

Proposals for achieving equitable global access for treatments, vaccines and diagnostics resulting from the ACT Accelerator

Intro

The Access to COVID-19 Tools Accelerator (ACT-A) was launched by the World Health Organization (WHO), governments and global health actors as an ‘unprecedented and inclusive partnership’ to address some of the challenges linked with the management of the COVID-19 emergency and the development and delivery of needed treatments, vaccines and diagnostics.

Many barriers can hinder the success of this partnership if they are not addressed from the outset. Such barriers include structural issues in the global biomedical research and innovation system, health systems weaknesses and imbalances in global health governance.

The participation of developing countries so governments can decide and implement their national strategies, and civil society organisations (CSOs) in order to bring the reality, needs and views of people that should benefit from the products are key.

Moreover the ACT-A partnership will need to address and find equitable solutions to several challenges: from the imminent need to develop, test and produce safe and effective tools to explore different ways of funding and pricing; from the scaling up manufacturing to meet global demand to organising supply chains that ensure health products are distributed fairly and made available to all people, especially the most vulnerable, in all countries and free of charge at the point of care.

The ACT-A cannot be a simple partnership to disburse funds and set out production timelines. Timely and equitable universal access to the developed health technologies is fundamental and requires clear commitments from all actors involved to prioritize the health of people everywhere and ensure that no one is left behind.

All health technologies financed and developed through ACT-A must be affordable, available and accessible to all on a global scale through appropriate provisions in the governance, decision-making and funding agreements. It is fundamental that all activities and outcomes have a global scope, regardless of the funders and partners involved, and are driven by principles of equitable access. All funding agreements must include specific provisions regarding accessibility to and affordability of resulting COVID-19 related health products as well as transparency on all aspects of the use of the funds.

This briefing sets out the principles and practices which should be operationalised within ACT-A to maximise the collective effort to ensure maximum global health impact and equitable reach. Specifically, the ACT-A partnership should:

- implement full transparency and guarantee public accountability from priority setting to delivery
- work towards the public common good
- guarantee adequate production and fair allocation with a global scope
- ensure that COVID-19 health tools will be affordable to healthcare payers and free to the public at the point of care in all countries
- guarantee collaboration across initiatives

1. Transparency and accountability

Full transparency should be at the core of the ACT-A and effective accountability mechanisms should be in place from inception.

Transparency will be key to securing public trust and support while keeping governments, donors, partners and fund recipients accountable for these investments and how they are used.

To this end, ACT-A partners must be fully transparent and accountable and be responsible for ensuring and enforcing transparency compliance throughout the whole ACT-A processes and collaborations which are established.

- **Development of the partnership, governance and decision-making:** Taking into account the global impact of the results of the partnership and the considerable public investments, the development of the ACT-A should be a timely, fully transparent and inclusive process. Meaningful engagement of public interest civil society organisations and communities in critical decision-making processes must be ensured, following the principles already proposed by civil society and community representatives¹ and establishing concrete and transparent mechanisms to fulfil this objective.
- **Priority setting:** Funding decisions on the selection of tools and interventions that are the most appropriate and effective in widely different settings and different countries must be transparent, free from conflict of interest and whenever possible, based on scientific evidence. A transparent process to prioritize the candidates with best efficacy and safety profile, as well as the ability to scale up manufacturing, should be established.
- **Access policies and practices:** All partners must publish their global access policies and the detailed access practices implemented. Access policies and practices need to respond to the principles of fair and equitable global access and address all phases from early stages of R&D to deployment and procurement.
- **Agreements with third parties:** The publication of every agreement between implementing partners, such as research institutes and consortia and private companies, must be a standard operating procedure for all organisations.
- **R&D and delivery:** The life sciences sector, including the pharmaceutical, medical devices industry and research institutions, must comply with full transparency on the development and deployment of COVID-19-related health products. This includes full transparency on: cost of R&D and manufacturing, public investment contributions and other forms of public support, know-how, clinical trials data and results, manufacturing capacity and selection of production facilities, patent applications and real price (without rebates) of all diagnostics, vaccines and therapeutics.
- **Ethical and Access Committee:** An independent committee - for the whole partnership but with sub-committees for the pillars - should be established to ensure specific focus on access issues from the outset and with a role, among others, to guarantee that single agreements with companies and other partners comply with agreed access principles. Ethical and Access Committee members must be chosen through a transparent process and potential conflicts of interest must be clearly addressed.
- **Public scrutiny:** As well as reporting to donors and actors within the partnership, regular public reports should be published to communicate progress, adherence to the access principles and practices, possible bottlenecks encountered and mitigation measures. This information should be timely, publicly available and accessible to facilitate public scrutiny.

¹ Letter, Civil Society & Community Engagement in the ACT Accelerator (2020). Available at: <https://www.globalfundadvocatesnetwork.org/wp-content/uploads/2020/06/Civil-Society-Community-Engagement-in-the-ACT-Accelerator-ACT-A.pdf>

2. Public common good

The ACT-A should be a truly collaborative effort with solidarity at its core in line with the WHO Solidarity Call to Action². Partners have the opportunity to set an example at the global level by sharing and pooling resources for the common good.

In order to improve efficiency, accelerate scientific progress and ensure global timely and equal access, partners should commit to sharing knowledge, intellectual property and data throughout all the stages of the partnership. To this end, and in response to the definition of public common good, explicit and binding obligations and safeguards should be included on funding and licence agreements throughout the whole ACT-A framework, including the different pillars and workstreams, to ensure that any resulting medical tool is globally available and affordable.

- **Open science:** To align innovation and timely access, open science and research practices for COVID-19-related health tools must be the standard. Funding should be made conditional on the open and real-time publication of results and data, including genetic data on the virus, promising compounds, clinical trial protocols and results.
- **Limits to exclusivities:** The race to develop and distribute COVID-19 tools to counter the pandemic can be hindered by secrecy and exclusivities. Enforcing intellectual property rights to control knowledge can be a key barrier to the progress of research itself, to large-scale production of affordable health technologies and to equitable global access. All partners involved must set up transparent and clear mechanisms to share technology, know-how, data and intellectual property. By making this sharing commitment conditional to funding and global, ACT-A would ensure that low cost versions of any available vaccines, treatments, and tests could be produced and distributed at a scale adequate for every population which needs them worldwide. Companies, research institutions and technology owners must commit either to not enforcing their existing intellectual property, or to sharing this knowledge and rights, by licensing them on a non-exclusive basis globally. Making ACT-A R&D activities conditional on mandatory inclusion to the WHO's Covid Technology Access Pool (C-TAP)³ represents a concrete opportunity to fulfil this aim through an already established tool.

3. Production and fair allocation

ACT-A should aim to maximize the global capacity of development, manufacturing and supply of multiple effective tools to enable as many people as possible to receive care as soon as possible. To this aim, all actors involved in ACT-A must take concrete steps at the earliest opportunity to ensure sufficient production, equitable allocation, and affordable pricing.

- **Scale-up production:** ACT-A partners must support the scaling-up of manufacturing capacity across regions to ensure global demand can be met in a timely manner. This includes increasing production capacities by developing new facilities, as well as facilitating transfer of technology on a non-exclusive basis, without geographical or income constraints, as well as diversifying manufacturers. ACT-A partners involved in production of COVID-19 tools must publish their plans on how they will address manufacturing capacities and technology transfer (including through timely adoption of generic and biosimilar products and define criteria for equitable allocation) to ensure global production and fair distribution. The strengthening of

² World Health Organisation (2020), Solidarity Call to Action. Available at: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/solidarity-call-to-action>

³ World Health Organisation (2020), Covid-19 technology access pool. Available at: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool>

supply chains for the distribution of laboratory testing, reagents and supporting materials, essential medical supplies, COVID-19 diagnostics, medicines and vaccines should be supported by, but not limited to capacity building.

- **Equitable allocation framework:** Health tools developed through ACT-A must be equitably allocated both between developed and less-developed countries, and within countries. The establishment of fair allocation procedures, which are binding and consistent between states and informed by ethical values and public health needs are vital in this regard. This means the most vulnerable and those at highest risk must be prioritized, with supply based on need, rather than ability to pay. An equitable allocation framework must be developed through a transparent and inclusive mechanism and made publicly available. All ACT-A partners must inform and report on how they will guarantee fair allocation. An equitable allocation framework must furthermore take into account the shifting national epidemic profiles and trends and the state of the national health system to deliver COVID services, including the human resources for health density per population capita, the prevalence of key co-morbidities that could worsen outcomes for people with COVID-19 - including HIV and TB -, as well as a country's availability and access to health care services, intensive care and oxygen therapy.
- **Truly global scope:** A truly global scope is needed: nationalist or exceptionalist behaviours will only hinder the success of ACT-A and the overall response to this pandemic. Actions driven by national or private interests could prevent or delay health tools from reaching those at highest risk and the most vulnerable, especially in resource-limited countries. Partners should commit to the global vision of ACT-A as a prerequisite for participation.

4. Affordability

To truly ensure equitable global access and leave no one behind, specific measures on the price of COVID-19 health tools need to be implemented. Health products need to be affordable, available and appropriate for the setting in which they are used and for the gender of the healthcare workers and patients. Access to COVID-19 health products should not compromise equitable access to health products that are essential for other public health needs.

- **Fair and transparent prices:** ACT-A partners must implement transparent methodology for price setting and real prices should be publicly available. Companies need to be transparent in their cost of goods (COGs) and public contributions and subsidies received. Those data must be used in price negotiations. Partners and governments must ensure full transparency in price negotiations with suppliers, including when negotiating volume-based agreements.
- **Free at the point of care:** All actors involved should ensure that treatments, vaccines and diagnostics are priced fairly and affordably to healthcare payers and are free to the public at the point of care in all countries. Legally binding arrangements with private and public partners should be included in all the agreements to realise this aim.

5. Cooperation among initiatives

Whilst it is to be celebrated that several international collaboration initiatives have sprung up to tackle the COVID-19 pandemic, it is imperative that these initiatives do not compete for support and funding to the detriment of each other and of the global effort.

- **Avoiding competition between initiatives:** Governments, donors, and international institutions must ensure that any other initiative for the development and delivery of needed COVID-19 health tools is included or at least aligned with ACT-A and integrates equitable global access principles and practices. This alignment can be achieved through embedding regular and meaningful exchange of information between initiatives, seeking shared stakeholders or shared working groups to facilitate this communication, and committing to full

transparency and support for other initiatives with complementary aims. ACT-A leaders and partners have the opportunity to showcase how cross-initiative collaboration can be built into processes from the earliest stages of development. Transparency and public accountability are critical in ensuring coordination between various initiatives.

Conclusions

The ACT-A has the potential to galvanise governments and global health actors to operationalise the proposed equitable global access policies and practices: implement full transparency and guarantee public accountability from priority setting to delivery, work towards the public common good, guarantee adequate production and fair allocation with a global scope, ensure that COVID-19 health tools will be affordable to healthcare payers and free to the public at the point of care in all countries and create cooperation among initiatives.

Only by integrating those principles and practices and putting the public interest at the core, ACT-A will become a truly unprecedented and inclusive partnership which can contribute to addressing some of the global challenges created by the COVID pandemic.

This briefing was developed within the European Alliance for Responsible R&D and Affordable Medicines

Contact: Viviana Galli, viviana@medicinesalliance.eu

Supporting organisations

1. Access to Medicines Ireland
2. Action against AIDS
3. Africa Health Research Organization
4. AIDES
5. AIDS and Rights Alliance for Southern Africa
6. AIDS-Fondet (The Danish AIDS Foundation)
7. Aidsfonds
8. Altroconsumo
9. ARAS - Romanian Association Against AIDS
10. Asociación por un Acceso Justo al Medicamento (AAJM), Spain
11. Association des Femmes de l'Europe Méridionale (AFEM)
12. Caribbean Vulnerable Communities
13. Centro de pensamiento "Medicamentos, Información y Poder". Universidad Nacional de Colombia d
14. CHOSING IS LIFE CBO
15. Chronic Illnesses Advocacy & Awareness Group
16. Consumer Association the Quality of Life-EKPIZO
17. CurbingCorruption
18. DSW (Deutsche Stiftung Weltbevölkerung)
19. Ecologistas en Acción, Spain
20. European AIDS Treatment Group
21. European Alliance for Responsible R&D and Affordable Medicines
22. European Public Health Alliance (EPHA)
23. FONDATION EBOKO
24. Fundación IFARMA
25. Girls To Mothers' Initiative
26. Global Coalition of TB Activists
27. Global Health Advocates/ Action Santé Mondiale
28. Global Justice Now
29. Health Action International (HAI)
30. Humanity & Inclusion
31. Ibn Sina Academy of Medieval Medicine and Sciences
32. IFARMA Foundation
33. Initiative for Health & Equity in Society
34. Jointed Hands - Zimbabwe
35. Just Treatment
36. Kamukunji Paralegal Trust (KAPLET)
37. Knowledge Commune
38. Knowledge Ecology International (KEI)
39. MSF Access Campaign
40. Nelson Mandela TB HIV Community Information and Resource Center CBO Kisumu Kenya
41. Nigerian Youth Champions for Universal Health Coverage

42. Organization for Health Education Research Services

43. OTMeds - Observatoire de la transparence dans les politiques du médicament

44. Oxfam

45. Pharmaceutical Accountability Foundation

46. Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)

47. Prescrire

48. Princess of Africa Foundation

49. Public Citizen

50. Public Eye

51. Salud por Derecho

52. Salud y Fármacos

53. Sanayee Development Organization SDO

54. Save the Children

55. SELACC - Secretariado Latinoamericano y del Caribe de Cáritas

56. Sidaction

57. SOCIEDAD CANARIA DE SALUD

PUBLICA

58. SOMO Centre for Research on Multinational Corporations

59. STOPAIDS

60. Test Aankoop/Test Achats

61. The International Rescue Committee

62. The ONE Campaign

63. Transparency International Health Initiative

64. Treatment Action Group (TAG)

65. Universities Allied for Essential Medicines - UAEM Brazil

66. Universities Allied for Essential Medicines - UAEM Europe

67. Vaccine Network for Disease Control

68. Wemos

69. World Vision Deutschland e.V.

70. Wote Youth Development Projects

71. Yolse, Santé Publique et Innovation

72. Youth Voices Count

Supporting individuals

1. Alonso Bilbao Jose Luis
2. Bannenberg Wilbert, Pharmaceutical systems consultant
3. Bomu Joshua Jasho
4. Citro Brian, Assistant Clinical Professor of Law, Northwestern Pritzker School of Law
5. Dimitroulias Catherine Sophie, Politologue, juriste, mediateure de justice près la Cour d'Appel de Paris
6. Hakizinka Ida
7. Jarvis Jordan, Doctoral Student
8. Jazra Nelly, Docteur en economie
9. Kamal-Yanni Mohga, Global health policy advisor
10. Kamugasha Roger Paul
11. Kumar Blessina, CEO Global Coalition of TB Activists
12. Lama Reena
13. Mdluli John, HoD Community Engagement
14. Mehta Sonal, Regional Director, South Asia Region IPPF
15. Muriithi George Mugi, Industrial Pharmacist
16. Nam Heesob, PhD, Patent Attorney
17. Rafiq Zulaikha, Professional Consultant
18. Rahman Fifa, Board Member for NGO Delegation, Unitaid Executive Board
19. Rizvi Ali, Filmmaker / Activist
20. Tushabe Bruce
21. Vawda Yousuf, Professor
22. Villa Luisa
23. Wangenya Edward
24. Yakhama Kristine