Farma ter Verantwoording

GCCP practices, principles and scoring

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About

Whether Covid-19 medicines will be available and affordable to all who need them is largely dependent on the developer's/manufacturer's development, testing and marketing behaviour. To our knowledge, no monitoring exercise has systematically evaluated the behaviour of developers/manufacturers of Covid-19 vaccines and therapeutics.

The objective of the Good Covid-19 Company Practices project is to maximize transparency of company behaviour and equitable access to Covid-19 vaccines and therapeutics. The Good Covid-19 Company Practices (GCCP) present 18 company actions to evaluate to what extent pharmaceutical developers'/manufacturers' behaviour is in line with human rights principles and international standards for equitable access to medicines.

The Pharmaceutical Accountability Foundation has identified overarching human rights principles that should guide company action regarding their responsibilities towards access to medicines:

(A) Commitments and Accountability;

(C) International Cooperation;

(E) Equality, non-discrimination & equity;

(T) Transparency.

This document includes a list of the 18 good company practices grouped under the four human rights principles (A,C,E,T). 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.

Below is the list of 18 company practices (A1, A2…) and scoring criteria outlining how company behaviour is judged. Further information can be found in the Methodology document.

A. Commitments and Accountability

A1 The company publishes a global access plan for its product.

Human Rights Guidelines for Pharmaceutical Companies
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.

Scoring criteria

GREEN: The company has published an access plan;

YELLOW: The company has published an access plan, but not for all countries;

RED: The company has not published an access plan.

A2 The company commits to comply with human rights standards in relation to product development and marketing.

Human Rights Guidelines for Pharmaceutical Companies
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.

Scoring criteria
GREEN: The company requires the independent verification of their compliance with a code that includes human rights standards in relation to product development and marketing;

YELLOW: The company commits to complying with a code that includes human rights standards in relation to product development and marketing;

RED: The company makes no statement about adhering to a code that includes human rights standards in relation to product development and marketing, or the codes that the company commits to does not include human rights standards.

C. International cooperation

C1 The company commits to C-TAP or MPP

Human Rights Guidelines for Pharmaceutical Companies
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. They should also include any necessary transfer of technology. The terms of the licences should be disclosed.

Scoring criteria:

GREEN: The company is actively contributing to C-TAP or MPP;

YELLOW: The company commits to support MPP or C-TAP but has not taken action;

RED: The company made no clear statement of supporting C-TAP or MPP.

C2 The company commits to not enforcing the exclusive rights of Covid-19 related patents.

Human Rights Guidelines for Pharmaceutical Companies
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. They should also includeany necessary transfer of technology. The terms of the licences should be disclosed.

Scoring criteria
GREEN: The company does not enforce all patent rights on the COVID product worldwide or licenses patent rights in this field of use;

YELLOW: The company does not enforce patents in some jurisdictions or is open to licensing of its patent rights in this field of use in some jurisdictions;

RED: The company normally enforces all patent rights for its COVID product and is not open non-enforcement or to licensing its patent rights in this field of use.

C3 The company supplies to, or signs agreements with, the vaccines or therapeutics pillar of the ACT Accelerator.

Human Rights Guidelines for Pharmaceutical Companies
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.

42) When participating in a Public Private Partnership, a company should continue to conform to these Guidelines.

43) If a company joins a Public Private Partnership, it should disclose any interest it has in the Partnership's decisions and activities.

44) So far as these Guidelines bear upon the strategies, policies, programmes, projects, and activities of Public Private Partnerships, they shall apply equally to such Partnerships.

45) A company that joins a Public Private Partnership should take all reasonable steps to ensure the Partnership fully conforms to these Guidelines.

Scoring criteria
GREEN: Company has supplied to the vaccines or therapeutics pillar of the ACT Accelerator or signed an agreement to supply.

YELLOW: Company states it is negotiating with the vaccines or therapeutics pillar of the ACT Accelerator but no agreement is yet signed.

RED: Company has published it cannot supply the vaccines or therapeutics pillar of the ACT Accelerator.

E. Equality, non-discrimination & equity

E1 The company makes the active ingredient available on reasonable grounds. [Only for therapeutics]

Human Rights Guidelines for Pharmaceutical Companies
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.

Scoring criteria
GREEN: The company makes API available to any buyer on publicly established and foreseeable grounds;

YELLOW: The company makes limited quantities of API available for compounding or testing (for example to pharmacopoeias or laboratories);

RED: The company restricts access to, or does not share or sell API.

E2 The company commits to full technology transfer to other manufacturers.

This includes rights in patents, data, knowhow, and access to biologic resources, to third parties to scale up production and expand access specifically in low- and middle-income markets.

Human Rights Guidelines for Pharmaceutical Companies
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. They should also include any necessary transfer of technology. The terms of the licences should be disclosed.

Scoring criteria
GREEN: company commits to technology transfer to entities necessary to produce the Covid-19 product without any territorial restrictions.

YELLOW: company commits to technology transfer to entities with territorial restrictions.

RED: company does not commit to technology transfer.

E3 The company commits to non-profit or 'fair' pricing.

Human Rights Guidelines for Pharmaceutical Companies
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.

Scoring criteria
GREEN: The company publishes evidence of non-profit pricing for its COVID product;

YELLOW: The company commits to non-profit pricing of COVID product(s) but has not yet published evidence, or commits to non-profit pricing only for a restricted period of time;

RED: The company uses for-profit pricing / no commitment to no-profit pricing.

E4 The company equitably distributes supplies globally. [Only applies to vaccines]

Human Rights Guidelines for Pharmaceutical Companies
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.

Scoring criteria
GREEN: The company sells maximum 20% of its 2020-2021 stocks to HICs;

YELLOW: The company sells between 20%-50% of its 2020-2021 stocks to HICs;

RED: The company sells more than 50% of its 2020-2021 stocks to HICs

E5 The company does not seek protection beyond the minimum criteria in TRIPS, or enforces TRIPS+ measures [where applicable].

Human Rights Guidelines for Pharmaceutical Companies
26) The company should respect the right of countries to use, to the full, the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994), which allow flexibility for the purpose of promoting access to medicines, including the provisions relating to compulsory licensing and parallel imports. The company should make and respect a public commitment not to lobby for more demanding protection of intellectual property interests than those required by TRIPS, such as additional limitations on compulsory licensing.

Scoring criteria
GREEN: The company does not seek protection beyond the minimum criterion of TRIPS, or enforces any TRIPS+ measure in any jurisdiction on its COVID-19 product;

YELLOW: The company enforces/applies for TRIPS+ measures on a COVID product in some jurisdictions but not in others;

RED: The company enforces/applies for TRIPS+ measures in any jurisdiction where it can do so.

E6 The company agrees to waive exclusive rights in regulatory test data [where applicable].

Human Rights Guidelines for Pharmaceutical Companies
31) As a minimum, the company should consent to National Drug Regulatory Authorities using test data (i.e. the company should waive test data exclusivity) in least-developed countries and also when a compulsory licence is issued in a middle-income country.

Scoring criteria
GREEN: The company waives regulatory test data in all jurisdictions where the law provides for data exclusivity;

YELLOW: The company waives regulatory test data in a few but not all jurisdictions where the law provides for data exclusivity OR the company makes a vague statement about waiving regulatory data exclusivity but does not take action to do so;

RED: The company does not take any action to waive regulatory test data exclusivity.

T. Transparency

T1 The company publishes its R&D costs.

Human Rights Guidelines for Pharmaceutical Companies
23) The company should make a public commitment to contribute to research and development for neglected diseases. Also, it should either provide in-house research and development for neglected diseases, or support external research and development for neglected diseases, or both. In any event, it should publicly disclose how much it contributes to and invests in research and development for neglected diseases.

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.

Scoring criteria

GREEN: The company publicly declares its R&D costs for COVID product(s);

YELLOW: The company makes a vague declaration (for example, declares R&D costs of whole portfolio, but not for COVID-product specific);

RED: The company has not made a public declaration of R&D costs.

T2 The company publishes its profit margin.

Human Rights Guidelines for Pharmaceutical Companies
38) The company should disclose:

i. as much information as possible about its pricing and discounting arrangements;

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.

Scoring criteria
GREEN: The company publicly declares its profit margin for COVID product(s);

YELLOW: The company makes a vague declaration on the profit margin (for example, company-wide declaration, not product specific), or states its profit margin only for a restricted time period;

RED: The company has not made a public declaration on the profit margin.

T3 The company publishes the average and/or marginal costs of production.

Human Rights Guidelines for Pharmaceutical Companies
38. The company should disclose:
i) as much information as possible about its pricing and discounting arrangements;

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.

Scoring criteria
GREEN: The company publicly declares the production costs for the COVID product;

YELLOW: The company makes a vague declaration on production costs for its COVID product (for example, a company-wide declaration, not product specific);

RED: The company has not made a public declaration on the production costs.

T4 The company publishes its production capacity

Human Rights Guidelines for Pharmaceutical Companies
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.

Scoring criteria
GREEN: The company has published their production capacity;

YELLOW: The company has published its capacity, but exact capacity remains vague;

RED: The company has not published a statement about its production capacity

T5 The company publishes the public subsidies it received during product development and/or testing.

Human Rights Guidelines for Pharmaceutical Companies
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.

Scoring criteria
GREEN: The company has published a statement specifying the public funding (sources and amounts) it receives to develop COVID products;

YELLOW: The company has published a statement saying that it receives public funding for the development of COVID products, but does not mention sources or amounts;

RED: The company has not published a statement about public funding it receives.

T6 The company publishes the text of licensing agreements.

Human Rights Guidelines for Pharmaceutical Companies
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. They should also include any necessary transfer of technology. The terms of the licences should be disclosed.

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.

Scoring criteria
GREEN: The company publishes the full text of licensing agreements, or agrees that

the licensing partner does so;

YELLOW: The company publishes licensing agreement with highly redacted clauses, or agrees that the licensing partner does so;

RED: The company does not publish any licensing agreement, or does not allow that the licensing partner does so.

T7 The company registers its clinical trials in public repositories.

Human Rights Guidelines for Pharmaceutical Companies
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.

Scoring criteria
GREEN: The company registers any trials plus results disclosed in public clinical trial databases or other transparent register;

YELLOW: The company registers the trial before its marketing approval but does not disclose any data;

RED: The company registers no trial before product is approved or registers trial(s) but does not disclose data after the product is marketed