SUMMARY OF SYMPOSIUM 1 – LEGISLATION Sunday 27 May

Background

National Medicines Policies (NMPs) need to be underpinned by a strong and effective legislative framework. The objectives of this symposium were (i) to explore the ways in which the law may act to support the strategies of NMPs; (ii) to consider situations where laws may act in a way contrary to good medicines management, and (iii) to suggest practical approaches and possible legal solutions to support effective NMP implementation.

Key legal concepts

- ***Governance*** – is the manner of governing and management. Good governance is effective, equitable, accountable, transparent, and follows the rule of law.
- ***Rule of law*** – has requirements of order, separation of powers between judiciary and political process and is based on equal and effective application of the law.
- ***Law*** – defines the universal principles and establishes the agency, creates the legal mandates and creates the infrastructure, processes and capabilities for the agency to perform its functions.
- ***Regulation*** – an administrative process that provides the authority to act within an existing law. Regulations can be changed more quickly than legislation.
- ***Policy*** – not law but can be effective as a regulatory tool.
- ***Standards, codes, models and guidelines*** - can have the effect of law and can be useful to support the implementation of medicines policies

Country experiences and lessons learned

Bhutan (population 750,000) **-** The Drug Regulatory Authority (DRA) was established under the Medicines Act (2003) and pre-dated the 2008 Constitution which mandated free basic health services for all citizens. The DRA is responsible for registering drugs used in both the public and private sector, ensuring manufacturing standards, performing regular inspections, maintaining a list of registered products available in the public domain and is responsible for the registration of competent persons. There is no local manufacturing capacity apart from a single manufacturer for traditional medicines. All medicines are imported, mainly from India and to a lesser extent Bangladesh; there are 390 essential medicines for use in humans.

Experience in 2010-2011 identified some legislative challenges. Bhutan had in place a three year contract price for pharmaceuticals; however suppliers defaulted on the contract giving rise to an acute shortage of drugs. While contract law may have provided legal remedies for default, the practical result was no access to essential medicines. Bhutan law stated there were no exemptions to the requirement for the registration of medicinal products. However, these circumstances with an acute shortage of essential medicines necessitated the introduction of exemptions to manage drug supply for these drugs.

In this case, the legal response was to effectively suspend the application of the law by use of regulations, i.e. to create exemptions from legal requirements.

The practical response to managing the challenges of registering medicines in a small country with limited capacity and facilities for drug evaluation was for Bhutan to recognize evaluations undertaken by other reputable DRAs.

Palau (population 20,000) – Medicines services are provided by one pharmacist. While there has been obligatory funding for essential drugs in Palau, obtaining the money from the legislature was difficult. The high total costs of medicines for Palau was addressed by creating a minimum inventory list and this had the effect of dramatically reducing the total medicines bill. 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 for the purchase of medicines. The Government created a hospital trust fund; once legislation was introduced for compulsory health insurance and medical savings financed through 2.5% taxation on all citizens, the trust fund had money to apply to the purchase of medicines. This guaranteed access to funds has dramatically increased the availability of essential medicines in Palau.

In this case, the legal mandate (obligatory funding through an appropriation) was not matched by financial structures that could guarantee access to funds when needed to buy medicines. The practical response was to create a financial structure supported by an ongoing source of funds through taxation to meet the legal requirement for obligatory funding.

Viet Nam (population XXX) – There have been problems with access to medicines due to high medicine prices; in some cases the prices of innovator brands have been 47 times and generic medicines 12 times international reference prices. Prices for generics were set at 80% of the innovator brand prices, these high prices reflected the costs of informal payments to doctors and institutions to encourage them to prescribe and purchase generic products. It was suggested that around 40% of the generic medicine prices went to incentivizing doctors to prescribe. The result was that quality use of medicines was compromised by use of poorer quality products and less appropriate drug choices because of the payments received.

These activities occur in environments where there are low salaries for health professionals, opportunities for incentive payments, an acceptance and rationalization of informal payments as a professional norm and few consequences for corrupt practices. The financial benefits are a trade-off with personal ethics and values; change requires prescribers to recognize and respond to this trade-off.

There are both legal and policy responses in these situations. Policy options include more appropriate remuneration for doctors (and other health professionals), and good health system management practices that are effective, equitable, accountable, transparent, and follow the rule of law. The legal responses include the enforcement of existing laws (Viet Nam is a member of the Convention on Corruption) and where appropriate the drafting of new law to address concerns about corrupt practices.

Issues in law and National Medicines Policies

- The legal community needs to know what is required for good practice in the medicines sector.

- Legal language matters – mandatory implies the Government shall and is obliged to do something, terms such as “within boundaries of possibility” allows for some flexibility in interpretation of responsibilities.
- A key issue is how to raise political commitment to enforce the rule of law; an increase in civil society activity can help to increase the pressure on politicians.
- The law must be enforced and be seen to be enforced. It is not necessary to arrest all who break the law, however it is important to arrest and successfully prosecute a few, and to make it widely known that there are consequences for illegal actions.
- Not all breaches are crimes requiring legal intervention and prosecution. There are other violations that are civil offences and these can be punished with monetary fines. Depending on the laws in place, manufacturers not complying with GMP (e.g. counterfeiting by the supplier of a product such as diethylene glycol to a manufacturer) may have civil penalties imposed such as fines and orders that require actions and responses by the manufacturer. In many settings fines for breaches are too small to act as a deterrent.
- There needs to be accountability and transparency in the development of legislation to avoid the perception of undue influence of lobby groups such as the pharmaceutical industry.
- Effective enforcement requires well functioning institutions. Drug inspectors usually have a scientific background and generally are not given the authority to act under the law. If inspectors are not given the powers to seize suspect materials and products, or to shut down plants or close facilities, they must work with the police who do have those powers.

Ways forward

- Training of medicines inspectors to collect sufficient data and evidence to enable successful prosecution in a court of law.
- Better dissemination of best practice models and legal tools. National laws should be collected and submitted in digital form to the WHO database of national laws and regulations. National laws can be compared to effective legislation in other settings.
- Capacity building for lawyers at the local level is important. International experts have a role in helping to upskill local lawyers and develop this capacity. The Access to Opioid Medication in Europe (ATOME) project (http://www.atome-project.eu) provides an example. The aim of the project is to identify and remove barriers that prevent people from accessing medicines that could improve end of life care, alleviate debilitating pain and treat heroin dependence. Funded by the European Commission's 7th Framework Programme, ten ATOME partners from academic and public health organisations work with country legal teams, government officials, public health and medicine experts to conduct legislative and policy reviews. The outcome of these reviews will lead to recommendations that will facilitate access for all patients requiring treatment with medicines controlled under international drug conventions.