sustainable pharmaceutical policy development pharmaceutical corporates need to be consulted and taken on board before arriving at any national medicines policy framework. This will ensure that the much-needed balance between profits and public demands, between money minting and patient-care, between corporate and social obligations and between patents and the public good is maintained.

With ever increasing obligations that pharmaceutical companies particularly the generic drug manufacturers have to fulfill as envisaged under various international trade agreements like TRIPS-plus (trade-related aspects of intellectual property right), FTA (free trade agreement), TPP (trans-pacific partnership), RCEP (regional comprehensive economic partnership) etc., it is becoming increasingly

difficult to indulge in trans-national trade of generic drugs owing to stringent patent regimes being invoked to protect innovations and intellectual property rights guaranteed under stiff patent regimes across nations. Several companies like Gilead are entering into trade negotiations and voluntary licensing agreements with indigenous generic manufacturers of countries with a view to restrict use of generic versions of patented drugs like Sofosbuvir locally and escape compulsory licensing provisions while at the same time protecting their data exclusivity privileges. Thus both generic and innovator product manufactures are important stakeholders in the development of any pharmaceutical policy framework related to import, export, pricing, R&D, investments, innovations and patents of medicines.

Doha Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001 reaffirmed flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines. In Paragraphs 4 to 6 of the Doha Declaration, governments agreed that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health [7]. Accordingly, while reiterating their commitment to the TRIPS Agreement, WTO member states affirmed that the agreement can and should be interpreted and implemented in a manner supportive of their right to protect public health and, in particular, to promote access to medicines for all. Following this Declaration, at the end of 2015, United Nations Secretary-General Ban Ki-moon established a UN High-Level Panel on Access to Medicines with the mandate "to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies". The scope of the work of the panel being global and ambitious is likely to address access challenges relating to access to medicines globally. At national level countries need to work on this policy incoherence between justifiable rights of inventors and public health by taking manufacturers and innovators on board during the process of policy formulation and implementation [8].

5. Healthcare personnel

Healthcare providers include prescribers, pharmacists and nurses who comprise the triad of patient-care and share a common interface with the end-users of medicines i.e., the patients. They are the primary stakeholders in ensuring rational prescribing, rational dispensing and rational use of safe and effective medicines in any settings. Irrespective of what kind of drugs are made available by the manufacturers and drug regulators in the market, doctors continue to be the pivots who choose on behalf of patients what drugs they must consume whereas pharmacists and nurses can ensure proper use of medicines through patient counseling and promote their adherence to the prescribed medications. Similarly well-informed and well-educated patients can ensure an appropriate use of medicines prescribed and thereby therapeutic outcomes and benefits of the pharmacotherapy can be maximized whereas their harms and risks can be minimized leading to a positive benefit-harm ratio.

Implementation of generic drug policies has faced several impediments and even stiff opposition from doctors, pharmacists and pharmaceutical traders in many countries as a result of certain perverse incentives offered by pharmaceutical companies through their sales promotion agents. Doctors often cite empirical evidence generated through years of experience in support of prescribing branded medicines and even

go to the extent of terming generic drugs as a big risk to their reputation owing to their perceived low quality and effectiveness. They also cite substitution of generics by unqualified and inadequately trained pharmacists as a reason to their skepticism towards prescribing generics. Their faith and belief in the quality and effectiveness of branded medicines seems to be as firm and unshakeable as their suspicion about the quality and effectiveness of generics.

It goes without saying that pharmaceutical companies spend heavily upon the promotion of branded medicines and offer huge financial incentives to doctors for prescribing the same that are often disproportionate and unjustified. That is the reason why WHO too has listed avoidance of perverse financial incentives as one of twelve core policies to promote more rational use of medicines [9]. No definite mechanism or regulations to curb unethical prescribing by doctors or to control unjustified distribution of exorbitant gifts by pharmaceutical companies are in place in many developing countries. Thus the aim of policy-makers should be to consult health-workers during the process of policy development seeking their cooperation and support in promoting generics, following ethical practices in drug promotion and prescribing, avoiding perverse incentives and instilling confidence for prescribing generics accompanied by an assurance to regulate their quality.

Pharmacists are critical to the medicines management process, yet are often largely detached from policy development. Logically, they should inform government policies which impact on their work or where their skills could be best applied to implement health care policy and medicines utilization in particular. It therefore becomes critically important that the pharmaceutical profession engages with national policy makers and in the strategic planning for health care [10]. Role of pharmacists assumes importance in observing good storage practices, good distribution and dispensing practices, efficient inventory control, demand forecasting and medication management practices, providing professional clinical pharmacy and pharmaceutical care services, drug and poison information services, offering patient counseling and promoting rational use of medicines besides ensuring drug safety through pharmacovigilance, adverse drug reaction monitoring and therapeutic drug monitoring services in all health system pharmacy settings. Of late pharmacist's role in social and administrative pharmacy, managed care and specialty care pharmacy including pediatric, geriatric, obstetric and palliative care has increased significantly. Similarly, nurses are responsible for ensuring administration of right drug to the right patient at the right time in its right dose and formulation. Together pharmacists and nurses can help a great deal in minimizing medication errors and other drug-related problems including inappropriate indication, unaddressed indication, inappropriate dose, duration or frequency of medication, drug interaction, adverse drug reaction, need for laboratory test or a compliance problem. While devising policy provisions for all these activities in consonance with the local needs and demands, due consultation with healthcare workers mentioned above can prove to be fruitful in addressing ground realities and concerns and evolving a framework that is best suited to the procedures and practices in vogue at the ground level.

One-size-fits-all approach is least likely to work in such matters as legislations vary from region to region and so do the roles, responsibilities and functions of pharmacists and nurses. While in most of the countries pharmacists are not legally authorized to prescribe medicines or make changes in the therapeutic regimen of the patients on their own, in some countries they can prescribe drugs as consulting pharmacists or assume full responsibility of patient's medication management as required for the practice of pharmaceutical care. In countries like India a qualified and trained

pharmacist can at best make a suggestion for a change in the therapeutic regimen to the patient's attending physician but cannot make any change in the prescription on his own thus considerably limiting his role in providing pharmaceutical care. This aspect needs to be kept in mind in pharmaceutical policy development vis-à-vis clinical pharmacy and pharmaceutical care services by qualified and trained pharmacists. Use of the terms "qualified" and "trained" is deliberate in light of the fact that in many developing countries unqualified and inadequately trained professionals are also designated as "pharmacists". Future policy direction should be in consonance with the concept of seven-star pharmacist, introduced by WHO and adopted by the International Pharmaceutical Federation (FIP) in 2000 in its policy statement on Good Pharmacy Practice that sees the pharmacist as a caregiver, communicator, decision-maker, teacher, life-long learner, leader and manager [11].

6. NGOs, civil society and consumer groups

Civil Society Organizations have a long history of involvement on health and access to essential medicines, consumer protection and promotion of transparency, including many national as well as international groups. In-country CSOs are focused on health in different ways – as service providers, advocates for rights, or providers of care and support for people with specific health problems [12]. While formulating medicines policies, policy-makers need to address various socio-economic, legal, administrative and political factors that act as barriers in the equitable access and rational use of medicines and involve civil society and consumer groups in the policy formulation process. Civil society groups can take social activists and philanthropists from various sections of the society like academia, media, judiciary, health, politics, public service, trade and industry on board & launch a sustained campaign for rational use of quality medicines & make logical interventions through persistent advocacy, persuasive pressure and consistent lobbying in the formulation of robust & comprehensive national pharmaceutical policies, their subsequent implementation in a time-bound manner followed by their continuous monitoring, evaluation and improvement on regular basis. Civil society and consumer associations can act as pressure groups to overcome government inaction and sluggishness in policy implementation by developing adequate political connections with the power centres and utilizing them in the best interests of the policy making and enforcement. By carefully using media, legislature and even judiciary and executive if required in a transparent, legitimate and democratic manner, civil society groups can build pressure upon the governments for timely adoption and implementation of policy provision required to ensure availability and affordability of safe and effective medicines of good quality in sufficient quantities at both private and public sector facilities at all times in a year.

Non-governmental, not-for-profit, self-governed, volunteer-based organizations (NGOs) like *Medicines Sans Frontiers (MSF)*, *Health Action International (HAI), Management Sciences for Health (MSH)* [13] have been doing a commendable job in partnering with governments, civil society, private sector and health care workers to build resilient and sustainable health systems [14]. Their humanitarian missions are saving lives and improving the health of the world's poorest and most vulnerable people by providing medical assistance to people affected by conflict, epidemics, disasters, or exclusion from healthcare. Their role in pharmaceutical policy development remains crucial owing to the fact that their philanthropic activities are driven by the humanitarian spirit of social service and not by any business or profit motives.

In 1999, in the wake of Doctors Without Borders aka Médecins Sans Frontières (MSF) [15] being awarded the Nobel Peace Prize, MSF launched the Campaign for Access to Essential Medicines, since renamed the Access Campaign. Its purpose has been to push for access to, and the development of life-saving and life prolonging medicines, diagnostic tests and vaccines for patients in MSF programmes and beyond.

Similarly in India a NGO named *Jan Swasthya Abhiyan* (JSA) [16] formed in 2001 is constituted of 21 national networks and organizations and state level JSA platforms. Network partners of the JSA include a range of organizations, including NGOs working in the area of health, feminist organizations, people's science organizations, service delivery networks and trade unions. At present it is the major national platform that co-ordinates activities and actions on health and health care across the country. Based on their field experiences, such NGOs can provide significant inputs on how to enhance access to medicines, how to promote their rational use among patients, how to achieve universal health coverage and how to strike a balance between various trade-offs while achieving these goals.

7. Pharmaceutical traders

Pharmaceutical traders including super-stockists, stockists, career and forwarding agents, wholesalers, retailers and medical representatives comprise a crucial link between pharmaceutical industry and the prescribers. They have a big stake in promoting branded medicines due to their business interests and have a very significant potential to circumvent prescribing practices towards that direction. In fact it has been observed that pharmaceutical traders pose hurdles in the implementation of generic drug policies and sometimes even resort to protests and agitation to protect their business interests owing to the fact that generics are a lot cheaper than branded medicines and therefore have little scope for the similar pharmaceutical promotion and marketing practices as are prevalent for the branded medicines. Most of such promotion practices are unethical and several countries like India had to devise rules for curbing such practices that lead to distribution of exorbitant gifts and incentives among physicians that are quite often disproportionate and unjustified [17].

In the year 2009, Medical Council of India (MCI) amended "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation 2002" [18] and brought out the code of conduct for doctors and professional associations of doctors in their relationship with pharmaceutical and allied health sector industry that prohibits them from accepting any gifts, travel facility or hospitality, from any pharmaceutical company or the health care industry. However, even as the Government of India is still debating a code with the drug industry to curb unethical practices, big houses worldwide have started disclosing payments made to physicians, including dollars spent on consulting gigs, clinical trials and even meals. Even though the intention behind framing the code of conduct appears good, the greater issue is the enforcement of these guidelines that seems to be an uphill task. Until and unless MCI or other enforcing body is given enough teeth to enforce these codes, introspection and self-regulation by the doctors remain the only way to curb the ever-rising unethical practices in the health care sector. The proposed self-regulatory code of pharmaceutical companies lacks teeth and has several loopholes since it is not legally binding on companies [19]. Recently in the Supreme Court of India it was revealed by the Federation of Medical and Sales Representatives Association of India, while citing a report by Central Board of Direct Taxes (CBDT), that, "Over Rs 1,000 crore freebies have been given by Dolo

company for the 650 mg Paracetamol formulation and that the doctors were prescribing an irrational dose combination [Ref: Business Today dt. August 19, 2022].

Given such a dismal scenario vis-à-vis ethical pharmaceutical marketing and promotion practices being followed by pharmaceutical companies and traders particularly in developing countries that seriously impairs the implementation of generic drug policies and impedes the progress towards universal health coverage, it becomes essential to undertake sustained negotiations with not only the representatives of pharmaceutical industry but those of the pharmaceutical traders as well so that their genuine grievances, if any are addressed well in time and they are left with no reason to sabotage policy implementation at a later stage. Their involvement and integration with the pharmaceutical policy development process will go a long way in smooth and hassle-free promulgation and execution of the policy provisions and will minimize any chances of obstruction and hindrances in the policy implementation.

8. Health insurance providers

Evidence produced by Sommers et al. [20] on the effects of health insurance on health care and health outcomes in US for the period between 2007 and 2017 revealed that coverage expansions significantly increase patients' access to care and use of preventive care, primary care, chronic illness treatment, medications, and surgery and these increases appear to produce significant, multifaceted, and nuanced benefits to health. They further concluded that some benefits may manifest in earlier detection of disease, some in better medication adherence and management of chronic conditions, and some in the psychological well-being born of knowing one can afford care when one gets sick [20]. This signifies the role and importance of health insurance providers as stakeholders in pharmaceutical policy development.

However, assessing the impact of insurance coverage on health is complex since health effects may take a long time to appear, can vary according to insurance benefit design, and are often clouded by confounding factors, since insurance changes usually correlate with other circumstances that also affect health care use and outcomes [20]. A central aspiration of Universal Health Coverage (UHC) is to protect households from catastrophic health expenditures [21]. UHC aims to provide financial risk protection by increasing prepaid coverage, whether from the fiscal or from health insurance funds, thus decreasing reliance on out-of-pocket expenditure [22]. Governments and national health systems must provide adequate financing to ensure the inclusion of essential medicines in benefit packages provided by the public sector and all health insurance schemes [23].

The path to universal coverage involves important policy choices and inevitable trade-offs. The way pooled funds – which can come from a variety of sources, such as general government budgets, compulsory insurance contributions (payroll taxes), and household and/or employer prepayments for voluntary health insurance - are organized, used and allocated, influences greatly the direction and progress of reforms towards universal coverage [22]. Pooled funds can be used to extend coverage to those individuals who previously were not covered, to services that previously were not covered or to reduce the direct payments needed for each service. These dimensions of coverage reflect a set of policy choices about benefits and their rationing that are among the critical decisions facing countries in their reform of health financing systems towards universal coverage. Choices need to be made about proceeding along each of the three dimensions, in many combinations, in a way that best fits their objectives as

well as the financial, organizational and political contexts [22]. It is here that the health insurance providers as stakeholders can help in making choices during the process of pharmaceutical policy development regarding the best trade-offs that can be made in a given country situation identifying the most needed insurance services, vulnerable populations and cost-sharing packages that are most suitable in the local context.

9. Academia and professional associations

Primary role of the academia and professional associations is to generate evidence through systematic and scientific research that could eventually take shape in the form of a policy document which in turn could be implemented on ground and brought into actual practice. At a later stage they could also research into the effectiveness and outcome of various policy measures and generate evidence for the improvement and modification of policy provisions in the best interest of patients. Thus, continuous monitoring and evaluation of accepted policies could be efficiently achieved leading to constant refining and improvement of the policies at the end of each cycle.

Academia could also conduct research into the actual needs, demands and aspirations of the patients that in turn would translate into policy framework and thus generate need-based policies. Such a bottom-up approach in policy-making could maximize the outcome and minimize the failure rate of government policies and enhance their acceptability among common masses. Academia serves as an important human resource for the governments and drug regulators to bank upon for the expert advice and guidance not only during policy formulation but during policy implementation and evaluation as well. Their constant involvement could lay a roadmap for effective enforcement of policy provisions and help in raising sufficient resources for health, removing financial risks and barriers to access and promoting efficiency and eliminating waste thus clearing the pathway towards Universal Health Coverage.

Professional Societies, Bodies and Associations of experts in the medical field evolve guidelines for the management of various diseases and disorders making use of best practices around the world and making suggestions for the first, second and third choice of pharmacotherapies for the benefit of the patients. These guidance documents could serve as an important resource in arriving at Standard Treatment Guidelines for various diseases and thereby help in devising essential medicines lists and guide Drugs and Therapeutics Committees in their decision-making vis-à-vis selection, quantification and procurement of drugs in hospitals. Therefore, the expert opinion of academia and professional associations could lend a sound scientific foundation to any policy formulation process which makes them important stakeholders in the pharmaceutical policy development.

10. Patients

Last but not the least most important stakeholders of pharmaceutical policy development are the patients since they are at the centre of attention of all other stakeholders mentioned above. They are the end-users of medicines manufactured by pharmaceutical companies, licensed, approved and regulated by governments, marketed, supplied and sold by pharmaceutical traders, prescribed by doctors and dispensed by the pharmacists, thereby making them the fulcrum that bears all the load of efforts and activities of others in the chain. Success or failure of any policy

framework rests upon the relief or hazard that it brings to the patients and provides some succor to them in alleviating their sufferings from the disease. Health indicators, patient satisfaction and overall health of a society can be the outcome measures to judge the success and effectiveness of any newly developed policy framework. Therefore, during the course of pharmaceutical policy formulation needs, demands and aspirations of patients need to be given due consideration in order to make the policy patient-driven and outcome-oriented one. Focus of the policy making has to shift ostensibly from products to patients, from patent protection to patient protection, from industry orientation to public health orientation, from club good to public good, from corporate-driven to consumer-driven framework. That alone can help in making quick progress towards achieving universal health coverage and securing the health and well-being of patients through social solidarity, social security and social justice, for any society that claims to be civilized, just and humane must be able to provide basic health access to its citizens irrespective of their paying capacity.

As we know now, health is not just about diagnosing ailments, hospitals and social services; it is an issue of social justice. Getting good health care is not a privilege; it is considered a fundamental right. Access to essential medicines has been viewed as an integral component of the right to health, which is a basic human right. Ensuring equitable access to quality pharmaceuticals is thus a key development challenge and an essential component of health system strengthening and primary health care reform programmes throughout the world. WHO in its Preamble [24] states, "The enjoyment of the highest attainable standard of health is one of the fundamental Rights of every human being without distinction of race, religion, political belief, economic or social condition [24]."

Article 12 of the 1966 International Covenant on Economic Social and Cultural Rights (OHCHR) [25] recognizes the right of everyone to "the enjoyment of the highest attainable standard of physical and mental health" including through a health-care system that is "economically accessible to all" and details the steps that states should take to achieve this. In consonance with this recognition, providing access to affordable essential medicines in developing countries has been listed as one of the Millennium Development Goals (UNMDG) [26] outlined by United Nations Organization i.e. MDG 8E (MDG, 2008), Target 17, Indict.46. The Millennium Development Goals whose deadline expired in 2015 were followed by the Sustainable Development Goals (UNSDG) [27] with an extended deadline of 2030 that also contain a commitment to "provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health". The new 2030 agenda, summarized in the Sustainable Development Goals (SDGs), sets a clear path for future action by placing equity and universal health coverage on centre stage. The health goal, SDG 3 - 'Ensure healthy lives and promote well-being for all at all ages' – underscores the importance of access to medical products and that of the Universal Health Coverage (UHC). UHC is the aspiration that all people obtain the health services they need without suffering financial hardships paying for them.

Coulter [28] has suggested that the twenty-first century health service user is at once 'a decision-maker, a care manager, a co-producer of health, an evaluator, a potential change agent, a taxpayer and an active citizen whose voice must be heard by decision-makers'. In view of all these facts due recognition needs to be accorded to the right to health and the right to equitable access to medicines of patients in any pharmaceutical policy development process and adequate policy provisions need to be incorporated to ensure these rights. Policy-makers need to address both the social determinants of

health, including poverty, and the social determinants of equity, including racism, if they seek to improve health outcomes and eliminate health disparities through their policies. Achieving health equity requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health and health care disparities [29]. Without the due recognition of these rights of patients any policy development process will be incomplete and inadequate and will not be result-oriented so far as patient satisfaction and well-being is concerned. In fact all drug policy provisions must have the patient as their main focus of attention while being drafted and finalized and the policy planning must be directed at giving maximum relief and benefit to the patients rather than the pharmaceutical industry or the traders.

11. Engagement of stakeholders for pharmaceutical policy development

It is a common practice that governments after drafting policy documents put them in public domain either through print media or through their official websites inviting feedback and suggestions from common masses for their improvement that evokes and yields a few responses from the concerned citizens. However sufficient feedback is not received quite often reducing this whole exercise merely to a formality that hardly bears any tangible results. There is no systematic and organized engagement of various stakeholders mentioned above in some structured manner as a result of which policy document lacks in amalgamation of divergent viewpoints and cross-sectional opinions. In the fitness of things, important stakeholders mentioned above rather need to be consulted and engaged in a very sustained and systematic manner arranging their regular review meetings in clusters and allowing intense brainstorming and refining of ideas. Roberts [30] in his commentary on "Making drug policy together" has argued that stakeholder consultation is intended to inform policy by helping to provide the evidence-base for policy development on one hand and on the other, it provides an opportunity for representation of the views and experiences of a range of individuals and organizations who are interested in and/or affected by drug policy. He further argues that the use of various forms of evidence (for example, statistical data and service user narratives) is critical for meaningful stakeholder engagement and public participation in drug policy, as well as effective policy design and implementation [30].

Stakeholder engagement could be achieved by following means:

1. Constitution of expert committees for policy planning, formulation, implementation, monitoring, evaluation and improvisation.

2. Holding workshops, seminars and symposia in academic institutions for creation of awareness regarding the issues involved and incubation of ideas for policy development.

3. Convening a series of round table meetings of various groups of stakeholders and subject experts in clusters for evolving policy provisions in tune with globally accepted, well established norms and standards.

4. Compiling and consolidating written feedback and suggestions received from common masses, concerned citizens and professional bodies and incorporating valid and relevant suggestions into the final draft.

5. Giving wide publicity to the final draft through print and electronic media by holding discussions on TV and Radio channels and generating further feedback for improvement of the draft policy before its finalization.

Only such a peer review process could lead to development of fool-proof, comprehensive, effective, inclusive, outcome-oriented, coherent, acceptable and well considered policy documents that shall in the long run prove to be successful in achieving the desired health-related goals and objectives. Broadly defined, a stakeholder is a person, group, or organization involved in or affected by a course of action. As per Lemke and Harris-Wai [31] stakeholder engagement refers to the process by which an organization involves people who may be affected by the decisions it makes or who can influence the implementation of decisions. Stakeholders may support or oppose decisions and may be influential in the organization or within the community in which they operate. Stakeholder engagement identifies areas of agreement as well as disagreement and provides an opportunity to understand more fully what might be driving key stakeholder differences. Stakeholder input may also help articulate the values of the broader community affected and align policy recommendations with these expectations [31].

Several different models describe a type of continuum, or different levels, of stakeholder involvement in decision making [32]. For example, the International Association of Public Participation's spectrum of participation defines five broad levels of increasing involvement in the engagement process: (i) inform (e.g., fact sheets, websites, open houses), (ii) consult (e.g., public comment, focus groups, surveys, public meetings), (iii) involve (e.g., workshops, deliberative polling), (iv) collaborate (e.g., citizen advisory committees, consensus building, participatory decision making), and (v) empower (e.g., citizen juries, delegated decisions) [33]. Although there is no perfect, one-size-fits-all model for developing policies or guidelines, defining stakeholder roles in any or all stages of genomics policy making is important to better evaluate and understand the policy-making process. A number of frameworks have been developed in various disciplines to assist policy makers in planning for policy development and analysis, and some include a specific component addressing key stakeholder consultation [34, 35].

Conklin et al. [36] have concluded from the results of a systematic scoping review that there is a need to build research capacity through incentives for more robust evaluations of public involvement in healthcare policy and to synthesize a better evidence base that consistently takes a common approach. In so doing, a greater step can be made towards a stronger evidence base for whether public involvement improves processes and/or outcomes of decision making and policy. Such evidence is a minimum requirement for comparatively assessing which areas of health-care policy are the most amenable to the use of public participation and then within a given area, what type of public involvement makes a difference in what context(s) [36]. In 2015 WHO published guidelines for developing country pharmaceutical pricing policies in which it was reiterated that "in establishing the legislative/administrative framework, countries should clearly define the roles and responsibilities of the decision-makers and other stakeholders, and the process of decision-making and the countries should ensure that health technology assessment processes are transparent and the assessment reports and decisions should be made publicly available and effectively disseminated to all stakeholders [37].

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