

A black and white photograph of a group of children, likely in a school setting, smiling and looking towards the camera. The image is slightly blurred and has a dark, blue-tinted overlay.

**Scoping
Report &
Stakeholder
Review**



Access To Medicine Index

Scoping Report & Stakeholder Review

December 2006

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Access To Medicine Index Framework

20%	Access to Medicines Management
20%	Research & Development for Neglected Diseases
18%	Equitable Pricing
15%	Patents & Licensing
10%	Policy Influence & Lobbying
7%	Drug Donations
5%	Philanthropic Activities
5%	Ethical Promotion & Marketing Activities

KEY FINDINGS OF THE ACCESS TO MEDICINE INDEX FRAMEWORK

Background Research

The Access To Medicine Index project builds on a large body of work published on this issue in recent years. Innovest has collected and reviewed the latest academic, industry, and other third party reports on Access To Medicine (ATM) and related issues.

ATM Questionnaire

A questionnaire was designed to help identify the key issues to be included in an evaluation of pharmaceutical companies' ATM strategies and performance based on the background research. The questionnaire was delivered to over 200 leading ATM experts around the globe. This key stakeholder group includes academics, consultants, investors, government representatives, and NGOs.

Key Stakeholder Roundtables

Key stakeholder roundtables were held in London and New York to discuss and debate the questionnaire results and refine ATM indicators. Each stakeholder roundtable included representatives from the key stakeholder groups who shared their expertise and continued to provide input during the Access To Medicine Index building phase. During this phase of the project, we focused initially

CONTINUED ON NEXT PAGE...

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KEY FINDINGS OF THE ACCESS TO MEDICINE INDEX PROJECT (CONTINUED)

on the opinion of key stakeholders, with the aim of seeking industry input once a broad consensus was reached on all possible indicators.

Access To Medicine Index Framework

Through a comprehensive research and evaluation process a preliminary weighting system was formulated by Innovest which will ultimately determine company benchmarking within the Access To Medicine Index.



Foreword

Providing access to medicine to all the world's citizens is one of the most important challenges of our time. There is a major imbalance in global access to medicine between rich and poor countries, and according to the WHO, approximately 30% of the world's population – between 1.3 and 2.1 billion people living mainly in lesser developed nations – lack regular access to the medicines they need to improve their health and quality of life.

In an era where the march towards globalisation may ignore the needs of the more vulnerable members of society, the role of the pharmaceutical industry during this period of rapid change is of critical importance, in helping to deliver some of the benefits of globalisation to the wider community. Some progress is already being made and the pharmaceutical industry is beginning to tackle this challenge, but the effectiveness of their input is so far difficult to assess.



WIM LEEREVELD
*Founder & Chairman, Access
To Medicine Foundation*

That is why the **Access To Medicine Foundation** believes that the efforts being made in this sector to increase global access to medicine should be measured, reported on and tracked over time, using an agreed set of indicators and benchmarks. A periodic Access To Medicine benchmarking index would provide insights into the relative performance levels of the companies involved and highlight examples of best practice that in turn may inspire the entire industry in helping to deliver one of the eight UN Millennium Development Goals.

A key objective of this multi-stakeholder initiative – founded in 2005 - is to stimulate improvements in global access to medicines by developing an **Access To Medicine Index**, that provides the necessary transparency in relation to the performance of the largest pharmaceutical companies. In essence, the **Access To Medicine Index** aims to provide an annual overview of the extent to which the world's leading pharmaceutical companies address the risks and opportunities presented by the access to medicine issue. The **Access To Medicine Index** will serve as a robust foundation for accelerating the debate between the pharmaceutical industry and its stakeholders on access to medicine issues, and it is hoped will be a catalyst for improving access to medicine responses of the industry.

The development of the **Access To Medicine Index** comprises two separate research phases. This first report sets out the work and findings of phase I, in which the framework of the Index is defined. The next step, phase II of the ATM program, is to actually measure the performance of the pharmaceutical industry against these benchmarks and to compile the Index itself.

Therefore, we are delighted that Innovest has agreed to take the lead in creating the framework that will form the basis of the Index going forward. It is by mobilising their



expertise in this area that we can ensure the success of the ATM work. Their professionalism encourages all of us.

Finally, we are very grateful for the generous contributions of many people and organisations that have supported us to date, and who share our view that the **Access To Medicine Index** will represent an important new initiative in tackling the disease burden of many of the world's poorer countries.

Funding partners of **The Access To Medicine Foundation** are:

Aedes (European Agency for the Development and Health)

DGIS (Dutch Ministry of Foreign Affairs)

HIVOS (Humanist Institute for Cooperation with Developing Countries)

ICCO (Interchurch organisation for development co-operation)

Oxfam Novib (Netherlands)

Rabobank

ACCESS TO MEDICINE FOUNDATION

Launched in 2005, the Access To Medicine Foundation was established with the goal of developing an Access To Medicine Index that will offer objective and comparative information regarding the approaches of pharmaceutical companies to access to medicines issues. The foundation is based in Haarlem, The Netherlands.
www.access-to-medicine.org

INNOVEST STRATEGIC VALUE ADVISORS

Founded in 1995, Innovest is an internationally recognized investment research and advisory firm. It specializes in analyzing corporate performance on environmental, social and strategic governance issues, with a particular focus on their impact on competitiveness, profitability and share price performance. The firm currently has over USD1.1 billion under direct sub-advisory mandates, and has clients in 20 countries. Innovest's coverage includes more than 80 industry sectors including Pharmaceuticals within which the largest 45 global firms are covered by our Healthcare analysts. Innovest was rated the #1 global provider of "non-traditional" investment research in the 2006 Thomson Extel survey of major institutional investors. www.innovestgroup.com



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Disclaimer

As a multi-stakeholder and collaborative project, the findings, interpretations, and conclusions expressed herein may not necessarily reflect the views of all members of the Key Stakeholder Group or the Organizations they represent. The report is intended to be for information purposes only and it is not intended as a promotional material in any respect. The material is not intended as an offer or solicitation for the purchase or sale of any financial instrument. The report is not intended to provide, and should not be relied on, for accounting legal or tax advice or investment recommendations. Whilst based on information believed to be reliable, no guarantee can be given that it is accurate or complete.



Acronyms

ABPI	Association of the British Pharmaceutical Industry
ARV	Antiretroviral
ATM	Access To Medicine
CEO	Chief Executive Officer
CSR	Corporate Social Responsibility
EFPIA	European Federation of Pharmaceutical Industries and Associations
HDI	Human Development Index
HIC	High Income Country
HIV	Human Immunodeficiency Virus
IFPMA	The International Federation of Pharmaceutical Manufacturers & Associations
KPI	Key Performance Indicator
LIC	Low Income Country
MDGs	Millennium Development Goals
MIC	Middle Income Country
NGO	Non-governmental organization
PDP	Product Development Partnership
PPP	Public Private Partnership
PhMRA	The US Pharmaceutical Manufacturers and Research Association
R&D	Research and Development
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
WHO	World Health Organization
WTO	World Trade Organization



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Executive Summary

BACKGROUND TO THE ACCESS TO MEDICINE INDEX PROJECT

Built on Extensive Body of Research on ATM Issues

The pharmaceutical industry is specifically recognized in the UN Millennium Development Goals as an actor that contributes to their ultimate realization. As manufacturers of life saving drugs and innovators in the development of new treatments, pharmaceutical companies can play a significant role in their sphere of influence. What is this role? How far does it extend? And how should it evolve to address the lack of access to treatments to disadvantaged people?

More than 60 Experts in ATM Answered Online Questionnaire

On behalf of the Access To Medicines Foundation, Innovest Strategic Value Advisors has completed phase I of a study to determine how best to evaluate pharmaceutical companies' strategy and performance on improving the access to medicine for those in need in developing and developed countries. The aim of the Access To Medicine Index is to build a rational yet aspirational framework to analyze pharmaceutical companies' responses to the access challenge and to encourage continuous improvement. This Interim Report represents progress to date on achieving this goal.

STUDY STRUCTURE

An online questionnaire was created and sent to over 200 experts worldwide on the access to medicine subject. Questions were derived from published research on the subject as well as from Innovest's expertise in evaluating the Pharmaceutical industry. Open feedback was gathered from a wide range of stakeholders including NGOs, academia, consultants, investors and government officials on pharmaceutical company practice and potential contribution.

Stakeholder Roundtables in London and New York

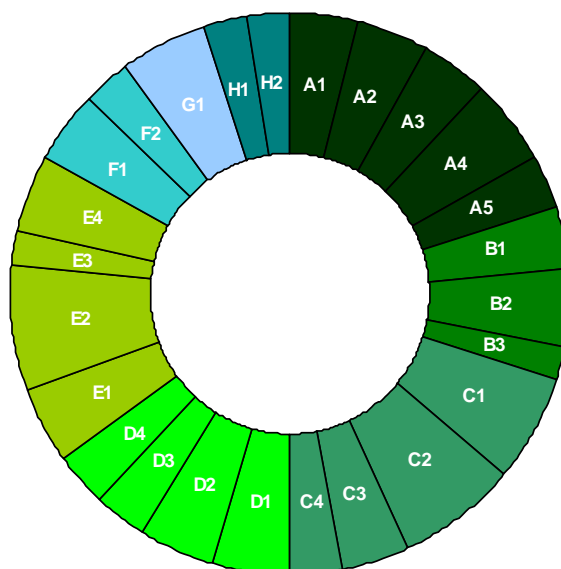
Subsequently, two roundtables were conducted in London and New York, to which key stakeholders were invited to participate and further discuss and refine a framework to assess pharmaceutical companies' performance. Pharmaceutical company representatives were excluded at this stage in order to collate a broad stakeholder consensus on all possible indicators, however their involvement and collaboration is critical to the project going forward.



SUMMARY OF RESULTS

The study to date has determined that pharmaceutical companies should be involved in eight specific areas, with stakeholder discussions concluding that the following criteria and weightings should be used to best evaluate company performances. Weightings have been assigned to each of the eight criteria based on the stakeholder discussions.

Indicators Breakdown



A. Access to Medicines Management (20%)

- » A1. Governance: The company has a governance system which includes direct board level responsibility and accountability for its ATM strategy. (20%)
- » A2. Policy: The company has a public global policy in place, in which it explains its rationale for ATM, its contents and details its specific objectives and targets. (20%)
- » A3. Systems: The company has clear management systems to implement and monitor its ATM strategy. (20%)
- » A4. Stakeholder Input: The company has a mechanism for stakeholder engagement which inputs into ATM management. (25%)
- » A5. Reporting: The company produces a public annual report on ATM management which addresses all key issues, has qualitative and quantitative reporting on all key issues and enables an assessment of strategy. (15%)



8 Access to Medicine Criteria

B. Policy Influence & Lobbying (10%)

- » B1. The company and subsidiaries provides disclosure of lobbying positions/activities at national, regional and international level that impact ATM. (35%)
- » B2. The company annually discloses financial support in terms of amounts, beneficiaries and channels; including at least key opinion leaders, patient associations, political parties, trade associations and academic departments, through which it seeks to influence public policy and national, regional and international practice. (45%)
- » B3. The company can demonstrate there is a process of board approval of the above reporting as appropriate to the nature and scale of the activity. (20%)

C. R&D in neglected diseases (20%)

- » C1. The company provides evidence of in-house investment in R&D into neglected diseases. This may be reflected in terms of dedicated scientists, projects, and a dedicated neglected disease division. (30%)
- » C2. The company invests in R&D on neglected diseases in partnership with product development Public Private Partnerships (PPPs), Academic Departments and the World Health Organization (WHO). (35%)
- » C3. The company shows temporal evidence of a research program to find formulation suitable for environments in developing countries for all patient groups. (20%)
- » C4. The company undertakes other activities (not covered by other C criteria) to support R&D into neglected diseases and improved formulation of existing medicines for developing countries. (15%)

D. Patents & Licensing (15%):

- » D1. The company does not enforce patents in least developed countries. (30%)
- » D2. The company demonstrates the existence of, and discloses the terms of non exclusive voluntary license agreements to increase access to medicines in developing countries. (30%)
- » D3. The company can demonstrate evidence of consent given to NDRAs (National Drug Regulatory Authorities) to use test data/override test data exclusivity for registration purposes in least developed countries. (20%)
- » D4. The company does not extend patent duration, or file patents for new indications for existing medicines in developing countries. (20%)

E. Equitable Pricing (18%):

- » E1. The company can demonstrate efforts to register relevant drugs in developing countries. (25%)



- » **E2. The company has a policy to facilitate access to medicines in developing countries through pricing mechanisms, which includes reporting on scope, pricing levels and pricing reviews. (40%)**
- » **E3. The company has mechanisms in place to prevent product diversion. (10%)**
- » **E4. The company has a policy for the very poorest in all markets. (25%)**

F. Drug Donations (7%):

- » **F1. The company has a signed policy that fully conforms to the WHO's Guidelines for Drug Donations. (60%)**
- » **F2. The company discloses the absolute volume of its drug donations and number of patients treated per year. (40%)**

G. Philanthropic Activities (5%):

- » **G1. The company has philanthropic programs related to access to medicines not covered by any of the other criteria. (100%)**

H. Ethical Promotion & Marketing Activities (5%):

- » **H1. The company has a marketing policy which explores gender related issues and labeling possibilities in developing countries. (50%)**
- » **H2. The company has a signed policy that fully conforms to the WHO's Ethical Criteria for Medicinal Drug Promotion. (50%)**



Project Objective

TO IMPROVE ACCESS TO MEDICINE

Access to Medicine Issue

The UN Millennium Development Goals signed in 2000 by all 191 United Nations member states recognize that pharmaceutical companies are among those who share the responsibility of providing access to essential drugs in developing countries. Several of these goals refer to the relationship between health and poverty and include targets relating to child mortality, maternal health and infectious diseases such as HIV/AIDS, Malaria and Tuberculosis. In addition the last goal calls for a “global partnership for development” and highlights the cooperation between governments and pharmaceutical companies to provide access to affordable drugs in developing countries¹.

The responsibility for improving access to medicines does not solely rest on the pharmaceutical industry but rather on the international community as a whole. Input from external actors such as NGOs, Grassroots Communities, National Governments, International Organizations, the Private Sector and Investors, amongst others are essential, however the pharmaceutical industry certainly plays a critical role in complementing and leveraging government efforts to develop effective access policies².

In addition, the pharmaceutical industry faces risks associated with the access to medicines issue. At stake is a lot more than just good public relations. Failure to properly address the current health crises around the world may not only tarnish a company’s reputation but also call into question its license to operate. Business risks include endangering the credibility of the intellectual property system and reducing business opportunities in emerging markets³.

Access To Medicine Index

The main purpose of the Index is to facilitate the propagation of advanced policy solutions, improve cooperation between stakeholders, increase awareness across the board, as well as contributing to superior equity and debt investment decisionmaking for the investment community.

The purpose of the rational yet aspirational Access To Medicine Index is to evaluate pharmaceutical companies’ efforts to improve access to medicines and to benchmark these against those of their competitors. The project aims to encourage and highlight best practice and evaluate which companies’ efforts are actually increasing access to medicines on the ground, especially in developing countries. The Index will provide



objective and comparative information on the status of some of the largest pharmaceutical companies worldwide.

The findings will also contribute to the evaluation of what constitutes best practice in the programs and initiatives of the pharmaceutical industry, and which activities actively militate against global inequality in access to medicines.

The Index also aims to determine and the responsibility of pharmaceutical companies within the scope of the access to medicine issue. Discussion and debate with external stakeholders, who play significant roles in improving access on a global scale in their own right, also allows for delineation of company accountability. The intended audience for this initial report and for the Index itself includes:

- » **The Pharmaceutical Industry (companies and industry associations)**
- » **Foundations and Donor Agencies**
- » **Responsible Investors**
- » **Pharmaceutical Sector Analysts**
- » **Other Industry Stakeholders**



Methodology

BACKGROUND RESEARCH

The Access To Medicine Index framework has built on a large body of work published on this issue in recent years. Innovest has collected and reviewed the latest academic, NGO, industry and other third party reports on access to medicines and related issues. Previous reports that have drawn on stakeholder opinion to formulate benchmarks on the issue of ATMs by the Pharmaceutical Shareowners Group, the UK Department for International Development and World Health Organization, have all been central to the research process and direction of the Index framework. Issues that were highlighted in these and other key studies on the subject of ATMs are supplemented with the latest research and developed throughout this report. This research phase allowed a comprehensive list of assessment criteria to be defined, which subsequently served as a basis for questionnaire.

ATM QUESTIONNAIRE

An online questionnaire (See Appendix 1) was created and sent to over 200 leading experts in the area of access to medicine and healthcare issues. The stakeholder groups that were represented in the survey included; academics, consultants, investors, government, and NGOs. The stakeholders were selected based on their expertise on the issue and work in the field of ATMs. The prominence of their organization or department was also taken in to account when selecting stakeholders. Contacts from the Access To Medicine Foundation and Innovest's experience in the healthcare sector and surrounding issues were also approached.

Of the 200 experts contacted more than 60 replied to the questionnaire. Stakeholders were asked to express their judgment on company practice relating to access to medicine and were also offered the opportunity to make additional comments and remarks on this matter, which were then used to prompt discussions at the roundtables. The 32% response rate is low but could be expected for the first round of Index development. In future years this number is expected to grow as awareness of and interest in the Index increases.



KEY STAKEHOLDER ROUNDTABLES

From the larger stakeholder group 15 key stakeholders were selected for their diverse and respected expertise on the impact of companies on access to medicines. Key stakeholder roundtables were conducted in London and New York to discuss and debate the questionnaire results and refine ATM indicators drawn from the questionnaire analysis. Each stakeholder roundtable included representatives from the key stakeholder groups who shared their expertise and continued to provide input during the Access To Medicine Index criteria building phase. The roundtables were facilitated by an expert independent consultant from Peoplematters Ltd; a professional organization specializing in designing and garnering the best responses for these types of meetings. Stakeholders attending the London roundtable were asked to work in sub-groups to discuss a criterion and refine a set of indicators provided, based on questionnaire analysis. Sub-groups were created based on people's expertise and responses to the questionnaire. Cross-fertilization of ideas allowed the roundtables to draw majority consensus on the issues discussed, with all stakeholders having the opportunity to comment on all findings.

Stakeholders in New York were presented with the initial set of criteria and indicators derived from the questionnaire as well as those refined at the London roundtable. Innovest compiled the results from both roundtables and distributed the findings to all key stakeholders for final approval and comments. The results of this process are documented in the main body of this report.

At this stage Innovest purposely sought no input from the Pharmaceutical Industry or its representation in order to derive a broad consensus on all indicators from an external stakeholder perspective. The industry will be included in subsequent phases of the project in order to provide perspective on the findings and allow any omissions to be incorporated. The inclusion and support of the industry is essential to the success of this project.

ACCESS TO MEDICINE INDEX FRAMEWORK FORMULATION

Through a comprehensive research process a preliminary weighting system was formulated by Innovest which will ultimately determine the company composition and rankings of the ATM Index itself. Weightings were assigned to each criterion based on the apparent importance and effectiveness of the strategy, in improving access to medicines based on stakeholder discussion. This method was also employed for each of the indicators within the set of criteria. The indicator weighting demonstrates the importance and effectiveness of each indicator is in improving the performance of the criterion. The weighting is essential in order for strategic performance to be ascertained.



The following eight sections of the report will discuss each of the criteria in detail, with indicators and weightings explaining in more detail the stakeholder expectations for pharmaceutical companies. Potential metrics provide the reader with an insight into the avenues for benchmarking performance in these areas.



Access to Medicines Management

Box 1

“DFID encourages pharmaceutical companies to go further by:

- Engaging in widespread differential pricing of essential medicines in developing countries, especially the worlds poorest, to support the development of viable markets. Particular attention should be paid to medicines produced by one manufacturer, where competition is often limited.
- Increasing R&D investments in diseases affecting developing countries, including through engagement in PPP.
- Working to support broader health and development goals in developing countries, including by considering voluntary licenses.
- Reporting on activities designed to increase access to essential medicines.”

Increasing People’s Access to Essential Medicines In Developing Countries
DFID, 2005

KEY ISSUES FOR STRATEGIC MANAGEMENT

Background Research

A management system is the framework of processes and procedures used to ensure that an organization can fulfill all tasks required to achieve its objectives⁴. How can this definition be related to the Access to Medicines context? In 2004, the Pharmaceutical Shareowner group, comprising 14 institutional investors, engaged with pharmaceutical companies to ensure that they were addressing the key risks associated with the issue. The group identified the following components as best practices in strategic management⁵ :

- » **Articulate the business case**
- » **Promote leadership at board level**
- » **Take a forward-looking approach**
- » **Assess alternative options**
- » **Show flexibility and breadth**
- » **Collaborate and share best practice**
- » **Demonstrate responsible use of influence in public policy**
- » **Track performance and be transparent**

In 2005, the UK’s DFID provided guidance to pharmaceutical companies by encouraging them to adopt numerous practices including; implementation of differential pricing mechanisms in developing countries, increased R&D for neglected diseases, and consideration for health and development goals in developing countries and reporting on access to medicines programs⁶.

Combining the results from the online questionnaire and the stakeholder roundtables Innovest derived a total combined weighting of 20% for all the criteria falling within the ‘key issues for strategic management’ category.

Our research indicates that the following indicators are considered to be essential components of a comprehensive access to medicine management framework.

A1. Governance: The company has a governance system which includes direct board level responsibility and accountability for its ATM strategy.



Box 2

81.5% of all respondents agreed and/or strongly agreed that it is essential for pharmaceutical companies to formulate and oversee ATM issues at the board level to ensure long-term continuity.

The results of the questionnaire indicated that a large majority of stakeholders consider that it is essential for pharmaceutical companies to have oversight of their ATM strategy at the board level.

Discussions at the roundtables concluded that responsibility should be institutionalized and not specifically driven by the CEO, especially given the current high turnover of CEOs in the sector. The strategy should be critically overseen and signed-off on by the company's board of directors. Accountability was viewed as the key word in this indicator.

Potential metrics that companies will be measured on will include information on the skill set of employees involved, time spent on the issue at a board level, committees, links to incentivization and specific departmental responsibility.

This indicator accounts for 20% of the overall 'key issues for strategic management' criterion weighting.

A2. Policy: The company has a public global^a policy in place, in which it explains its rationale for ATM, its contents and details its specific objectives and targets.

Box 3

83% of all respondents agreed and/or strongly agreed that when making ATM investment decisions outside pure philanthropy, the business rationale should be presented (including the risk management element and the projected value of any tangible returns).

Discussions with key stakeholders concluded that an access to medicine policy should be a central part of a pharmaceutical company's culture and business strategy. The rationale for specific projects should be clearly communicated and in particular the concerns about risks and opportunities should be disclosed. During the questionnaire, 83% of all respondents agreed and/or strongly agreed that when making ATM investment decisions outside pure philanthropy, the business rationale should be presented (including the risk management element and the projected value of any tangible returns). Some stakeholders questioned spending resources on assessing the rationale at this stage and favored the 'learning by doing' strategy, but agreed that quantitative modeling would encourage a 'snap into action' by companies.

Discussions concluded that pharmaceutical companies should not only disclose their global ATM policy but should also provide detail on its content and scope. The inclusion of the word 'global' was of significant importance to stakeholders who strongly believe it is crucial for pharmaceutical companies to address the ATM issues not only in developing countries but in all markets.

Potential metrics may include target and objective attainment, level of integration within the company and the global extent of the policy.

This indicator accounts for 20% of the overall criterion weighting.

Box 4

74.6% of all respondents agreed and/or strongly agreed that large pharmaceutical companies should disclose the monetary value and nature of long-term dedicated resources (including specific research facility, staff and budget versus PR cost) for ATM strategies.

^a See Glossary for Definition.



A3. Systems: The company has clear management systems to implement and monitor its ATM strategy.

Stakeholders agreed that it is essential to assess how a company delivers a strategy, fulfills all tasks required to meet its objectives and how effective the implemented programs are at improving access to treatments to people in need. Questionnaire results stated that 74.6% of all respondents agreed and/or strongly agreed that large pharmaceutical companies should disclose the monetary value and nature of long-term dedicated resources (including specific research facility, staff and budget versus public relations cost) for ATM strategies.

Potential metrics used to evaluate this indicator will ascertain normalized levels of resources including budgets, employees and training, as well as explore the management and funding models used, together with the methods implemented to audit such systems. Assessment of the company's effectiveness of its strategy would be made in terms of the degree to which a company has engaged in the access to medicines debate, how it has performed against its own key performance indicators as well as the feedback on effectiveness from a wide range of stakeholders and especially local NGOs.

This indicator accounts for 20% of the overall criterion weighting.

A4. Stakeholder Input: The company has a mechanism for stakeholder engagement which inputs into ATM management.

Results from the questionnaire indicated that 91.5% of all respondents agreed and/or strongly agreed that large pharmaceutical companies should collaborate with stakeholders in designing the type of ATM programs that would be the most effective and appropriate within the context of each country.

At the two roundtables, there was general agreement that stakeholder engagement was the most critical part of this criterion. Stakeholders are seen as the key to allowing greater access to medicine primarily as a result of their 'on-the-ground' knowledge. However some stakeholders highlighted that a distinction should be made between stakeholders such as patients groups or organizations that receive funding from pharmaceutical companies and grassroots community and/or NGOs on the ground who are independent and have a better understanding of local realities.

Potential metrics will aim to detail specific stakeholder relationships, their importance, levels of engagement and critically positive outcomes.

This indicator accounts for 25% of the overall criterion weighting.

A5. Reporting: The company produces a public annual report on ATM management, with qualitative and quantitative reporting on all key issues and enables an assessment of strategy.

Box 5

91.5% of all respondents agreed and/or strongly agreed that large pharmaceutical companies should collaborate with stakeholders in designing the type of ATM programs that would be the most effective and appropriate in different country context.



There was a consensus among stakeholders on the issue of transparency of company action and a common view to push for regular reporting. The idea was not to be prescriptive or to require a specific framework for reporting on the issue but rather to give leeway to encourage companies to report on a regular basis.

Potential metrics will assess competency and quality of reporting with a specific focus on accuracy and external verification.

This indicator accounts for 15% of the overall criterion weighting.



Public Policy Influence & Lobbying

KEY ISSUES FOR PUBLIC POLICY & LOBBYING

Box 6

“Corporations should disclose their lobbying positions on key public policy issues, as well as membership and funding of trade associations, think-tanks and campaigns to influence public policy.”

Under The Influence, Exposing Undue Corporate Influence Over Policy-Making at the WTO, ActionAid International, January 2006.

Background Research

Lobbying practices are crucial to the holistic ATM approach of a company. In order to demonstrate consistency with ATM strategies, as well as give credence to such strategies, companies should not demonstrate contradictory political approaches.

Trade Related aspects of Intellectual Property Rights (TRIPS) related legislation and the lobbying for stricter applicability according to many is having, and will continue to have, a negative effect on public health by increasing prices and decreasing availability of newer drugs.⁷ The latest recommendations from Oxfam⁸ call for companies to stop lobbying developed country governments to promote stricter intellectual property rules worldwide, and stop pressuring developing countries to accept stronger intellectual property rules. The report also claims that lobbying the US government to impose TRIPS-plus rules has reaped major strategic and monetary benefits for pharmaceutical companies. IFPMA's response to the report refutes intellectual property as a major obstacle to access, highlighting the WHO's List of Essential Medicines, and the fact that 95% are not patented anywhere in the world, and 99% are not patented in sub-Saharan Africa.⁹ It must be noted that this WHO list will be updated next year, but does not take account for diseases where medicines are currently not readily available.

Many believe it is in the interest of business for the 'black box' of lobbying to be comprehensively opened up, allowing the interface between private business and governments to be more transparent and better understood.¹⁰ There exists however practical issues in determining the level of consistency - How does one measure issues such as political lobbying?¹¹ It is our aim to explore the possibilities of this question.

The indirect lobbying activities of pharmaceutical companies through patient and advocacy groups, has been a major issue of contention in recent years. The UK House of Commons Health Committee Enquiry into 'The Influence of the Pharmaceutical Industry'¹² noted that the level of support which patient organizations receive from pharmaceutical companies is not known and that such groups need to openly declare "all significant funding and gifts in kind". In April 2006, the ABPI's revised code of practice came in to force, now requiring all members to disclose "Core funding, unrestricted grants, sponsorship and partnership activities, including non-financial support, should be transparent".¹³ Despite this strong stance patient organization websites do not provide enough information for visitors to assess

Box 7

77% of respondents agreed and/or strongly agreed that disclosure of companies' political contributions and lobbying stances across jurisdictions positively impacts the transparency of access to medicines strategies.



whether a conflict of interest with companies exists. An ethical code to guide patient organizations and their staff members on how actually to operate and interact with companies is also necessary, if patient organizations are to remain independent and truly represent the interests and views of patients.¹⁴

Research indicates that pharmaceutical companies would benefit from greater transparency but given the current lack of disclosure on this issue and reservations from stakeholders over difficulties in collecting such information, Public Policy Influence & Lobbying has been given a lower weighting of 10%.

Our research indicates that the following indicators are considered to be essential components to assessing Public Policy Influence & Lobbying.

B1. The company and subsidiaries^b provides disclosure of lobbying positions/activities at national, regional and international level that impact ATM.

Stakeholders believe that a formal 'political contributions report' would allow for consistency analysis with specific ATM policies. In order to complete this analysis Innovest will focus especially on the approach of companies towards lobbying and public policy as it relates to patents and licenses. All stakeholders conceded that this would be difficult to achieve in the first instance, but would add great value to a company's holistic ATM approach.

Potential metrics may explore the levels of spending through various lobbyists and disclosure at varying scales of impact, including direct and indirect lobbying activities.

This indicator accounts for 35% of the overall criterion weighting.

B2. The company annually discloses financial support in terms of amounts, beneficiaries and channels; including at least key opinion leaders, patient associations, political parties, trade associations and academic departments, through which it seeks to influence public policy, and national, regional and international practice.

A number of stakeholders expressed caution/ concern over the high weighting given to this criterion due to the expected availability of data from companies. It was noted that the aspirational nature of the Access To Medicine Index framework did need indicators that were forward-looking

Potential metrics may include; a full analysis of the various beneficiary groups, the amount of money they receive from a company and from its Political Action Committee (PAC), the money beneficiaries receive from a company as a percentage of total receipts and their respective lobbying positions. These will allow for the

Box 8

67.9% of respondents agreed and/or strongly agreed that the policy stance taken by the Pharmaceutical Research and Manufacturers of America (PhRMA) relating to the TRIPS Agreement reflects negatively on large pharmaceutical companies.

^b See Glossary for Definition.



determination of the company's relative strength of support and control of policy positioning.

This indicator accounts for 45% of the overall criterion weighting.

B3. The company can demonstrate there is a process of board approval of the above reporting as appropriate to the nature and scale of the activity.

It was acknowledged in discussions that it would be impossible to expect all policy driven expenditures to be passed by the board of directors for approval, but some accountability was needed, especially when large amounts of resources were being expended.

Potential metrics may explore the level of board involvement in overall policy position strategies and ascertain where accountability lies.

This indicator accounts for 20% of the overall criterion weighting.



R&D for Neglected Diseases

KEY ISSUES FOR RESEARCH AND DEVELOPMENT INTO NEGLECTED DISEASES

Background Research

Globally, an estimated 2.3 million children are living with HIV, the vast majority in sub-Saharan Africa. Only 5% of children receive treatments and there are no appropriate tests for diagnosing infants and very few adapted tools to treat children¹⁵.

TB is curable but kills 2 million people every year. TB is the leading cause of death among HIV infected people; the WHO estimates that TB accounts for up to a third of AIDS deaths worldwide¹⁶. Existing TB drugs and diagnostics are not adequate to combat the disease. People with XDR-TB (Extreme drug-resistance in tuberculosis) are resistant to both of the first-line antibiotics used to treat TB as well as to two classes of second-line drugs, making treatment with existing drugs impossible.¹⁷

Malaria infects between 300 and 500 million people every year and causes between one and three million deaths annually. The virulent strain of the malaria parasite has grown resistant to chloroquine, the most common drug used to combat the disease. Since 2001 the World Health Organization has recommended using artemisinin-based combination therapy (ACT) as first-line treatment for uncomplicated malaria in areas experiencing resistance to older medications. However, the supply of artemisinin is not meeting demand.

The WHO estimates that over 1 billion people suffer from one or more neglected tropical diseases¹⁸.

Drugs for some of these diseases exist, but most are old, toxic and becoming less effective because of resistance. According to the Global Forum for Health Research, an independent international foundation promoting research into neglected diseases, only 10% of global funding for health research is devoted to 90% of the world's health problems.¹⁹ There is an urgent need for investment in new and improved technologies to address diseases affecting the poor in developing countries. Only 1.3% (21 out of 1,556) of new drugs developed over 30 years was for neglected tropical diseases²⁰.

R&D is one of the areas where pharmaceutical companies can make a major contribution to enhance access to medicines to fight neglected diseases in developing countries. "The vision for the pharmaceutical industry's role in global healthcare is to create and develop medicines that save and improve the lives of millions of people and, in partnership with governments and other organizations, to help improve access to them."²¹

Box 9

"Achieving all the MDGs will require addressing health and its determinants in a comprehensive way and will necessitate further health research, of high quality, focused on the needs of developing countries and vulnerable populations."

Statement by the Global Forum for Health Research at the conclusion of Forum 8, Mexico City, November 2004



The research indicates that pharmaceutical companies would be *most* effective in improving access to medicines by poor people through focusing on their core business and by investing in R&D for neglected diseases. Therefore R&D was given the highest possible weight in the Index framework: 20%. At this stage, discussions did not include distinction between R&D for vaccines or for medications, a topic which may be addressed going forward.

Our research indicates that the following indicators are considered to be essential components to assessing a company's R&D policy.

C1. The company provides evidence of in-house investment in R&D into neglected diseases^c. This may be reflected in terms of dedicated scientists, projects, and a dedicated neglected disease division.

The large majority of stakeholders agreed and/or strongly agreed that large pharmaceutical companies with relevant capabilities in their current portfolio should dedicate a specific amount of their overall R&D budget each year for research into vaccines (75.5% of respondents) and medications (77.4% of respondents) for neglected diseases.

Potential metrics for this indicator may include the number of dedicated full time equivalent staff and resources assigned to R&D on neglected diseases, as well as the number of in-house projects currently being undertaken on neglected diseases, including the level of development of those projects.

This indicator accounts for 30% of the overall criterion weighting.

C2. The company invests in R&D for neglected diseases in partnership with product development Public Private Partnerships (PPPs), Academic Departments and the World Health Organization (WHO).

Some stakeholders voiced concerns about the definition of PPPs. Discussions concluded that a distinction should be made between PPPs that are an activity or function (e.g. private sector drug donations or information campaigns on public health issues) and PPPs that are actual structures or organizations (e.g. vaccine and drug development organizations, with headquarters, staff, product portfolios, etc.)²².

There was a consensus on the merits of expending resources on partnerships as opposed to in-house R&D. On the questionnaire, 56% all respondents (85% of all academics, 63% of all investors, 55% of all governments, 47% of all NGOs and 43% of all consultants) agreed and/or strongly agreed that PPPs are the most successful model for large companies to emulate in designing an ATM program that spans from research to distribution. Nevertheless, key stakeholder Dr Mary Moran stated that "PPPs in the area of neglected disease drug development will only be successful if they: provide skills the private partner does not have (e.g. insectariums, knowledge of

Box 10

"PPPs in the area of neglected disease drug development will only be successful if they: provide skills the private partner does not have (e.g. insectariums, knowledge of parasite metabolic pathways/targets; guidance on target patients/public health markets etc); are structured so that the private partner works in their area of maximum skill/ minimum risk (e.g. drug discovery, regulatory support), and the public sector works in their area of maximum skill/minimum risk (e.g. clinical development). PPPs and projects that don't do this are likely to fail."

**Dr Mary Moran,
The George Institute for
International Health, Director
Pharmaceutical R&D Policy
Project (PRPP).**

^c See Glossary for Definition.



parasite metabolic pathways/targets; guidance on target patients/public health markets etc); are structured so that the private partner works in their area of maximum skill/ minimum risk (e.g. drug discovery, regulatory support), and that the public sector works in their area of maximum skill/minimum risk (e.g. clinical development). PPPs and projects that do not do this are likely to fail²³.

Potential metrics may include exploring the various partnership strategies employed by companies and analyzing positive outcomes to lend support to this debate.

This indicator accounts for 35% of the overall criterion weighting.

C3. The company shows temporal evidence of a research program to find formulation suitable for environments in developing countries^d for all patient groups.

The quality of drugs imported into developing countries with a tropical climate may be adversely affected if their formulations have not been optimized for stability under these conditions. In addition, without adequate nutrition AIDS sufferers can not absorb the drug needed to slow the virus. Taking AIDS drugs on an empty stomach also causes severe stomach aches, dizziness and nausea. Discussions concluded that R&D into heat stable and more appropriate formulations for those with little food or water was needed to improve access to medicines.

At both roundtables, pregnant women, children and HIV patients were highlighted as key examples of patient groups neglected by R&D activities. For example there are concerns about mother-to-child transmission. Women, who use antiretroviral therapies (ARVs) to treat their own HIV infection and protect their babies, face the risks of becoming resistant to ARVs and of passing this drug resistance through their breast milk to their children. There is extensive research that points to the lack of adequate treatments for new-born babies and children. Finally even though single dose treatments and fixed-dose combination exist, these are not available everywhere and as some patients have to take several drugs per day this may hamper follow-up treatment and increase the risk of drug resistance.

Possible metrics may include the number of trials and their phases, bioequivalence tests and filings with regulators.

This indicator accounts for 20% of the overall criterion weighting.

C4. The company undertakes other activities (not covered by other C indicators) to support R&D into neglected diseases and improved formulation of existing medicines for developing countries.

There was a debate about the relevance for a pharmaceutical company to invest in R&D for neglected diseases outside its area of expertise. Of investors, 63%

Box 11

63% of all investors disagreed and/or strongly disagreed that large pharmaceutical companies should invest in R&D into vaccines and/or medications for Neglected Diseases outside of their proven areas of expertise, while only 11% of all governments, 33% of all NGOs, 28% of all consultants and academics disagreed or strongly disagreed.

^d See Glossary for Definition.



disagreed or strongly disagreed that large pharmaceutical companies should invest in R&D into vaccines and/or medications for neglected diseases outside of their proven areas of expertise, while only 11% of all governments, 33% of all NGOs, 28% of all consultants and academics disagreed or strongly disagreed.

At the roundtables, it was noted that there are valuable R&D Philanthropy efforts such as the sharing of library compounds and the training of scientists that can form a part of an effective R&D strategy outside of traditional measures.

Potential metrics will consider strategies to provide patients lacking R&D expertise with data management and analysis assistance, clinical trial support, medicinal chemistry advice, members for expert scientific advisory committees, employee sabbaticals and the sharing of product libraries. However there is some concern that these activities are easier to enact and therefore should not be rewarded as highly as other R&D expenses.

This indicator accounts for 15% of the overall criterion weighting.



Patents & Licensing

KEY ISSUES FOR PATENTS & LICENSING

Box 12

“The results of the survey on the impact of TRIPS agreement on restricted access to technologies in the pharmaceutical sector show that Indian firms do face several difficulties with India's TRIPS compliance in this regards, and have also had to abandon R&D projects in recent years.”

Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firms Strategy in the Indian Pharmaceutical Industry, Padmashree Gehl Sampath.

Background Research

In 1994, at the Uruguay round, WTO members negotiated an agreement on patent rules, known as TRIPS. In 2001, developing countries expressed concern that developed countries were insisting on a narrow interpretation of TRIPS. The developing countries initiated a round of talks that resulted in the Doha Declaration; a WTO statement that reaffirms the right of developing countries to use safeguards created under TRIPS to ensure that medicines are available and affordable, and that generic drugs can be produced and imported at a lower cost than brand version.

Now, five years after the Doha Declaration, trade rules still remain a major barrier to accessing affordable versions of patented medicines. While the US government has been accused of imposing the so-called “TRIPS plus” rules, which undermine the flexibilities offered to developing countries to adapt the TRIPS agreement to their country context the pharmaceutical industry has been seen as a supporter of such a policy.²⁴

Patents are traditionally considered an effective means to boost R&D for unmet medical needs as they allow pharmaceutical companies to protect their innovation for 20 or more years, thereby helping to recoup costly R&D costs. In addition, by spurring innovation, patents increase medical discoveries which contribute to a better access to treatments. Nevertheless, there have been recent concerns about the relevance of this argument and, in particular, the report released in April 2006 by the World Health Organization Commission on Intellectual Property, Innovation and Public Health concludes that intellectual property protection has not led to increased innovation and access to treatment for people in developing countries.²⁵ Patents are certainly important but they alone can not stimulate innovation for diseases prevalent in developing countries, where profit opportunities are limited.

On the other hand the absence of intellectual property rights is often associated with a drop in prices of medicines due to generic drug competition, which turns out to be an effective way of improving access to medicines. In 2001, before India implemented the TRIPS agreement, Indian generic producers were able to market ARVs for much less than large pharmaceutical companies: USD360 per patient per year compared to USD10,000 per patient per year. Due to such dramatic global decrease in ARV prices, the number of people receiving treatment has substantially increased reaching 1.6 million in developing countries in 2006.²⁶ India, like other developing countries, was allowed to delay implementation of the TRIPS agreement



until 2005 but had to establish a “mailbox” system to receive and file patent applications from the beginning of 1995. The large majority of generic drugs on the market are not be affected by the compliance with TRIPS as it is impossible to file a patent retrospectively. However, new applications and pending applications in the “mailbox” are likely to be patented which may reduce the access to affordable medicines to people.

Research, together with stakeholder discussion, indicates that technology transfer agreements should not be included as an indicator in the Index framework, primarily as their positive impact on access to medicines has not yet been proved. “In many parts of the world, producing medicines domestically makes little economic sense. If many countries begin local production, the result may be less access to medicines, since economies of scale may be lost if there are production facilities in many countries.”²⁷

Our research indicates that the following indicators are considered to be essential components to assessing pharmaceutical companies Patents & Licensing practices. This criteria is weighted at 15% All indicators pursue a similar goal, which is to encourage the entry of generics on the market in order to reduce the price of medicines.

D1. The company does not enforce patents in least developed countries.^e

There was a general consensus among stakeholders that pharmaceutical companies should not enforce their patent right in least developed countries. Questionnaire results showed that 71.7% of all respondents agreed and/or strongly agreed that drug patents should not be enforced in least developed countries (LDCs) after 2016.

According to TRIPS, LDCs have until 2016 to abide by the TRIPS agreement. Nevertheless, some LDCs are already compliant with TRIPS but their population is not in a position to afford expensive branded medicines. The rationale behind this indicator is that by developing a patent relaxation policy, a company will let the market open to generic entry and the importation of cheaper drugs, which will improve the access to medicines by poor people.

Some stakeholders had few reservations with patents being enforced on the proviso that Voluntary Licenses and Technology Transfers were implemented. In some cases, local companies face administrative barriers (e.g. delay in drug registration) often too cumbersome for them to deal with without outside support. Therefore, local companies enter into voluntary license agreements with originator companies which assist them in the regulatory process and help them to overcome the difficulties relating to registration. Voluntary licenses will be discussed below.

Box 13

71.7% of all respondents agreed and/or strongly agreed that drug patents should not be enforced in LDCs after 2016.

^e See Glossary for Definition.



Possible metrics include third party reports of violation and the exploration of the number and reasons why companies have enforced patents in LDCs.

This indicator accounts for 30% of the overall criterion weighting.

D2. The company demonstrates the existence of, and discloses the terms of non exclusive voluntary license agreements to increase access to medicines in developing countries.

As noted previously, pharmaceutical companies can enter into licensing agreements with governments or local drug manufacturers and provide them with the right to produce a patent protected drug and sell it on the local market for a lower price. The questionnaire indicated that 75% of all respondents agreed and/or strongly agreed that voluntary drug license agreements by the patent-holding large pharmaceutical companies with local governments or local pharmaceutical companies are an effective strategy to improve access to medicines.

General agreement concluded that current Voluntary License Agreement disclosure was insufficient and left stakeholders with many questions on the exact benefits of such strategies. Licenses' terms vary greatly and may impose significant restriction on the amount of production, the right and quantities allowed to export and the customers (NGOs, government, private sector).

Potential metrics will include the number of voluntary licenses and will aim to improve disclosure on the various terms and conditions of agreements including restrictions on production, sourcing, co-formulation, imports and exports, as well as full provision of crucial technological patents to allow equally high production yields. The time taken to make the first product from first issue of license will also be assessed.

This indicator accounts for 30% of the overall criterion weighting.

D3. The company can demonstrate evidence of consent given to NDRAs (National Drug Regulatory Authorities) to use test data/override test data exclusivity for registration purposes in least developed countries.

Data exclusivity refers to the protection of clinical test data that is required to be submitted to a regulatory agency to approve the safety and efficacy of a new drug. It allows pharmaceutical companies to prevent generic drug manufacturers from using the safety and efficacy evidence that they produced to file the originator drug. As a consequence, generic companies are forced to repeat time-consuming, expensive studies in order to receive regulatory approval. Therefore, even when a drug is not under patent, data exclusivity creates a patent-like monopoly, which has dramatic consequence on ATM²⁸.

This indicator will investigate originator companies and their policies on data exclusivity and sharing test data with generic companies allowing for efficient registration.

Box 14

75% of all respondents agreed that voluntary drug license agreements by the patent-holding large pharmaceutical companies with local governments or local pharmaceutical companies are an effective strategy to improve ATM.



Potential metrics will look at issues of contention and the impacts on delivering access.

This indicator accounts for 20% of the overall criterion weighting.

D4. The company does not extend patent duration, or file patents for new indications for existing medicines in developing countries.

There are several ways for a pharmaceutical company to extend patent life. The company could complain that National Drug Regulatory Authorities take an unreasonable time to examine an application or a patent office to approve a patent. The company could also file a patent for each new use of a drug, which will prolong the patent life for 20 or more years²⁹.

A consensus emerged at the roundtables that pharmaceutical companies should not adopt such practices which are compromising ATM.

Potential metrics will detail evidence that shows the number of times companies have extended patents or 'refiled' patents.

This indicator accounts for 20% of the overall criterion weighting.



Equitable Pricing

KEY ISSUES FOR EQUITABLE PRICING

Box 15

"All companies should adopt transparent and consistent pricing policies, and should work towards reducing prices on a more consistent basis for low and lower middle income developing countries."

WHO, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, April 2006.

Background Research

Many factors restrict access to medicines: poverty (i.e. lack of money to buy medicines), lack of political will of governments, poor health infrastructures, and inappropriate drug selection. The price of medicines is also a key barrier in poor countries.³⁰ The cost of medicine represents the greatest share of health-care expenditures for people in poor countries. Expenditure on pharmaceuticals ranges from 10-20% of expenditure on health in the richest countries and 20-60% in poorer countries.³¹

Equitable pricing is the adaptation of prices which are charged by the manufacturer or seller to countries with different purchasing power. Equitable pricing is especially important for newer essential medicines that are still protected by patents or other instruments that provide market exclusivity. Widespread equitable pricing is economically feasible provided that low-priced medicines do not leak back to high-income countries.³²

Médecins Sans Frontières (MSF) finds that there are still common problems affecting the availability of the most needed essential medicines: (1) that in the absence of competition from multiple producers, companies may charge prohibitive prices (2) that most originator companies establish a country premium, thereby excluding patients in some developing countries, (3) that even if companies announce discounted prices for their products in some eligible developing countries, the products are in fact not always available or affordable, and (4) that pediatric HIV/AIDS is neglected by most pharmaceutical companies.³³

DFID indicates that "In 2002 the working group on increasing access to essential medicines in developing countries found that differential pricing was economically and commercially viable."³⁴

Our research confirms the relevance of equitable pricing as an effective practice to address ATM and therefore weighted this criterion at 18%. The following indicators are considered to be essential components to assessing the practice of Equitable Pricing by companies.

E1. The company can demonstrate efforts to register relevant drugs in developing countries.

Box 16

76.5% of all respondents disagreed and/or strongly disagreed that registration of drugs relevant to healthcare priorities in developing countries is currently sufficient.



In order to reach the market a drug needs to be approved by a country's National Drug Regulatory Authority, which means that the drug has been proven to meet certain quality, safety, and effectiveness criteria. General agreement among stakeholders concluded that there was a need for additional drug registration in developing countries.

A consensus emerged at the roundtables that drug registration could be an indicator under "Patents & Licensing" and under "Equitable Pricing". Innovest decided that the drug registration issue would better fall under "Equitable Pricing" as the US has been targeted by a negative media campaign about its attempt to turn National Drug Regulatory Authorities into patent offices when entering into Free Trade Agreements with developing countries (e.g. Chile)³⁵. If the NDRA becomes the enforcer of patents, it will not be able to register generic versions of patented drugs. In the TRIPS agreement there is no reference to such role.

Stakeholders commented that it was important to expose the shortfalls in civil society, highlighting systematic failures and countries with especially poor records on registration. Through the benchmarking of companies on this issue, data may draw attention to NDRAs with recurring failures in registration efficacy. Stakeholders did acknowledge the political implications of such transparency.

Potential metrics will look at the time lapse of registration in rich and poor countries, the transparency around reporting on registration status, and the work with the WHO to get on the pre-qualified and essential drugs lists.

This indicator accounts for 25% of the overall criterion weighting.

Box 17

60.8% of all respondents agreed and/or strongly agreed that large pharmaceutical companies should have a three-tier pricing policy (for countries ranked High, Middle and Low on the Human Development Index) for all Neglected Diseases Medication.

Box 18

78.5% of all respondents agreed and/or strongly agreed that the risk of drug diversion can be addressed by various means, including use of different colour drugs and packaging schemes, which include the destination address.

E2. The company has a policy to facilitate access to medicines in developing countries through pricing mechanisms, which include reporting on scope, pricing levels and pricing reviews.

Differential pricing strategies were the source of much debate among stakeholders at the roundtables with a call for much greater research in this area, including economically modeling to provide guidance for companies on the most effective methods of pricing. It was noted this could only materialize with greater transparency by pharmaceutical companies in worldwide pricing strategies.

Potential metrics will look for transparency in pricing policies, explore various methods linked to disease prevalence and human development, along with tiered pricing and other such scales (Global Fund Price) identified and analyzed for performance.

This indicator accounts for 40% of the overall criterion weighting.

E3. The company has mechanisms in place to prevent product diversion.



Drug diversion is defined here as the diversion of licit drugs for illicit purposes. There was a consensus among stakeholders around a need to address diversion practices as a means of preventing reverse import of drugs destined for developing country markets. This is of particular concern for single-source products that are sold at high prices in high developed countries. However some stakeholders voiced concerns that this issue is highly overstated and marginally important to ATM.

Potential metrics will look into anti-diversion policies (including use of different color drugs and packaging schemes) and progress made over the years to reduce the amount of drugs diverted and their monetary value.

This indicator accounts for 10% of the overall criterion weighting.

E4. The company has a policy for the very poorest^f in all markets.

It was acknowledged that companies should implement strategies for markets where consumers are unable to even pay the cost price of drugs. The rationale behind this indicator is that poor people in high or middle income countries are not more capable of paying for expensive drugs than poor people in low income countries where pharmaceutical companies may have a differential pricing policy in place and may offer drugs at cost. This indicator will investigate the flexibilities offered by pharmaceutical companies to poor people at a country level.

Potential metrics will look into policies and scope, discounts and beneficiaries.

This indicator accounts for 25% of the overall criterion weighting.

^f See Glossary for Definition.



Drug Donations

KEY ISSUES FOR DRUG DONATIONS

Background Research

Donation programs can make major contributions to improved global public health, particularly when directed at time-limited needs such as disease eradication.³⁶ Studies have shown that tropical disease drug donation PPPs have provided considerable benefits, facilitating greater drug availability with negligible negative side-effects. The donation programs have been embraced by countries (specifically in Sri Lanka, Uganda and Zambia) with rudimentary health infrastructure. There are however concerns that donation programs function where there is a substantial danger of overwhelming the limited absorptive capacity of national health systems by diverting staff, duplicating financial, monitoring and evaluation systems, and incurring ancillary costs for governments. It is therefore vital to continue operational support as well as to assure drug supplies during the maintenance phase of these programs, if disease resurgence is to be avoided.³⁷

Concerns that activities such as donations are ultimately unsustainable,³⁸ supported by questionnaire analysis suggests that in the past, post-emergency drug donations have been inefficient and ineffective, is the main reason for the lower weighting in this section. Innovest research indicates that the majority of pharmaceutical companies have extensive well-publicized donations programs that do currently improve access to medicines. Drug Donations was given a low weight in the Index framework: 7%

The following indicators are considered to be essential components to assessing the practice a company's Drug Donations policy.

F1. The company has a signed policy that fully conforms to the WHO's Guidelines for Drug Donations.

Stakeholder agreement on the comprehensive nature of the World Health Organization's Guidelines allowed for little debate on this issue.

Analysis will follow performance against the various safeguards within the Guidelines, even in situations where a company has not publicly acknowledged or follows the Guidelines. Analysis will follow performance against the various safeguards within the Guidelines, even in situations where a company has not publicly acknowledged or follows the Guidelines. The Guidelines intend to ensure that drug donations are relevant to the country context and are announced and needed by the recipient country. They also ensure that donated drugs are of good quality and that they have



a shelf life of more than a year. Other principles include presentation, packing, labeling, information and management.

This indicator accounts for 60% of the overall criterion weighting.

Box 19

40.4% of all respondents agreed or strongly agreed that direct drug donations should only be as a part of a disease eradication program.

F2. The company discloses the absolute volume of its drug donations and number of patients treated per year.

Whereas this indicator was generally seen as a less effective avenue to pursue for companies, greater transparency of action was called for. The reporting of the total value of donations was deemed not necessary as most stakeholders acknowledge that the monetary value of donations, currently disclosed by a large number of companies, has little relevance, with costs often based on the most expensive drug prices and generally without the evaluation of the number of full treatments provided.

Potential metrics will include the number of fixed dose treatments received by patients and the number of employees dedicated to such programs.

This indicator accounts for 40% of the overall criterion weighting.



Philanthropic Activities

KEY ISSUES FOR PHILANTHROPIC ACTIVITIES

Box 20

"When faced with the overwhelming task of influencing the economic condition of a host country, there is a tendency for companies to choose philanthropic means of influence. Philanthropy is more commonly reported and publicized because it is easier to implement, measure and promote than other means."

**Business & Economic Development:
Pharmaceutical Sector Report,
BSR and AccountAbility,
December 2004.**

Background Research

In 2002, Oxfam, Save the Children, and VSO called on the pharmaceutical industry to contemplate various initiatives for improving access to medicines, highlighting that many companies were defining access to medicines policies largely in terms of philanthropic ventures.³⁹ In the years since this observation access to medicine strategies have evolved quite rapidly with the focus shifting away from philanthropy.

There was general agreement among stakeholders that philanthropy should be rewarded but not seen as a long-term strategy for improving access to medicines, and therefore philanthropy was given 5% weight in the Index framework. The following indicators will be considered when assessing a company's philanthropic activities.

G1. The company has philanthropic programs related to access to medicines not covered by any of the other criteria.

Despite conjecture over apportion of monetary and other resources to Philanthropy over other avenues, there was almost universal acknowledgement that current company programs do have a positive impact on access to medicines. Stakeholder debate centered on the issue of responsibility; particularly the role of capacity building as an auxiliary obligation for pharmaceutical companies. Questionnaire respondents strongly favored both infrastructure and training initiatives across all regions, many arguing strongly for capacity building activities to lessen infrastructure barriers currently preventing access. Respondents argued that with companies needing structured healthcare infrastructures to facilitate access programs, it would be justified to expect they should play a role in any public healthcare improvements.

Potential metrics will consider normalized spending, capacity advancement, employee matched donations and the disclosure of sustainability and/or exit strategies for such programs.

This indicator accounts for 100% of the overall criterion weighting.

Box 21

71.4% of all respondents agreed or strongly agreed that as part of any drug donation program in Sub-Saharan Africa, large pharmaceutical companies must provide adequate training to healthcare workers for drug distribution.



Ethical Promotion and Marketing Activities

KEY ISSUES FOR ETHICAL PROMOTION AND MARKETING ACTIVITIES

Box 22

"The ethical criteria for drug promotion has been devised by the World Health Organization, to prevent the occurrences of inappropriate pharmaceutical promotion. The ethical criteria should ideally be adopted and implemented by member countries. However, evaluation of the implementation of this ethical criteria in developing countries is lacking."

**Dr. Sulanto Saleh-Danu,
International Network for
Rational Use of Drug (INRUD)
Indonesia.**

Background Research

Pharmaceutical companies have been criticized for allegedly overstating a drug's benefits and understating the risks of taking a particular medicine⁴⁰. This unethical promotion can lead to irrational drug prescribing and drug use, and to needless injury or even death. The issue of responsible marketing is particularly important in developing countries where regulatory controls and independent information are lacking or if they do exist are less stringent than in High Developed countries⁴¹. Studies found that doctors in developing countries rely heavily on industry-based sources of information⁴².

In 1988, the WHO published a set of Ethical Criteria for Medicinal Drug Promotion⁴³. These criteria are intended to provide a strong ethical framework for drug promotion and ensure that the customer gets the proper information and not advertising in disguise.

There was general agreement among stakeholders that an extra criterion should be added to allow for the analysis of corporate marketing strategies, specifically for campaigns in developing countries. It was suggested that ethical performance should make up a small section of the Index framework and therefore responsible marketing was weighted at 5%. The following indicators will assist in the evaluation of marketing and promotional activities in relation to keeping a consistent ATM message.

H1. The company has a marketing policy which explores gender related issues and labeling possibilities in developing countries.

Concern was voiced that companies are inaccurately targeting patients in developing countries and hampering overall access to effective treatments. Some stakeholders mentioned that there was a need to address gender issues when marketing drugs and especially in relation with microbicides, which are substances intended to reduce or prevent transmission of HIV and/or other sexually transmitted infections (STIs) when applied topically to genital mucosal surfaces⁴⁴.

Potential metrics will include the adoption of a specific marketing code for these regions and for women and third party reports on abuse.



This indicator accounts for 50% of the overall criterion weighting.

H2. The company has a signed policy that fully conforms to the WHO's Ethical Criteria for Medicinal Drug Promotion.

Analysis will follow performance against the various safeguards within the guidelines.

Potential metrics will include the number of warning letters received from regulatory authorities and the number of breaches per year by employees.

This indicator accounts for 50% of the overall criterion weighting.



The Access To Medicine Index Framework

The following chart summarizes each of the criteria and indicators that make up the Access To Medicine Index framework. Weightings summing to 100% have been assigned to each of the eight criteria based on stakeholder discussions and Innovest expertise. The same process has been used to determine the weighting of each indicator listed under each criterion.

20%	A. Access to Medicines Management
20%	A1. Governance: The company has a governance system which includes direct board level responsibility and accountability for its ATM strategy.
20%	A2. Policy: The company has a public global policy in place, in which it explains its rationale for ATM, its contents and details its specific objectives and targets.
20%	A3. Systems: The company has clear management systems to implement and monitor its ATM strategy.
25%	A4. Stakeholder Input: The company has a mechanism for stakeholder engagement which inputs into ATM management.
15%	A5. Reporting: The company produces a public annual report on ATM management which addresses all key issues, has qualitative and quantitative reporting on all key issues and enables an assessment of strategy.
10%	B. Public Policy Influence & Lobbying
35%	B1. The company and subsidiaries provides disclosure of lobbying positions/activities at national, regional and international level that impact ATM.
45%	B2. The company annually discloses financial support in terms of amounts, beneficiaries and channels; including at least key opinion leaders, patient associations, political parties, trade associations and academic departments, through which it seeks to influence public policy and national, regional and international practice.
20%	B3. The company can demonstrate there is a process of board approval of the above reporting as appropriate to the nature and scale of the activity.



20%	C. R&D for neglected diseases
30%	C1. The company provides evidence of in-house investment in R&D into neglected diseases. This may be reflected in terms of dedicated scientists, projects, and a dedicated neglected disease division.
35%	C2. The company invests in R&D on neglected diseases in partnership with product development Public Private Partnerships (PPPs), Academic Departments and the World Health Organization (WHO).
20%	C3. The company shows temporal evidence of a research program to find formulation suitable for environments in developing countries for all patient groups.
15%	C4. The company undertakes other activities (not covered by other C criteria) to support R&D into neglected diseases and improved formulation of existing medicines for developing countries.
15%	D. Patents & Licensing
30%	D1. The company does not enforce patents in least developed countries.
30%	D2. The company demonstrates the existence of, and discloses the terms of non exclusive voluntary license agreements to increase access to medicines in developing countries.
20%	D3. The company can demonstrate evidence of consent given to NDRAs (National Drug Regulatory Authorities) to use test data/override test data exclusivity for registration purposes in least developed countries.
20%	D4. The company does not extend patent duration, or file patents for new indications for existing medicines in developing countries.
18%	E. Equitable Pricing
25%	E1. The company can demonstrate efforts to register relevant drugs in developing countries.
40%	E2. The company has a policy to facilitate access to medicines in developing countries through pricing mechanisms, which includes reporting on scope, pricing levels and pricing reviews.
10%	E3. The company has mechanisms in place to prevent product diversion.
25%	E4. The company has a policy for the very poorest in all markets.
7%	F. Drug Donations



60%	F1. The company has a signed policy that fully conforms to the WHO's Guidelines for Drug Donations.
40%	F2. The company discloses the absolute volume of its drug donations and number of patients treated per year.
5%	G. Philanthropic Activities
100%	G1. The company has philanthropic programs related to access to medicines not covered by any of the other criteria.
5%	H. Ethical Promotion and Marketing Activities
50%	H1. The company has a marketing policy which explores gender related issues and labeling possibilities in developing countries.
50%	H2. The company has a signed policy that fully conforms to the WHO's Ethical Criteria for Medicinal Drug Promotion.



Access To Medicine Index Framework – Next Steps

INDUSTRY ENGAGEMENT

The next stage in building the Access To Medicine Index will involve consultation with the Pharmaceutical Industry and its representation on the work done to date. This will explore the various research possibilities and viewpoints while maintaining the core framework developed through the original stakeholder group. It is essential to engage with the industry to provide perspective on the findings and allow any omissions to be incorporated. The findings of the Scoping Report & Stakeholder Review will be presented by Innovest through face-to-face meetings with the 20 companies identified in Appendix 4. The aim is to present the findings and discuss issues, concerns and potential improvements with relevant members of the selected companies. Ideally we will look to present these findings to employees with varying degrees of responsibility and perspectives on access to medicines, especially those with responsibility for Access To Medicines, CSR, R&D, Logistics, Philanthropy, Political Contributions and Corporate Affairs. We will also continue to engage with industry groups such as; IFPMA, EFPIA, ABPI and PhMRA. This will help ensure the Index also considers the availability of specific data.

INDEX FRAMEWORK REFINEMENT

The list of criteria, indicators, metrics and weightings based on the industry consultation phase will be amended by Innovest to ensure that the Index fulfills the expectations of the key stakeholder group, whilst incorporating the knowledge gained from our engagement with industry representatives.

PERFORMANCE ASSESSMENT

In the next phase, Innovest will assess and benchmark the relative performance of 20 pharmaceutical companies according to the Access To Medicine Index criteria and indicators. Research will involve analyzing publicly available information and interviewing key company representatives in order to ensure full data provision, to be able to accurately develop the Access To Medicine Index.



ANNUAL REVIEW

It is expected that the Access To Medicine Index will continue to evolve over a number of years, cementing standards in the early years as debate and research evolves. The Access To Medicine Foundation and Innovest will continue to work in partnership to review the Index on a yearly basis amending and editing indicators, criteria, metrics and weightings based on new research studies conducted on the subject, as well as through monitoring expert discussions at an international, regional and national level. An annual questionnaire will provide further insight on developing issues associated with improving access, providing further support to the Index. Company performance will be reassessed considering the latest best practices and progress made to improve access to medicines.

TAKING THE INDEX LIVE

For the Index to achieve maximum impact “on the ground”, it will need to influence the actual investment choices and *behavior* of major investors – giving more favourable consideration to companies more heavily weighted in the Index. The ideal scenario in this regard would be to create an *investable* Access to Medicine Index which would maximize investment flows to superior ATM performers while simultaneously incentivizing laggards. One prominent example of this is the Dow Jones Sustainability Index, which now directly influences over \$2 billion. Innovest itself has previously constructed an analogous index in the field of community investment and development. That index, co-developed with a leading global index provider, is currently the basis for the multi-million dollar investment portfolio of a foundation with a strong programmatic commitment to the area. The index is currently managed by one of the largest asset managers in the world.

It would be our intention during Phase II to initiate similar discussions in conjunction with the Access to Medicine Foundation. Given the number of major global foundations with a strong interest in ATM issues, it is possible that a significant volume of investment capital could be mobilized in this manner.



Appendix 1: The Questionnaire

Respondents were asked for their expert opinion on the following statements. There was the opportunity after each section for comments to be made and space at the end for comments and suggestions outside of the defined criteria.

1. Access to Medicines Management	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree	No Response
a) It is essential for large pharmaceutical companies to formulate and oversee ATM strategies at the board level to ensure long-term continuity.						
b) When making ATM investment decisions outside pure philanthropy, the business rationale should be presented (including the risk management element and the projected value of any tangible returns).						
c) Large pharmaceutical companies should disclose the monetary value and nature of long-term dedicated resources (including specific research facilities, staff and budget for PR costs) for ATM strategies.						
d) Reducing costs in the pharmaceutical industry value chain should be incorporated into all large pharmaceutical company ATM strategies.						
e) Large pharmaceutical companies should collaborate with stakeholders in designing the type of ATM programs that would be the most effective and appropriate in different country contexts.						

2. Public Policy Influence and Lobbying	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree	No Response
a) Lobbying by large pharmaceutical companies in developing countries can positively improve healthcare infrastructures and the drug registration process.						



b) The policy stance taken by the Pharmaceutical Research and Manufacturers of America (PhRMA) relating to the TRIPS Agreement reflects negatively on large pharmaceutical companies.						
c) Disclosure of companies' political contributions and lobbying stances across jurisdictions positively impacts the transparency of access to medicines strategies.						
d) Financial incentives from foundations or governments for development of particular drugs, focus the attention of pharmaceutical companies away from neglected diseases and negatively impact efforts to tackle them – The definition of neglected diseases in this instance includes HIV/AIDS, Malaria and Tuberculosis, as well those neglected tropical diseases (NTDs) as defined by the World Health Organization.						

3. Research and Development into Vaccines and Medication for Neglected Diseases	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree	No Response
a) There is a need for more investment in basic scientific understanding of several of the parasites, bacteria and certain viruses causing neglected diseases before it will be cost-effective for large companies to dedicate resources to the development of Vaccines of sufficient efficacy.						
b) Large pharmaceutical companies should invest in R&D into Vaccines and/or Medication for neglected diseases outside their proven areas of expertise.						
c) Large pharmaceutical companies with relevant capabilities in their current research portfolio should dedicate a specific amount of their overall R&D budget each year for research into Vaccines for neglected diseases.						
d) Large pharmaceutical companies with relevant capabilities in their current research portfolio should dedicate a specific amount of their overall R&D budget each year for research into Medication for neglected diseases.						
e) Public-Private Partnerships are the most successful model for large companies to emulate in designing an ATM program running from research to distribution.						



f) Large pharmaceutical companies with compound libraries no longer in use or old mothballed research programs should make arrangements to provide the data to parties who are in a position to take forward the R&D efforts.						
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g. The Pharmaceutical Sector is currently investing an acceptable level of resources into R&D for Vaccines to prevent:	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree	No Response
i. Adult HIV/AIDS in developing countries						
ii. Adult HIV/Aids in developed countries						
iii. Pediatric HIV/AIDS in developing countries						
iv. Malaria						
v. Tuberculosis in developing countries						
vi. Other neglected diseases						

h. The Pharmaceutical Sector is currently investing an acceptable level of resources into R&D for Medication to treat:	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree	No Response
i. Adult HIV/AIDS in developing countries						
ii. Adult HIV/Aids in developed countries						
iii. Pediatric HIV/AIDS in developing countries						
iv. Malaria						
v. Tuberculosis						
vi. Other neglected diseases						

4. Patents/Licensing	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree	No Response
a) After 2016, drugs patents should not be enforced in countries listed in the UN Human Development Index as Low Human Development Countries - For information on the Human Development Index go to:						



http://hdr.undp.org/reports/global/2005/pdf/HDR05_HDI.pdf						
b) Voluntary drug license agreements by the patent-holding large pharmaceutical companies with local governments or local pharmaceutical companies are an effective strategy to improve ATM.						
c) Large pharmaceutical companies enter into technology transfer agreements with entities in developing countries involving less up-to-date equipment and techniques than those available in countries high on the Human Development Index.						

5. Differential Pricing	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree	No Response
a) Registration of drugs relevant to healthcare priorities in developing countries is currently sufficient.						
b) Companies' provision of differential pricing options for the private sector in developing countries is currently comparable to that for the public sector.						
c) Differential pricing can help support viable markets, and competition can lead to lower prices.						
d) Large pharmaceutical companies should have a three-tier pricing policy (for countries ranked High, Middle and Low on the Human Development Index) for all neglected diseases Medication.						
e) The risk of drug diversion can be addressed by various means, including use of different color drugs and packaging schemes, which include the destination address.						

6. Drug Donations	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree	No Response
a) Direct drug donations should only be as a part of a disease eradication program.						
b) Drug donations in post emergency situations (e.g. tsunami, hurricane, earthquake, etc.) are often inefficient in their distribution.						



c) Drug donations as a part of a Public Private Partnership are an effective way of ensuring access to medicines in:	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree	No Response
i. Sub-Saharan Africa						
ii. East Asia and the Pacific Region						
iii. Eastern Europe & Central Asia						
iv. South Asia, Middle East & North Africa						
v. Latin America & the Caribbean						
vi. North America & Western Europe						

7. Philanthropic Activities	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree	No Response
a) Contributions by large pharmaceutical companies to healthcare infrastructure, including in both structural and human capability, is necessary to facilitate drug delivery to patients due to lack of capacity in local and national government in:						
i. Sub-Saharan Africa						
ii. East Asia and the Pacific Region						
iii. Eastern Europe & Central Asia						
iv. South Asia, Middle East & North Africa						
v. Latin America & the Caribbean						
vi. North America & Western Europe						

b) As part of any drug donation program, large pharmaceutical companies must provide adequate training to healthcare workers for drug distribution:	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree	No Response
i. Sub-Saharan Africa						
ii. East Asia and the Pacific Region						
iii. Eastern Europe & Central Asia						
iv. South Asia, Middle East & North Africa						
v. Latin America & the Caribbean						
vi. North America & Western Europe						



Appendix 2: List of Questionnaire Respondents

Academia

Professor Alan Fenwick, Imperial College, Director Schistosomiasis Control Initiative, Dept Infectious Disease Epidemiology.

Professor Alan Whiteside, University of KwaZulu-Natal, Director Health Economics & HIV/AIDS Research Division (HEARD).

Professor Brigitte Granville, Queen Mary, University of London, Professor of International Economics and Economic Policy.

Professor Frederick Abbott, Florida State University, Edward Ball Eminent Scholar Professor of International Law.

Dr Jessica Ogden*, International Center for Research on Women (ICRW), HIV/AIDS Specialist.

Professor Marleen Boelaert, Institute of Tropical Medicine Antwerp, Public Health Department.

Dr Mary Moran, The George Institute for International Health, Director Pharmaceutical R&D Policy Project (PRPP).

Consultant

Mr Bernard Trude*, Healthlink Worldwide, Executive Director.

Mr Brendan May*, Weber Shandwick, Head of Corporate Responsibility & Sustainability.

Dr David Gershon, Standard and Poor's, Healthcare Economics and National Institute for Pharmaco-Economics and Healthcare Policy, Chairman.

Mr Francis Weyzig, Stichting Onderzoek Multinationale Ondernemingen (SOMO), Senior Researcher.

Mr Ian Bradley, Arthur D Little, Consultant.

Ms Jacqui Patterson, Independent Consultant.

Mr Mian Imran Masood, The Network for Consumer Protection Islamabad, Assistant Coordinator Pharmaceuticals, Advocacy and Research Unit.



Ms Ritu Khanna, SustainAbility, Advisor.

Ms Sophia Tickell, SustainAbility and Pharma Futures Project, Chair and Director.

Dr Wilbert Bannenberg, Public health consultant in the field of essential medicines for developing countries, Consultant.

Government

Professor Carel Ijsselmuiden, Council on Health Research for Development (COHRED), Director.

Dr Carter Diggs, USAID Malaria Vaccine Development Program, Senior Technical Advisor.

Mr Daniel Graymore, DFID, Private Sector Adviser Business Alliances Team and Global AIDS Policy Team, Policy Division.

Dr Edvard Beem, ZonMw - National health council appointed by the Ministry of Health (VWS) and the Netherlands Organisation for Scientific Research (NWO), Managing Director.

Dr Diarmuid McClean, Irish Aid, Development Specialist.

Mr Harry Schooten, Netherlands Ministry of Foreign Affairs DGIS Department, Health Adviser.

Dr Judith de Kroon*, The Netherlands-African Partnership for Capacity Development and Clinical Interventions against Poverty related Diseases (NACCAP), Senior Programme Coordinator.

Ms Miriam Naarendorp*, Ministry of Health (MOH) Suriname, Pharmacy Policy Coordinator.

Dr Richard Laing, World Health Organization (WHO), Policy, Access and Rational Use, Medicine Policy and Standards.

Dr S K Sharif, Ministry of Health Kenya, Provincial Medical Officer of Health.

Mr Sisule Musungu, South Centre and Health Action International Africa, Access to Knowledge and Intellectual Property and Chairman.

Investor

Mr Aled Jones*, Formerly Jupiter Asset Management SRI Analyst.

Ms Celine Suarez*, Domini Social Investments, Research Analyst.



Mr Daniel Rosan, Interfaith Center on Corporate Responsibility (ICCR), Program Director Public Health, Access to Capital.

Ms Gemma Taylor-Gee, ABN Amro Asset Management SRI Engagement Specialist.

Ms Karen Shaw, Schroders Asset Management, SRI Analyst.

Mr Kenny Bell, Baillie Gifford, Corporate Governance and SRI Manager.

Mr Martin Eijgenhuijsen, ABP Investments, Senior Portfolio Manager.

Ms My-Linh Ngo, Henderson Global Investors, Senior Analyst Sustainable & Responsible Investment.

Mr Neil Brown, Threadneedle Asset Management, Head of Governance and Responsible Investment.

Dr Raj Thamotheram, AXA Investment Managers, Responsible Investment Team.

Mr Steve Lippman, Trillium Asset Management, Vice President of Social Research.

Dr Stewart Adkins, Formerly Lehman Brothers, Senior Analyst Pharmaceuticals.

Mr Terence Berkleef, ABN Amro Asset Management, SRI Analyst.

NGO

Dr Anne Merriman, Hospice Africa in Uganda, Founder and Director of Policy and International Programs.

Ms Annelies den Boer, Wemos Foundation, Project Manager Medicines.

Dr Charles Gardner, The Rockefeller Foundation, Associate Director.

Dr Christopher Elias, Program for Appropriate Technology in Health (PATH), President.

Ms Ellen T'Hoën*, Médecins Sans Frontières (MSF), Access to Essential Medicines Campaign.

Mr Ed Vreeke, Asrames asbl, Director.

Mr Frans de Laaf, Oxfam Novib, Responsibility for Special Projects.

Ms Helena Vines Fiestas, Oxfam GB, Policy Advisor Private Sector.

Ms Helene Rossert, AIDeS, General Director.

Dr J. Carl Craft, Medicines for Malaria Venture (MMV), Portfolio Manager.



Dr Jean-Marie Kindermans, European Agency for the Development and Health (AEDES), Medical Doctor in Public Health.

Mr Jerald Sadoff*, Aeras Global TB Vaccine Foundation, President and Chief Executive Officer.

Ms Joelle Tanguy, Global Business Coalition (GBC) on HIV/AIDS, Managing Director.

Dr Maria Freire, Global Alliance for Tuberculosis Drug Development, President and Chief Executive Officer.

Mr Mark Harrington, Treatment Action Group (TAG), Executive Director.

Ms Marieke van der Werf, KNCV Tuberculosis Foundation, Senior Director.

Dr Melinda Moree, Malaria Vaccine Initiative (MVI) Program for Appropriate Technology in Health, Chief Executive Officer.

Dr Mohga Kamal-Smith, Oxfam GB, Health Policy Advisor.

Prince Ngongo Bahati, International Aids Vaccines Initiative (IAVI) Africa, Program Officer.

Ms Philippa Saunders, Essential Drugs Project, Director.

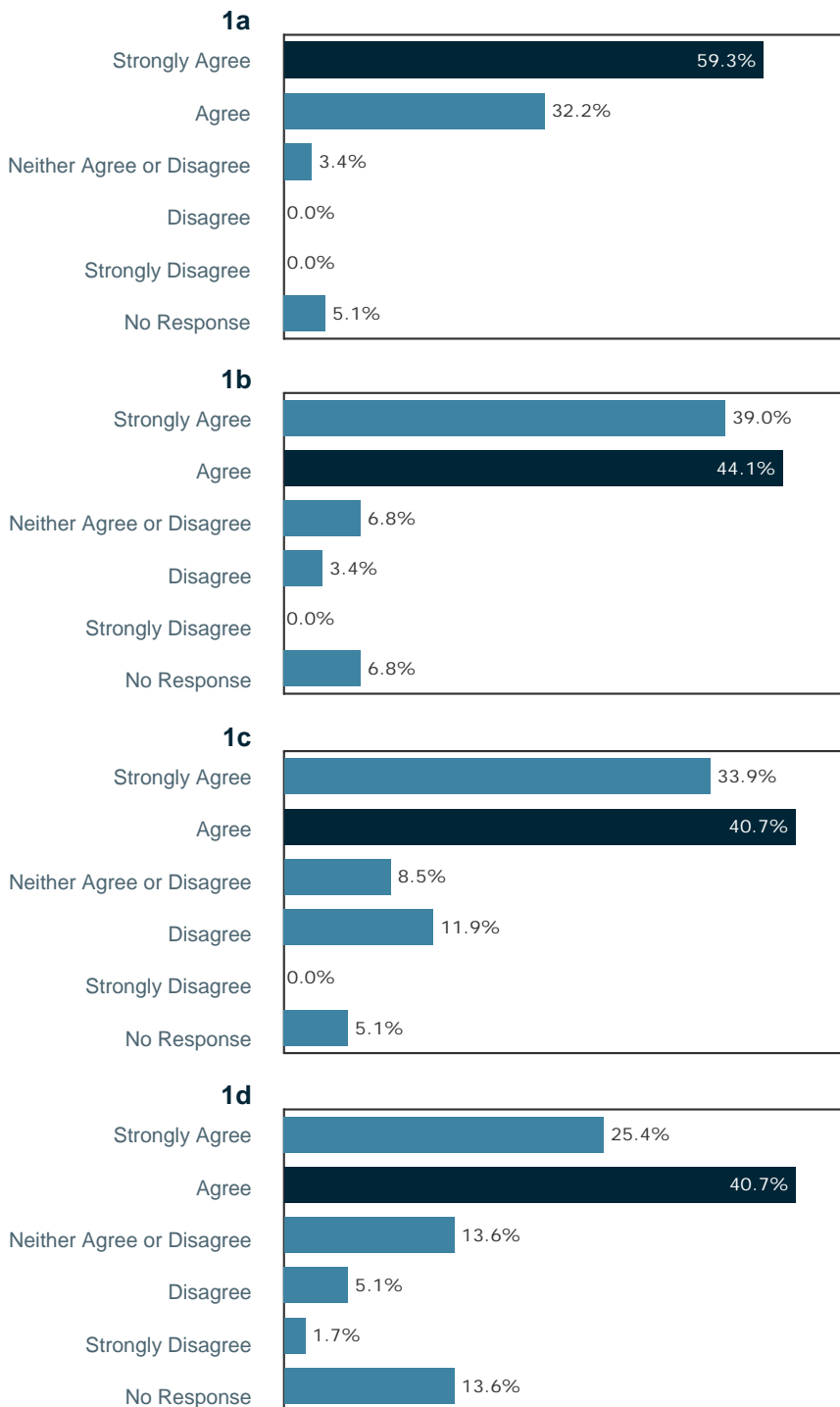
Dr Tim Reed, Health Action International (HAI) Europe, Director.

Dr Zeda Rosenberg, International Partnership for Microbicides (IPM), Chief Executive Officer.

*Denotes those respondents who completed parts of the questionnaire.

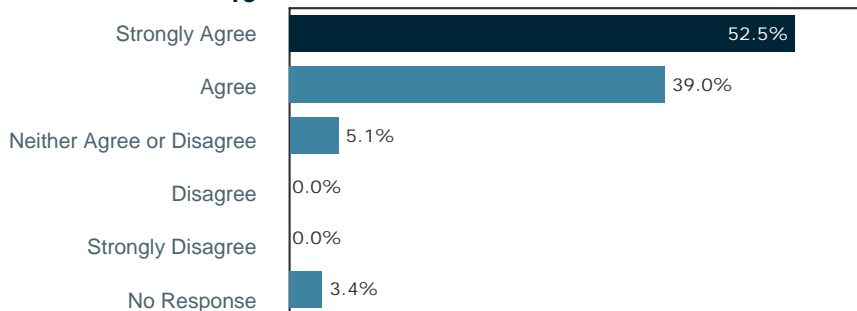


Appendix 3: Questionnaire Results

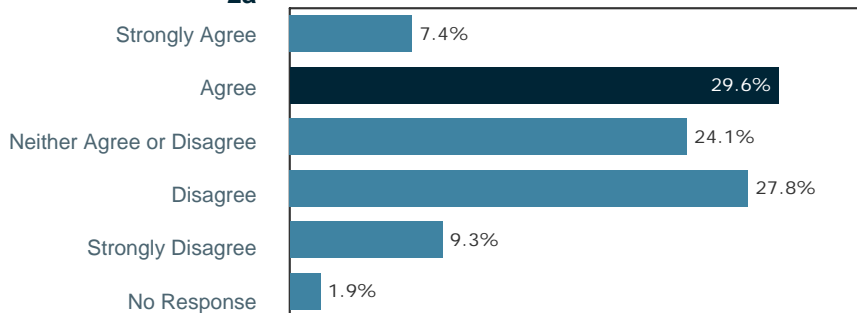




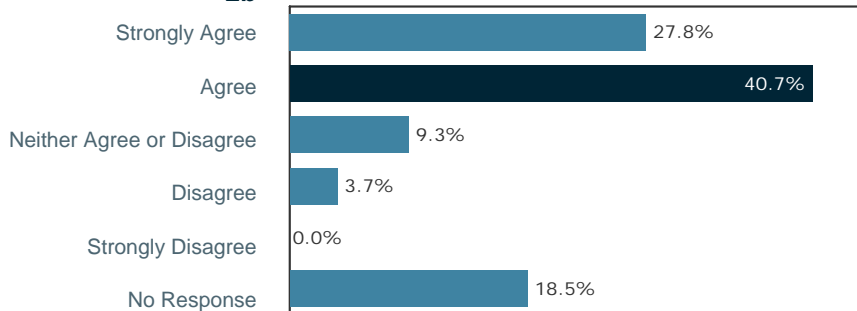
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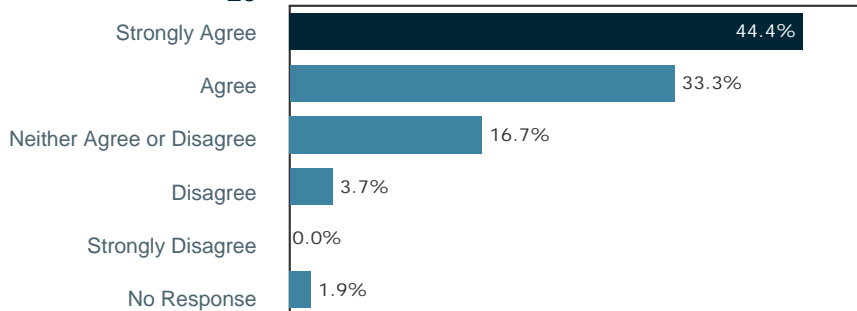
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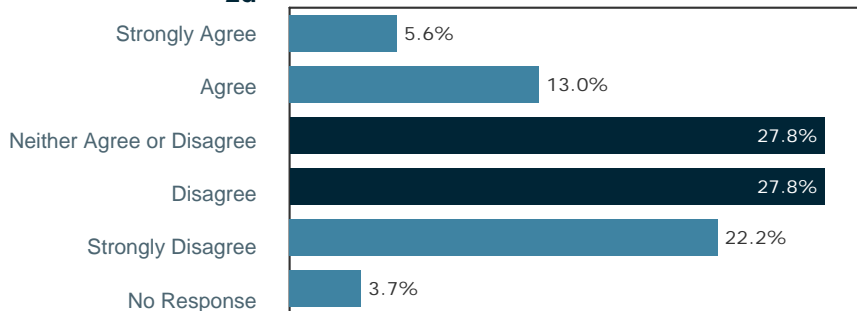


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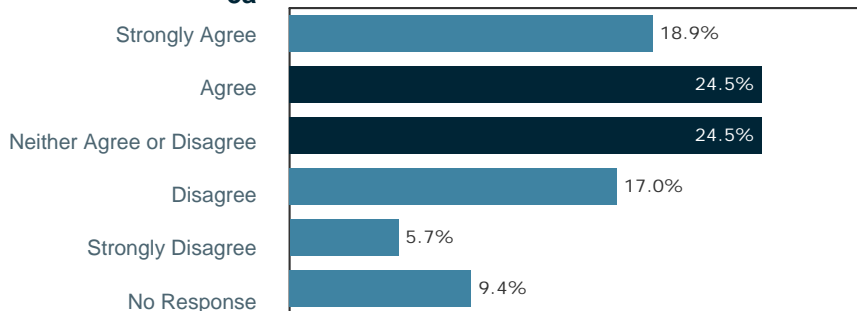




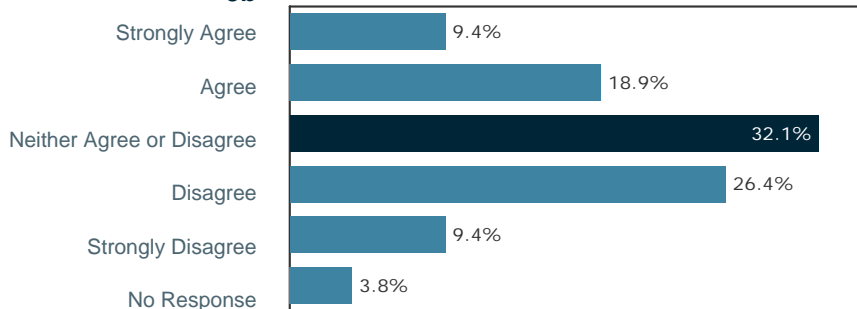
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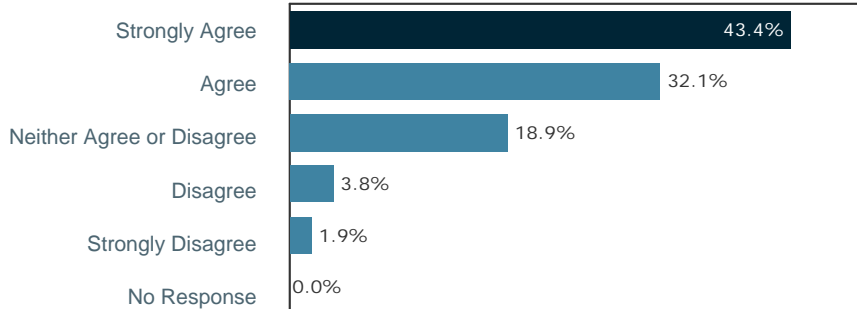
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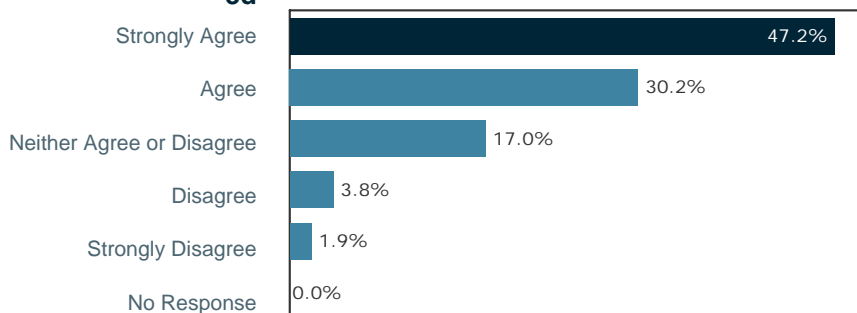


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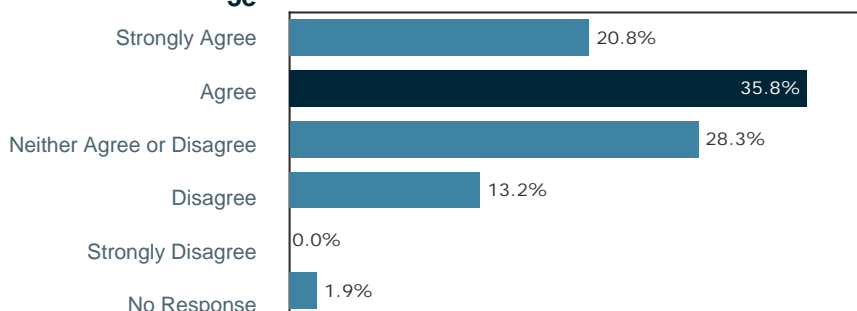




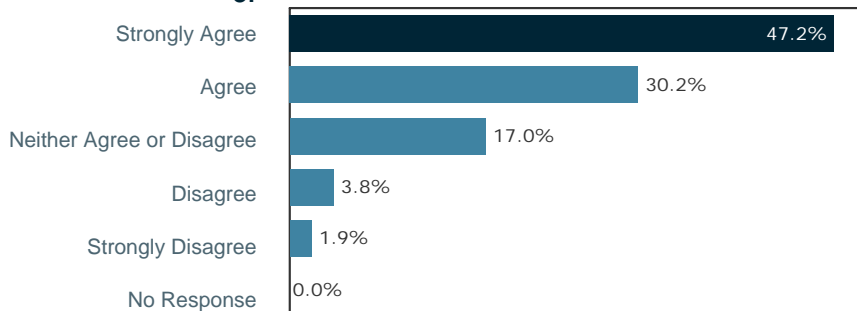
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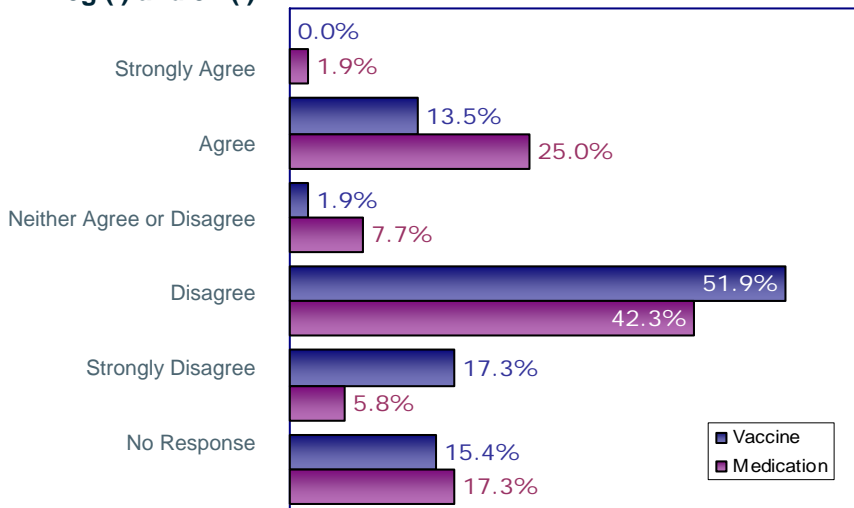


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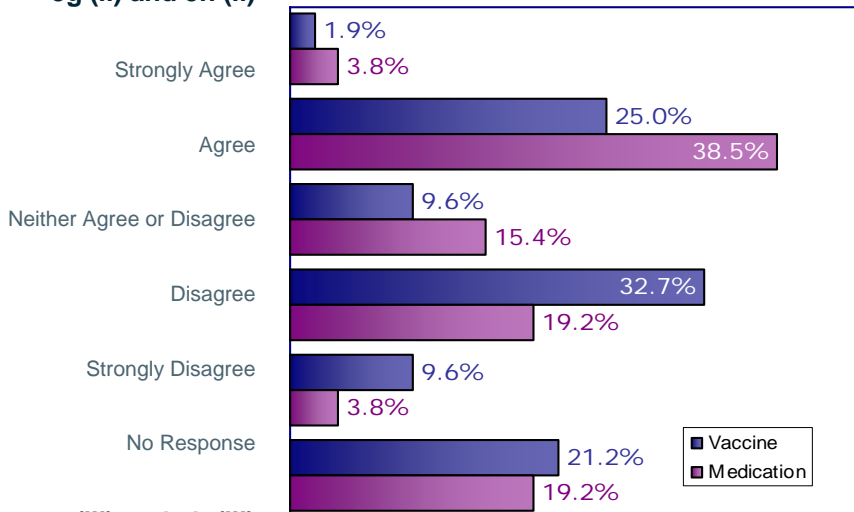




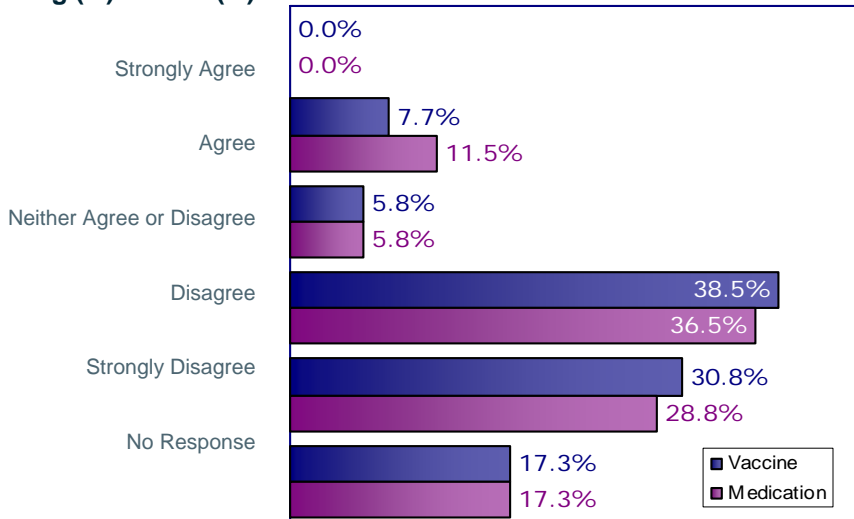
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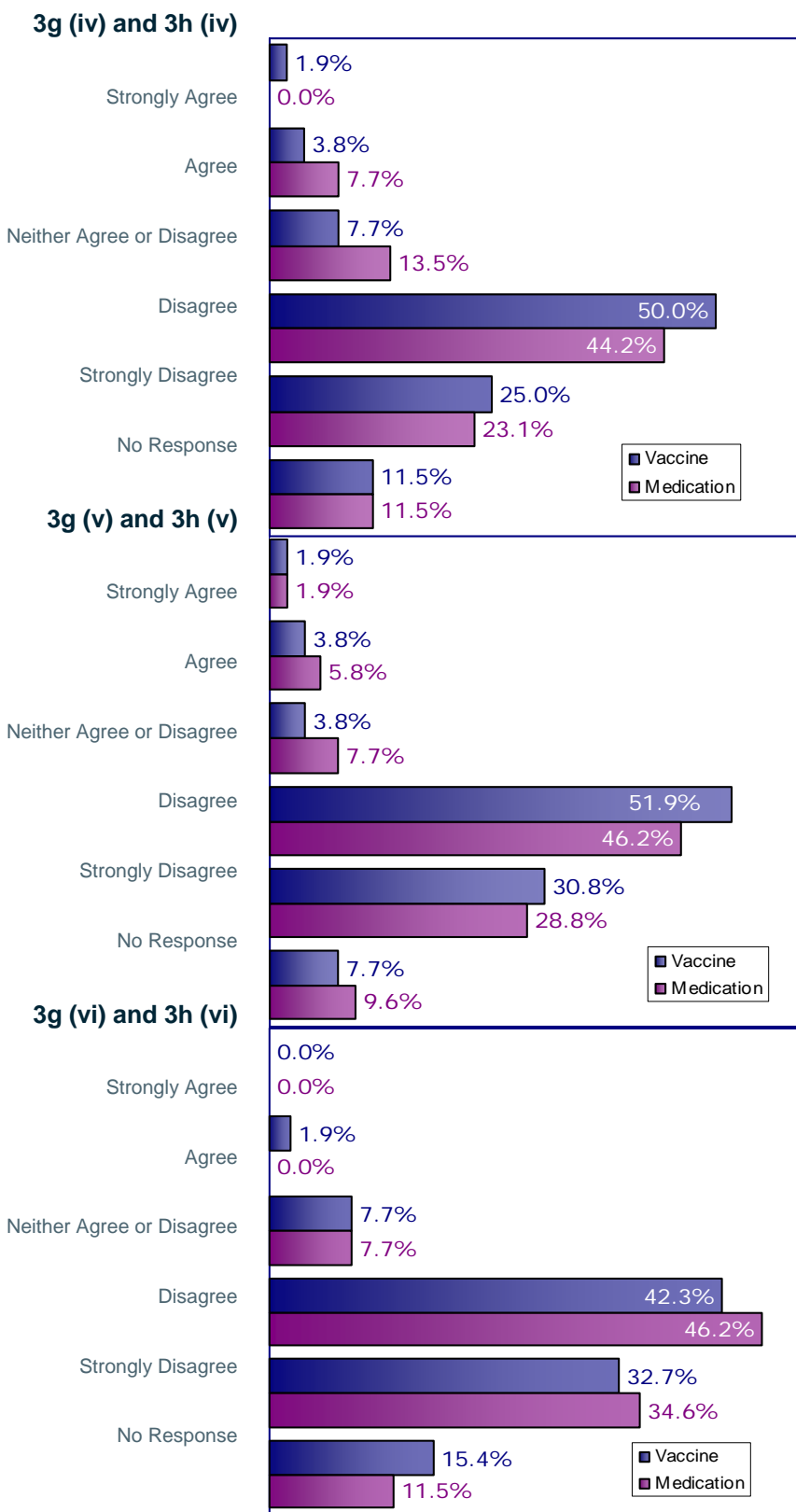


3g (ii) and 3h (ii)



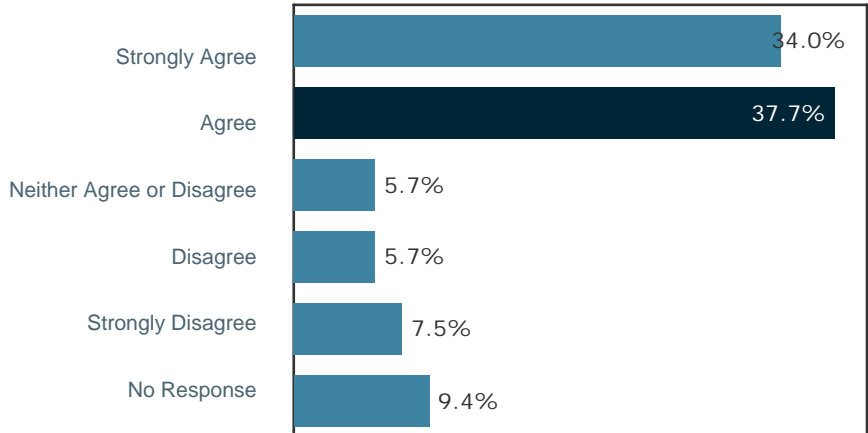
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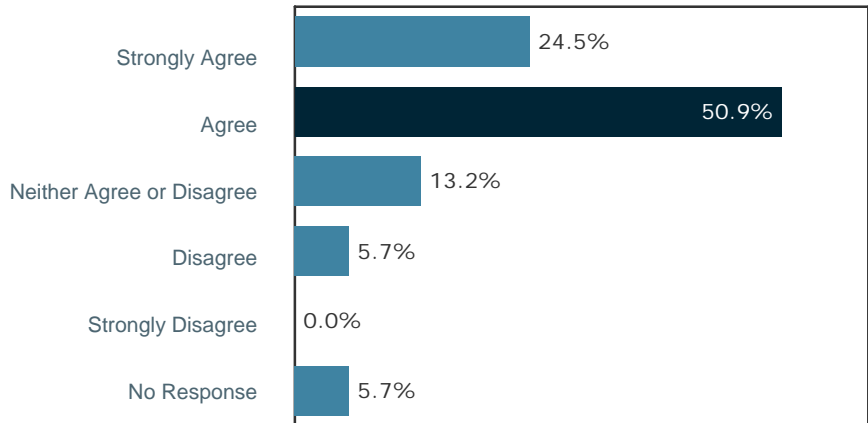




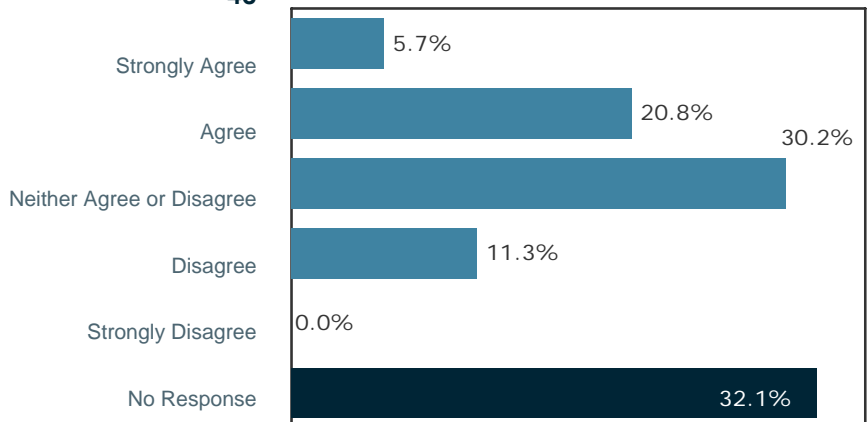
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4b

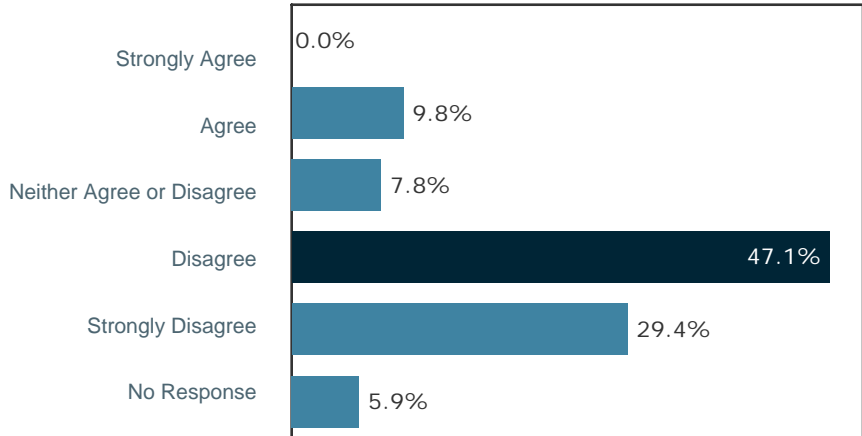


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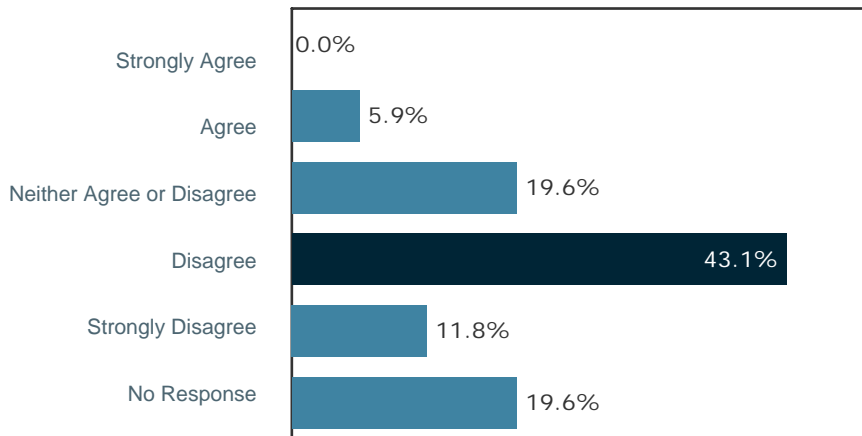




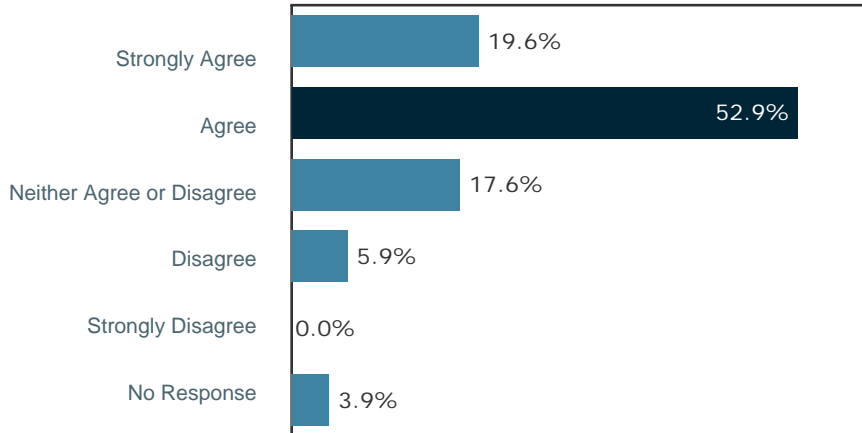
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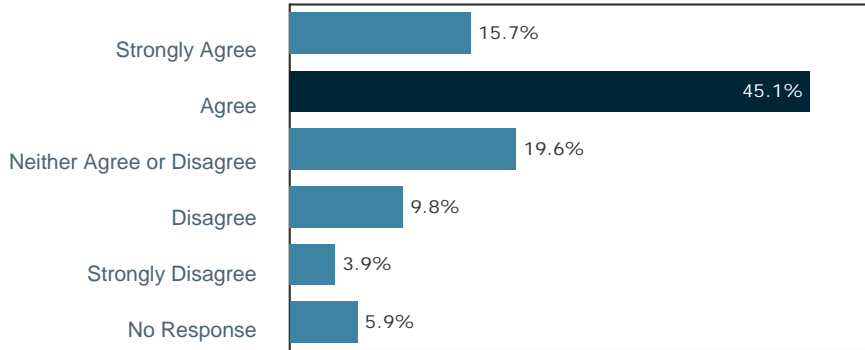


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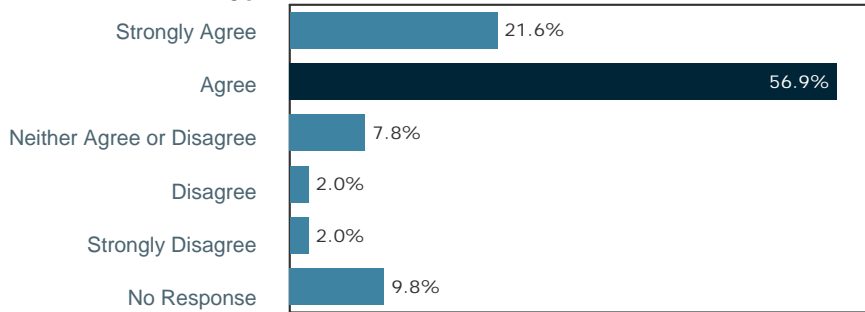




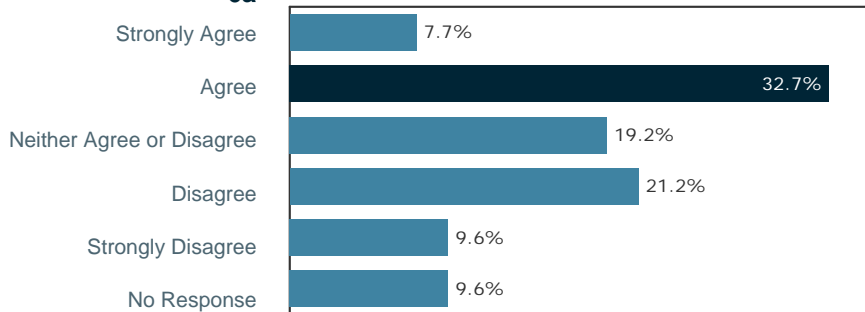
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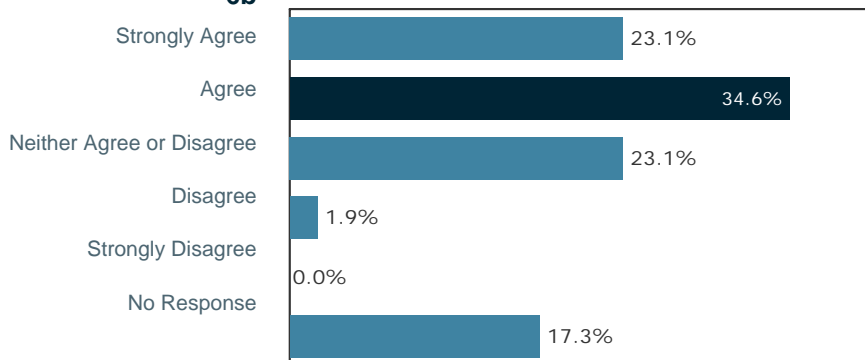
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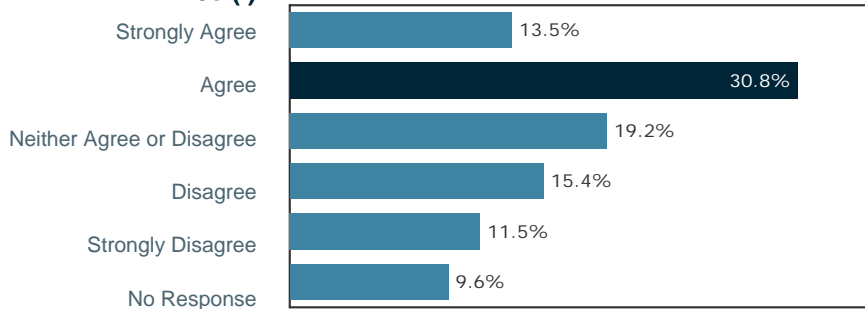


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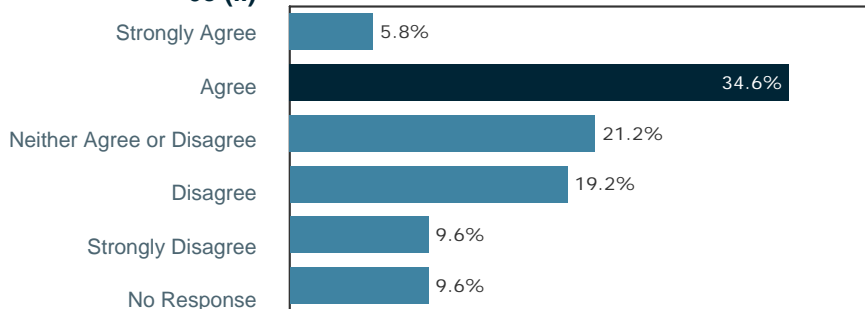




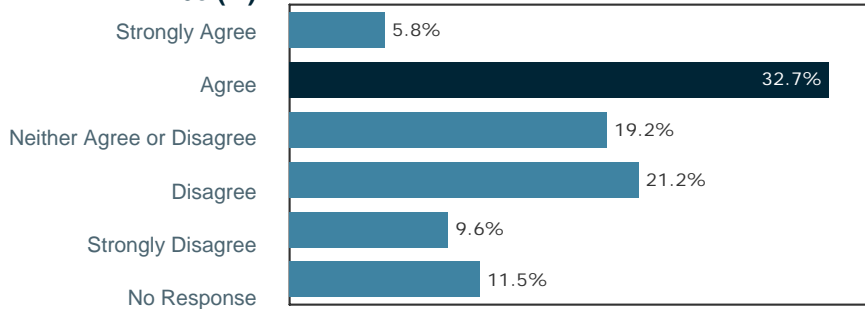
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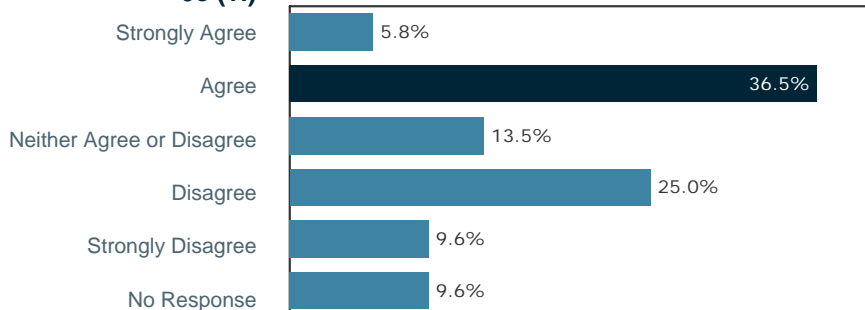
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6c (iii)

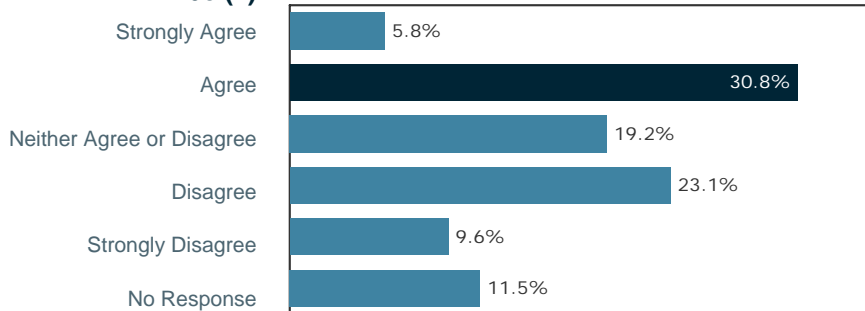


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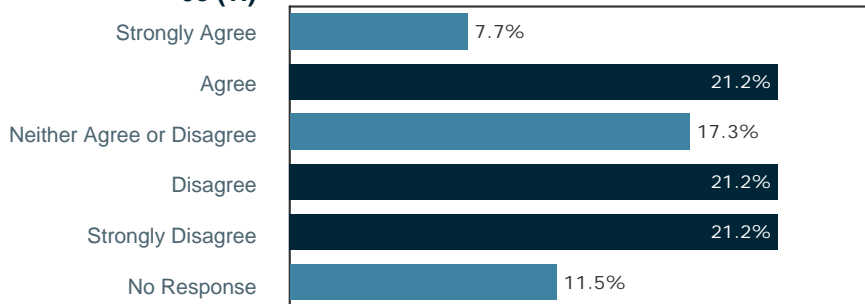




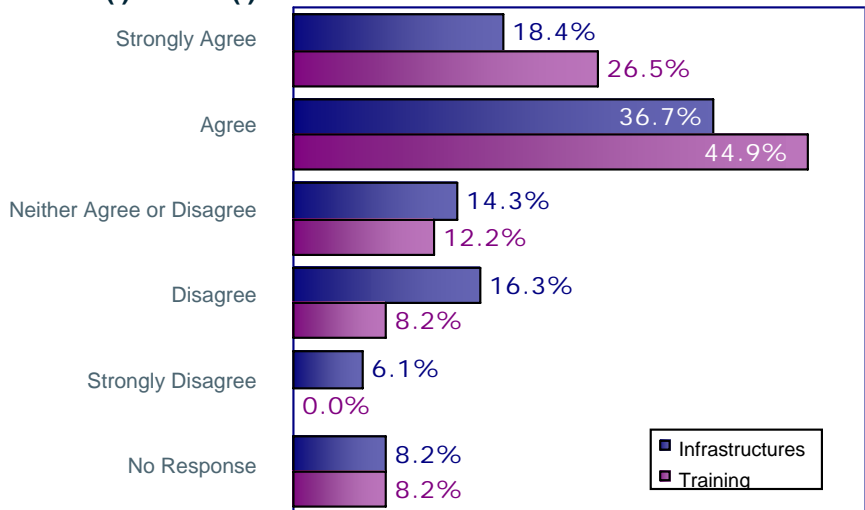
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6c (vi)

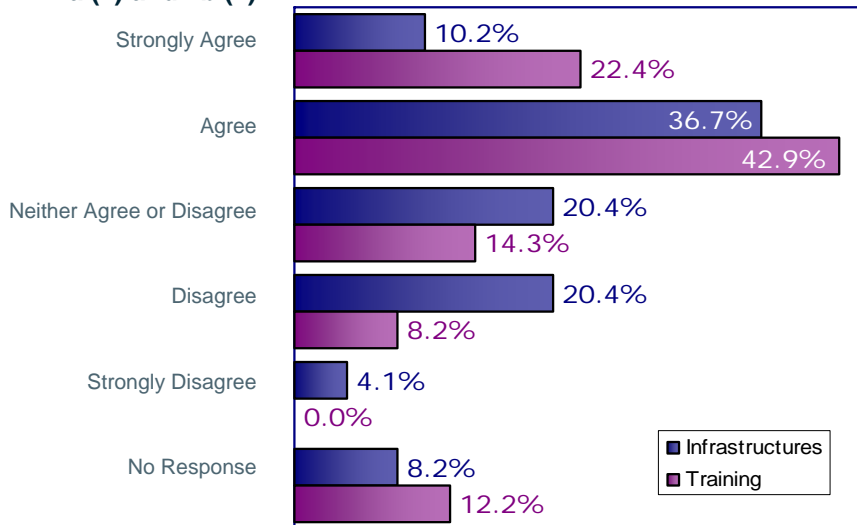


7a (i) and 7b (i)

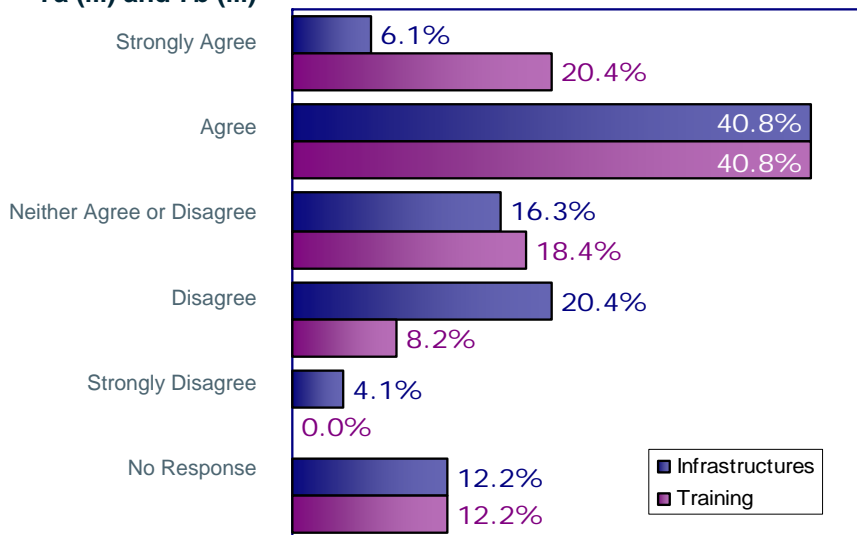




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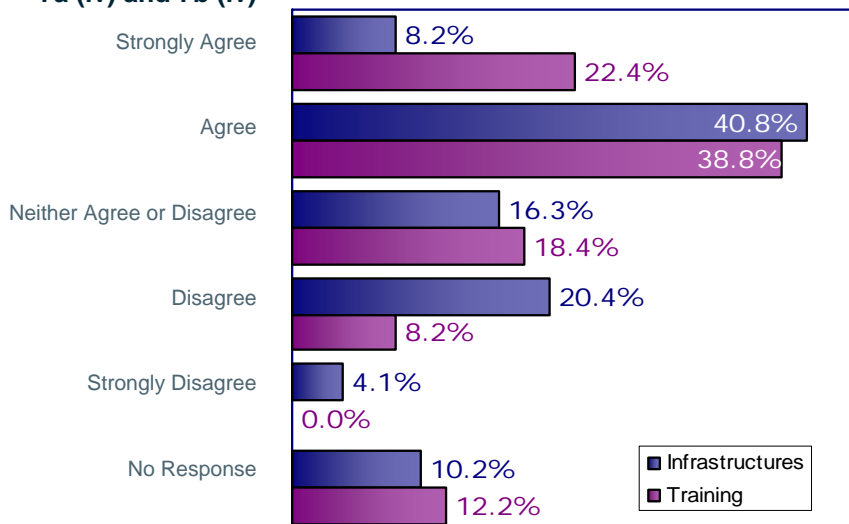


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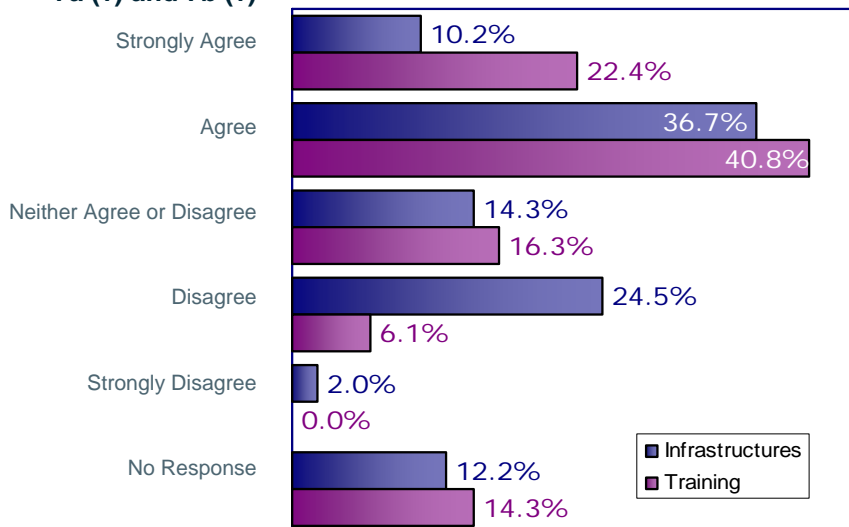




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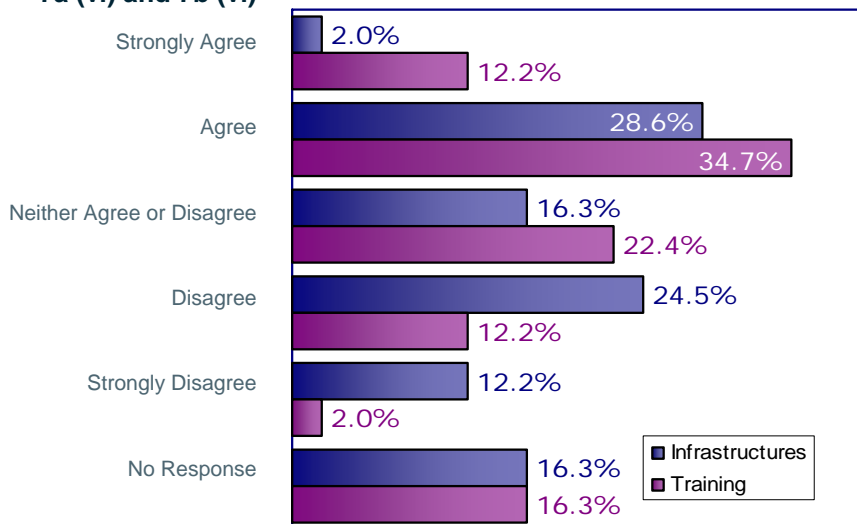


7a (v) and 7b (v)





7a (vi) and 7b (vi)





Appendix 4: List of Pharmaceutical Companies

ABBOTT LABORATORIES INC – Illinois, USA.

ASTRAZENECA PLC – London, UK.

BAXTER INT – Illinois, USA.

BAYER – Leverkusen, Germany.

BRISTOL MYERS SQUIBB CO - New York, USA.

ELI LILLY & CO – Indiana, USA.

GENZYME – London, UK.

GILEAD SCIENCES – California, USA.

GLAXOSMITHKLINE PLC – London, UK.

JOHNSON & JOHNSON – New York, USA.

MERCK & CO INC – New York, USA.

MERCK KGAA – Darmstadt, Germany.

NOVARTIS AG – Basel, Switzerland.

NOVO NORDISK – Copenhagen, Denmark.

PFIZER INC – New York, USA.

RANBAXY LABORATORIES LTD – New Delhi, India.

ROCHE HOLDING LTD – Basel, Switzerland.

SANOFI-AVENTIS – Paris, France.

SCHERING PLOUGH CORP – New York, USA.

WYETH – New York, USA.

In the event that any of the above companies fails to disclose adequate information to substantiate inclusion in the Index, the following company will be included:

BOEHRINGER INGELHEIM – Ingelheim, Germany.



Glossary

DEFINITIONS

Developing Countries

All Middle Income Countries (MICs) and Low Income Countries (LICs) in the Human Development Index (HDI).

Libyan Arab Jamahiriya	Kazakhstan	Palestinian territories	Morocco
FYR of Macedonia	Lebanon	Algeria	Namibia
Antigua and Barbuda	Ecuador	El Salvador	São Tomé and Príncipe
Malaysia	Armenia	Cape Verde	India
Russian Federation	Philippines	Syrian Arab Republic	Solomon Islands
Brazil	China	Guyana	Myanmar
Romania	Suriname	Viet Nam	Cambodia
Mauritius	Saint Vincent and the Grenadines	Kyrgyzstan	Botswana
Grenada	Paraguay	Indonesia	Comoros
Belarus	Tunisia	Uzbekistan	Lao People's Democratic Republic
Bosnia and Herzegovina	Jordan	Nicaragua	Bhutan
Colombia	Belize	Bolivia	Pakistan
Dominica	Fiji	Mongolia	Nepal
Oman	Sri Lanka	Republic of Moldova	Papua New Guinea
Albania	Turkey	Honduras	Ghana
Thailand	Dominican Republic	Guatemala	Bangladesh
Samoa (Western)	Maldives	Vanuatu	Timor-Leste



Venezuela	Turkmenistan	Egypt	Sudan
Saint Lucia	Jamaica	South Africa	Congo
Saudi Arabia	Islamic Republic of Iran	Equatorial Guinea	Togo
Ukraine	Georgia	Tajikistan	Uganda
Peru	Azerbaijan	Gabon	Zimbabwe

Global

All countries in the Human Development Index (HDI).

Least Developed Countries

All Low Income Countries (LICs) in the Human Development Index (HDI).

Madagascar	Kenya	Benin	Ethiopia
Swaziland	The Gambia	Côte d'Ivoire	Central African Republic
Cameroon	Guinea	United Republic of Tanzania	Guinea-Bissau
Lesotho	Senegal	Malawi	Chad
Djibouti	Nigeria	Zambia	Mali
Yemen	Rwanda	DR Congo	Burkina Faso
Mauritania	Angola	Mozambique	Sierra Leone
Haiti	Eritrea	Burundi	Niger

Neglected diseases

The ten diseases identified by the World Health Organization (WHO) [see below] as well as Buruli Ulcer Disease and Pediatric HIV.

Subsidiary

A company which is owned or controlled by another firm or company. Subsidiaries include firms in which a company owns more than 50 percent of the outstanding voting stock, as well as firms in which a company has the power to direct or cause the direction of the management and policies.

Very Poorest

People who have an income below the poverty line with no discretionary disposable income, by definition. The poverty threshold, or poverty line, is the level of income



below which one cannot afford to purchase all the resources one requires to live. Determining the poverty line is usually done by finding the total cost of all the essential resources that an average human adult consumes in one year. This approach is needs-based in that an assessment is made of the minimum expenditure needed to maintain a tolerable life.

Originator Company

An innovative company that carries out the research and development of new drugs.

World Health Organization (WHO) neglected diseases

These are list below.

- » **Human African Trypanosomiasis (HAT or sleeping sickness)**
- » **Chagas disease (American Trypanosomiasis)**
- » **Dengue**
- » **Leishmaniasis (Kala Azar, Black Fever, Sandfly disease, Dum-Dum Fever or Espundia)**
- » **Leprosy (Hansen's disease)**
- » **Lymphatic Filariasis (Elephantiasis)**
- » **Malaria**
- » **Onchocerciasis (River Blindness)**
- » **Schistosomiasis (Bilharzia or Bilharziosis)**
- » **Tuberculosis**



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