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# Editorial

Welcome to the first issue of *Journal of Generic Medicines* — the first journal ever dedicated to the activities and issues affecting the generic medicines industry. The Journal is being launched at one of the most exciting but challenging times for the industry.

With a large number of well-known products becoming open to generics competition as a result of patent expiry, the opportunities look increasingly good. However, the industry also faces increasing difficulties, particularly in the regulatory, pricing and intellectual property areas in which it must operate.

## **THE POTENTIAL OF GENERIC MEDICINES**

Increasing patient access to pharmaceutical healthcare by improving the availability of generic medicines has been a feature of many governments' healthcare policies for some time. But the need for generic medicines has taken a more dramatic turn in recent years.

In the 'Western' and more prosperous areas of the world an ageing population makes greater availability of generic medicines critical to sustainable healthcare provision. The answer to ensuring adequate pension provisions for an ageing population may elude policy makers, but in the healthcare delivery sector a solution is readily available: increased use of generics. The simple fact is that without the increased use of generic medicines countries will simply not be able to meet the rise in costs that an ageing population creates. Moreover, policy makers are beginning to understand that promoting generic medicines can also act as a major stimulant to pharmaceutical innovation. This is achieved in two ways. First, the very nature of competition requires originator companies to develop new and more advanced therapies in order to remain commercially successful. Secondly, the savings made from generic medicines can be used to finance the cost of more expensive innovative products. There is a symbiotic relationship between generic competition and pharmaceutical innovation. This is beneficial to all sides of pharmaceutical industry and, most importantly, to the patients that it seeks to serve. While this relationship may have been understood for some time in the USA it is a relatively new idea for policy makers in Europe.

The global social dimension of generic medicines has also been highlighted in relation to healthcare delivery to developing and least developed countries, partly in response to AIDS/HIV, malaria and tuberculosis. This crucial need for quality affordable generic medicines in these countries and the interrelation with patent rights has made generic medicines a major diplomatic issue within the World Trade Organization. It will be important to see how governments and companies from different parts of the globe react to this crisis over the coming years.

## **INCREASINGLY DIFFICULT ENVIRONMENT FOR GENERICS**

Despite clear opportunities that patent expiries bring for the generics industry, the environment in which companies are operating is becoming increasingly difficult and the subsequent challenges immense.

The market has become more competitive as established companies add to their product portfolios and new companies enter the generics market. Healthcare systems' demands for quality products at increasingly lower prices accelerates pressure on the industry to undergo

consolidations, develop new markets, improve manufacturing techniques, seek new sources for active ingredients and provide added value to their products.

The generics industry must also operate within an environment of mounting intellectual property restraints. One of the most concerning restraints is the rise in the scope and length of data exclusivity provisions which effectively delay the starting date for generic registration procedures. Generics companies are also restrained by the increasing use of 'strategic patenting', ie the practice of filing numerous patents covering a whole range of the product during different stages of the development cycle and, linked to the patent strategy, making modifications to the original product including excipient/compound changes, controlled release formulations, delivery systems and single-isomer formulations, etc.

## GLOBAL DEVELOPMENTS

At the time of publishing this first issue, the industry will soon have to respond to a whole range of new developments and possible new legislative frameworks. These include a revised Hatch–Waxman Act in the USA; a revised European Union Pharmaceutical Law in Europe; a new agreement/understanding on TRIPS paragraph 6 concerning the application of compulsory licensing and the right to import for countries with no manufacturing base; changes in patent laws in India; US and EU developments establishing regulatory pathways for biosimilar generic medicines; possible changes to the payments systems under the US Medicare system; the possible threat of patent extensions in New Zealand; the possible introduction of paediatric patent extensions in the EU; and the effects of generics substitution in South Africa — to name but a few. The generics industry will also have to follow closely the developments of the World Intellectual Property Organization's Substantive Patent Law Treaty which could have major implications for the future intellectual property environment in which the industry operates. Similarly, developments at the International Committee for Harmonisation (ICH) are shaping regulatory standards primarily affecting the USA, EU and Japan but which, in turn, will have implications for other regions as well.

It is within this challenging environment, with both opportunities and threats for the global generic medicines industry, that *Journal of Generic Medicines* is launched. *Journal of Generic Medicines* will provide its readers with carefully selected peer-reviewed papers covering the regulatory, legal and market-related issues that impact on the industry's activities. We hope that this will become not only a principle source of information for those operating in the generic medicines sector but also a forum for ideas and debate.

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