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Dear Ms. Balbin,

Following UN letter (OL/ITA 3/2021), dated October 14, 2021, I have the honor to submit Italy's reply to Joint Communication by the six UN Special Procedures that have requested Italian Authorities to provide them with information related to unequal access to COVID-19 vaccines, medicines, health technologies, diagnostics and health therapies.

By this reply, we take the opportunity to reiterate our firm willingness to continue full and extensive cooperation with all UN Special Procedures Mandate-Holders.

Should additional information be made available, allow me to ensure you that we will promptly share it with you.

Please accept, Ms. Balbin, the assurances of my highest consideration.

Sincerely yours,

/ Ambassador Gian Lorenzo Cornado

To the attention of: Working Group on the issue of human rights and transnational corporations and other business enterprises; the Special Rapporteur on the right to development; the Special Rapporteur on the right to everyone to the enjoyment of the highest attainable standard of physical and mental health; the Independent Expert on the promotion of a democratic and equitable international order; the Independent Expert on human rights and international solidarity and the Special Rapporteur on extreme poverty and human rights,



MINISTRY OF FOREIGN AFFAIRS AND INTERNATIONAL COOPERATION

Inter-ministerial Committee for Human Rights

Italian Reply to the Joint communication sent by the Working Group on the issue of human rights and transnational corporations and other business enterprises; the Special Rapporteur on the right to development; the Special Rapporteur on the right to everyone to the enjoyment of the highest attainable standard of physical and mental health; the Independent Expert on the promotion of a democratic and equitable international order; the Independent Expert on human rights and international solidarity and the Special Rapporteur on extreme poverty and human rights



Italian Reply to the Joint communication sent by the Working Group on the issue of human rights and transnational corporations and other business enterprises; the Special Rapporteur on the right to development; the Special Rapporteur on the right to everyone to the enjoyment of the highest attainable standard of physical and mental health; the Independent Expert on the promotion of a democratic and equitable international order; the Independent Expert on human rights and international solidarity and the Special Rapporteur on extreme poverty and human rights

Following the Joint Communication from Special Procedures, the Italian authorities are pleased to provide the following information.

At the outset, Italy would like to remind that the commercial aspects of intellectual property fall into the exclusive competence of the European Union, according to the art. 207 of the Treaty of the Functioning of the European Union.

The position of the EU on the role of intellectual property in the framework of trade policy responses to the COVID-19 crisis is contained in the enclosed communication of the EU to the Council for Trade Related Aspects of Intellectual property rights. of June 4, 2021 (Document IP/C/W/680).

Italy would therefore like to refer to the answer that the European Union has provided on this point (Ref. Ares (2022) 793376 - 03/02/2022 - sante.ddg1.c.4(2022) 384166).

As for replies to the questions posed by the UN SPs, all the following indications are provided according to the national capacity of the Country.

We recognise the extensive COVID-19 immunisation as a global public good and our commitment for all collaborative efforts in this respect. At this regard, in order to improve global access to Covid-19 vaccines, we take the opportunity to underline the critical importance, inter alia, to strengthen the resilience of supply chains, to increase and diversify global, local and regional vaccine manufacturing capacity, as well as to build expertise in this field, to make available raw materials needed to produce vaccines and to build infrastructures to deploy vaccines.

Italy has been involved in the production of Covid-19 vaccines, through collaboration with Oxford University for the production of the Astra Zeneca vaccine, in the Pomezia (RM) industrial site, which has signed a contract with Europe for millions of doses. Another industrial site interested in the production of Covid-19 vaccines is Catalent in Anagni. Italy has started testing a new vaccine nationwide and supports multiple production sites to prevent drug and vaccine shortages.

Since the beginning of the pandemic, Italy has been among the first countries to support the importance of equal and universal access to vaccines, treatments and tests for Covid-19, based on a principle of international solidarity according to which no one will be safe until everyone is safe. Indeed the Italian Government strongly believes that only through international cooperation and the strengthening of the global health system it will be possible to put an end to the pandemic.

On this basis in 2020 Italy, together with its main partners, contributed to the creation of the ACT Accelerator ("Access to Covid-19 Tools Accelerator") and, its vaccine pillar, the "COVAX Facility". contributing to the latter with a package of 385 million euros and the donation of 45 million vaccine doses. According to the latest data almost 38 million doses have been delivered on the ground.

Vaccines are a key tool to gradually eradicate the virus, but, in the meanwhile, people may still get sick. Italy has recently financed the ACT-A Oxygen Task force with a view of ensuring availability of this essential tool in the Covid-19 response and beyond.

Furthermore, as the Presidency of the G20, Italy has placed health and pandemic preparedness at the center of the international agenda in the face of new potential health threats. Italy has co-hosted with the European Commission the Global Health Summit, under G20 Presidency, and the principles adopted - the Rome Declaration - will be a blueprint for common action and to strengthen the early warning and overall preparedness to avoid the next pandemic, also in advancing the One Health approach.

Italy has promoted, in the context of the G20 Presidency, a concrete discussion on financing. The G20 Health-Finance last October 29 proposed a set of recommendations, establishing a joint Task-Force for coordination between health and financial authorities. We believe that this initiative can improve, also from a financial point of view, international governance in the area of prevention, preparedness and response to future pandemics, fostering collaboration between the G20, the WHO, other global health actors, the World Bank and international financial institutions.

Italy will engage constructively in the negotiations of a new agreement, convention or other legal instrument on pandemic preparedness to further strengthen the multilateral health architecture, with the World Health Organization at its center, and building resilient national health systems.

Italy, through the Ministry of Health, has been following the 'race' for the development of vaccines that can contribute to the protection of populations and the interruption of deleterious effects of the pandemic from the very beginning.

Italy participated in the European instrument of the Advance Purchase Agreement (APA), to be offered to companies that were developing anti-Covid-19 vaccines. Each country, after the conclusion of each agreement, is entitled - unless it exercises an opt-out - to a share ("pro rata") related to the country's population in relation to the total EU population. In the case of Italy, the share is therefore 13.65%. The APAs provide for matching of an initial quota on cost of vaccines made available by the EU Commission, to be used from ESI (Emergency Support Instrument) funds, further financed by the EU Member States if needed. Subsequent coverage, up to the full price of the vaccine, are paid by EU Member States, only on the basis of positive results in phase III studies and after the delivery of doses with marketing authorisations. Contracts are then signed by the European Commission with concerned companies.