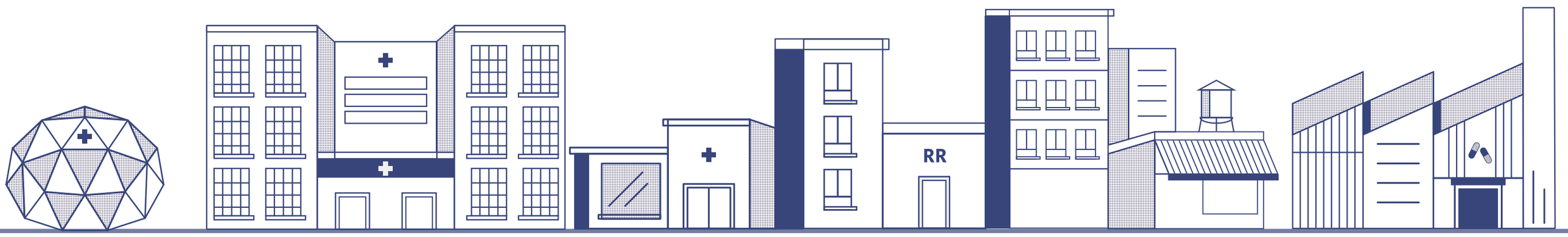
iMed

*"Access **and** Innovation for Medicines"*

iMed: Innovating Medicines Entrepreneurship and Delivery



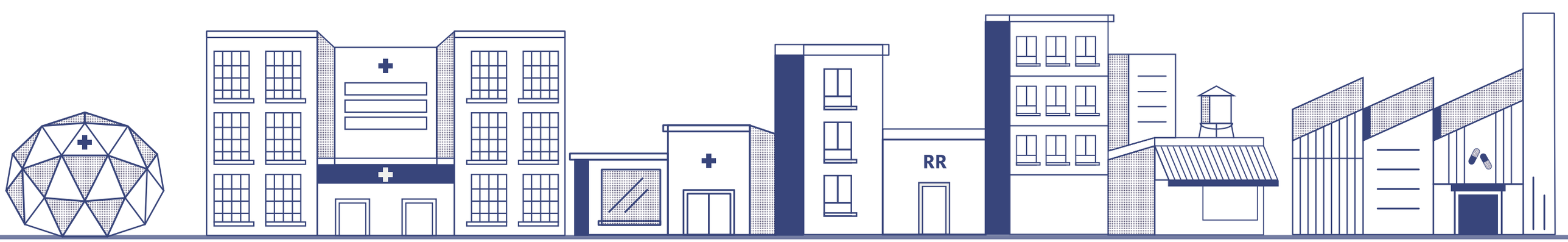
Summary I

- Millions of people lack access to life-saving medicines because of high prices and many health providers are in crisis facing tough choices about what medicines they can afford to provide.
- But under patents high prices are needed to pay for the investments in the creation of new, innovative medicines.
- We end up stuck in a dilemma between access or innovation.
- Actually we can have both — using remuneration rights in place of patent exclusivity.

Summary II

- The problem today is that we have one payment for both innovation and manufacturing
- What if we had two payment streams: one for innovation and one for manufacturing
- Innovation would have its own stream of revenue so manufacturers don’t need to pay for a license and they can produce medicines cheaply and competitively
- This increases access to treatment for patients and maintains the same amount of money for innovation
- Access and innovation can thrive together

Current dilemma



Today, millions of people around the world lack access to life-saving medicines because of high prices.

Health providers are in **crisis**, and have to make tough choices about what medicines they can afford to provide.

But we need high prices to pay for the investments to **create new**, innovative **medicines**.

Policymakers end up stuck in a dilemma:

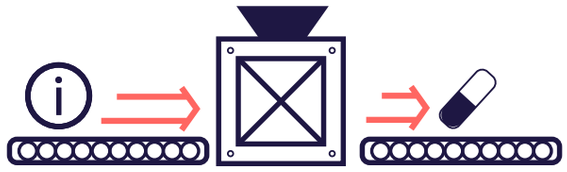
access **or** innovation

There is a solution that delivers both:

access **and** innovation

Today when we purchase a pill we are paying for two things:

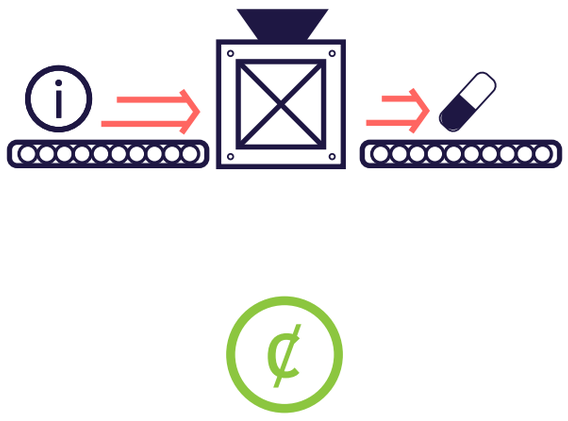
R&D **and** manufacture



One is expensive the other one is cheap:

A. The R&D behind the innovation can cost millions or even billions of dollars.

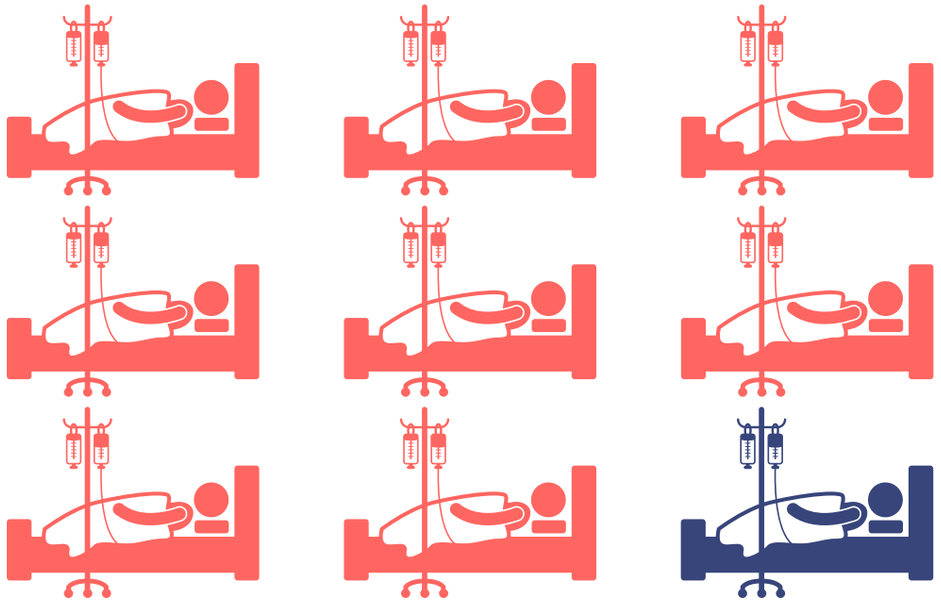
B. The manufacture of the medicine can cost as little as a few dollars.



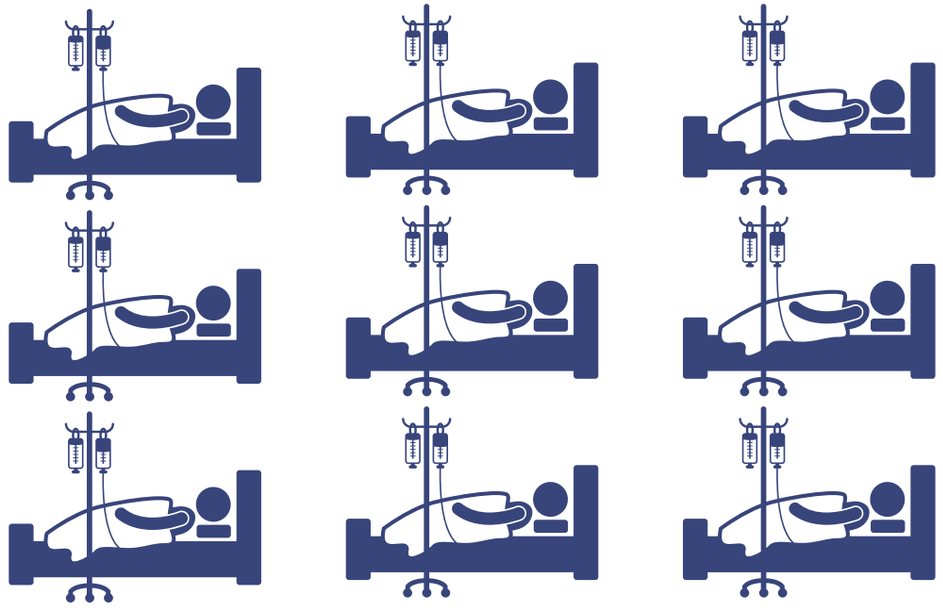
Today we pay for both in a single payment per treatment

Thus, when we buy a pill for $100
we will be paying 1% ($1) for manufacture
and 99% ($99) towards the R&D.

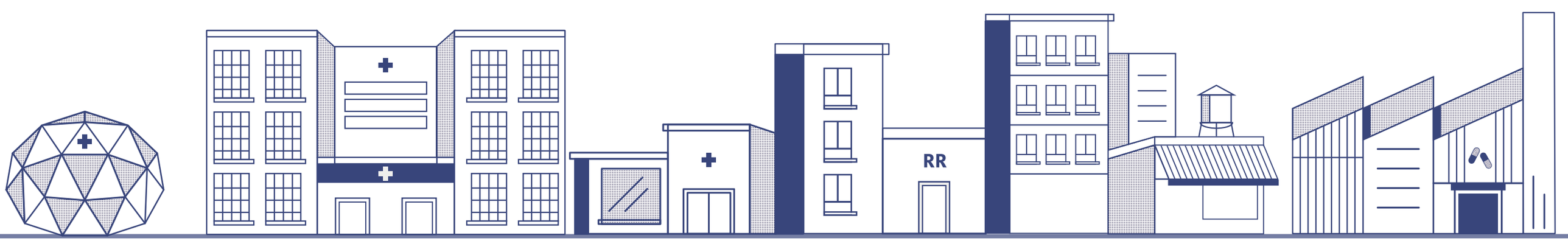
With the budget we have, the current payment model means we can only afford to treat a limited number of patients, because we pay for R&D every time we buy an individual treatment.



If we pay for R&D and manufacture separately we can pay for innovation **and** have greater access.



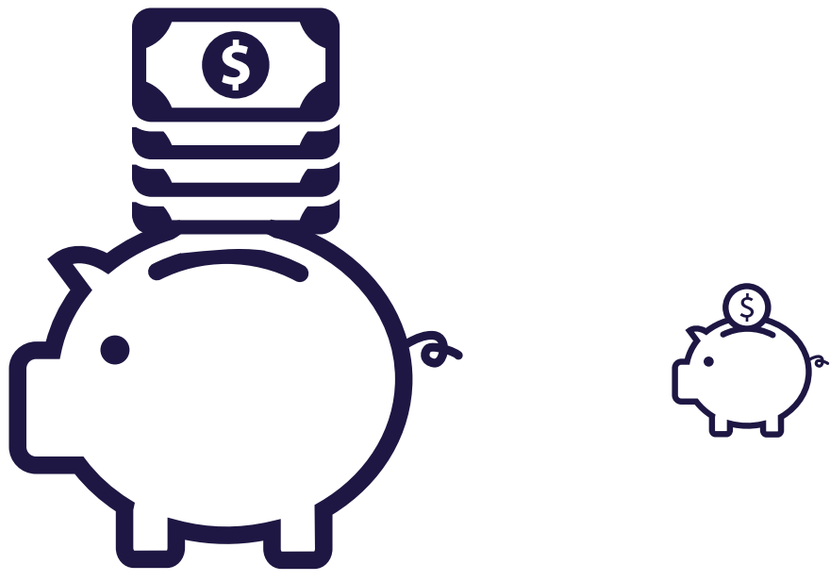
How does it work?



How does it work?

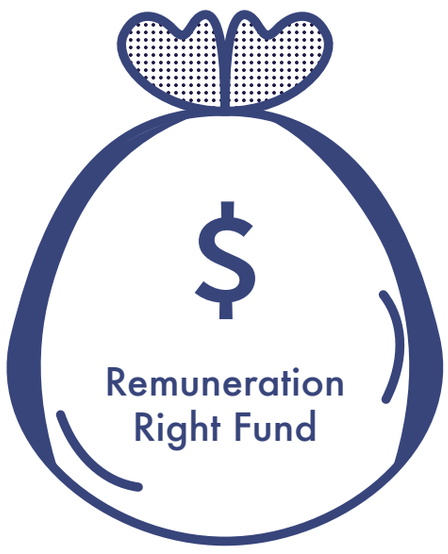
We create two payment streams:

- one to pay for the R&D
- one to pay for the manufacture



How does the R&D payment stream work?

To pay for R&D we create a Remuneration Rights Fund for medicines.



How does the Remuneration Rights Fund work?

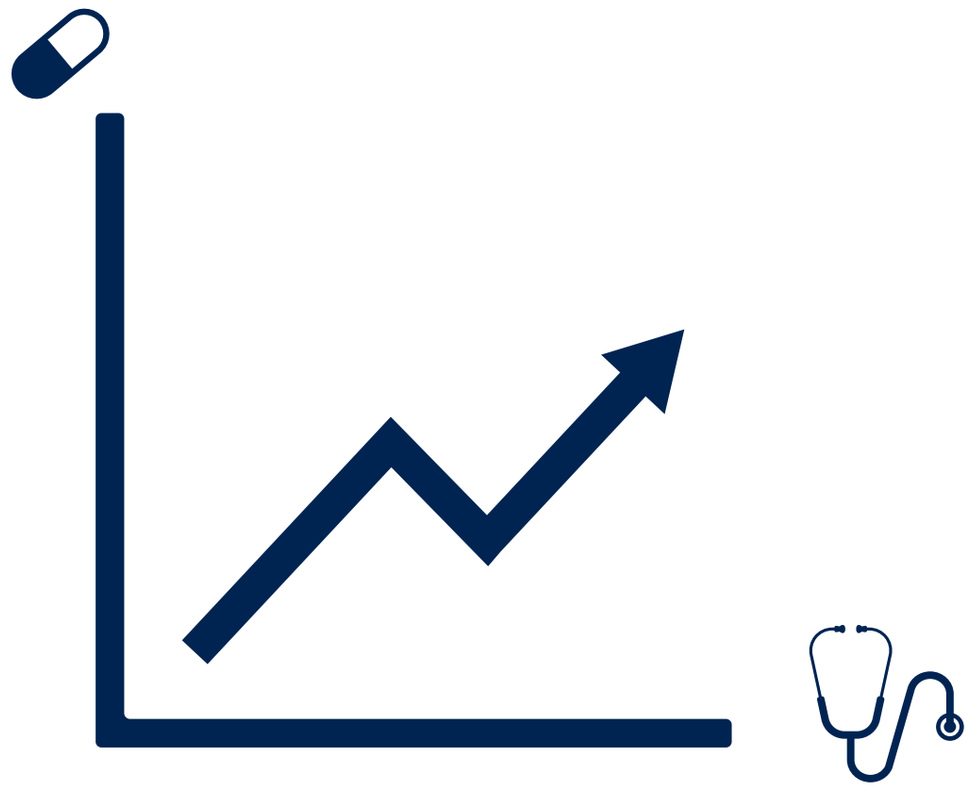
We each pay a fixed amount from our healthcare insurance or from our government healthcare into the Remuneration Rights Fund for medicines.

How do innovators get paid?

When a pharmaceutical company invents a new medicine they register for a Remuneration Right. This entitles them to get paid from the Remuneration Rights Fund.

How do innovators get paid?

The fund pays pharmaceutical companies based on the **health benefits** of its innovation.



How do we estimate health benefits?

The fund would be distributed based on the health benefits of each innovation, for example:

Health Benefits = (Number of people treated) **x** *(estimated benefit per patient)*

We can derive estimates of the number of people treated from aggregate pharmaceutical prescribing data that we already track. Benefit per patient can be derived from both pre-approval clinical trials and research, and, more importantly, tracking performance once in use via clinical trials and other monitoring. Pharmaceuticals go through clinical trials before they can be prescribed to demonstrate efficacy and safety. This would provide initial estimates of benefit per patient. Once in use, additional data would accumulate that would provide ever more accurate estimates of clinical effectiveness. Finally, many countries already have dedicated HTA agencies (health technology assessment) that do this kind of analysis in order to estimate the value for money of potential treatments.

How would it work for rare diseases?

We could address rare diseases by including a multiplier so that they get a higher total health benefit:

Health Benefits = (number of people treated) **x** (*estimated benefit per patient)*
x *(health prioritisation multiplier, for rare diseases)*

How do we technically distribute the money?

- A transparent pre-defined algorithm determines how to distribute monies in the Fund each year based on health benefits.
- Each innovator gets paid a share of the fund equal to the proportion of total health benefits due to their innovation.

The pre-definition of a transparent distribution mechanism means the fund is state-independent: the government's only role is to ensure the fund exists and is funded. Bureaucrats and policymakers will have no control over distribution of monies from the fund. Funds would be distributed on a regular e.g. annual basis based on estimated health benefit in the previous period (today most pharmaceuticals are only reimbursed after use so this would be little different, in fact innovators might well receive payment more promptly under this scheme than they do today).

Un-restricted access

In exchange for a Remuneration Right, **all R&D** has to be available **freely** to manufacturers and researchers to **use** and **build on**.

Medicines at low competitive prices

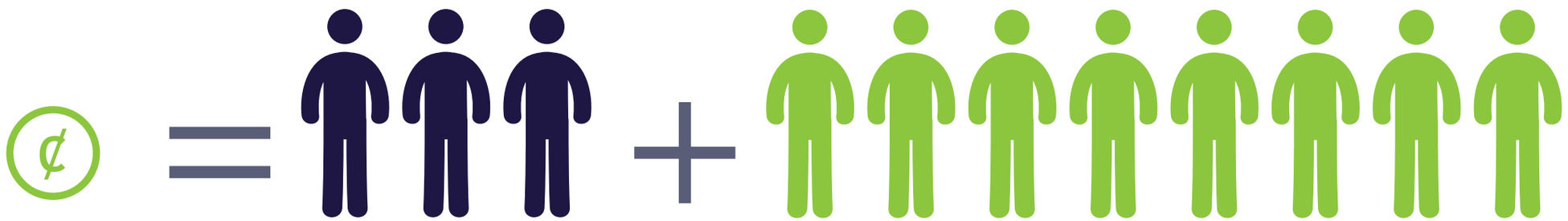
Now that R&D has its own separate stream of revenue, manufacturers don’t have to pay for a license to make the treatment.

Medicines at low competitive prices

This means they can manufacture high quality treatments without restriction which can be purchased by health care providers at low competitive prices, like generics today.

That means a lot more access

For a little bit more money we can get a lot more treatment!



What does more access mean in practice?

Today with the payment system we have, we can treat *50 people for $100,000*.

Under Remuneration Right Fund we could now treat *150 people for $102,000* (only 2% increase).

That is 100 lives saved!

How does it work in detail?

Under today's case we have:

- ($1980 *R&D* + $20 *manufacture*) **x** 50 *patients* = $100,000 for 50 patients

  $99,000 for R&D and $1000 for manufacture = $100.000

- ($1980 *R&D* + $20 *manufacture*) **x** 150 *patients*= **$300,000 for 150 patients**

  → Because we cannot afford a 200% increase in our medicines budget that means we can't treat these extra 100 patients. That means **access is denied** for many patients and **there is no additional money for R&D**.

How does it work in detail?

Under the Remuneration Right Fund model we have:

- $99,000 R&D + ($20*manufacture* x 50 patients)= $100,000 for 50 patients

  99,000 for R&D and $1000 for manufacture = $100,000

- $99,000 R&D + ($20 *manufacture* x 150 *patients*)= **$102,000 for 150 patients**

  99,000 for R&D and $3000 for manufacture = $102,000

  → Because we pay for R&D and manufacture separately we can now have **triple the amount of medicine for only 2% increase**. That means R&D is financed at the same level as today and we can treat all the extra 100 patients.

How does it work in detail?

Under today's case we have:

- ($1980 *R&D* + $20 *manufacture*) **x** 50 *patients* = $100,000 for 50 patients
  $99,000 for R&D and $1000 for manufacture = $100.000
- ($1980 *R&D* + $20 *manufacture*) **x** 150 *patients*= $300,000 for 150 patients

  →We cannot afford a 200% increase to treat 100 extra patients. So access is denied and there is no additional money for R&D.

Under Remuneration Right Fund we have:

- $99,000 R&D + ($20*manufacture* x 50 patients)= $100,000 for 50 patients
  99,000 for R&D and $1000 for manufacture = $100,000
- $99,000 R&D + ($20 *manufacture* x 150 *patients*)= $102,000 for 150 patients
  99,000 for R&D and $3000 for manufacture = $102,000

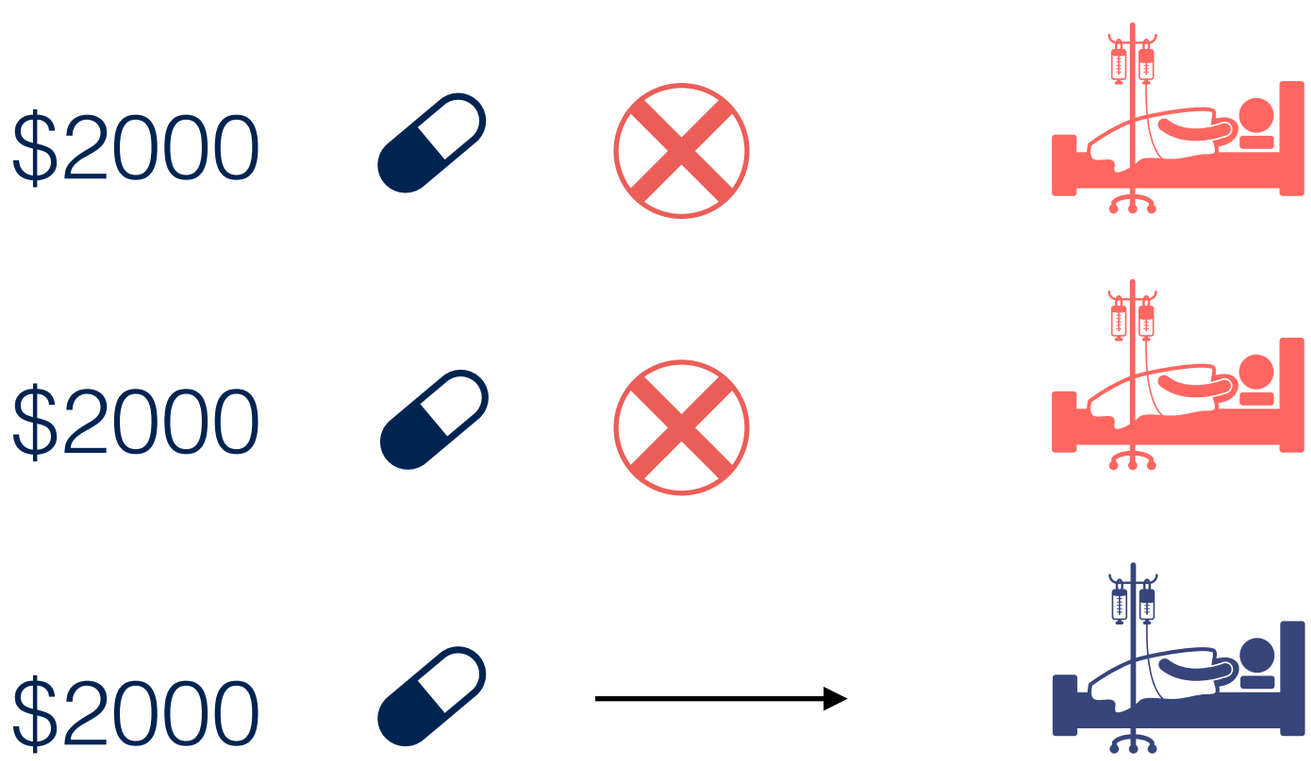
  → We can now have triple the amount of medicine for only 2% increase. Here R&D is financed the same as today and we treat an extra 100 patients because we pay for R&D and manufacture separately.

In Summary

When we purchase a treatment we only pay for the manufacturing costs, which means many more people can have access. *R&D is paid for via Remuneration Rights and is much money for R&D as before.*

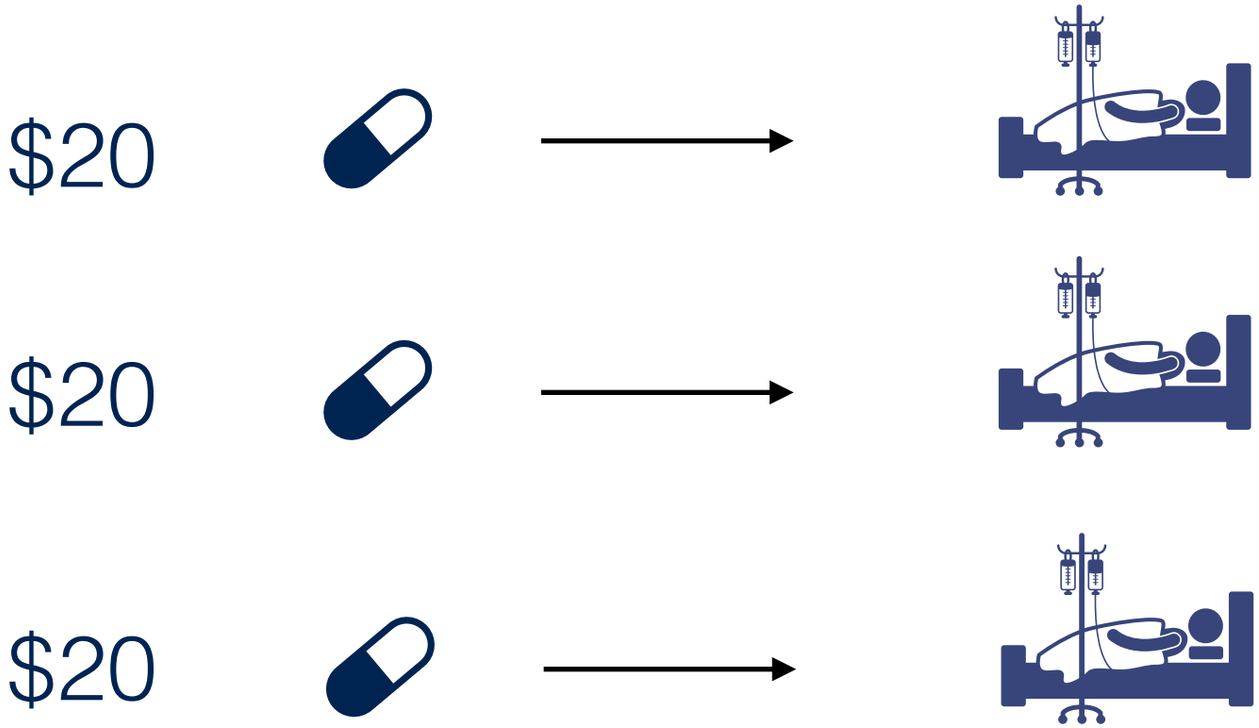
What is the difference with the past?

In the past only few people could afford the treatment because the one payment method had to cover both the cost of manufacture and the R&D in each treatment.

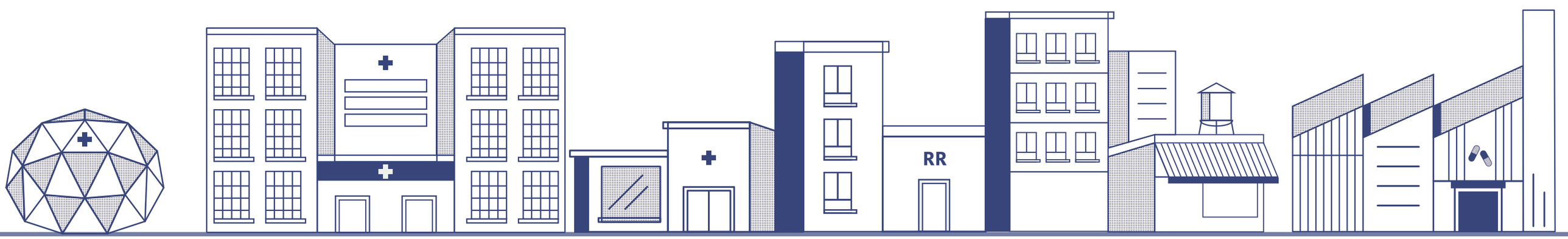


What are the benefits?

Now health care buyers, governments and insurers can afford to purchase many more treatments, because they only have to cover the cost of manufacture.



Conclusion



We can move from the current one payment stream to a two payments streams

The benefits will be:

- Increased access and affordability for medicines for millions of people

- An efficient and competitive market for manufacture and medical innovation with innovation more closely aligned to medical needs

- Continued funding for medical R&D and incentives for pharmaceutical companies at current levels

- Increased access to information for researchers and innovators

We already have the capacity to make this happen:

- We already pay for R&D and manufacturing of medicines through our taxes and insurance.
- We already measure the use and benefits of medicine e.g. UK's National Institutional for Clinical Excellence (NICE)
- We already have the legal infrastructure to assign ownership in innovations

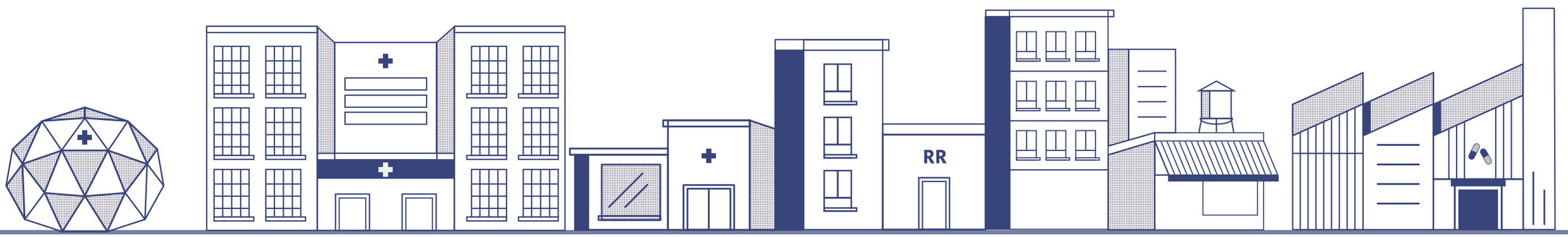
Summary I

- Millions of people lack access to life-saving medicines because of high prices and health providers are in crisis.
- But high prices are needed to pay for the investments in the creation of new, innovative medicines.
- We end up stuck in a dilemma between access or innovation
- Actually we can have both — using remuneration rights!

Summary II

- The problem today is that we have one payment for both innovation and manufacturing
- What if we had two payment streams: one for innovation and one for manufacturing
- Innovation would have its own stream of revenue so manufacturers don’t need to pay for a license and they can produce medicines cheaply and competitively
- This increases access to treatment for patients and maintains the same amount of money for innovation
- Access and innovation can thrive together

Credits



Credits

The iMed approach has roots in several previous efforts. First, the Medical Innovation Prize Fund proposal, first introduced in the U.S. Congress by Bernie Sanders in 2005, and currently before the U.S. Senate as S. 495: Medical Innovation Prize Fund Act.

Similar proposals were advanced by several countries in the World Health Organization from 2008 to 2012, during negotiations on the delinkage of R&D incentives from product prices, and delinkage has been endorsed by a number of academic experts, international bodies, NGOs and legislators, and more recently in the area of incentives for the development of antibiotic drugs (See: http://delinkage.org)

The design of modern market entry rewards for drug development is based upon the pioneering work by James Love and Tim Hubbard, beginning with proposals that grew out of a collaboration with Aventis on radical IP scenarios, and later led to several proposals for practical implementation of delinking, beginning with the Sanders bills in 2005. Among other experts who have supported work on delinkage of R&D incentives from prices are Joseph Stigltiz and Aidan Hollis, and in the antibiotics field, Outterson.

2004. Tim Hubbard and James Love, “A New Trade Framework for Global Healthcare R&D,” PloS Biology, February 17, 2004.

2005. James Love and Tim Hubbard, “Paying for Public Goods,” in Code: Collaborative Ownership and the Digital Economy. Edited by Rishab Aiyer Ghosh. MIT Press, Cambridge, 2005. (pp. 207 229).

2007 November 28. James Love and Tim Hubbard. “The Big Idea: Prizes to Stimulate R&D for New Medicines,” Chicago-Kent Law Review, Volume 82, Number 3 (2007).

2009. James Love and Tim Hubbard, “Prizes for Innovation of New Medicines and Vaccines,” Annals of Health Law, Vol. 18, No 2, pages 155-186.

Appendix

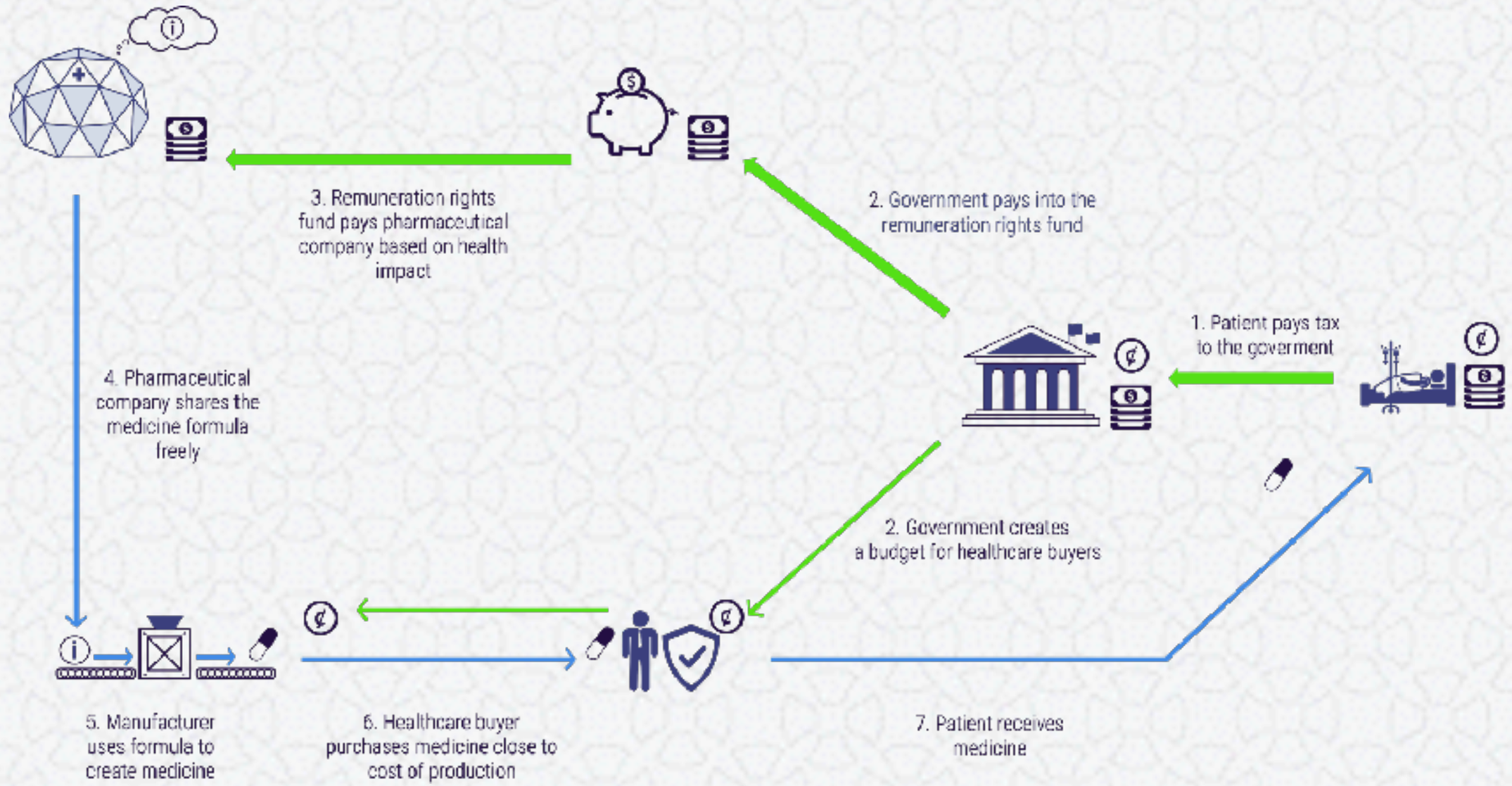
Policymakers are stuck in a dilemma:

access **or** innovation

High prices are needed to fund innovation but high prices mean less access as fewer people can afford treatment – and, crucially, the lost purchases of those who cannot afford treatment benefit no-one as the patients remain sick and the pharmaceutical company gains no revenue.

Conversely, lowering prices for medicines to increase access for patients might mean less money for pharmaceutical companies to invest in innovation.

Overview of the two-part payment remuneration rights system



Note: this diagram is intentionally heavily simplified. For example, publicly funded research is omitted. It also focuses on the case where healthcare insurance is government coordinated. However, a similar structure applies in the case of private insurance.

What are the implications for research?

Free access to existing R&D means more innovations because researchers and innovators can use and build on the work of others quickly and easily.

Today, innovation is being held back because researcher and innovators cannot build on (or sometimes even use) other people's innovations unless they pay a high license fee.

Under remuneration rights, reuse still involves payment from A to B (like patents) but unlike patents rather than an automatic block remuneration rights require equitable remuneration. Concretely, a new innovation A builds on an existing innovation B then the owner of the remuneration right in A will need to pay some of their revenues to the owner of the remuneration right for B. The level of this compensation will be negotiable, starting from a default value and with recourse to the courts if an agreement fails to be reached just like today.

How do we estimate health impact?

The fund would be distributed based on health benefits of each innovation. The amount of money going to each innovation would be given by the following formula:

$$\frac{\textit{(Number of people treated)} \times \textit{(estimated benefit per patient)}}{\textit{Total health benefits from all innovations cover by RRF}} \times \textit{Money in RR Fund}$$

How do we estimate health impact?

The fund would be distributed based on health benefits of each innovation. The amount of money going to each innovation would be given by the following formula adjusted for rare diseases:

$$\frac{\textit{(Number of people treated)} \times \textit{(estimated benefit per patient)} \times \textit{(health prioritisation multiplier, for rare diseases)}}{\textit{Total health benefits from all innovations cover by RRF}} \times \textit{Money in RR Fund}$$

How does reuse work?

Under remuneration rights, reuse still requires compensation. However, rather than the automatic blocking of a monopoly patent it provides entitlement to equitable remuneration.

Concretely: suppose a new innovation B builds on an existing innovation A. Under remuneration rights the owner of the remuneration right for B will need to pay a portion of their revenues to the owner of the right for A. By default (there will a default value set for this that can be amended by negotiation and with ultimate recourse to the courts, just like today, if an agreement fails to be reached).

How can we move to Remuneration Rights?

We already have the technical capacity to make this happen:

- We already pay through our taxes and insurance for R&D and manufacturing of medicines.
- We already measure the use and benefits of medicine e.g. UK's National Institutional for Clinical Excellence (NICE)
- We already have the legal infrastructure to assign ownership in innovations

We have the legal and political capacity to make this happen

- Remuneration rights are compliant with existing norms and international agreements like TRIPs
- Transition from patents to remuneration rights could be done on an incremental country by country basis (i.e. one country could switch to remuneration rights whilst other countries remained on patents)
- Within a country, transition could be done either via a wholesale replacement of patents by remuneration rights (TRIPs compliantly) or on a voluntary basis where innovators license patents into a remuneration rights fund.