

Medicines' production and
the absence of innovation

RUNNING ON EMPTY

Running on empty

Medicines can play an important part in the control and treatment of disease, if they are produced to respond to public health needs, and if the policies that support their production provision and use remain in line with this goal. It is therefore of concern that although more and more money is given over to the production of medicines, fewer and fewer are being produced to meet the urgent health needs¹. Health Action

International (HAI) Europe believes this to be a consequence of emphasis on competitiveness at the expense of public health in both the pharmaceutical industry and the policy making that informs it.

¹ See for example US FDA: Innovation or Stagnation: challenges and Opportunities on the Critical Path to New Medical Products, March 2004, www.fda.gov/oc/initiatives/criticalpath/whitepaper.html

Policy making sets the wrong priorities

»Innovative medicines include those which are either more effective, or cause fewer or milder adverse effects, or are easier to use than existing ones used for the same purpose, although not all commercial innovations have the same therapeutic value.« [High Level Group on Innovation and Provision of medicines, G10 Medicines Report, 07 May 2002]

Recent policy documents of the European Union, including the *G10 Medicines Report* and the Dutch EU Presidency *Priority Medicines for the Citizens of Europe and the World* initiative lay the emphasis in innovation on commercial innovation in medicines – the production of medicines that keep European pharmaceutical manufacturers concurrent with their competitors elsewhere (but particularly in the USA). The value of

medicines to the public, and their safety are generally presented as secondary concerns. These EU policy documents directly contradict the standards set for provision of medicines to the public, where therapeutic value must be the first concern, but they suggest that health is in some degree negotiable against commercial competitiveness and economic targets. HAI reminds these policy makers that the policies and operations of EU institutions should act at all times in support of the fulfilment of the right to health of EU citizens, as indicated by article 152 of the Treaty establishing the European Community. Investment in medicines that respond to public health needs, is a necessary condition in fulfilling the right to health, and such investment is warranted whether or not it can be related to competitiveness in the short or long term.

Rewarding monopoly encourages inefficiency

The first mistaken priority in European policy making, in placing commercial over therapeutic value, leads to a second, in the proposition of solutions for the absence of medicines to meet public needs. Both the *G10 Medicines* and the *Priority Medicines* reports see the solution in the crisis in innovation in the greater investment of public money in the proprietary pharmaceutical industry – to spur innovation where the industry has shown itself otherwise unwilling to invest its own resources.

But because the strategy of the pharmaceutical industry – investing in those medicines where the greatest profit can be made at the lowest cost – is an essentially low-risk strategy, such investment is unlikely to engender a change of course and lead to pharmaceutical manufacture to respond to public health priorities. Indeed various incentives have been offered over the last twenty years without significant advances, and are already exceedingly expensive. Equally, because in the prevailing research and development

system, novelty is rewarded by the granting of monopoly, it is in the interest of the industry both to assure that novelty is defined as broadly as possible, and to devote far greater resources attempting to convince the public of the greater value of marginal improvements of medicines, than to actually invest in the production of therapeutically innovative medicines.

Policy makers have failed to come up with appropriate responses. The criteria set forth in the *G10* report as constituting innovation are helpful to commercial competitiveness because they lower the standard at which a product would be considered new and therefore eligible for intellectual property protection in Europe. But they do not promote therapeutic innovation. The *Priority Medicines Report* is unhelpful because it skirts the fundamental issue. In its introduction it notes that *»the complex relationship between pharmaceutical research and development, innovation, intellectual property, pricing and trade is not addressed here [p V]«*.

As a result, both the *G10 Medicines Report* and *Priority Medicines* fail to go to the heart of the problem: pharmaceutical companies' ›innovation‹ is geared

towards guaranteed markets and is rewarded by monopolies through the granting of patent protection.

The public pays the costs

The costs of these monopolies are borne by the state, insurers and, ultimately, the consumer. It is far more convenient for pharmaceutical companies to tweak existing molecules than to produce new ones, and to invest heavily in marketing (sometimes spurious) incremental gains over existing therapies than to come up with truly therapeutically novel medicines putting advances in science to their best use. Over time the consequence has been what we see today – that the pipeline for many diseases where medicines

are urgently needed remain empty, where the pipelines for the nth variant of a blockbuster medicines are clogged.

The public invests in, but does not see the benefit of, and is in fact sometimes harmed by this process of financing and rewarding research and development. The challenge EU policies fail to confront is to come up with other mechanisms for financing research and development that would represent better value for money for consumers.

Creative approaches for public good

Innovation does not have to be rewarded by the granting of monopoly. Indeed the assumption that innovative scientists see large personal financial gain as the only or even the best reward for their sharing their intellectual property is belied by three cases:

- The development of the polio vaccine: Jonas Salk declined to patent the polio vaccine saying in response to the question of ownership: »[Who owns the patent on this vaccine?] Well, the people, I would say. There is no patent. Could you patent the sun?«¹ To his mind no greater reward could be achieved than the protection of humanity from the ravages of a terrible disease. The complete eradication of polio from much of the world is in large part due to its widespread availability and affordability.
- The selfless collaboration of the scientists who contributed to the mapping of the human genome – and

the awareness and action of political decision makers to protect the information on the genome for the public good, equally illustrates that monetary gain is not the necessary motivator of innovative minds. Indeed with the human genome project science united to compete against commercial interest for the benefit of humanity.

- Similarly the global response of scientists to the outbreak of SARS virus, sharing of knowledge in determining the viral code, and collaboration in the development of a vaccine, mean that in a relatively short period of time the world may have an adequate should be able to respond to a pandemic that would otherwise have devastating consequences for humanity.

¹ Interview with Edward Murrow, *See It Now*, April 12, 1955, as quoted in Smith, Jane S. *Patenting the Sun: Polio and the Salk Vaccine*. New York, NY: William Morrow and Company, Inc. 1990. pp. 305-312.

A patent problem

When taken in contrast to the history of the licensing and sale of the first antiretroviral therapies – which were all developed with public money in publicly funded institutions but subsequently licensed to private manufacturer, and sold to consumers at exorbitant price – or indeed against the prices of new, patented, cancer medications which are priced out of the reach of even insured people in wealthy countries, at EUR 10,000 – 40,000 per person per year, then it is clear that the system of rewarding innovation by granting monopoly is perversely limiting the enjoyment of the advancement of science, and public health. This con-

clusion has been reached by a number of bodies of eminent scientists including the UK Royal Society.¹ The false assumption that granting monopoly is the only way to spur innovation is underpinned by the equally false notion that creative scientists see large monetary reward as the only sufficient reward for their efforts. Indeed granting monopoly may benefit large commercial entities which own intellectual property but prejudice against those scientists who produce it.²

¹ UK Royal Society, *Keeping science open: the effects of intellectual property policy on the conduct of science*, April 2003

² *Ibid* pg 4

Recommendations

HAI Europe welcomes the discovery and circulation of innovative medicines which offer a decisive therapeutic advantage on those already available, and recognises that adequate financing is required for innovation in medicine. But that financing can be achieved in a manner of ways, and depends upon:

- Clear recognition that public health needs and therapeutic value of medicines are overriding concerns in the production and provision of medicines to the public. Competitiveness of the European pharmaceutical industry with other regions of the world should not be the driving force behind European health policy.
 - Honest investigation of the use of alternative, sustainable mechanisms to finance public needs-driven therapeutic innovation.
 - Subsequent investment in such models for funding R&D that address public health priorities, the provision of public goods, and ensure access to medicines while encouraging competition, risk-taking, initiative, openness and the sharing of information.
- The institution by the European Commission and the European Investment Bank of fiscal mechanisms to provide funds for public needs-driven research and medicines production which:
 - provide scientists freedom to build upon the work of others;
 - support diversity and competition among researchers and managers of research;
 - recognize the importance of intelligent and cost effective incentives to invest in promising research projects that address health care needs;
 - disseminate and transfer technological knowledge and capacity in a manner conducive to social and economic welfare and development;
 - facilitate equitable access to new medical technologies.
 - Disclosure by the European Commission and the European Investment Bank of criteria for and evidence of investment in the public interest including enumeration of allocations, products, clear therapeutic value and equality of accessibility.

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This policy paper is one in a series outlining HAI Europe's position on key issues affecting European medicines' policy. Together with its counterparts in Latin America, Africa and Asia-Pacific, HAI Europe campaigns for access to, and rational use of, medicines.