To: Jonge, H.M. de (Hugo)[5.1.2e @minvws.nl]
Cc: 5.1.2e , 5.1.2e , (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 5.1.2e , (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e 5.1.2e 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e , 5.1.2e , 5.1.2e (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 5.1.2e , (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 1 2 , (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 5.1.2e , [5.1.2e @minvws.nl]
From: 5.1.2e , 1 2 , (5.1.2e)
Sent: Sun 2/28/2021 11:44:21 AM
Subject: FW: Johnson & Johnson COVID-19 Vaccine Authorized by FDA
Received: Sun 2/28/2021 11:44:22 AM
image003.png

Ha Hugo,

Was niet naar goede adres gestuurd.

Groet,
5.1.2e

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Van: Office Of 5.1.2e 5.1.2e 5.1.2e < 5.1.2e @its.jnj.com>
Datum: zondag 28 feb. 2021 3:02 AM
Aan: Minister van VWS < 5.1.2e @minvws.nl>
Kopie: 5.1.2e @minvws.nl' < 5.1.2e @minvws.nl'>
Onderwerp: Johnson & Johnson COVID-19 Vaccine Authorized by FDA

Johnson & Johnson

janssen Infectious Diseases & Vaccines
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

February 27, 2021

First Single-Dose Vaccine Represents Significant Advance in Fight Against Global Pandemic

Dear Minister De Jonge,

Johnson & Johnson today announced that the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for the Company's single-dose COVID-19 Vaccine, developed by its Janssen Pharmaceutical Companies. **The Janssen vaccine now becomes the first single-shot COVID-19 vaccine authorized for use in the United States.**

This decision was based on the totality of scientific evidence, including data from the Phase 3 ENSEMBLE study, demonstrating that the Janssen vaccine **prevented COVID-19 and protected against severe disease, hospitalization, and death.**

Johnson & Johnson has begun shipping its COVID-19 vaccine to the U.S. government and **plans to deliver 100 million single-dose vaccines in the United States during the first half of 2021.** The U.S. government will manage allocation and distribution of the vaccine in the U.S. This will be prioritized according to the populations identified by the CDC's Advisory Committee on Immunization Practices (ACIP) guidelines.

Johnson & Johnson also recently announced its submission of a Conditional Marketing Authorisation Application to the **European Medicines Agency** as well as an application for Emergency Use Listing (EUL) with the **World Health Organization** for the vaccine. In addition, rolling regulatory submissions have been initiated in several countries worldwide.

Equitable access is at the forefront of Johnson & Johnson's COVID-19 response. The Company's single-dose vaccine and its compatibility with standard vaccine distribution channels align with WHO's recommendations for medical

interventions in a pandemic setting, which emphasize **ease of distribution, administration, and compliance.** The Johnson & Johnson COVID-19 vaccine is estimated to remain stable for two years at -4°F (-20°C), and a maximum of three months in routine refrigeration at temperatures of 36-46°F (2 to 8°C).

We believe the Johnson & Johnson single-shot COVID-19 vaccine is a critical tool for fighting this global pandemic. A vaccine that protects against COVID-19, especially the most dire outcomes of hospitalization and death, can help ease the strain on health systems worldwide and the fears of millions around the globe.

Full details on today's FDA authorization can be found in our press release. The Janssen COVID-19 Vaccine has not been approved or licensed by FDA. Read more:
Janssen COVID-19 Vaccine - EUA Fact Sheet for Healthcare Providers Administering Vaccine (janssenlabels.com)

We will continue to keep you updated regarding the Janssen COVID-19 vaccine, including progress being made with other regulatory bodies around the world.

With best regards,

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5.1.2e

Johnson & Johnson