Farma ter Verantwoording

Good Covid-19 Company Practices (GCCP) Policy Brief

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How are pharmaceutical companies[1] performing in the race to develop and distribute Covid-19 vaccines and therapeutics for all?

The Good Covid-19 Company Practices (GCCP) present 18 actions that allow us to monitor whether these pharmaceutical companies are acting in line with human rights principles and international standards for equitable access to medicines. The Pharmaceutical Accountability Foundation's GCCP scorecard illustrates how four Covid-19 vaccine companies (AstraZeneca, Johnson & Johnson, Moderna and Pfizer) and three therapeutics companies (Regeneron, Eli Lilly and Gilead) are performing on these 18 good practices. Each company receives a green, yellow, or red score on those company practices that can be judged based on information in the public domain.

How does the Good Covid-19 Company Practice scorecard work?

Whether Covid-19 medicines will be available and affordable to all who need them is related to the company's intellectual property management, licensing, pricing and distribution policies.

The Pharmaceutical Accountability Foundation has identified four overarching human rights principles that should guide company action on their Covid-19 vaccines / therapeutics: (1) Commitments & accountability; (2) Transparency; (3) International Cooperation; (4) Equality, non-discrimination & equity.

The 18 Good Covid-19 Company Practices were developed by translating human rights principles and international standards into concrete company behaviours.

Main findings to date

- Three out of four vaccine companies state they are guided by the United Nations Guiding Principles on Business and Human Rights. This means these companies are aware of their human rights responsibilities and the critical impact of their actions on the enjoyment of human rights worldwide.
- Vaccine companies performed best on transparency practices (such as disclosure of R&D costs, profit margins, and production capacity). There is still room for some vaccine developers and all therapeutics companies to improve the transparency of their R&D and marketing practices.
- Most vaccine and therapeutics companies have taken little action to make their products available on an equitable and non-discriminatory basis worldwide. The GCCP identified important examples of companies committing not to enforce their patents on vaccines (Moderna[2]) and to fairly price vaccines (Johnson & Johnson[3]). These are steps all companies producing Covid-19 medicines should take (where applicable). Most vaccine and therapeutics companies in our sample failed to engage in responsible licensing of their Covid-19 products.

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[1] The term 'pharmaceutical company' is used broadly to include companies working independently and in consortia to develop and/or market a pharmaceutical to prevent or treat COVID-19.

[2] 'Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic' (*Moderna*, 8 October 2020) <https://investors.modernatx.com/node/10066/pdf> accessed 15 December 2020.

[3] Johnson & Johnson, 'Testimony of Macaya Douoguih,M.D., M.P.H. Head of Clinical Development and Medical Affairs, Janssen Vaccines and Prevention Johnson & Johnson Submitted to the Oversight & Investigation Subcommittee of the U.S. House of Representatives Energy & Commerce Committee (*J&J*, 21 July 2020) <https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony%20-%20Douoguih%2020200721_0.pdf> accessed 29 November 2020; de Balie, 'Turning Tables: Een Vaccin voor Iedereen?' (de Balie, 07 December 2020) <https://debalie.nl/programma/turning-tables%20-een-vaccin-voor-iedereen-07-12-2020/> accessed 07 December 2020.

The good, the bad, and the hazy company practices in our study

Good

- Johnson & Johnson[4] and AstraZeneca[5] both committed to non-profit vaccine pricing for the duration of the pandemic.
- AstraZeneca has increased the world's capacity to produce its vaccine. They have four agreements with manufacturers in different territories, helping the first vaccine supplies reach more people in a shorter amount of time than if AstraZeneca remained the world's only producer.
- Gilead signed non-exclusive licensing agreements to manufacture its therapeutic drug remdesivir[6] for distribution in 127 (mostly) low and lower-middle income countries.[7] Non-exclusive licensing is important to overcome the obstacles that patent rights cause; for example, it may enable multiple manufacturers to produce the Covid product. This may ramp up the availability of the product.

Bad

- No company is currently supporting the WHO's Covid-19 Technology Access Pool[8] or the Medicines Patent Pool[9]. Nor have most companies published their licensing agreements. Non-exclusive licensing is important to overcome the obstacles that patent rights cause; for example, it may enable multiple manufacturers to produce the Covid product. This may ramp up the availability of the product.
- Moderna has openly stated it seeks to earn profit from its Covid vaccine despite having received sizable public funding for research and development from the US government.[10]
- All vaccine developers, except AstraZeneca, have made agreements to sell more than 50% of their expected 2020-2021 supplies to high-income countries, thereby limiting the supplies available to potential low- and middle-income country purchasers.[11]

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[4] Johnson & Johnson, 'Testimony of Macaya Douoguih,M.D., M.P.H. Head of Clinical Development and Medical Affairs, Janssen Vaccines and Prevention Johnson & Johnson Submitted to the Oversight & Investigation Subcommittee of the U.S. House of Representatives Energy & Commerce Committee (*J&J*, 21 July 2020)

[5] AstraZeneca, 'AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19' (*AstraZeneca*, 23 November 2020) <https://www.astrazeneca.com/media-centre/press-releases/2020/azd1222hlr.htm>l accessed 20 January 2021.

[6] Note: this good practice happened before the WHO Solidarity trial found that remdesivir *"had little or no effect on overall mortality, initiation of ventilation and duration of hospital stay in hospitalized patients."* https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments

[7] Gilead, 'Voluntary Licensing Agreements for Remdesivir' (*Gilead*) <https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir> accessed 15 December 2020.

[8] The WHO's Covid-19 Technology Access Pool (C-TAP) is an initiative aimed at compiling voluntary shared Covid-19 technology related knowledge, intellectual property and data. It aims to accelerate the development and marketing scale-up of Covid-19 related products in order to make products available globally and equitably. See <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool> (accessed 16 December 2020).

[9] The Medicines Patent Pool (MPP) is a WHO-backed organisation that partners with relevant stakeholders to prioritise and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. It has offered its expertise to C-TAP to address the current Covid-19 crisis. See https://medicinespatentpool.org/ and https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-prepared-to-offer-expertise-in-licensing-and-patent-pooling-to-address-the-current-covid-19-crisis/, accessed 16 December 2020.

[10] 'Moderna Announces Expansion of BARDA Agreement to Support Larger Phase 3 Program for Vaccine (mRNA-1273) Against COVID-19' (*Moderna*, 26 July 2020) <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-expansion-barda-agreement-support-larger-phase> accessed 28 November 2020

[11] Ewen Callaway, 'The Unequal Scramble for Numbers' (*Nature*, 24 August 2020) <https://www.nature.com/articles/d41586-020-02450-x> accessed 10 November 2020.

Hazy

- Vaccine and therapeutic companies do not publish on their website their exact R&D costs and profit margins on their Covid-19 products, and there is limited transparency of their product prices.
- It is unclear how companies will realise their commitments to equitably distribute their Covid-19 products worldwide.

Policy recommendations

For companies developing/manufacturing Covid-19 products

- Those who have not already done so should **commit to aligning their business practices with human rights principles**, such as the United Nations Guiding Principles on Business and Human Rights and the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.
- Each company should **engage with the WHO C-TAP and the MPP** to offer licensing agreements. Such agreements need to include terms and conditions that are driven by public health needs as pioneered by the MPP.[12] Agreements need include transfer of IP, know-how, data and technology where needed to (re)-produce the product.[13] Licence agreements should be made publicly available in full text.
- Major company action is still needed to ensure medicines are not only **fairly priced** but also **equitably distributed** worldwide.[14] This action includes realising technology transfer, non-profit/fair pricing, and not enforcing or licensing of patents on lifesaving Covid-19 medicines.

For governments

- Those who have not already done so should commit to WHO C-TAP and realise those commitments by, among other things, applying funding conditionalities to publicly funded developers of Covid-19 products.
- Stimulate companies to adhere to GCCP through procurement contracts or funding agreements.
- Use and support the use of TRIPS flexibilities when needed.

For WHO/GAVI/CEPI

- Require companies contracted by the ACT Accelerator (vaccines and therapeutics) to adhere to GCCP.
- WHO should provide model licensing agreements (such as MPP) and regular updates on progress made with C-TAP.

[12] Medicines Patent Pool, 'Business Model' (*MPP*) <https://medicinespatentpool.org/who-we-are/business-model/> accessed 20 January 2021.
[13] Paul Hunt, 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (11 August 2008) UNGA 63rd session (2008) UN Doc A/63/263.
[14] See Paul Hunt.

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