Background and Facts.

# The Health Impact Fund in a few sentences.

The Health Impact Fund provides a complementary system for the development of pharmaceutical innovations – especially ones intended for poor patients who cannot afford expensive medicines.

**How does it work?** The Health Impact Fund is financed by states and charitable contributors. It would give pharmaceutical innovators the option of registering any new product for annual reward payments.

**One special feature:** the price of registered products is limited to the costs of manufacture and distribution, and therefore affordable even for poor patients. The price of registered medicines is delinked from their R&D cost.

A second special feature: reward payments for pharmaceutical innovators depend solely on the annual health gains achieved by their registered medicines. The more such a new medicine improves or lengthens human lives, the more money goes to its innovator.

# Background.

### Pharmaceutical research is currently funded from patent-protected markups.

The development of new medicines is very expensive. To cover these R&D costs, states provide 20-year patents. Under the protection of such temporary monopolies, pharmaceutical firms sell their new products at very high prices. This system has two adverse effects:

**First adverse effect:** in the current system, the diseases of the poor are unattractive areas for pharmaceutical research. This is so because poor patients cannot afford to buy expensive medicines. The diseases of the poor are therefore generally neglected by pharmaceutical research. Remedies against hair loss are more likely to be sought than remedies against deadly diseases of poverty, such as dengue, leishmaniasis or Ebola.

**Second adverse effect:** new medicines are generally unaffordable for the poor. Even when new medicines are developed, against hepatitis C for example, they are almost always sold at profit-maximizing monopoly prices. These far exceed what most patients can afford. The same also holds for medicines against global diseases such as cancer.

The Health Impact Fund provides a complementary system that strengthens world health. With the Health Impact Fund, pharmaceutical companies obtain an additional option that, through new incentives, mitigates the two adverse effects.

### The Essence.

### Health gains as the standard.

The purpose of medicines is to improve and preserve health. The Health Impact Fund aligns research, development and marketing with precisely this purpose. This is so because the reward payments that any innovator receives for its registered innovation result exclusively from the health gains that this medicine achieves year by year. The more a registered product lengthens or improves human lives, the higher are the reward payments that its innovator receives from the Health Impact Fund. In this calculus, the health of all human beings is weighted equally, regardless of whether they are rich or poor.

### Covering the costs of pharmaceutical firms.

With the publicly funded reward payments that the Health Impact Fund pays out for each registered medicine, the firm can recoup its R&D costs and earn profits in addition.

### Delinking a medicine's price from its R&D costs.

Registered medicines can then be sold at the affordable cost price, which covers merely the variable costs of manufacture and distribution. Such medicines are therefore affordable even to very poor patients.

# Frequent questions.

### Should the Health Impact Fund replace the existing system of incentives?

Clearly: no. The conventional incentives from patent-protected markups remain in place. The Health Impact Fund merely gives pharmaceutical innovators the additional option of registering a new medicine and then receiving reward payments according to health impact.

### How is the Health Impact Fund financed?

The Health Impact Fund might be financed by states, for example, most plausibly in proportion to their gross national incomes. Another possible source of funding are international taxes, which might be imposed on greenhouse gas emissions or on certain destabilizing financial transactions.

### How much money does the Health Impact Fund require?

A stable and efficient Health Impact Fund would require at least €3 billion. Of course, it could also work with a larger amount and would then attract a larger number of product registrations.

### Is this amount realistic?

€3 billion per year is less than 0.3% of what the world currently spends on pharmaceuticals. If all countries participated, then each would need to contribute merely 0.0036% of its gross national income to the Health Impact Fund. And these contributions would be offset by substantial savings through better health and productivity worldwide.

### What if some affluent countries initially don't want to contribute?

Their abstention would have some positive effects as well: medicines that are registered with the Health Impact Fund could still be sold with large patent-protected markups in such non-contributing affluent countries. This opportunity would make registration more appealing and would also give non-contributing states an incentive to join the Health Impact Fund scheme.

### How does the Health Impact Fund reward participating pharmaceutical innovators?

Pharmaceutical innovators can register any new product with the Health Impact Fund and then receive annual reward payments that are tied exclusively to the measured health gains achieved: the larger a product's contribution to reducing the burden of disease, the higher the reward payment. A registered product is rewarded during its first ten years.

### And how are health gains measured?

Health gains are measured in quality-adjusted life years (QALYs) and assessed through statistical sampling.

### What are quality-adjusted life years?

The methodology of quality-adjusted life years has been in use for approximately 30 years. One quality-adjusted life year might be, for instance, one additional year of fully healthy life gained by a patient. Or it could be a gain of two life years in poor (50%) health. Or it might involve no lengthening of life at all, but rather an improvement in health only – as when a medicine averts a four-year-long disease that would have reduced the patient's health from 100% to 75%; this health gain of four times 25% also counts as saving one quality-adjusted life year.

### How do quality-adjusted life years affect the distribution of reward payments?

Each year, the Health Impact Fund assesses the quality-adjusted life years achieved by each registered drug. Based on these assessments, the fixed annual reward pool is then distributed over the registered products. Thus if, in a given year, some medicine achieves 10% of the health gains produced by all medicines registered with the Health Impact Fund, then this medicine is rewarded with 10% of that year's reward pool.

### Does the idea of a Health Impact Fund thus far exist only on paper?

No. There has already been a 5-year pilot project about the measurability of health gains, which included field work in India and was supported by a €2 million grant from the European Research Council. This project has shown how the therapeutic effects of medicines can be assessed even in poor countries.

### How can the Health Impact Fund be realized politically?

The developers of the Health Impact Fund idea are currently seeking support for another pilot project. Its purpose is to try out the central elements of the Health Impact Fund on a smaller scale – for example, with a single reward pool of €100 million. Pharmaceutical innovators would be invited each to propose one new initiative, involving an already-patented medicine of theirs, toward achieving additional health gains in some impoverished area of the world. An expert committee would select four of these proposals and give them three years for implementation. At the end of the period, the reward pool would be distributed in proportion to the health gains achieved.

### What initiatives might innovators propose for this new pilot project?

Important selection criteria would be the magnitude and measurability of the expected health gains as well as the proposal's innovation potential and inclusion of poor population segments. Pharmaceutical innovators might propose, for example, to develop a heat-stable or pediatric version of one of their medicines, or the design of a new product-specific therapy or diagnosis protocol suitable for the tropics. The objective of the pilot is to show that health gains can be reliably and consistently measured. It would also show how much additional health impact can be achieved by means of such new incentives. It is hoped that, with the help of states, foundations and others, such a larger pilot project can soon be implemented.

Support the new pilot project and feel free to contact the Health Impact Fund team at: Max@healthimpactfund.org

# Advantages for ...

### ... patients

- Expanded arsenal of available medicines.
- Cutting-edge pharmaceuticals at affordable prices.

### ... pharmaceutical innovators.

- New incentives for essential but heretofore unprofitable R&D projects.
- The opportunity to help poorer patients without ruining themselves or those patients financially.
- Enlarged contributions to world health.
- Improved public image.
- Realization of the internationally agreed Sustainable Development Goals.

### ... states and taxpayers.

- Greater chance that patients will receive the medicines that are best for them.
- Much improved efficiency in the health sector.
- Reduced dangers from invasive diseases of the poor.
- Improvements in global health.
- Reduction of the economic burdens from disease.
- Gains in epidemiological knowledge from the required health impact assessments.
- Genuine North-South partnership for the production of global public goods.
- Establishment of a transformative innovation in the promotion of innovations.

# International Advisory Council

- **Kenneth J. Arrow** († 21. Februar 2017), Professor of Economics and Operations Research, Stanford University; Nobel Prize Winner in Economics.
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- Heidemarie Wieczorek-Zeul, former German Federal Minister for Economic Cooperation and Development.
- **Richard Wilder**, General Counsel and Director of Business Development at the Coalition for Epidemic Preparedness Innovations.