Transparency and drug regulators

From everyday painkillers to life saving treatments, the prescription medicines and pharmaceutical drugs we use contain ingredients that are sourced, manufactured and distributed in a variety of ways around the world. Most governments have set up some form of control or regulation within their country to ensure safe access and rational use of these medicines and drugs. This work is directed by specifically appointed governing bodies known as National Regulatory Authorities (NRA) or Drug Regulatory Authorities (DRA). These regulators also collaborate with pharmaceutical companies and regulatory authorities from other countries to guide regional and at times international laws related to the import, export and use of medicines. However, political and economic sensitivities often result in secretive negotiations between these groups as well as a strong reluctance to disclose information. This makes transparency in drug regulation a long standing controversial issue that continues to hinder wider efforts to tackle problems in the medicines market.

Addressing the Challenges

The pharmaceutical industry can be immensely profitable, with vast investments and many gains to be made from patent drugs that are licensed and protected from copying. However, this promise of potential profits also tempts criminal elements to create sub-standard and fake drugs as well as illegal markets that siphon off up to an estimated 25% of global public health spending.[1] A study by the Centre for Medicine in the Public Interest, cited by the World Health Organisation (WHO), predicts that the counterfeit drug trade alone could be worth as much as US$75 billion by 2010 - a 92% increase from 2005 [2].

The human cost is even higher and affects all countries, although the problem is far more pronounced in the poorest countries where fake medicines do not just kill individuals, but also spread killer strains of drug-resistant tuberculosis, HIV and malaria. This is highlighted by recent cases such as the one in South East Asia where up to half of the amount of artesunate tablets (the life-saving anti-malarial drug), bought in the region, were fakes that contained no active ingredient at all [3]. And in Haiti, Nigeria, Bangladesh, India, and Argentina where more than 500 children and adults are known to have died after being subscribed fake paracetamol syrup that contained the toxin diethylene glycol [4].

As drug makers increasingly draw ingredients from a variety of countries, the inherently different nature of materials and production systems used to produce medicines already highlights just how difficult it is to regulate a drug's supply chain from start to finish. Similarly, medicines such as vaccines intended for global use, are increasingly being manufactured and first licensed in countries with the highest disease burdens. This presents several ethical challenges that are proving difficult to resolve. Furthermore, developments of cutting edge technologies and widespread

use of the Internet, place increasingly heavy demands on regulatory systems and knowledge bases.

Even in cases where a drug is licensed, initial studies before it is launched may not necessarily reveal its true safety pattern [5] and so it should not be exempt from scrutiny or regulation once it has been released on to the market. This is especially relevant in cases where far too little heed has been paid to the safety and performance of approved drugs. Recent high-profile worldwide recalls of medicines such as Vioxx [6] and Trasylol [7] that had been kept on the global market for up to 4 years (despite overwhelming evidence of their debilitating and lethal side effects) underscore the importance of public access to all clinical data before and after a drug has been authorized for marketing.

These and other reports and statistics can however be disputed because the full extent of problems are not often reported by pharmaceutical companies, governments and drug regulators who are very reluctant to disclose their data. Drug regulatory systems are therefore widely viewed with suspicion and regarded as dangerously secretive institutions that are riddled with conflicts of interest and flawed procedures. Regulatory authorities often reject this notion stating that the full extent of negotiations, agreements or problems cannot always be declared without affecting public confidence, national reputation or legitimate business.[8] But if more is not done to achieve greater transparency and mutual accountability in drugs regulation, many well intentioned commitments will not translate into reality and can rapidly devolve into divergent, occasionally contradictory, approaches. What is beyond dispute, is that as the global pharmaceutical trade continues to grow, fake drugs, illegal markets and unethical trade practices will grow at an even faster rate. [9]

Achieving greater transparency

International cooperation and the other channels for exchanging information between countries, drug regulators, law enforcement agencies and the pharmaceutical industry are becoming increasingly vital for achieving transparency in every country. Growing public expectations and new technologies in drug development are also beginning to encourage regulators to find new ways to detect, prevent and publicly report problems with medicines safety. This practice, known as pharmacovigilance [10] is increasingly being taken up by developing countries that are rapidly setting up their own pharmacovigilance centers to complement the work done by their national drug regulatory authorities.

More evidence of progress in recent years includes new collaborations and legislations that have been established and made publicly available for the first time. These include the new regulatory pathways set out in Article 58 of the EU pharmaceutical legislation intended for markets outside of the European Union[11], and the 2005 Roadmap to improve cooperation and transparency between the US, Europe and the

The global market is predominantly governed by highly influential drug regulars that include:

- The Federal Drug Administration (FDA) which governs drug regulation in North America and sets global standards
- The European Medicines Association (EMEA), which licenses drugs for European Union countries
- China's State Food and Drug Administration (SFDA) and
- India's Central Drugs Standard Control Organisations (CDSCO) that both set national legislation and standards for international exports to Africa, Asia and other parts of the world.

Middle East. [12]

The World Health Organisation also provides a valuable forum for strengthening collaboration between drug regulators and independent experts by hosting the International Conference of Drug Regulatory Authorities (ICDRAs).[13] The annual conference which has been held since 1980 provides a much needed neutral platform for drug regulators to make information available in the public domain[14] as well as an effective mechanism for drug regulators to provide important technical input to WHO's global recommendations and guidelines.

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