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 19 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 3 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

a. Good: global access plan

b. Better: global access plan based on human rights standards, with measurable targets (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.')

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

a. Good: official human rights statement (website or press release)

('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.')

b. Better: integration of human rights into company practices. Eg: adopting the human rights-based approach, conducting health equity impact assessments, having a CSR/ESG branch in the company…

('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')

C International Cooperation

C1 The company commits to C-TAP or MPP

a. Good: committed to C-TAP or MPP

b. Better: what have you shared (or are you intending to share) with C-TAP or MPP?

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

a. Good: not enforcing patents

b. Better: no patent thickets/evergreening, not for a limited duration at the discretion of the company

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

a. Good: signed agreement with COVAX or makes donations

b. Better: supplied the contracted quantities in time to COVAX (+ which percentage of your production that actually ends up in COVAX? How many donations actually arrive and are they near their expiry date?)

C4 The company agrees to license its Covid-19 medical products to other companies

a. Good: licensing

b. Better: non-exclusive, transparent licensing (see annex on guide to responsible licensing) (+how many has the company issued?)

E Equality, non-discrimination & equity

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

a. Good: the company does not monopolise the production of raw materials to prevent generic manufacturing

b. Better: the company is willing to dispense of the raw material to other companies and enables the production of generics/pharmaceutical compounding

E2 The company commits to full technology transfer to other manufacturers

a. Good: 'standard' technology transfer

b. Better: 'full' tech transfer (legal, skills, knowledge and IP)

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

a. Good: fair pricing

b. Better: non-profit

c. Nuanced: differential pricing – good if at least 1/10 of the price that the HIC paid

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

a. Good: at least 50% of supplies have been sold to low **or** middle income countries

b. Better: at least 50% of supplies have been sold to low income countries or COVAX

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

a. Good: the company does not enforce TRIPS+ measures

b. Better: the company does not seek protection beyond the **minimum** criteria in TRIPS

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

T Transparency

Note: all questions are for the specific COVID vaccine/therapeutic only; not for all products of the company

T1 The company publishes its R&D costs.

T2 The company publishes its profit margin.

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

T4 The company publishes its production capacity.

a. Good: the company publishes its production capacity

b. Better: the company delivers on its global production promises

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

a. Good: the company publishes the public subsidies received

b. Better: if any public subsidies were received during product development and/or testing, the company recognises those rights to the product.

T6 The company publishes the text of licensing agreements.

T7 The company registers its clinical trials in public repositories.