

The art of saving lives: getting 'global' right - part two

By Mary Moran 4 December 2017

In <u>part one</u> of this two-part series, I welcomed the recent announcement of Australian aid funding of up to \$75m over five years for global Product Development Partnerships (PDPs) to accelerate access to new and effective global health products. In this post, I look at what could be done to ensure that Australia's policy frameworks and funding parameters closely match global health research and development (R&D) needs.

Creating an effective policy framework

Global pharmaceutical R&D is a highly regulated industrial and clinical process that stretches over a decade or more, and which is new and unfamiliar to the public sector. Investing effectively in delivery of new global health products will mean thinking outside traditional bilateral and regional aid paradigms, and developing new approaches and policies.

Thinking global

The key to success in global health product development is to embrace the benefits of a networked global health R&D approach, rather than attempting to shoehorn it into a traditional bilateral or regional aid paradigm. Although the best ideas for an Ebola vaccine may come from academic or industry breakthroughs anywhere in the world, the trials will need to be done in West Africa (the only place where Ebola now exists), vaccine development will likely involve large vaccine companies in the US, India or Europe, and the costs and risks need to be shared across public and philanthropic donors globally – no-one company or country can crack this alone. And why would they want to?

Shared global efforts also make financial sense. By pooling costs, risks and scientific leads, global efforts – like PDPs and the new CEPI fund to develop vaccines for emerging diseases – can dramatically reduce the cost and risk for each donor government. Trying to insert bilateral or regional interests into the global R&D process is counter-productive, slowing it down and driving up the cost of success and the risk of failure. It seems harmless for

Australia to ask, "If we join in, can we give our funding to an Australian research group?" or "If we fund this global product, can we do the TB clinical trials in PNG?". But this is simply robbing Peter to pay Paul, as it can mean diverting funding from the best global lead, or slowing product development by months or years due to the difficulties of patient recruitment in a place like PNG (poor or no roads, mountainous terrain, lack of reliable follow-up).

The most effective aid paradigm is one that values and incorporates not only important regional goods but also global goods that benefit the region. There is no more cost-effective avenue to get the new tools we need: where good global R&D efforts exist, Australia should join them.

Ensuring policy is fit for purpose

It's unfair to expect bureaucracies to suddenly devise high-performing investment strategies for something they've never done – in this case global health product development. The natural response can be to manage it not as a global good but as a domestic research grant; first identifying how much money will be disbursed and when, clarifying what kind of organisations are eligible, setting a 3-year time frame (or less), forming a small selection committee of trusted experts (often Australian academics), requiring annual reports against

deliverables, and generally letting the grant run to its end irrespective of progress. But this approach is poorly suited to global health R&D – or at least, poorly suited to maximising its impact. Global health R&D is a new and very different field and needs new and different policy approaches.

The most effective investment strategy for contributing to global product development is to set a funding envelope over a sensible time frame (five or more years, as seen with DFAT's recent Indo-Pacific Health Security initiative), select priority investment areas for Australia and for our region and stick with these (changing horses every few years is a waste of funds), and use both aid and product development expertise in making investment decisions.

It is then crucially important to allow full flexibility within the funding window: unlike research grants, product development trials cannot commence without full up-front funding (it is unethical to start a trial while not having the funds to finish it); and even the most foolhardy industry expert would hesitate to predict when or how many products will successfully transition to the next funding stage, and thus how much funding will be needed year by year. Given this, it is important that DFAT's new PDP Fund does not feel constrained to stick to pre-defined annual funding levels, maximum disbursements over fixed periods, maximum number of allowed recipients etc. Far from reducing risk, these

types of rules increase risk by removing the flexibility to give the right amount of funding to successful projects at the right time.

Two useful guiding principles for investing in this new area are: tailor the size and timing of government investment to what is in the pipeline – when a breakthrough comes along, don't starve it of funds because it doesn't match guidelines that you yourself have created. And, as much as possible, avoid tying your hands in advance with too many rules, requiring a messy untying process if circumstances change, as they often do in the unpredictable world of R&D innovation.

A final note

The thoughts above are minor quibbles in the larger context. Between 2000 and 2015, the global health R&D effort has helped to halve global malaria, wipe out the African meningitis belt, and cut deaths in children under five by a staggering 44% – all in just fifteen years. It is wonderful to see DFAT's role in this global effort, and I congratulate them on the new PDP Fund and their expanded global role.

I nevertheless believe that the policy and paradigm modifications suggested in my two posts could significantly increase the effectiveness of Australia's investment. In summary:

- Commit to global health R&D as a formal part of the aid program, with a stable funding envelope and durable in-house support structures.
- Expand DFAT's investment to include not only low-risk R&D areas and health security threats, but also high-burden regional diseases and higher risk, higher impact products like vaccines.
- Avoid distorting global approaches to R&D by seeking to insert unwieldy bilateral or regional elements.
- Ensure R&D policies are fit for purpose. A good starting point is to firm up long-term funding levels and investment scope, which are currently too changeable, and to avoid restrictive investment guidelines these may be useful for managing research grants but can be counter-productive for product development.

Taken together, these modifications could significantly increase both the financial and health returns on DFAT's global health R&D investment.

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The exception is the Biomedical Translation Fund, which has sought to blend industry investment approaches with government requirements.

About the author/s

Mary Moran

Dr Mary Moran is the Executive Director of Policy Cures. She has over 20 years experience in health policy and practice, including 10 years specialising in neglected disease policy. She has conducted projects for a wide range of public and multilateral health organisations with a focus on policy solutions for emerging issues related to neglected disease R&D.

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