Farma ter Verantwoording

Good Covid-19 Company Practices (GCCP) Methodology

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The Good Covid-19 Company Practices (GCCP) monitor company practices with regards to the development and manufacturing of Covid-19 vaccines/therapeutics against a matrix of 18 GCCP criteria. These GCCP criteria were developed by translating human rights principles and international standards into concrete company behaviours.

We collect information from the public domain regarding company behaviour and evaluate it using the Covid-19 Company Practices to monitor how businesses developing/marketing Covid-19 vaccines/therapeutics are realising their human rights responsibilities, and how their behaviour is changing over time.

Human rights principles and international standards selection

The main legal basis for these practices is the right to the highest attainable standard of physical and mental health and the right of everyone to enjoy the benefits of scientific progress and its applications in the International Covenant on Economic, Social, and Cultural Rights. The UN Committee on Economic, Social, and Cultural Rights has interpreted the Covenant rights as follows:

> **General Comment No. 14 on the right to health (article 12) in the International Covenant on Economic, Social, and Cultural Rights**
>
> *45. For the avoidance of any doubt, the Committee wishes to emphasize that it is particularly incumbent on States parties and other actors in a position to assist, to provide "international assistance and cooperation, especially economic and technical" which enable developing countries to fulfil their core and other obligations indicated in paragraphs 43 [including provision of essential medicines] and 44 [including immunization against infectious diseases and the prevention, control, and treatment of epidemic and endemic diseases] above.*
>
> **General Comment No. 24 on State obligations under the International Covenant on Economic, Social and Cultural Rights in the context of business activities**
> *22. The Committee is particularly concerned that goods and services that are necessary for the enjoyment of basic economic, social and cultural rights may become less affordable as a result of such goods and services being provided by the private sector, or that quality may be sacrificed for the sake of increasing profits. The provision by private actors of goods and services essential for the enjoyment of Covenant rights should not lead the enjoyment of Covenant rights to be made conditional on the ability to pay, which would create new forms of socioeconomic segregation.*

These Good Practices are further based on the human rights principles and international standards related to these rights, in particular Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (2008) and The United Nations Guiding Principles on Business and Human Rights.

An overview of the main principles and human rights responsibilities applicable to pharmaceutical companies is summarised in Table 1.

Table 1. Human rights responsibilities underlying the Good Covid-19 Company Practices. From Paul Hunt's Guidelines on the Human Rights Responsibilities of the Pharmaceutical Industry.

Principle	**Definition of responsibility**
International cooperation	25. The company should engage constructively with key international and other initiatives that are searching for new, sustainable, and effective approaches to accelerate and enhance research and development for neglected diseases. 30. As part of its access to medicines policy, the company should issue non-exclusive voluntary licences with a view to increasing access, in low-income and middle-income countries, to all medicines. The licences, which may be commercial or non-commercial, should include appropriate safeguards, for example, requiring that the medicines meet the standards on quality, safety and efficacy set out in Guideline 20 [on pharmaceutical regulatory requirements]. They should also include any necessary transfer of technology. The terms of the licences should be disclosed.
Transparency	6. In relation to access to medicines, the company should be as transparent as possible. There is a presumption in favour of the disclosure of information, held by the company, which relates to access to medicines. This presumption may be rebutted on limited grounds, such as respect for the confidentiality of personal health data collected during clinical trials. 38. The company should disclose: i. as much information as possible about its pricing and discounting arrangements;
Equality, non-discrimination & equity	5. Whenever formulating and implementing its strategies, policies, programmes, projects, and activities that bear upon access to medicines, the company should give particular attention to the needs of disadvantaged individuals, communities, and populations, such as children, the elderly and those living in poverty. The company should also give particular attention to the very poorest in all markets, as well as gender-related issues. 33. When formulating and implementing its access to medicines policy, the company should consider all the arrangements at its disposal with a view to ensuring that its medicines are affordable to as many people as possible. In keeping with Guideline 5, the company should give particular attention to ensuring its medicines are accessible to disadvantaged individuals, communities, and populations, including those living in poverty and the very poorest in all markets. The arrangements should include, for example, differential pricing between countries, differential pricing within countries, commercial voluntary licences, not-for-profit voluntary licences, donation programmes, and Public Private Partnerships. 34. The arrangements should take into account a country's stage of economic development, as well as the differential purchasing power of populations within a country. The same medicine, for example, may be priced and packaged differently for the private and public sectors within the same country.
Commitments & accountability	1. The company should adopt a human rights policy statement which expressly recognises the importance of human rights generally, and the right to the highest attainable standard of health in particular, in relation to the strategies, policies, programmes, projects and activities of the company. 2. The company should integrate human rights, including the right to the highest attainable standard of health, into the strategies, policies, programmes, projects, and activities of the company. 10. The company should have a publicly available policy on access to medicines setting out general and specific objectives, time frames, reporting procedures, and lines of accountability.

Some of the Good Covid-19 Company practices are also related to standards in international law including the Trade-Related Aspects of Intellectual Property Rights (15 April 1994) and the Doha Declaration on the TRIPS Agreement and Public Health (2001).

Good Covid-19 Company Practices development

We translated human rights principles and international standards into concrete company behaviours for access to medicines through iterative review rounds. In round 1 a list of good practices was developed by Wilbert Bannenberg (WB). In round 2 we retained those practices that are aligned with human rights principles and international standards (identified by WB, Katrina Perehudoff (KP), and Tessa Jager (TJ)). We also developed a stoplight scoring system for each practice that can be judged based on information in the public domain.

In round 3 the practices and scoring system were reviewed by external experts in pharmaceutical policy, intellectual property, and the political economy of pharmaceuticals.

In round 4 WB and TJ independently piloted the list of company practices on 4 vaccine and 3 therapeutics companies to determine their applicability and adequacy. We revised the practices and scoring system following feedback from round 3 and 4.

This process resulted in 18 Good Covid-19 Company Practices that can be categorised in four domains corresponding with overarching human rights responsibilities of companies: commitments & accountability, transparency, international cooperation; equality, non-discrimination & equity.

Company selection

A purposive sample of seven Covid-19 vaccine and therapeutics developers and/or manufacturers were selected if they had products in phase 3 clinical trials, with (emergency / restricted) use authorization, or market authorisation in any country. See Table 2.

Table 2. List of seven Covid-19 vaccine and therapeutics developers and/or manufacturers included in the GCCP evaluation.

Type of product	Companies and their products
Vaccines	• Moderna - mRNA-1273 • Pfizer/ BioNTech / Fosun Pharma - BNT162b2 • Johnson & Johnson (Janssen) - Ad26.COV2.S • AstraZeneca/University of Oxford - AZD1222
Therapeutics	• Gilead - remdesivir • Eli Lilly - bamlanivimab • Regeneron/Roche - casirivimab+imdevimab

Data collection & analysis

Data was collected through an online snowball search of Google Scholar and by crowdsourcing information from the Covid-19-Access Listserv and the Covid-19 Innovations for All Consortium. To the best of our knowledge, the evidence on which the scores are based is truthful and reliable, and that can be found in the public domain. To aid the transparency of this assessment, a brief description of the evidence underlying each score is publicly available on our website.

Information about company behaviour was scored on a three-point scale (green-yellow-red) that was tailored to each of the 18 company practices. In general, the scale denoted:

- Green: Behaviour is compliant with Good Covid-19 Company Practice
- Yellow: Behaviour is partially compliant with Good Covid-19 Company Practice
- Red: Behaviour is not compliant with Good Covid-19 Company Practice

Practices for which there is too little information in the public domain to score are indicated in grey.

Company consultation

Prior to publication each of the seven companies were invited to provide information about their activities related to each of the 18 practices. Responses were received from six out of seven companies. Their substantive responses were used to confirm or supplement our findings.

Any practices for which we could not find information online and that the companies did not specify further will be scored black.

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