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Legislation an essential tool for ensuring access to medicines policy goals

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ABSTRACT

Effective national legislation is critical to support the activities of a Medicines Regulatory Authority. However, the law is an under-recognized mechanism for managing issues in the implementation of access to medicines and other medicines policy goals. Regulations are a more flexible tool, have legal effect and the advantage that they can be created or changed without the need to go to the Parliament. Closer collaboration between the health and legal sectors is important as is political commitment for enforcement of the law. Some regional case studies illustrate the opportunities to use the law as an effective tool to implement medicine policies and to meet access to medicine challenges.

Key words: Case studies, Law, medicines regulation, medicinal products

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BACKGROUND

Effective medicines legislation and regulations are critical to establishing the framework for and supporting the activities of a Medicines Regulatory Authority (MRA). The value of law to achieving health objectives has been demonstrated in a few areas such as tobacco control.^[1] In some cases, misapplied or inadequate laws can act counter to good health outcomes, for example, laws limiting access to narcotic analgesics may deny patients effective pain relief or palliative care.^[2] Some of the key requirements for effective legislation and the importance of greater collaboration between the legal and health sectors to achieve good medicines law were discussed in a symposium at the Asia Pacific Conference on National Medicines Policies.^[3] In this symposium, solutions available to all MRAs and grounded in law and regulation were demonstrated as key to solving several MRA challenges. These are reported in this article along with some observations on ways forward to making the law an explicit component of medicines policy work.

and governance. Legislation includes all forms of laws including international treaties, national legislation and sub-national laws. The law (legislation) defines the universal principles and establishes the MRA, creates the legal mandates and the infrastructure, processes and authority for the MRA to perform its functions. Regulations are used as a legal tool to amplify legislation, to provide more detail and to define the processes, annex schedules or other practical elements required to support MRA activity. Regulations are a more flexible tool, yet still have legal effect and have the advantage that they can be created or changed without the need to go to the Parliament. Policies, standards, codes, models and guidelines can have the effect of law and are useful to support the implementation of medicines policies. Governance is the manner of governing and management; good governance is effective, equitable, accountable, transparent and follows the rule of law. However, having medicines law is not enough. There must be political will to respect and enforce the law.

THE ROLE OF LEGISLATION

Three key legal concepts and their application are relevant for medicines law – legislation, regulation

COUNTRY EXPERIENCES AND LESSONS LEARNED ABOUT GOOD PRACTICES

Three different country experiences were presented

and these demonstrated the value of legislation and administrative regulation to solving medicines regulatory and access issues. Though each problem was different, legal tools were part of the solution. These included suspension of a law through the use of an administrative regulation, the segregation of tax revenue by a law to fund medicines purchases and the integration of non-health sector law to combat corruption.

Bhutan

In the case of Bhutan (population 750 000), a supplier default on a 3 year contract for pharmaceuticals led to an acute shortage of medicines in 2010-2011. The MRA established under the Bhutan Medicines Act (2003) requires that all medicinal products are registered by it. There is currently no local manufacturing capacity in Bhutan apart from a single manufacturer for traditional medicines. So all medicines are imported, mainly from India and to a lesser extent Bangladesh. Faced with the acute shortage of essential medicines, a solution had to be found and it was found in the law. The application of the law was effectively suspended through a regulation that created an exemption from registration requirements if a product had been approved by selected reputable MRAs in another country. This legal solution could be effective in any country with limited capacity and facilities for medicine evaluation.

Palau

The challenges in Palau (population 20 000) related to medicines financing. While the law of Palau obligates the government to provide essential medicines, it had been difficult to obtain enough money from the legislature to purchase them as funding for medicines must compete with other demands on the national budget. Two solutions were implemented. The first was to create a minimum inventory list of medicines. In effect this was an essential medicines list, an important tool for medicines regulation and prioritisation for purchasing. This dramatically reduced the number of different medicines to be purchased and consequently the total medicines bill which had been higher than the funds available. While this reduced the amount of money required from the legislature, it did not deal with the issue of not having the money available when needed to buy medicines. In response, through legislation, the Government created a hospital trust fund in parallel with the introduction of compulsory health insurance and medical savings. These were financed through a 2.5% tax on all citizens, which were designated by law to the trust fund for the purchase of medicines. This guaranteed access to funds has dramatically increased the availability of essential medicines in Palau.

Corruption

The third country experience discussed was that of corruption, an activity affecting both developed and emerging economies. An example came from an Asian

country where high medicines prices were in part due to 'informal' payments that encouraged doctors to prescribe and institutions to purchase particular generic products. It was estimated that around 40% of the generic medicine prices went as incentives to doctors to prescribe. These payments resulted in the purchase of medicines of lower quality, as well as influencing prescribing practices, sometimes towards less appropriate medicine choices. This situation is more likely to occur in environments where there are low salaries for health professionals, an acceptance and rationalisation of 'informal' payments as a professional norm and few consequences for corrupt practices. There are practical, policy and legal responses in these situations. The practical is to ensure appropriate remuneration for doctors and other health professionals. Policy options include efficient, supervised health system management practices for quality assurance of medicines and procurement; legal responses include collaborating with the justice and law enforcement sectors to enforce existing laws. Sometimes it may be necessary to enact new legislation to define illegal and criminal behaviours such as bribery, unjust enrichment or other abuses. The United Nations (UN) Convention against Corruption is available to guide countries on best practices.^[4] Countries ratifying the convention must follow it by aligning national laws and practices with those required by the convention. Anti-corruption work being undertaken in other sectors of government may provide a framework and model for similar activities in the health sector.

BUILDING LEGAL CAPACITY AND STRENGTHENING SYSTEMS WITH LEGISLATION

The absence of lawyers from the work of the pharmaceutical sector in some countries is a real barrier to the use of effective legal tools and therefore effective regulation. Greater collaboration between the legal and health sectors on medicines law is required. The medicine and health sectors need to work together to learn how to access legal tools and resources; the legal community need to understand good practice in the medicines sector so that good legal practices can be applied. Appropriate legislation jointly drafted needs to be enacted and relevant laws and regulations enforced.

A practical example of this lack of collaboration is found in the example of inspection of medicine facilities. Conference participants reported that often, medicines inspectors do not have sufficient authority to act under the law or there is insufficient evidence obtained to sustain successful prosecution in the courts. In some cases, new or amended legislation may be required to provide the necessary authority to inspectors and regulators. Along with this, there should be training on how to use the

powers such as those to seize suspect materials and products, or to shut down manufacturing plants.

Regulators (usually with pharmacy/life sciences but no legal background) must know how to work with law enforcement agencies and also learn the information that must be collected to aid police and prosecutors to take action under relevant laws. Effective enforcement requires political commitment and well-functioning legal institutions and strong co-ordination between various government agencies. Increasing civil society engagement in matters related to health in general, and to the availability and affordability of good quality medicines in particular, will be an important means for maintaining the pressure on politicians and giving voice to the concerns of patients. This will help ensure accountability and transparency in the development of medicines legislation and avoid the perception of undue influence of lobby groups such as the pharmaceutical industry on policy development.

WAYS FORWARD

Capacity building and sharing of knowledge and experiences are important to strengthen the use of legislation as a tool for medicines policies development and implementation in the region; working collaboratively with the legal sector is essential. Best practice legal models and tools from other parts of the world should be identified and disseminated. There is considerable scope for increased use of more flexible administrative regulations to support MRA functions and activities. Regular meetings and sharing of best practices could be an effective strategy. A model best practices template for least developed countries with no manufacturing capacity may be useful.

It is important that the law is respected and upheld, and that the civil and criminal sanctions available are applied. In some jurisdictions, there are mismatches between breaches and the penalties that can be imposed; these need to be addressed. Well publicized legal action may serve as an effective deterrent to infringements of

medicine-related law by others. Local legal capacity may need to be increased and building teams with international experts may assist. An example of an effective model is the Access to Opioid Medication in Europe (ATOME) project in which local lawyers are trained on international standards on opioid medicines practice after which they assess national laws to identify legislative barriers to access to opioid medicines and recommend solutions.^[2] Efforts are being made to raise awareness of corrupt practices in the pharmaceutical sector and programmes such as the World Health Organization's (WHO's) Good Governance for Medicines programme^[5] and the Medicines Transparency Alliance (MeTA)^[6] promote good governance, transparency and accountability.

The recognition of law as an essential tool for medicines policy is overdue. This conference was an important step towards putting legal processes firmly on the regional agenda to support national medicines policies and their implementation.

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