

Comments on the Evaluation Framework, Evaluation Criteria and Inventory of Financing Proposals of the WHO Expert Working Group (EWG) on R&D Financing

Response to a Request from the Secretariat of the EWG

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1. Background.....	2
2. The Purpose of this Response	2
3. High-Level Criteria.....	3
3.1. How do respondents understand their task?.....	3
3.2. Interpreting respondents' responses.....	4
3.3. Comments about the proposed criteria.....	4
3.4. Other possible criteria	7
3.5. Comment boxes	8
4. Inventory and Evaluation Framework.....	8
4.1. Fundraising	8
4.2. Allocation.....	9
4.3. Funding source.....	9
4.4. Some categorization issues and suggested additions to the Framework file	10
5. Cross-Cutting Evaluation via Core Technical Components of Financing Proposals	12
5.1. Having a prize/reward or prize-like/reward-like component	12
5.2. Having or possibly having an auction or auction-like component	13
5.3. Using (usually by creating new) financial instruments (e.g. bonds, risk-sharing instruments, or specific financial funds)	13
5.4. Modifying risk	14
5.5. Needing to influence investors/financial markets.....	16
5.6. Where financing proposals interact and sometimes potentially conflict.....	17
5.7. Other technical component lenses.....	18
5.8. The challenge of application and the need for a reality check	18

¹ For related activity, please see www.economics.ox.ac.uk/members/andrew.farlow.

1. Background

In November 2008 the Director-General of the World Health Organization established an Expert Working Group (EWG) to “examine current financing and coordination of R&D, and proposals for new and innovative sources of funding to stimulate R&D related to Type II and III diseases, and the specific R&D needs of developing countries in relation to Type 1 diseases”, with a view to making recommendations to the 2010 World Health Assembly.² As part of this task, the EWG is conducting a comparative review of proposals to finance increased research and development (R&D) for the needs of the developing world.

Before going any further, I would like to add my appreciation, to that of others, for the instigation by the WHO of this comparative exercise. Given the limited budgets but limitless needs, R&D financing mechanisms have to be as efficient as possible and be combined in ways that are as efficient as possible. As the accompanying material points out: “Largely, funds have been raised and delivered in much the same fashion...regardless of the development problem being tackled.”³ This suggests that financing mechanisms have so far been insufficiently tailored to the task at hand, and therefore less efficient than might otherwise have been the case. In principle the framework being put together by the EWG is a way to move towards creating more equal footing for all proposed financing mechanisms and for choosing a combination of financing mechanisms on the basis of their relative ability to achieve particular goals. This is to be applauded.

2. The Purpose of this Response

I have been asked by the Secretariat to the EWG to comment on the draft evaluation framework, the evaluation criteria and the completeness or otherwise of the inventory of financing proposals being considered by the EWG. That is, the task is to evaluate the method of evaluation of the proposals, especially its robustness, and not per se to evaluate the proposals themselves. Clearly an understanding of many of the proposals helps one to think through *how* to evaluate them, but I shall try to avoid too much evaluation of specific proposals and too many of my own biases.⁴

The crucial phrase in the background material is “the *relative ability* of proposals to achieve the desired R&D goals” (emphasis added). The background paperwork also says things like “How well does it achieve this objective?...the likely performance of proposals...” etc. Let’s think about this for a moment.

² Further details at <http://www.who.int/phi/ewg>.

³ Background paper from the Taskforce on International Innovative Financing for Health Systems, co-chaired by the UK Prime Minister and the President of the World Bank 2009.

⁴ I have previously seen and commented on the inventory and some of the grouping of proposals, and so will avoid repeating any of that.

Where a financing proposal has not already been tried (many of them), there is no track record of performance evidence on which to make a judgment regarding this relative ability. In cases where proposals have been tried, not all have been conducted as natural 'experiments' to generate the necessary evidence to evaluate their relative performance, while in other cases there is a monitoring and evaluation framework in place and some performance evidence. Where proposals have been tried in one way but not in others, there is more of a track record of evidence but it is still limited. Finally, of those proposals enacted, some enactments have not matched their proposals.

This means that to get some notion of this 'relative performance ability', in many cases we still have to keep one eye on the theoretical possibilities (including by looking for similarities with previously tried proposals) and another eye on how proposals are likely to be applied in practice, which may differ significantly from theory.

3. High-Level Criteria

The criteria listed in the 'Criteria' file have come from what seems to have been a comprehensive search of published criteria, filtered and adapted to suit R&D financing. In sum, I think that the criteria are appropriate as benchmarks against which financing mechanisms should be evaluated, but in the case of some proposals I am not sure what useful information will come from simple agreement-scale responses, especially in the less straightforward cases. Below, I suggest some additional thoughts for possible further criteria and adaptations of wording of the current criteria. In reviewing the 'criteria' file, I first look at the task respondents are asked to perform, and then I look at the criteria they are supposed to use.

3.1. How do respondents understand their task?

Respondents have to respond to the statement "This criterion is one of the most important" on a five-point scale ranging from 'Strongly disagree' to 'Strongly agree'. The statement is not "This is important", which has quite a different meaning.

Is "This criterion is one of the most important" meant relative to the specific proposal? That is, for each proposal on the inventory (all 91) are respondents supposed to allocate across all 17 criteria three or four ticks for each of the possible five responses, so that they in effect rank the importance of criteria against each proposal? This would seem to be the logic of the language. On this understanding, a respondent who allocated 'Strongly agree' to most criteria for one proposal and 'Strongly disagree' to most criteria for another proposal is therefore getting the task wrong. What if some respondents interpret what is expected of them as to rank importance of criteria per proposal, and other respondents respond as if they are ranking the proposals? How are the results aggregated and interpreted?

In assessing "This criterion is one of the most important", is it being suggested that the typical respondent understands the workings of all 91 proposals on the inventory? If not, then there should be a 'Don't know' response for each criterion. Is it better to get a selective response (where respondents leave blank all those proposals they do not understand or about which they don't wish to hazard a guess) than enforce a comprehensive but not especially illuminated, or illuminating, response?

3.2. Interpreting respondents' responses

Since it is difficult to understand how each respondent understands each proposal and what they think the purpose of their response to it is, it will be difficult to interpret in all cases what a response means. For example, are respondents responding to an actual application of an R&D financing mechanism or to an idealized application or to what they feel is a probable application or to a caricatured (either negatively or positively) application? Since we don't ask and can't get inside their heads we can't know.

Even as somebody who has devoted a great deal of time to studying different R&D financing mechanisms, I could not respond to a range of criteria for a number of proposed financing mechanisms on an agreement scale of 'Strongly disagree' to 'Strongly agree'. My best response in those cases would be 'it depends'. Indeed, the more one analyses some of the financing proposals and understands the challenges of enacting them, the more difficult it is to not have a nuanced response to some of the criteria listed here. However, there is little ability in the questionnaire to indicate that a response is conditional.

3.3. Comments about the proposed criteria

For each criterion, please see exact wording in the original file (here I simplify to the key word or phrase).

Criterion 1: Revenue related. The list of 'qualitative aspects' in criterion 1 requires the respondent to form an average opinion over aspects that may, in their opinion, go in conflicting directions and some of which they may not be able to have an opinion on.

Criterion 2: Suitability. This seems a bit open to interpretation. Isn't the 'long enough' component of the definition covered by criterion 11?

Criterion 3: Cost (set-up, operation, transaction costs). The operating and transaction costs of some recently enacted financing mechanisms have turned out much higher than initially presumed. These costs are not necessarily a bad thing if they are part of making a financing mechanism work well. And since all mechanisms have running costs, it is not the costs but the outcome relative to the costs that really matters. Evaluation mechanisms are in place for IFFIm, AMCs, AMFm, and various metrics for PDP performance, and most other current mechanisms. In the case of financing proposals not yet enacted, there is an opinion exercise about these costs. Given that this is an extremely problematic issue, would an open discussion exercise involving thrashing through this evidence not work best? Maybe this could be as a complement to a questionnaire-style approach? The reader can probably guess that where there is a monitoring and evaluation mechanism in place and a group vested with the job of calculating these costs, I feel it makes sense to put good reliance on that, and to have a rigorous, open, monitoring of the monitors.

The notion of transaction costs in criterion 3 also captures the notion that, in order to work, some financing mechanisms have high informational needs. Some notion of monitoring difficulties (caused for example by asymmetric information) could be part of this criterion. The real problems come when it is difficult to monitor and information is hard to extract, not per se from the costs of trying to do this.

Criterion 4: Efficiency. An investment lens tells us that for many 'Allocation' proposals, efficiency depends on many features. Again, is it probable or actual efficiency? A respondent may strongly agree that a mechanism might be efficient conditional on certain things being done right, or inefficient if certain things are done wrong, but the response options don't allow this conditionality to be conveyed.

When it comes to 'Fundraising' proposals, a standard problem with taxes is their deadweight cost and distortion. A tax on an externality (pollution, financial market instability, etc.), to the extent it is workable, is potentially less distorting than other types of tax, and clearly this should feed thoughts regarding the efficiency of 'Fundraising' options.

'Revenue potential/cost ratio': Again a potentially difficult ratio to expect an average respondent to have an answer to in all cases.

Criterion 5: Effectiveness/impact. This overlaps with criterion 7. This criterion seems to potentially cover a lot. Could this be rephrased more as a targeting criterion in its title to avoid ambiguity that this is what the criterion is really about?

Criterion 6: Risk management. It is important and good that this is a criterion. However, in most 'Allocation' mechanisms the precise amount of risk management achieved is a huge balancing trick between forces, depends on the enactment, and is potentially a difficult technical question. Again, I can only speak as someone who spends greater than average amounts of time thinking about financing mechanisms, and yet, in most cases I would still reserve judgment on this criterion and prefer discussion of evidence to an immediate expression of opinion in a questionnaire.

Criterion 7: Positive/negative interactions. This is actually a very important criterion. Again, it is a largely technical question, and gets more complicated the more financing mechanisms are at work and the complexity of them. Personally, I'd rather see someone spell out potential interactions and then ask for a debate about this. Without knowing what the other proposed mechanisms are that are interacting with the one currently being evaluated, one can only make a generalized average comment about tendencies for positive and negative interaction, which I don't think is what is intended (and this certainly can't be communicated in a response here). Surely this would need a comment box to clarify how a respondent formed an opinion? Does the criterion also cover possible unintended consequences (including consequences that may not have been perceived at the time)?

This criterion would also seem to cover legacy issues (including the creation of future legacy issues). This is the notion that once some financing mechanisms are set up, they still have to be dealt with in the future as 'legacies'. As one example, GAVI will almost certainly have to be renewed one way or another by 2015 if not earlier. It is a 'legacy' that future financing mechanisms will have to fit around and its replacement will take a portion of future funding. Similarly, Priority Review Vouchers now exist, as do orphan drug legislation, PDPs, government grants, etc. The relevant comparator is not the world without these, but one including them. History (and the choices we get to make) is somewhat path dependent.

Criterion 8: Technical feasibility. Regarding Legal and Regulatory hurdles, again I am aware of colleagues across the global health field with expert knowledge (sometimes from the experience of setting up and running financing mechanisms) I'd rather defer to in many cases than myself take an opinion. What is 'legal' also varies by jurisdiction. Some countries cannot sign up to some measures because of their domestic budgetary rules. So, this would not invite a straightforward degree-of-agreement choice. Would a 'Neither agree nor disagree' response reflect a response that really means 'Agree some times in some countries, but not agree other times in other countries'? Again, does the need for an average opinion undermine what we are after?

Criterion 9: Acceptability: Is this an opinion issue (say regarding what governments are politically determined to do on the basis of ideology) or a technical issue (what they can and cannot do technically)? Surely, that a financing mechanism will work more efficiently and get more value for money should trump one that does not, even if it has more current 'appeal'? Part of the purpose of this exercise is to shape this 'appeal' and not to take it as predefined other than if it is a technical constraint. Should 'appeal' not ultimately come from evaluating proposed mechanisms against other relevant criteria in the list and not be thought of a stand-alone issue? That is, 'appeal' is in part an output we seek to mould from this process, and overly constraining an output by a predetermined output might be a bit circular? Are we not after all trying to push the boundaries of what is acceptable? Perhaps this can be reworded as a 'political constraints' criterion or a technical constraints criterion?

Criterion 10: Prior experience of it. Rather (because of the need to agree/disagree) should this not read 'If this is based on a known approach, has that approach been successful/unsuccessful...?' How are prior-experience and non-prior experience cases dealt with in handling all the data from this questionnaire exercise?

Criterion 11: Long-term functioning. This seems to cover several issues. One is the 'foreseeable, predictable' issue. The other is the 'ever-increasing sums of money' issue (including a roll-over issue in some cases). Something can be foreseeable, predictable and allow long-term planning, even as it can have a built-in finite horizon. Other proposals need an infinite horizon (usually because of the needs of investor expectations). So, a response is difficult in some cases. This criterion also touches on legacy issues.

Criterion 12: Automaticity. It is quite possible for some respondents to put low weight on this criterion as "one of the most important" if it means "require to be repeatedly renewed", even when they value it being repeatedly renewed. For some proposed financing mechanisms, can this be answered without a questionnaire question? Most things just are automatic or repeated? The more important issue is whether they *need* to be repeatedly renewed rather than whether they are or are not.

Criterion 13: Scalability: This will depend on the specifics of a disease/product/geography? So a respondent can say that a mechanism is expandable (thinking of a particular disease/geography/product) knowing that the answer is 'no' for other diseases/geographies/products. So, again, do they give an average opinion? Or are financing mechanisms in all cases clearly meant for specific purposes?

Criterion 14: Time to implement. Does this require some notion of acceptability or otherwise of potential negative tradeoffs in order to push mechanisms through more quickly?

Criteria 15-17: These are crucially important.

Criteria 15: Accountability. Again, experience shows variance. Some PDPs for example have been very accountable and some have been very poorly accountable to the point of recklessly unaccountable. It is all down to governance structure. Is it 'does' or 'could'? Because of the diffuse way in which policy gets made, some mechanisms once set off don't really apportion accountability very easily (think of who takes the blame for a poor initial PRV experience? It is not clear).

Criteria 16: Governance and ownership. Should this not also include 'who' (for example those from developing countries?) is represented in the governance structure?

Criteria 17: Transparency. Criteria 15-17 overlap a bit. It is interesting, and good, to see that data on recipients as well as donors counts.

3.4. Other possible criteria

The Background file asks for comments on possible additional criteria. The following are tentative suggestions.

Access and product affordability/appropriateness: The report of the Commission on Intellectual Property, Innovation and Public Health (CIPIH), the precursor to the work of the EWG, conceptualized innovation as encompassing discovery, development and delivery. Access (to current as well as to future products) is therefore a part of innovation. Little of this is reflected here in the criteria (though of course various proposed mechanisms include it as a proposed virtue). More on this below.

How sensitive/robust/risky is a proposal likely to be to a poor application? In principle is it better to avoid financing mechanisms that are likely to be applied badly or that are too sensitive to critical core components going wrong or not being put in place? What if it is difficult to adjust to the presence of other financing mechanisms?

Term-setting issues, and the ability to respond to learning experiences: Those financing mechanisms relying on their terms being set or legislated very early (often so that investors don't face 'time inconsistency') may be hard to reset. Other mechanisms are more malleable, but, although flexibility/ability to adapt in the light of learning is a useful feature, in some cases it may also mean costly tradeoffs. To some respondents some ability to respond to a criterion related to these issues might be important.

Uncertainty: Especially regarding the amount of funds (for example if the amount depends on a chain of speculative reasoning and beliefs, how likely are funds to materialize and what will be the expected discounted value of such funds?).

Timing of enactment of financing proposal: The current criteria are formulated as if history/order/timing does not matter. However, since financing mechanisms need to adjust to the presence of each other, sometimes a different order of enactment and past history makes a difference to what is possible.

End-user preferences: There is some country-up thinking in some of the criteria (criterion 5 for example). A criterion like “Will it generate what the poor really want?” directly emphasizes the preferences of the end-users. Criterion 5 for example is interested in whether a proposed mechanism targets R&D towards developing country needs, but that criterion could be ‘passed’ even if it those needs were not particularly a high priority to those concerned. A criterion emphasizing the preferences of recipients might help?

Ability to support differential pricing strategies: In some disease cases, this is important. I suppose this may be covered under the criterion ‘Access and product affordability/appropriateness’.

3.5. Comment boxes

In most cases, when choosing a response to a criterion, there should be a comment box for the respondent to comment on his or her response. This may be especially necessary if they are unclear as to their interpretation of the question or wish to add caveats to their response or wish to make it conditional. It might be observed that this would generate 91 times 17 such comment boxes (1547 in total for anyone responding to all proposals). But, since most respondents are hardly likely to think through and tick 1547 responses, does this not anyway suggest that partial completion that is more telling is better than expecting full 1547 completion?

4. Inventory and Evaluation Framework

The evaluation Framework attempts to categorize or situate 91 financing and coordination proposals under two headings, ‘Fundraising’ and ‘Allocation’. On the whole the categorization is well thought-through, though, of course, subject to the fact that this is not a precise science and boundaries are sometimes fuzzy.

4.1. Fundraising

Most of the ‘Fundraising’ proposals are exactly that. But some stray over into the ‘Allocation’ space. These would seem (since the following is not an exhaustive list) to include (and this is only an informed opinion):

- Airline Solidarity Contribution (ditto Airline Ticket Voluntary Solidarity Contribution, VSC): An ‘Allocation’ mechanism too, since it has become heavily associated with the UNITAID component that has an underlying targeting logic. One supposes that if any of the other pure ‘Fundraising’ proposals come to be used for global health (carbon tax, Brazil’s CPMF, Currency Transaction Levy, the Tobin tax, etc.) they are likely to become associated with stakeholders/champions, and this will give them an ‘Allocation’ role too.
- BVGH business cases: The intent of BVGH is often articulated as being to highlight for private companies the size of markets they have overlooked. However, there is an

element of 'Allocation', since information uncovered in business case analysis can potentially help guide relative targeting of investor funds.

- Cost sharing for clinical trials: If this crowds out what governments would otherwise have done, it has 'Allocation' consequences.
- ETF (Exchange Traded Funds) by the Global Fund: Would those depositing expect some control over how the funds were allocated?
- More funding from State and Local governments: Ditto.
- Private Giving Campaign: Ditto.
- Sovereign Wealth Funds: If they are required to run at a profit, they will have to allocate across activities in a particular way.
- Scientific risk insurance: Categorized as 'Fundraising' in the inventory. In other cases where there is a similar risk component to a proposal, the proposal is often categorized as 'Allocation' (when it is indeed partly 'Fundraising' too).

Where 'Fundraising' and 'Allocation' become mixed in some way, there becomes an issue of governance and priority-setting in any 'Fundraising' mechanism. Who does the priority setting and how? What diseases are targeted? How much is towards R&D and how much is towards product purchase or health systems support? How does the approach affect the impact of other proposed financing mechanisms? And so on.

All 'Fundraising' categories have a potential crowding-out element, since governments have budget constraints to live within. Channeling a few billion dollars through one financing mechanism will crowd-out what might have gone through another mechanism. In financially constrained times, this bites more than ever. So, 'Fundraising' has 'Allocation' implications, and has to be thought of as part of the overall 'Allocation' framework.

4.2. Allocation

Many of the Allocation mechanisms are also 'Fundraising' mechanisms, in the sense of pulling in private financial capital for a while, to be repaid later (with interest and return for risk-taking) from taxpayer-raised funds through the workings of the 'Allocation' mechanism. In many cases 'Fundraising' is core to an Allocation proposal's success or failure. In most cases, a good enactment generates more funds into R&D than a bad enactment.

4.3. Funding source

In the Framework file, 'funding source' refers to the ultimate payee. Some mechanisms involve direct public funds (research grants, tax breaks, Minimum Volume Guarantees, etc.). Others can involve all manner of intermediate stages where private financial capital is involved (prizes, AMCs, Treaty, and, indeed, many of the financing mechanisms listed), but ultimately all this intermediate private finance is 'repaid' from the workings of the financing mechanism and that is why they are listed in the Framework file under the funding source category of 'public/not for profit'. The Framework file thus reflects the fact that in most cases, the ultimate payees are taxpayers/not for profits (including Foundations). I think a useful further 'funding source' subdivision nevertheless would be 'ultimate funding source = public/nfp; intermediate-stage funding source private finance'.

In spite of large increases in Foundation funding, the reality is that taxpayers still have to put most of the funding into any financing mechanisms chosen. Going forward, if there is to be a

surge of resources to help bring current product portfolios to fruition and to achieve widespread successful delivery, taxpayers will need to provide an ever-bigger proportion. This is why it is so important that resources be raised and spent as efficiently as possible and accountably (as recognized in the list of criteria). The strain on R&D finance that will be caused by the clean-up from the global financial crisis over the next five to ten years has made this more important than ever.

4.4. Some categorization issues and suggested additions to the Framework file

‘Proposals that were not R&D’

This categorization covers all kinds of insurance markets. In the poorest of settings this is probably not going to be a big source of funding (though even in the poorest regions of Africa simple banking and risk-sharing activities have been shown to have a major impact on decision-making and access to other interventions, so even here we should not rule out a role). In middle income and emerging economies this could be a significant source of funding (e.g. for cross-subsidization). Again, ‘partialling’ this out of the ‘Fundraising’ category could be because of the focus on developed-country taxpayer spending. However, should not a more complete picture include all possible sources of funding?

‘Efficiencies’

To the extent some of these work, they are ‘Fundraising’? Why not include delivery efficiencies? Innovations in delivery (say, more efficient supply chains) increase the value of product innovations/production. I mention this because of familiarity with colleagues in Oxford working on vaccine supply chains, locating some appalling weak spots that contribute to product wastage; these weak spots obviously weaken the value of efforts to expand access and hence the value of the original R&D. Why also not include things like ‘building the evidence base’ and ‘activating market’ and ‘building health systems’ at the country-level? In my current work on TB vaccines I am increasingly convinced that having countries ‘primed’ is as important as having global procurement funds, and that this is key to getting delivery timelines down. A big side effect of faster timelines is that this dramatically pushes up the present discounted value of all R&D investments.

At the moment, sources of ‘Fundraising’ generated from ‘Proposals that were not R&D’ and from ‘Efficiencies’ and also generated by risk reduction, better coordination, diagnostics (better quality of which often cuts costs of R&D and improves the present discounted value of the end product) and so forth, go relatively unmeasured. These currently ‘unmeasured’ sources are also key to the relative evaluation of proposed financing and coordination mechanisms. It would be good to have some way of measuring the ‘value’ of these components in terms of funds ‘raised’ in the case of each proposed financing mechanism, so that we can better evaluate the *relative* impact of proposed financing mechanisms.

‘PDPs’

So far PDPs have taken a large amount of public/nfp money. But should not some of them factor in private sector revenues? At the moment they only do so in the inventory of financing proposal via the PDPFF proposal. More on this point below.

‘Priority Review Voucher’

The idea of a Priority Review Voucher is that a firm spends its own resources on developing a neglected disease product, recouping this cost (including to cover risk-taking) later from its acquisition of a PRV (and many other firms are supposed to spend and fail to develop neglected disease products and bear the loss, but be happy to do so because of the presence of the potential ‘windfall’ payment embodied in a PRV). How the ultimate source of the funding is categorized depends on the rich world drug/vaccine/diagnostic market that the voucher gets attached to (Does health insurance pay? The public sector pay? The private sector pay?). I suppose the logic of the categorization of PRV in the Framework file is that the private finance that a firm uses is repaid from sales based on the voucher. If payment was via a prize or prize-like mechanism it would be categorized it as public/nfp funding.

‘Product Development Partnership Financing Facility (PDPFF)’

This is listed as a ‘private’ source of funds because the underlying royalties are generated in high and middle-income countries, but it is not clear who is the ultimate payee, which seems to be the intent in the Framework categorization. For example, in the UK most TB vaccine sales would be taxpayer-funded.

Indigenous resources

I think insufficient attention is paid to the distinction between ‘global-level public/nfp’ and ‘country-level public/nfp’ and ‘country-level indigenous private’. For example, private purchases of malaria drugs cover a proportion of manufacturing and distribution costs. To the extent a margin can be charged to some groups, some of those purchases support development. Depending on the vaccine, if a HIV vaccine is ever developed and launched, there is no reason why IAVI or similar could not borrow some of the successful social entrepreneurial pricing models to heavily cross-subsidize Cost of Goods and even development costs of vaccines for the poor from vaccines sold in rich markets. Similarly for TB, there is some middle and higher income market, though again it very much depends on the target product profile. Dengue is another interesting case study, because again the wide and diverse range of coverage of dengue raises some interesting cross-subsidization possibilities. Some argue that pneumococcal vaccine could/should have exploited richer markets more than it did, and that there are lessons to be learned from that experience.

Just taking these cases, there are different enactments that lead to much more need for public resources (e.g. few-serotype pneumococcal vaccine, insufficient initial capacity to serve all markets, high monitoring) than other enactments (more-serotype pneumococcal vaccine, more effort to put capacity in place earlier, targeting to achieve protein-based vaccine technology earlier). Sticking with the vaccine case, there are a host of actions to, say, bolster HPV vaccine uptake that would give more reassurance such that more capacity could be in place such that COG for poorer markets could be lower. Again, different enactments lead to very different consequences in terms of public/taxpayer needs.

At the moment, the only category in the Framework file covering these cross-subsidization/differential pricing possibilities is the ‘Product Development Partnership Financing Facility (PDPFF)’. If the Framework file is only about locating what richer nations spend through financing mechanisms, then fair enough. If it is about creating a complete inventory of potential funding sources, then it may be less complete than might be possible.

Understanding where the indigenous financing possibilities lie would help to highlight cases that are almost entirely dependent on non-indigenous external (global-level) resources and hence a priority for global-level funding.

Private in-kind resources

I don't see any private in-kind resources indicated in the Framework file.

5. Cross-Cutting Evaluation via Core Technical Components of Financing Proposals

While the approach presented in the Background paper ('Introductory to inventory framework and criteria documents') seems to shift focus onto 'disease type', 'product type', 'R&D type', and 'Actors', evaluation nevertheless requires that we assess the "likely performance" of a proposal in the "R&D world and the policy world", which seems to require us to think through mechanism-type/technical component issues too. I doubt respondents will respond without to some degree thinking through mechanism-type lenses anyway. And anyone thinking through mechanism-type reasoning is already thinking through non-mechanism type-issues. No doubt, the eventual way to decide on proposals and mixes of proposals is to not see these as competing but complementary type-lenses.

One way to evaluate proposals that still allows room for their mechanism-type features is to gather them into categories according to key technical components and to use thinking about the probable working of these components, as lenses. Perhaps these 'lenses' could be added to the 'lenses' generated from questionnaire-style responses?

For example, if a mechanism relies on a prize/reward or a prize-like/reward-like feature, what are the possibilities and limitations of prizes/rewards (informational constraints case-by-case; the degree of challenge according to size of prize; amount of risk-taking supported; amount of possible time-inconsistency; etc.) and how key is this core component in each proposed mechanism anyway? Similarly, if there is an auction component, under what circumstances do auctions work well and under what conditions do they work less well (for example, plenty of competition and inability to collude is key to an efficient auction, and this may vary by application). If new financial instruments are required, under what circumstances are they likely to work, and under what circumstances are they likely to not work so well, or even fail? If a mechanism has many working components with a risk of coordination failure across some of the components, how robust is it likely to be? And so forth. In this spirit, here are some lenses (with some illustrative categorizations that are open to discussion):

5.1. Having a prize/reward or prize-like/reward-like component

Any mechanism with a prize or prize-like component is a 'Fundraising' mechanism (in the spirit of pulling in private financial capital to many competing developers for a while, to be repaid later, via payments to the winners via the prize or prize-like component) as well as an 'Allocation' mechanism. From the inventory of proposals, the following would seem to fall into this category (and remember, not all are prize mechanisms; the point is the prize-like reasoning of key components):

- Advance Market Commitment (AMC), when used as an R&D incentive
- Cancer Prize Fund
- Chagas Disease Prize Fund
- Fund for R&D in Neglected Diseases (FRIND) (may have prize-like element if there is a limited pot to be distributed)
- Health Impact Fund
- InnoCentive
- KEI Prize
- Orphan Drug (because of the race component?)
- Prize funds (general)
- Prize Fund to Support Innovation and Access for Donor Supported Markets
- Redesigned 'AMC' model
- R&D Treaty
- TB Diagnostic Prize Fund
- Priority Review Voucher (prize aspect since firms race to win it or race to win them if they are given out in a certain number per period of time)
- Transferable Intellectual Property Right (TIPR) (again, because of race to be first?)

5.2. Having or possibly having an auction or auction-like component

In several proposals the value of funds pulled in depends on the efficiency of an auction mechanism at some point. For other financing proposals, terms have to be set somehow, and auctions have been proposed for this purpose:

- Advance Market Commitment (AMC) (when used as an R&D incentive and an auction is used to set the size)
- Biomedical R&D Treaty (if tradeable credits are sold in auction-style markets to find the highest bidder)
- EU Emissions Trading Scheme (ETS)
- Fast-track option (FTO)
- Redesigned 'AMC' model (maybe, since not spelled out yet)
- Patent fees ("Green IP") (maybe, since not spelled out yet)
- Priority Review Voucher (PRV) (if secondary market to sell the voucher is auction-based)
- Transferable Intellectual Property Right (TIPR) (if secondary market to sell the property right is auction-based)

5.3. Using (usually by creating new) financial instruments (e.g. bonds, risk-sharing instruments, or specific financial funds)

The reason these are listed is because of the challenges, but also maybe the opportunities, in the current financial climate, of creating, selling, and sustaining new financial instruments, and because there may be some transferable lessons across past enactments using financial market instruments. Guarantees or guarantee-like instruments – which are also categorized under 'risk' – are included since they too have a financial 'contract/instrument' at their heart:

- Debt2Health (only in the sense of paying off an already-existing debt instrument)
- Diaspora bonds

- Double bottom line investing
- ETF (Exchange traded funds) by the Global Fund
- EU Emissions Trading Scheme (ETS)
- Fund for R&D in Neglected Diseases (FRIND)
- Global Development Bonds
- Global Premium Bonds
- Guarantees by public, bilaterals or IFIs Donor first loss funds
- International Finance Facility for neglected diseases (IFFnd)
- Product Development Partnership Financing Facility (PDPFF)
- R&D Neglected Diseases Fund
- Revolving fund to finance R&D for NTDs
- Scientific risk insurance
- Sovereign Wealth Funds (?)
- Taxation of pharmaceutical industry profits (?)

5.4. *Modifying risk*

This is similar to criterion 6. What happens regarding the amount and distribution of risk depends on how each proposal is enacted (i.e. it is both a ‘theory’ and ‘probable application’ issue). It would be useful to have some way of calculating a metric for valuing the risk impacts of different proposals. Risk reduction is, in colloquial economic parlance, a ‘free-lunch’; money need not be raised from taxpayers to pay for the value of risk reduction. Unlike many other ‘mechanisms’ there is also no crowding out problem.

Some quick points: Anything creating more stable funds is risk-reducing, though it depends on long-term sustainability issues too; all prize-mechanisms are a ‘mix’ in my view, because it depends on how they are enacted and the difficulty of the case; and this risk ‘lens’ needs greater subdivision into system-level (systemic) risk and individual-player (idiosyncratic) risk.

As above, most of the categorization below is a perception of where the balance of risk forces probably lie (and is only an illustrative judgment):

Reducing risk in principle

- Accelerated Review (reduced for those getting the review?)
- Clinical Trial efficiencies
- Cost sharing for clinical trials (reduce for private sector)
- EC Innovative Medicines Initiative (IMI) (reduce?)
- European Union MDG contract
- Global Development Bonds (some uses reduce)
- Guarantees by public, bilaterals or IFIs Donor first loss funds (reduce, but may increase if the risk is inefficiently shifted or turns out to have been mispriced)
- IAVI Innovation Fund (mostly reduce?)
- Incubator for companies focused on neglected diseases (mostly reduce?)
- Life Science Convergence Platforms (mostly reduce?)
- Minimum Volume Guarantee (MVG) (mostly reduce, but again depends if there are outsiders adversely affected)
- Regional Health R&D coordination offices (reduce mostly?)

- Risk pooling mechanisms / portfolio investment vehicle for neglected diseases (reduce, sometimes mix?)
- Scientific risk insurance (reduce if credible and terms set efficiently)
- Shared compound libraries (reduce?)
- Small Business Innovation Research (SBIR) (reduce if small companies have high hurdle rates and are credit constrained)
- Technology transfer agreements between countries (in principle reduce?)

Reduce risk, but sometimes a mix including increasing risk

- Affordable Medicines Facility - malaria (AMFm) (reducing, sometimes mix?)
- Anti-trust exemptions for joint biopharma collaborations (reducing, but does it raise risk for those not covered?)
- BVGH business cases (ideally reduce, but it depends on quality of inputs and outputs)
- Donor clubs for midsize philanthropists (reduce, if information sharing reduces risks, but mix if it also encourages lack of competing monitoring)
- Fund for R&D in Neglected Diseases (FRIND) (reduce, sometimes mix?)
- Global procurement funds (reduce, sometimes mix?)
- Guarantees by public, bilaterals or IFIs. Donor first loss funds (reduce, sometimes mix if guarantee set wrong or litigation)
- Information sharing re R&D portfolios (mostly reduce, though again for outsiders may increase)
- International Finance Facility for neglected diseases (IFFnd) (usually reduce, but some mix since sustainability needs clarifying)
- Risk pooling mechanisms / portfolio investment vehicle for neglected diseases (reduce in principle, but details unclear)
- Scientific risk insurance (reduce in principle, but depends on terms, mix if hard to set terms/guarantees)

Mix (reducing risk in some directions and for some players, increasing risk in other directions and for other players; again depends on both the theoretical mechanism and the way it is enacted)

- Advance Market Commitment (AMC)
- Biomedical R&D Treaty
- Cancer Prize Fund
- Chagas Disease Prize Fund
- Fast-track option (FTO) (mix?)
- Fast-track review (mix?)
- Redesigned 'AMC' model
- GSK patent pool (mix, depends on the 'player')
- Health Impact Fund (HIF) (mix?)
- Industry R&D Facilitation Fund (IRFF) (not sure balance, depends on how topped up and allocated)
- InnoCentive
- KEI Prize (Innovation Inducement Prize with Proportional Reward System)
- Orphan drug legislation
- Prize Fund to Support Innovation and Access for Donor Supported Markets

- Prize funds (general)
- Product Development Partnership Financing Facility (PDPFF) (mix, depends on horizon and governance issues)
- Product Development Partnerships (highly variable, depends on governance)
- R&D Neglected Diseases Fund (mix, again depends on governance issues)
- Revolving fund to finance R&D for NTDs (mix, depends on sustainability of outcomes of portfolio)
- TB Diagnostic Prize Fund
- Transferable Intellectual Property Right (TIPR)

5.5. Needing to influence investors/financial markets

In my view, the sophistication of evaluation of the investor-side of many financing proposals is often very weak. Frequently, investors have to be convinced that over very long periods of time a financing mechanism or a combination of financing mechanisms will work. If they are not convinced, a lot of taxpayer money is spent for an outcome much poorer than the idealized proposal. Intuitively, a decision needs to be made for each proposed financing mechanism whether the 'right' investor expectations can be made to stretch long enough (perhaps by adding strengthening features) and, if not, whether some proposals requiring shorter investor horizons should be preferred. Incidentally, many of the proposals in the inventory work via financial markets/venture capital, and less so via banks (to financial economists the distinction has interesting implications).

It turns out the list is very long (some are left off that do have an investor impact, but an impact that seems more second-order):

- Advance Market Commitment (AMC) especially if used as an R&D incentive
- Accelerated review
- Affordable Medicines Facility - malaria (AMFm)
- Anti-trust exemptions for joint biopharma collaborations
- Biomedical R&D Treaty
- BVGH business cases
- Cancer Prize Fund
- Chagas Disease Prize Fund
- Double bottom line investing
- EC Innovative Medicines Initiative (IMI)
- Fast-track option (FTO)
- Fast-track review
- Redesigned 'AMC' model
- Global procurement funds
- GSK patent pool
- Guarantees by public, bilaterals or IFIs Donor first loss funds
- Health Impact Fund (HIF)
- IAVI Innovation Fund
- Incubator for companies focused on neglected diseases
- Industry R&D Facilitation Fund (IRFF)
- InnoCentive
- Innovation promotion funds

- International Finance Facility for neglected diseases (IFFnd)
- KEI Prize (Innovation Inducement Prize with Proportional Reward System)
- Life Science Convergence Platforms
- Minimum Volume Guarantee (MVG)
- ND R&D tax breaks
- New Global Fund for R&D
- North-South collaborations
- Orphan drug legislation
- Priority review
- Priority Review Voucher (PRV)
- Prize Fund to Support Innovation and Access for Donor Supported Markets
- Product Development Partnerships
- Redesigned 'AMC' model
- Revolving fund to finance R&D for NTDs
- Risk pooling mechanisms / portfolio investment vehicle for neglected diseases
- Scientific risk insurance
- Small Business Innovation Research (SBIR)
- Synaptic Leap
- Taxation of pharmaceutical industry profits
- TB Diagnostic Prize Fund
- Technology transfer agreements between countries
- Transferable Intellectual Property Right (TIPR)

5.6. Where financing proposals interact and sometimes potentially conflict

It is recognized that financing proposals are rarely stand-alone. In fact, most R&D financing proposals sit alongside other R&D financing proposals. This raises the 'technical' problem of how to control one financing mechanism (or to make allowances in one mechanism) to take into account the actions of another financing mechanism so as to maximize impact, and also to avoid distorted choices. This is another 'technical lens' but this time it is about interaction of components and not about the components per se.

For example, any mechanism with a prize in it has to work out how to ensure the prize money goes only to those who put new private financial resources in, unless the prize allows in its terms and sizing for some sort of recirculation of the portion of the prize money not deemed to have been used to pull in the private financial resources, or grant-makers have stipulated a right to take some of the prize if their investments are successful. If grant-makers, and not just private financiers, are allowed access to the funds, how are adjustments made? What happens if a PDP regards a product as developed outside later-arriving PDPFF finance and wants to keep some or all the royalties for itself, or takes a PRV in exchange for lower royalties, or uses an AMC and a PRV, and so on? Under the terms of a Product Development Partnership Financing Facility (PDPFF), since the bonds are being repaid from royalties and governments underwrite the borrowing, there has to be some degree of resistance to pressure to select and launch products to achieve earlier or higher royalties than is socially optimal. How would a Minimum Volume Guarantee (MVG) sit alongside an AMC (the first needs there to be some bargaining power to get price down).

What if there are co-payments in a mechanism but not competitive pressures? What if a prize or prize-like component has become more like a pre-sunk subsidy, or a fait accompli bargaining game? What if a financing mechanism was enacted with the promise of an auction component, but the auction component was poorly set up or not set up at all? What if the terms of a guarantee conflict with some other mechanism? And so on. At some point, these interactions (and who is allowed to get what funding) will need policing.

It is unclear how anybody in a questionnaire response can summarize the average of possible interactions (and these were just some illustrations). Furthermore, for some financing mechanisms there may be a problematic component but a grain of truth nevertheless and there may be an idealized enactment and a more likely messy probable enactment; we don't wish to throw out babies with bathwater if modification and improvement are possible.

5.7. Other technical component lenses

Other technical component lenses might cut across proposals along the lines of, for example: how they deal with informational issues; the role of competition; affordability issues; and so forth. I did not have the time (and was not brave enough) to give this a try.

5.8. The challenge of application and the need for a reality check

Some of the items on the inventory of financing proposals have been tried. In reality not everything is enacted according to the blueprint at the start; there is a human and political element that comes into play between drawing board and application. Many initially apparently simple mechanisms have turned out to need surprisingly high support systems. For others, the way of enactment led to the shape of what came out not matching what went in (suggesting a lesson to help practitioners next time). This is just a selection from proposals listed in the inventory:

- Affordable Medicines Facility - malaria (AMFm). Turned out to have a great many more working components and needing strong monitoring and support mechanisms at the country level so that the subsidy will travel all the way down the supply chain.
- AMC has prize-like qualities when used as an R&D incentive. In practice the first application is primarily part of a product procurement fund with disbursement related to quantities over ten years, and is more price-subsidy than prize. Achieving the original goal has involved several times the originally tabled sums (according to GAVI \$5.6bn out to 2020 of which \$1.5bn is the AMC). The monitoring and evaluation exercise has turned out large (of the mechanism itself and of country-level epidemiology because of issues like serotype replacement). Success will come through many of the support activities of GAVI, PneumoADIP and WHO. One big challenge will be what happens to PCV-7 production when richer countries shift to PCV-10/PCV-13 (poorer countries should do the shift too). Long-term financial sustainability will require new generation cheaper-to-manufacture vaccines. Most mortality from pneumococcal out to 2020 will still need to be tackled by some other means (including the financing of those means). Again, we need to accept reality rather than see such observations as criticism per se, and compare and contrast the financing mechanism with other financing mechanisms on this basis.
- Brazil's CPMF (Provisional Contribution on Financial Transactions). Voted down in 2007.

- Donor clubs for midsize philanthropists. Judging from other philanthropy-based models, there will be issues of governance and accountability.
- EU Emissions Trading Scheme (ETS). There have been issues with the efficiency of the trading mechanism.
- IMF gold sales. The UK made a huge loss on its gold sales from badly mistiming the market.
- IFFnd. Its predecessor IFFIm is more likely to be rolled over and, much later, written off rather than repaid from development budgets. This may be the efficient way to deal with it, but it is different from the initial proposal. 'Roll-over' (including the politics of roll-over) of this, but also of many other financing mechanisms, will get more difficult if roll-over is only seen as paying back the previous facility.
- Lottery/games of chance. In practice lotteries tend to crowd out a lot of what governments would/should otherwise do, thus raising less 'new' revenue than predicted.
- Priority Review Voucher (PRV). The first ever PRV went to a product that had already been developed and that had been in widespread use for about 13 years, indeed a combination drug each part of which had already been approved in the US (so were not eligible for the PRV) but the combination of which had not been registered in the US (so was eligible according to the legislation enacted). Hence the first voucher had zero impact on pulling in new research and development funds. It was very good that the company involved had helped to develop the product for the developing world and backed its launch and wide-scale use, but the PRV was billed as a mechanism to pull in fresh financing and not as a retrospective windfall payment. The cost to society of this depends on how the first voucher is used. Also, it is not clear what auction mechanism is in place for reselling of vouchers, so it is not clear how smaller firms and biotechs will extract full value from any voucher they claim.
- Product Development Partnerships. There are some excellent/very good examples, but there are also some bad cases that waste resources and achieve slow and sometimes distorted progress, usually on account of governance issues and the incentives they face. In principle the situation is therefore rectifiable, but the care and attention to detail needed for efficiency and success goes beyond simplistic organizational models.

Given this past experience, it is very likely that those financing proposals on the inventory that are promoted as being simple to set up and run will be: i) much more complicated to set up and run than their advocates suggest; ii) not so robust if they have lots of components that need to work together to achieve the promised outcome; iii) much less simple when they need to interact with other proposed mechanisms. This is not a criticism, but a call to go beyond the usual "this costs little... this easily complements (other push or pull, etc.), this will be a major breakthrough", or similar-style language, and to face up to the somewhat messier reality. In summary, given the human element and the constraints of political systems, it is not the case that always WYSIWYG (What You See is What You Get), and those choosing amongst financing proposals should factor this in to any evaluation and selection criteria.