PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Senate Select Committee on COVID-19

Australian Government's Response to the COVID-19 Pandemic

22 May 2020

PDR Number: IQ20-000246

Question Subject: TGA approved medicines

Type of Question: Written

Senator: Katy Gallagher

Question:

Have any medicines been approved by the Therapeutic Goods Administration for the treatment of COVID-19. If so, which medicines.

Answer:

No medicines have been approved for the treatment of COVID-19 in Australia at this time.

Some products have been provided to individual patients through unapproved products pathways, such as the Authorised Prescriber and Special Access Schemes.

The Department of Health, through the Therapeutic Goods Administration (TGA), liaises closely with potential sponsors and international regulatory counterparts to monitor the intensive international research effort that is currently underway. The TGA will prioritise and expedite the evaluation of any applications from industry or research sponsors for the treatment of COVID-19 or vaccination against the SARS-CoV2 virus.

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Senate Select Committee on COVID-19

Australian Government's Response to the COVID-19 Pandemic

22 May 2020

PDR Number: IQ20-000248

Question Subject: Palmer Foundation hydroxychloroquine purchase

Type of Question: Written

Senator: Katy Gallagher

Question:

Is this claim by Mr Clive Palmer true: "Clive Palmer's Palmer Foundation has bought over 32,900,000 doses of hydroxychloroquine. Millions of doses of the drug have already arrived in Australia. The Palmer Foundation has already paid for the drug in the form of tablets and bulk pharmaceuticals. The Palmer Foundation has donated the drug to the Australian Government to be placed on the National Medical Stockpile so it may be made available free to all Australians."
If so:

(a) on what date/s did "million of doses of the drug" arrive in Australia.
(b) on what date did the Australian Government agree to accept a donation from Clive Palmer's Palmer Foundation and how was the agreement reached.
(c) on what date/s was the donation received.
(d) on what date/s was the donation "placed on the National Medical Stockpile".
(e) on what dates has the drug been "made available free to all Australians".

If not: What steps has the Australian Government taken to correct the record.

Answer:

To the extent information is known to the Department of Health the statement is factually correct.

(a) The donation of hydroxychloroquine arrived in Australia over a number of weeks between 16 April 2020 and 12 May 2020.

(b) Formal acceptance of the donation in writing from the Department was made on 15 April 2020, with the condition that the product be placed within the National Medical Stockpile and to be provided free of charge on physician's prescription either potentially for therapy or prophylaxis of COVID-19 infection and/or for use in clinical trials.

(c) The donation of hydroxychloroquine arrived in Australia over a number of weeks between 16 April 2020 and 12 May 2020.

(d) The product required analytical and physical testing by a TGA-certified commercial facility, prior to packaging and labelling by the same facility. The first shipment of 7 million tablets completed testing and packaging for the stockpile on 14 May 2020.

(e) The donation is available for dispatch from the National Medical Stockpile in accordance with advice of the Australian Government Chief Medical Officer.

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Senate Select Committee on COVID-19

Australian Government's Response to the COVID-19 Pandemic

22 May 2020

PDR Number: IQ20-000253

Question Subject: National Incident Room first stakeholder update on the outbreak

Type of Question: Written

Senator: Rex Patrick

Question:

In answer to a question on notice, the Health Minister has advised that on 10 January 2020 the National Incident Room provided "its first stakeholder update on the outbreak. This was provided to the Chief Medical Officer and the Minister's Office, as well as a number of other Australian Government agencies."
A. Which Government agencies were provided with that update?
B. Please provide the Committee with a copy of that initial stakeholder update?

Answer:

On 10 January 2020, the National Incident Room (NIR) in the Department of Health distributed 'Stakeholder Update 1' to the following Australian Government agencies:

- Attorney-General's Department
- Australian Federal Police
- Department of Foreign Affairs and Trade
- Department of Prime Minister and Cabinet
- Department of Defence
- Department of Home Affairs
- Department of Agriculture
- Department of Health

A copy of this Stakeholder Update is provided at Attachment A.

Australian Government

Department of Health

National Incident Room

Viral Pneumonia - China

Report Details

Report Type	Stakeholder Update
Issued	2020-01-10
Reference	NIR #2238
Update	1

Key Points

Epidemiological Situation

- Chinese authorities have made a preliminary determination of a novel (or new) coronavirus, identified in a hospitalised person with pneumonia in Wuhan, Hubei Province China[1].
- There are many different coronaviruses that affect humans and animal including for example, coronaviruses that cause the common cold but also more clinical serious conditions such as Severe Acute Respiratory Syndrome (SARS) and Middle Eastern Respiratory Syndrome (MERS).
- To date there has been 44 hospitalised cases of viral pneumonia in Wuhan reported to Australia's National Focal Point (World Health Organization (WHO) Event Information Site report 05 January 2020) However, open source media is reporting 59 cases (09 January 2020).
- There appears to be a common epidemiological link, where those affected attended (as vendors, traders or customers) a live seafood market. Media is reporting that the market also sold birds, other animals and organs from wildlife.[2]
- Chinese health authorities have implemented monitoring, control and prevention measures including contact tracing, isolation of cases and public risk communications. The market was closed and has undergone environmental sanitation and disinfection.[2]
- There is no evidence of ongoing human to human transmission at this time. Additionally, there has been no reported transmission to health care workers. [2]

[1] WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China https://www.who.int/china/news/detail/09-01-2020-who-statement-regarding-cluster-of-pneumonia-cases-in-wuhan-china - accessed 10 January 2020

[2] WHO Disease Outbreak News, Pneumonia of unknown cause - China https://www.who.int/csr/don/05-january-2020-pneumonia-of-unkown-cause-china/en/?fbclid=IwAR3dxY_pgmvcpud1Isir4DxYblsDnum1WGgnoFf_IsvR4PBoQLrC4F1_oww - accessed 10 January 2020

- There has been no reported deaths linked to this outbreak.[2]
- Investigation and laboratory testing in China is ongoing.

Full detail at Appendix A.

Response Actions

China

National authorities have reported the following response measures:

- One hundred and twenty-one close contacts have been identified and are under medical observation;
- Pathogen identification and the tracing of the cause is ongoing;
- Wuhan Municipal Health Commission carried out active case finding, and retrospective investigations have been completed;
- Environmental sanitation and further hygiene investigations are under way.[2]

Australia

- The National Incident Room is actively monitoring this outbreak.
- No specific measures are recommended for travellers to Australia at this time. This is consistent with the recommendations of the WHO under the IHR. [2]

Full detail at Appendix B.

Risk

More comprehensive information is required to understand the current status and epidemiology of the outbreak, and the clinical picture. Further investigations are also required to confirm the source, modes of transmission, extent of infection and any effective medical countermeasures.

Chinese authorities have noted, while the virus in question can cause severe illness in some patients, it does not transmit readily between people.

Australia has excellent public health laboratory capacity to test for and identify viral and bacterial agents and strong public health systems and border measures to detect and manage ill travellers.

Planned Action

Australian National Focal Point (Health)

- The National Incident Room will continue to review any available information on the outbreak and will update advice as and when required.
- More information around human-to-human or prolonged transmission, and potential vectors is needed before a formal risk assessment can be completed.

Authorised By

Celia Street, FAS Office of Health Protection

Distribution

MO (Health, FA, HA, AWR), AHPPC, CDNA, PHLN, NHEMS, Health (OHP SES, OHP MSAU, OHP EL2, IADHB, Media), DAWR, DFAT (Humanitarian, Health Policy, CHS), DIO, HA (ABF, EMA, Health Policy), PM&C

Further Information

This report is issued by the Australian National Focal Point (NFP). The Australian NFP is located in the Office of Health Protection at the Australian Government Department of Health and its activities are supported 24/7 by the National Incident Room. The Australian NFP is established under the *National Health Security Act 2007*.

For more information on the event(s) in this report, contact the NFP at or .

Appendix A: Epidemiological Situation

Situation

- On 31 December 2019, the WHO China Country Office was informed of cases of pneumonia of unknown aetiology (unknown cause) detected in Wuhan City, Hubei Province of China. As of 3 January 2020, a total of 44 patients with pneumonia of unknown aetiology have been reported to WHO by the national authorities in China. Of the 44 cases reported, 11 were severely ill, while the remaining 33 patients are in stable condition.[2]
- Chinese national authorities report that all patients were isolated and received treatment in Wuhan medical institutions. [2]
- China has strong public health capacities and resources to respond and manage respiratory disease outbreaks.[1]
- Preliminary identification of a novel virus in a short period of time is a notable achievement and demonstrates China's increased capacity to manage new outbreaks and share information. [1]
- In addition to treating the patients in care and isolating new cases as they may be identified, public health officials remain focused on continued contact tracing, conducting environmental assessments at the seafood market, and investigations to confirm the identity of the pathogen causing the outbreak. [1]
- High volumes of Chinese nationals undertaking international travel during the upcoming Lunar New Year season has prompted some Asian countries such as Singapore, Hong Kong, South Korea, Thailand and Taiwan to implement increased border surveillance.[3]

Background

- Human coronaviruses are common throughout the world.
- Coronaviruses are a large family of viruses with some causing less-severe disease, such as the common cold, and others more severe disease such as MERS and SARS. Some transmit easily from person to person, while others do not. According to Chinese authorities, the virus in question can cause severe illness in some patients and does not transmit readily between people. [1]
- It is the potential clinical severity of MERS-CoV and SARS-CoV has led to intensified global interest and the heightened concerns around disease transmission.

[3] China's new virus looms over Lunar New Year travel https://asia.nikkei.com/Spotlight/Society/China-s-new-virus-looms-over-Lunar-New-Year-travel - accessed 10 January 2020

Appendix B: Response Actions

In-Country

- China has a Physical Containment Level 4 Laboratory, based in Wuhan, where laboratory testing is being undertaken.

Border Measures in Australia

- No specific measures are recommended for travellers to Australia at this time. This is consistent with the recommendations of the WHO under the IHR.
- This novel coronavirus is not an LHD under the *Biosecurity Act 2015*, however existing processes for screening ill travellers at the border will capture individuals presenting with a fever. Should it become necessary, a disease can be determined as an LHD very quickly.

Laboratory Testing in Australia

- The preliminary determination of a novel coronavirus assists with disease detection and response.[1]
- Through the Victoria Infectious Diseases Reference Laboratory, Pathwest (WA), Queensland Health Forensic and Scientific Services and the Institute for Clinical Pathology and Medical Research (NSW) there is good capability to test for coronaviruses and capability to detect this novel coronavirus is being established.