

## **Submission to the WHO Committee on Public Health, Innovation and Intellectual Property (Section 1)**

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### **Incentives for Global Health**

#### **Track2 Team Detailed Comment on A/PHI/IGWG/2/2 (Draft Global Strategy and Plan of Action)**

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The two biggest hurdles in the struggle to address diseases that afflict the global poor occur at the ends of pharmaceutical product lifecycles: early in the innovation process and at the distributive end. At the start of innovation, there is little incentive for research and development in neglected disease areas; at the other end, poor distribution mechanisms in developing countries hinder the supply of drugs to people that need them most.

We propose Track2 to address these two challenges and several others referenced in the *Global Strategy and Plan of Action*. Simply put, the opt-in mechanism of Track2 would reward patent holders in proportion to the impact of their interventions on the global disease burden. In exchange for treaty-backed payments, Track2 innovators would allow for the open manufacture, distribution and sale of their products.

Such an arrangement would align the incentives of pharmaceutical companies with those of the widely dispersed network of organizations working on global health today: public health ministries, international organizations, development agencies, private foundations, procurement and distribution groups and NGOs. Given adequate monitoring and reporting, Track2 would consolidate spending across these diverse agents using the power of market-based incentives and the combined weight of global health agencies and pharmaceutical companies. A needs-based approach to prioritization and coordination of research and distribution efforts is woven into the fabric of the Track2 system, since rewards are greatest for addressing the most significant contributors to the disease burden.

Track2 addresses several of the most important elements of the global strategy, outlined in detail below:

#### **(2.1) Increasing funding for research and development that focuses on the health needs of developing countries**

Embedded in our needs-based model is a focus on diseases in the developing world, which contribute disproportionately to the global disease burden. Under Track2, funds flow to innovators that can successfully reduce this burden. The greatest gains are made implementing cost-effective

solutions where the burden is most acute. This has the benefit of sub-nationally targeting poor regions and the diseases that afflict them, encouraging a more narrowly tailored approach to R&D more likely to result in successful innovations. By creating an effective market for products that address diseases in the developing world, Track2 would encourage pharmaceutical companies and the R&D organizations that support them to devote more resources to the health needs of these populations.

### **(2.2) Supporting governments in improving national health research programmes and facilitating better coordination of stakeholders in this area**

Track2 supports governments by providing a reasonable alternative to compulsory licensing and other strategies that could endanger their reputation with the WTO. Under Track2, domestic generic producers would be encouraged to manufacture and sell new products as soon as they entered the market, rather than waiting for patents to expire on a given drug. Such competition would lower the price of drugs and fuel distribution channels, paving the way for greater cooperation between private sector partners and government agencies. India's low-cost pharmacy The Medicine Shoppe and South Africa's BroadReach distribution mechanism for anti retro-virals provide strong evidence that a multi-stakeholder model for distribution can result in improved access to medicines in poor regions.

### **(2.4) Improving global coordination and financing of medical research and development**

Track2 would require no new forum to coordinate medical research and development. Instead, companies and other agencies charged with improving public health would naturally gravitate towards R&D in those areas with the biggest impact on the disease burden – HIV/AIDS, TB, malaria, and diarrheal diseases, which primarily afflict poor people in developing countries, are among the top 10 contributors. Track2 would help identify the areas with the biggest impact by actively providing systematic reviews and needs assessment.

Our proposal would obviate the need for a treaty specific to medical research and development; instead, a broader treaty-backed mechanism, roughly proportioned to per-capita GNI, would provide the funding and the mandate for patent2's needs-oriented approach to R&D.

### **(3.2) Framing and supporting effective policies that promote the development of capacities for health innovation**

The pharmaceutical industry lobby is a powerful one. In many developed countries, firms invest heavily in influencing legislation to advance their interests. This traditionally pulls funding away

from health innovation in disease categories with low revenue potential and towards less life-threatening conditions in the developed world. The result, perversely, is the creation of stronger pipelines for weight-loss drugs than for lifesaving medicines. By making the latter profitable, Track2 has the unique advantage of aligning industry efforts to increase public funding for engines of innovation with those of advocates for a greater focus on diseases of the developing world.

This phenomenon would likely be echoed in poor countries, where multinational pharmaceutical companies would align themselves with local manufacturers and distributors to support innovation for diseases that contribute most heavily to the global disease burden.

#### **(4.1) Promoting transfer of technology and the production of health products in developing countries**

Under Track2, pharmaceutical companies would be much less concerned with product leakage, since any recorded health impact (even from unplanned distribution via “gray markets” for drugs) benefits the innovator. Since costs tend to be lower in developing countries, the migration of technology and infrastructure to enable drug production is a likely outcome of implementing such a scheme.

#### **(5.3) Exploring and promoting complementary incentive schemes for research and development**

In contrast to prizes and other ‘push’ schemes that rely on government planners and experts to determine the direction of R&D, Track2 is a ‘pull’ market solution that leaves it up to potential innovators (better informed and better motivated than planners) to decide how they can make the most effective contribution. There is no need to specify a specific reward, nor specific conditions a new medicine must meet. Whatever works is rewarded according to how well it works in reducing the global burden of disease. It further encourages companies to consider the cost of distribution of a given health product, going one step further than advance-market commitments by encouraging improved collaboration between key agents in the health sector instead of placing the burden of coordination on any sole entity.

Track2 can be implemented without violating the TRIPS agreement, because it is an optional system. Innovators have a choice between exclusive exploitation of the innovation under the usual patent system, or submitting their product to the Track2 system, relinquishing their ability to exclude others from the use of the patented innovations, but earning a reward through GBD reduction. This would not in any way affect national and international commitments regarding patent rights, since the decision of firms to drop their patent rights would be voluntary.

### **(6.1) Encouraging governments to invest in the health-delivery infrastructure**

Track2 offers a clear solution to the twin challenges of incentivizing R&D and improving drug distribution networks. Prize systems, as currently construed, focus only on the front end of bringing drugs to market. We realize that governments, particularly those saddled with large debt repayments, cannot be the sole investors in health infrastructure if widespread access is desired. Our system encourages *all* third-party procurement and distribution networks, public and private, to work with pharmaceutical companies to reduce the disease burden. This could have the desirable effect of prioritizing effective, longer-term interventions, such as improvements in basic sanitation, access to preventative care and locally implemented health solutions.

### **(6.2) Instituting mechanisms to regulate the quality, safety and efficacy of medicines and other health products**

Improved data are a crucial and cost-effective element of almost any health improvement initiative. The WHO's new International Health Regulations already require improved disease surveillance worldwide, and economists hold that surveillance should be treated as a global public good. Implementation of Track2 would give poor countries incentives to build reliable vital registration systems, which could also be mandated by treaty. Since Track2 rewards are linked to outcomes rather than drug development, private-sector partners would be similarly encouraged to support such systems.

### **(7.1) Securing additional and sustainable financing for research and development in order to address the health needs of developing countries**

The incentives of Track2 materialize only insofar as the rewards are certain. We envision a treaty in which willing countries commit to contributing a certain monetary amount per unit of GBD reduction, with possible additional provisions for monitoring and reporting requirements (as mentioned above). This amount can be proportioned to GNP — with some progressivity according to *per capita* GNP so as to exempt the poorest countries.

Track2 provides a comprehensive, market-based solution to core issues raised in the Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and engages the full spectrum of public and private groups working in global health. The Incentives for Global Health team comment on WHA60.30 describes Track2 in further detail and gives a brief overview of our work to date and near-term plans. We hope to develop the plan in collaboration with the Committee and welcome input from others working on similar proposals.

**The bottom line: We want to help the Committee implement the Global Strategy and Plan of Action and believe our proposal, Track2, offers a powerful tool to do so.**