मनोज कुमार, भा०प्र०से० कार्यपालक निदेशक

पत्रांक: SHSB/PM/552/2020/. **1**.0.9.५...

सेवा में,

प्रबंध निदेशक, BMSICL ,पटना सभी सिविल सर्जन

पटना/दिनांक. 29-05-2020

विषय: BMSICL से Hydroxychloroquine- 200mg Tablet प्राप्त करने के संबंध में। प्रसंग: इस कार्यालय के पत्रांक 197 दिनांक 14.04.2020 एवं 268 दिनांक 18.04.2020 महाशया/महाशय.

उपर्युक्त विषय के संबंध में कहना है कि प्रासंगिक पत्रों द्वारा जिलों में कोरोना वायरस (COVID- 19) के संक्रमण से बचाव हेतु चिकित्सकों एवं किमियों के रोग-प्रतिरोधक (Prophylaxis) के रूप में ICMR के National Taskforce for COVID-19 द्वारा अनुशंसित Hydroxychloroquine-200mg Tablet IP की 13,02,700 टैबलेट (10 Tab./Per Person- for 1st Day & next 3 weeks) एवं पुन: दो सप्ताह (04 Tablets. Per Person- for next 4th & 5th week) के लिए Hydroxychloroquine-200mg Tablet IP की 5,24,900 टैबलेट अर्थात 18,27,600 टैबलेट का जिलावार आबंटनादेश के अनुरूप BMSICL द्वारा जिलों को आपूर्ति की गयी है।

- 2. उक्त प्रासंगिक पत्रों द्वारा निर्गमित आबंटनादेश के अतिरिक्त चिकित्सकों एवं कर्मियों हेतु पुन: आगामी दो सप्ताह (04 Tablets. Per Person- for next 6th & 7th week) के लिए Hydroxychloroquine-200mg Tablet IP की 5,24,900 टैबलेट का जिलावार आबंटन एवं इसके अतिरिक्त Asympatomatic frontline workers and paramilitary/ police personnel involved in COVID-19 related activities के लिए 1,08,000 टैबलेट अर्थात कुल 6,32,900 टैबलेट का जिलावार आबंटनादेश इस पत्र के साथ संलग्न है।
- 3. भारतीय आयुर्विज्ञान अनुसंधान परिषद (ICMR) के D.O. No. VIR/4/2020/ECD-I, दिनांक 22.03.2020 के साथ उपलब्ध कराये गये National Taskforce for COVID-19 के Advisory on use of hydroxy-chloroquine एवं Recommendation for empiric use of hydroxy-chloroquine for prophylaxis of SARS-CoV-2 infection में निहित दिशा-निर्देशों के अनुरुप चिकित्सकों की निगरानी में Hydroxychloroquine-200mg Tablet का सदुपयोग सुनिश्चित किया जाये। मार्गदर्शिका के अनुसार Retinopathy, Hypersensitivity to HCQ, G6PD deficiency, Pre-existing cardiomyopathy and cardiac rhythm disorders से ग्रसित व्यक्तियों के लिए उक्त औषि को contraindications की श्रेणी में रखा गया है। इसके अतिरिक्त 15 वर्ष से कम आयु के बच्चों तथा गर्भवती महिलायें एवं स्तनपान कराने वाली माताओं को यह औषि नहीं दिये जाने की अनुशंसा मार्गदर्शिका में की गयी है। उक्त औषि का उपयोग प्रासंगिक पत्र एवं इस पत्र के साथ संलग्न ICMR के मार्गदर्शिका (कुल 06 पृष्ठ) के अनुरूप चिकित्सकों की निगरानी, में ही कराया जाये।

परिवार कल्याण भवन, शेखपुरा, पटना— 800 014, दूरभाषः 0612—2290328, फैक्सः 0612—2290322, वेबसाइट: www.statehealthsocietybihar.otg



4. अत: संलग्न जिलावार आबंटनादेश के अनुरूप Hydroxychloroquine-200mg Tablet की आपूर्ति BMSICL द्वारा रिजनल वेयरहाउस के माध्यम से सभी सिविल सर्जन/जिला औषधि भंडार को आपूर्ति की जायेगी।

अनुलग्नक: यथोकत।

विश्व सभाज

(मनोज कुमार)



मनोज कुमार, भा०प्र०से० कार्यपालक निदेशक

| SHSB/PM/552/2020/ |
|-------------------|
|                   |

सेवा में,

प्रबंध निदेशक, BMSICL,पटना सभी सिविल सर्जन

| The Action  |  |  |  |  |  |  |  |  |
|-------------|--|--|--|--|--|--|--|--|
| पटना/दिनांक |  |  |  |  |  |  |  |  |

again.

विषय: BMSICL से Hydroxychloroquine- 200mg Tablet प्राप्त करने के संबंध में। प्रसंगः इस कार्यालय के पत्रांक 197 दिनांक 14.04.2020 एवं 268 दिनांक 18.04.2020 महाशया/महाशय.

उपर्युक्त विषय के संबंध में कहना है कि प्रासंगिक पत्रों द्वारा जिलों में कोरोना वायरस (COVID- 19) के संक्रमण से बचाव हेतु चिकित्सकों एवं किमियों के रोग-प्रतिरोधक (Prophylaxis) के रूप में ICMR के National Taskforce for COVID-19 द्वारा अनुशंसित Hydroxychloroquine-200mg Tablet IP की 13,02,700 टैबलेट (10 Tab./Per Person- for 1st Day & next 3 weeks) एवं पुन: दो सप्ताह (04 Tablets. Per Person- for next 4th & 5th week) के लिए Hydroxychloroquine-200mg Tablet IP की 5,24,900 टैबलेट अर्थात 18,27,600 टैबलेट का जिलावार आबंटनादेश के अनुरूप BMSICL द्वारा जिलों को आपूर्ति की गयी है।

- 2. उक्त प्रासंगिक पत्रों द्वारा निर्गमित आबंटनादेश के अतिरिक्त चिकित्सकों एवं कर्मियों हेतु पुनः आगामी दो सप्ताह (04 Tablets. Per Person- for next 6th & 7th week) के लिए Hydroxychloroquine-200mg Tablet IP की 5,24,900 टैबलेट का जिलावार आबंटन एवं इसके अतिरिक्त Asympatomatic frontline workers and paramilitary/ police personnel involved in COVID-19 related activities के लिए 1,08,000 टैबलेट अर्थात कुल 6,32,900 टैबलेट का जिलावार आबंटनादेश इस पत्र के साथ संलग्न है।
- 3. भारतीय आयुर्विज्ञान अनुसंधान परिषद (ICMR) के D.O. No. VIR/4/2020/ECD-I, दिनांक 22.03.2020 के साथ उपलब्ध कराये गये National Taskforce for COVID-19 के Advisory on use of hydroxy-chloroquine एवं Recommendation for empiric use of hydroxy-chloroquine for prophylaxis of SARS-CoV-2 infection में निहित दिशा-निर्देशों के अनुरुप चिकित्सकों की निगरानी में Hydroxychloroquine-200mg Tablet का सदुपयोग सुनिश्चित किया जाये। मार्गदर्शिका के अनुसार Retinopathy, Hypersensitivity to HCQ, G6PD deficiency, Pre-existing cardiomyopathy and cardiac rhythm disorders से ग्रसित व्यक्तियों के लिए उक्त औषि को contraindications की श्रेणी में रखा गया है। इसके अतिरिक्त 15 वर्ष से कम आयु के बच्चों तथा गर्भवती महिलायें एवं स्तनपान कराने वाली माताओं को यह औषि नहीं दिये जाने की अनुशंसा मार्गदर्शिका में की गयी है। उक्त औषि का उपयोग प्रासंगिक पत्र एवं इस पत्र के साथ संलग्न ICMR के मार्गदर्शिका (कुल 06 पृष्ठ) के अनुरूप चिकित्सकों की निगरानी में ही कराया जाये।

परिवार कल्याण भवन, शेखपुरा, पटना— 800 014, दूरभाषः 0612—2290328, फैक्सः 0612—2290322, वेबसाइटः www.statehealthsocietybihar.org



4. अत: संलग्न जिलावार आबंटनादेश के अनुरूप Hydroxychloroquine-200mg Tablet की आपूर्ति BMSICL द्वारा रिजनम्न वेयरहाउस के माध्यम से सभी सिविल सर्जन/जिला औषधि भंडार को आपूर्ति की जायेगी।

अनुलग्नक: यथोक्त।

विश्वासभाजन् ह०/-(मनोज कुमार)

ज्ञापांक: <u>409</u>4.....

पटना. दिनांक. 29-05-2020

# प्रतिलिपि:

- प्रधान सचिव, स्वास्थ्य विभाग, बिहार, पटना को कृपया सूचनार्थ प्रेषित।
- सचिव, स्वास्थ्य विभाग, बिहार, पटना को कृपया सूचनार्थ प्रेषित।
- सभी जिला पदाधिकारी को कृपया सूचनार्थ एवं आवश्यक कार्रवाई हेतु प्रेषित।
- राज्य औषधि नियंत्रक, बिहार, पटना को सूचनार्थ एवं आवश्यक कार्रवाई हेतु प्रेषित।
- माननीय मंत्री, स्वास्थ्य के आप्त सचिव को सूचनार्थ एवं आवश्यक कार्रवाई हेत् प्रेषित।
- सभी सहायक औषि नियंत्रक/औषि निरीक्षक को सूचनार्थ एवं आवश्यक कार्रवाई हेतु
   प्रेषित।
- सिस्टम एनालिस्ट-सह-डाटा ऑफिसर, राज्य स्वास्थ्य सिमिति, बिहार को कार्यालय के अधिकृत वेबसाईट पर अपलोड करने हेतु प्रेषित।

कार्यपालक निर्देशक



# STATE HEALTH SOCIETY, BIHAR

Distribution of Hydroxychloroquine-200mg Tablet

| SI.<br>No. | District                               | No. of<br>Regular<br>Employees | No. of<br>Contractual<br>Employees | ASHA &<br>ASHA<br>facilitator<br>Selection | Total  | Hydroxychloroquine -   200mg Tablet   Hydroxych |         | Hydroxychloroq<br>uine -200mg<br>Tablet (@ 04<br>Tablets. Per<br>Person- for next<br>6th & 7th week) | Additional quantity<br>for Asympatomatic<br>frontline workers<br>and paramilitary/<br>police personnel<br>involved in COVID-<br>19 related activities | To be<br>distributed<br>to districts<br>on<br>29.05.2020<br>(9+10) |
|------------|--|--------------------------------|------------------------------------|--|--------|---|---------|--|---|--|
| 1          | . 2                                    | 3                              | 4                                  | 5  | 6      | 7   | 8       | 9  | 10  | 11   |
| 1          | ARARIA                                 | 334                            | 320                                | 2479                                       | 3133   | 31330   | 12600   | 12600  | 2000  | 14600  |
| 2          | ARWAL                                  | 214                            | 142                                | 717  | 1073   | 10730   | 4500    | 4500   | 2000  | 6500   |
| 3          | AURANGABAD                             | 700                            | 354                                | 2299                                       | 3353   | 33530   | 13500   | 13500  | 3000  | 16500  |
| 4          | BANKA                                  | 670                            | 273                                | 1820                                       | 2763   | 27630   | 11100   | 11100  | 4000  | 15100  |
| 5          | BEGUSARAI                              | 892                            | 481                                | 2410                                       | 3783   | 37830   | 15200   | 15200  | 3000  | 18200  |
| 6          | BHAGALPUR                              | 1073                           | 411                                | 2356                                       | 3840   | 38400   | 15400   | 15400  | 4000  | 19400  |
| 7          | BHOJPUR                                | 905                            | 260                                | 2221                                       | 3386   | 33860   | 13600   | 13600  | 4000  | 17600  |
| 8          | BUXAR                                  | 527                            | 220                                | 1501                                       | 2248   | 22480   | 9000    | 9000   | 4000  | 13000  |
| 9          | DARBHANGA                              | 742                            | 517                                | 3323                                       | 4582   | 45820   | 18400   | 18400  | 2000  | 20400  |
| 10         | EAST CHAMPARAN                         | 780                            | 722                                | 4547                                       | 6049   | 60490   | 24200   | 24200  | 4000  | 28200  |
| 11         | <b>G</b> AYA                           | 1423                           | *594                               | 3780                                       | 5797   | 57970   | 24200   | 24200  | 5000  | 29200  |
| 12         | GOPALGANJ                              | 484                            | 280                                | 2392                                       | 3156   | 31560   | 12700   | 12700  | 4000  | 16700  |
| 13         | JAMUI                                  | 436                            | 293                                | 1583                                       | 2312   | 23120   | 9300    | 9300   | 2000  | 11300  |
| 14         | JEHANABAD                              | 604                            | 187                                | 966  | 1757   | 17570   | 7100    | 7100   | 3000  | 10100  |
| 15         | KAIMUR                                 | 417                            | 287                                | 1570                                       | 2274   | 22740   | 9100    | 9100   | 2000  | 11100  |
| 16         | KATIHAR                                | 757                            | 436                                | 2791                                       | 3984   | 39840   | 16000   | 16000  | 2000  | 18000  |
| 17         | KHAGARIA                               | 449                            | 202                                | 1540                                       | 2191   | 21910   | 8800    | 8800   | 3000  | 11800  |
| 18         | KISHANGANJ                             | 319                            | 254                                | 1490                                       | 2063   | 20630   | 8300    | 8300   | 2000  | 10300  |
| 19         | LAKHISARAI                             | 426                            | 150                                | 898  | 1474   | 14740   | 5900    | 5900   | 2000  | 7900   |
| 20         | MADHEPURA                              | 707                            | 299                                | 1764                                       | 2770   | 27700   | 11100   | 11100  | 2000  | 13100  |
| 21         | MADHUBANI                              | 1000                           | 504                                | 4009                                       | 5513   | 55130   | 22100   | 22100  | 3000  | 25100  |
| 22         | MUNGER                                 | 677                            | 243                                | 969  | 1889   | 18890   | 7600    | 7600   | 3000  | 10600  |
| 23         | MUZAFFARPUR                            | 1208                           | 493                                | 3897                                       | 5598   | 55980   | 23400   | 23400  | 2000  | 25400  |
| 24         | NALANDA                                | 1165                           | 448                                | 2316                                       | 3929   | 39290   | 15800   | 15800  | 2000  | 17800  |
| 25         | NAWADA                                 | 664                            | 249                                | 1985                                       | 2898   | 28980   | 11600   | 11600  | 3000  | 14600  |
| 26         | PATNA                                  | 1702                           | 540                                | 3129                                       | 5371   | 53710   | 21500   | 21500  | 5000  | 26500  |
| 27         | PURNIA                                 | 734                            | 394                                | 2966                                       | 4094   | 40940   | 16400   | 16400  | 3000  | 19400  |
| 28         | ROHTAS                                 | 847                            | 385                                | 2509                                       | 3741   | 37410   | 15000   | 15000  | 3000  | 18000  |
| 29         | SAHARSA                                | 544                            | 273                                | 1683                                       | 2500   | 25000   | 10000   | 10000  | 3000  | 13000  |
| 30         | SAMASTIPUR                             | 1292                           | 363                                | 4075                                       | 5730   | 57300   | 23000   | 23000  | 2000  | 25000  |
| 31         | SARAN                                  | 739                            | 562                                | 3506                                       | 4807   | 48070   | 19300   | 19300  | 3000  | 22300  |
| 32         | SHEIKHPURA                             | 314                            | 165                                | 506  | 985    | 9850  | 4000    | 4000   | 2000  | 6000   |
| 33         | SHEOHAR                                | 137                            | 171                                | 572  | 880    | 8800  | 3600    | 3600   | 2000  | 5600   |
| 34         | SITAMARHI                              | 532                            | 326                                | 3014                                       | 3872   | 38720   | 15500   | 15500  | 4000  | 19500  |
| 35         | SIWAN                                  | 713                            | 348                                | 2885                                       | 3946   | 39460   | 15800   | 15800  | 3000  | 18800  |
| 36         | SUPAUL                                 | 377                            | 326                                | 2111                                       | 2814   | 28140   | 11300   | 11300  | 2000  | 13300  |
| 37         | VAISHALI                               | 931                            | 414                                | 3265                                       | 4610   | 46100   | 18500   | 18500  | 2000  | 20500  |
| 38         | WEST CHAMPARAN                         | 905                            | 739                                | 3461                                       | 5105   | 51050   | 20500   | 20500  | 2000  | 22500  |
| 129        | Grand Total                            | 27340                          | 13625                              | 89305                                      | 130270 | 1302700   | 524900  | 524900   | 108000  | 632900   |
| Tota       | al Stock as informed<br>by BMSICL      | 2.010                          |                                    | 55000                                      |        | 1002100   | 02.1000 | 02-1000  | 40000   | 640700   |
|            | etained by BMSICL r above distribution |                                |                                    |  |        |   |         |  |   | 7800   |

<sup>\*</sup> Source of number of employees (Regular/Contractual): HRIS Portal & Manav Sampada Portal

Assistant Director, Drug

SHSB

**Executive Director** 

SHSB

Letter No: 1094, Dated: 29.05.2020

<sup>\*</sup> The above distribution (as indicated in Col. 9 & 10) is in addition to the earlier distribution (Col. 7 & 8) made on 14.04.2020 & 18.04.2020 (Vide L.No. 197 Dt. 14.04.2020 & 268 Dt.

# Revised advisory on the use of Hydroxychloroquine (HCQ) as prophylaxis for COVID-19 infection (in supersession of previous advisory dated 23<sup>rd</sup> March, 2020)

#### 1. Background

The Joint Monitoring Group under the Chairmanship of DGHS and including representatives from AIIMS, ICMR, NCDC, NDMA, WHO and experts drawn from Central Government hospitals reviewed the prophylactic use of Hydroxychloroquine (HCQ) in the context of expanding it to healthcare and other front line workers deployed in non-COVID and COVID areas, respectively.

The National Task force (NTF) for COVID-19 constituted by Indian Council of Medical Research also reviewed the use of HCQ for prophylaxis of SARS-CoV-2 infection for high risk population based on the emerging evidence on its safety and efficacy. The NTF reviewed the data on in-vitro testing of HCQ for antiviral efficacy against SARS-CoV-2, safety profile of HCQ reported to the pharmacovigilance program of India, and data on the use of HCQ for the prophylaxis of SARS-CoV-2 infection among health care workers (HCWs) and reported its findings as detailed below:

## 1.1 In-vitro study

At NIV, Pune, the report of the in-vitro testing of HCQ for antiviral efficacy showed reduction of infectivity /log reduction in viral RNA copy of SARs-CoV2.

# 1.2 Safety Profile of HCQ

The data on assessment of HCQ prophylaxis among 1323 HCWs indicated mild adverse effects such as nausea (8.9%), abdominal pain (7.3%), vomiting (1.5%), hypoglycemia (1.7%) and cardio-vascular effects (1.9%). However, as per the data from the Pharmacovigilance program of India, there have been 214 reported instances of adverse drug reactions associated with prophylactic HCQ use. Of these, 7 were serious individual case safety reports with prolongation of QT interval on ECG in 3 cases.

#### 1.3 Studies on prophylaxis of SARS-CoV-2 infection

- A retrospective case-control analysis at ICMR has found that there is a significant dose-response relationship between the number of prophylactic doses taken and frequency of occurrence of SARS-CoV-2 infection in symptomatic healthcare workers who were tested for SARS-CoV-2 infection.
- Another investigation from 3 central government hospitals in New Delhi indicates that amongst healthcare workers involved in COVID-19 care, those on HCQ prophylaxis were less likely to develop SARS-CoV-2 infection, compared to those who were not on it. The benefit was less pronounced in healthcare workers caring for a general patient population.
- An observational prospective study of 334 healthcare workers at AIIMS, out of which 248 took HCQ prophylaxis (median 6 weeks of follow up) in New Delhi also showed that those taking HCQ prophylaxis had lower incidence of SARS-CoV-2 infection than those not taking it.

### 2. Eligibility criteria for HCQ prophylaxis

The Advisory earlier issued (dated 23<sup>rd</sup> March, 2020; available at: <a href="https://www.mohfw.gov.in/pdf/AdvisoryontheuseofHydroxychloroquinasprophylaxisforSARSCoV2infection.pdf">https://www.mohfw.gov.in/pdf/AdvisoryontheuseofHydroxychloroquinasprophylaxisforSARSCoV2infection.pdf</a>), provided placing the high risk population (asymptomatic Healthcare Workers involved in the care of suspected or confirmed cases of COVID-19 and asymptomatic household contacts of laboratory confirmed cases of COVID-19) under chemoprophylaxis with HCQ.

In light of all of the above, the Joint Monitoring Group and NTF have now recommended the prophylactic use of HCQ in the following categories:

- 1. All asymptomatic healthcare workers involved in containment and treatment of COVID19 and asymptomatic healthcare workers working in non-COVID hospitals/non-COVID areas of COVID hospitals/blocks
- 2. Asymptomatic frontline workers, such as surveillance workers deployed in containment zones and paramilitary/police personnel involved in COVID-19 related activities.
- 3. Asymptomatic household contacts of laboratory confirmed cases.

#### 3. Exclusion/contraindications

- The drug is contraindicated in persons with known case of:
  - 1. Retinopathy,
  - 2. Hypersensitivity to HCQ or 4-aminoquinoline compounds
  - 3. G6PD deficiency
  - 4. Pre-existing cardiomyopathy and cardiac rhythm disorders
- The drug is not recommended for prophylaxis in children under 15 years of age and in pregnancy and lactation.

Rarely the drug causes cardiovascular side effects such as cardiomyopathy and rhythm (heart rate) disorders. In that situation the drug needs to be discontinued. The drug can rarely cause visual disturbance including blurring of vision which is usually self- limiting and improves on discontinuation of the drug. For the above cited reasons the drug has to be given under strict medical supervision with an informed consent.

#### 4. Dosage

| S. No. | Category of personnel   | Dosage   |
|--------|---|--|
| 1      | Asymptomatic household contacts of laboratory confirmed cases   | 400 mg twice a day on Day 1, followed by 400 mg once weekly for next 3 weeks; to be taken with meals |
| 2      | All asymptomatic healthcare workers involved in containment and treatment of COVID-19 and asymptomatic healthcare workers working in non-COVID hospitals/non-COVID areas of COVID hospitals/blocks     Asymptomatic frontline workers, such as surveillance workers deployed in containment zones and paramilitary/police personnel involved in COVID-19 related activities | 400 mg twice a day on Day 1, followed by 400 mg once weekly for next 7 weeks; to be taken with meals |

# 5. Use of HCQ prophylaxis beyond 8 weeks [in categories 4 (2) above]

In clinical practice HCQ is commonly prescribed in a daily dose of 200mg to 400mg for treatment of diseases such as Rheumatoid Arthritis and Systemic Lupus Erythematosus for prolonged treatment periods with good tolerance. With available evidence for its safety and beneficial effect as a prophylactic drug against SARS-COV-2 during the earlier recommended 8 weeks period, the experts further recommended for its use beyond 8 weeks on weekly dosage with strict monitoring of clinical and ECG parameters which would also ensure that the therapy is given under supervision.



Based on the available evidence, it has been opined that HCQ is relatively safe, when certain contraindications are avoided, and has some beneficial effect as a prophylactic option.

## 6. Monitoring

- An ECG (with estimation of QT interval) may be done before prescribing HCQ prophylaxis.
- An ECG should be done in case any new cardiovascular symptoms occurs (e.g., palpitations, chest pain syncope) during the course of prophylaxis.
- An ECG (with estimation of QT interval) <u>may be</u> done in those who are already on HCQ prophylaxis before continuing it beyond 8 weeks.
- One ECG should be done anytime during the course of prophylaxis.

# 7. Key considerations

While following above recommendations, it should be noted that:

- 1) The drug has to be given under strict medical supervision with an informed consent.
- 2) The drug has to be given only on the prescription of a registered medical practitioner.
- 3) Advised to consult with a physician for any adverse event or potential drug interaction before initiation of medication. The contraindications mentioned in the recommendations should strictly be followed.
- 4) Health care workers and other frontline workers on HCQ should be advised to use PPE. Front line workers should use PPEs in accordance with the guidelines issued by this Ministry (available at: <a href="https://www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf">https://www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf</a> and <a href="https://www.mohfw.gov.in/pdf/UpdatedAdditionalguidelinesonrationaluseofPersonalProtectiveEquipmentsettingapproachforHealthfunctionariesworkinginnonCOVID19areas.pdf">https://www.mohfw.gov.in/pdf/UpdatedAdditionalguidelinesonrationaluseofPersonalProtectiveEquipmentsettingapproachforHealthfunctionariesworkinginnonCOVID19areas.pdf</a>) or by their respective organization.
- 5) They should be advised to consult their physician (within their hospital/surveillance team/security organization) for any adverse event or potential drug interaction before initiation of medication. The prophylactic use of HCQ to be coupled with the pharmacovigilance for adverse drug reactions through self-reporting using the Pharmacovigilance Program of India (PvPI) helpline/app. (available at:
  - https://play.google.com/store/apps/details?id=com.vinfotech.suspectedadversedrugreaction&hl=en\_I N)
- 6) If anyone becomes symptomatic while on prophylaxis, he/she should immediately contact the health facility, get tested as per national guidelines and follow the standard treatment protocol. Apart from the symptoms of COVID-19 (fever, cough, breathing difficulty), if the person on chemoprophylaxis develops any other symptoms, he should immediately seek medical treatment from the prescribing medical practitioner.
- 7) All asymptomatic contacts of laboratory confirmed cases should remain in home quarantine as per the National guidelines, even if they are on prophylactic therapy.
- 8) Simultaneously, proof of concept and pharmacokinetics studies should be continued/ taken up expeditiously. Findings from these studies and other new evidence will guide any change further in the recommendation.
- 9) They should follow all prescribed public health measures such as frequent washing of hands, respiratory etiquettes, keeping a distance of minimum 1meter and use of Personal protective gear (wherever applicable).

Note: It is reiterated that the intake of above medicine should not instil a sense of false security.





# प्रोफेसर (डा.) बलराम भार्गव, पदम श्री

एनडी, डीएम. एकआरसीपी (जी.), एकआरसीपी (ई.), एकएसीसी, एकएएसए, एकएएमएस, एकएनएसस, एकएससी, एकएन.ए. डी.एस.सी.

सचिव, भारत सरकार स्वास्थ्य अनुसंधान विभाग स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं महानिदेशक, आई सी एम आर

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# Secretary to the Government of India

Department of Health Research Ministry of Health & Family Welfare & Director-General, ICMR



भारतीय आयुर्विज्ञान अनुसंधान परिषद

स्वास्थ्य अनुसंधान विभाग स्वास्थ्य एवं परिवार कंल्याण मंत्रालय भारत सरकार वी, रामलिंगस्वामी भवन, अंसारी नगर नई दिल्ली - 110 029

# Indian Council of Medical Research

Department of Health Research Ministry of Health & Family Welfare Government of India V. Ramalingaswami Bhawan, Ansari Nagar New Delhi - 110 029

> D.O.No.VIR/4/2020/ECD-I 22<sup>nd</sup> March, 2020

Dear Madam

Please find attached the final recommendation of the National Taskforce for COVID-19 for the use of hydroxychloroquine as prophylaxis. This recommendation supersedes the earlier recommendation dated 21,3,2020

With regards

Yours sincerely,

Belian Deepen

(Balram Bhargava)

#### Encl: As above

Smt. Preeti Sudan,
Secretary (Health & Family Welfare)
Ministry of Health & Family Welfare,
Nirman Bhawan,
New Delhi-110008.



# Advisory on the use of hydroxy-chloroquine as prophylaxis for SARS-CoV-2 infection

The National Task force for COVID-19 constituted by Indian Council of Medical Research recommends the use of hydroxy- chloroquine for prophylaxis of SARS-CoV-2 infection for high risk population. Copy is annexed.

The Advisory provides for placing the following high risk population under chemoprophylaxis with hydroxy chloroquine:

- Asymptomatic Healthcare Workers involved in the care of suspected or confirmed cases of COVID-19
- Asymptomatic household contacts of laboratory confirmed cases

The protocol recommended by the National Task force has been approved by the Drug Controller General of India for restricted use in emergency situations.

While following the above recommendations, States should take note of the following:

- The placing of healthcare workers under chemoprophylaxis should not instill a sense of false security. They should follow all prescribed public health measures such as frequent washing of hands, respiratory etiquettes, keeping a distance of minimum 1m and use of Personal protective equipment (wherever applicable).
- They should self-monitor their health and report to health authorities immediately in the event of them becoming symptomatic.
- The high risk contacts of a positive case placed under chemo prophylaxis, should remain in home quarantine while on prophylactic therapy.
- 4) As recommended by the said Task Force, the drug should only be given on the prescription of a registered medical practitioner. The contraindications mentioned in the recommendations should strictly be followed.
- 5) Apart from the symptoms of COVID-19 (fever, cough, breathing difficulty), if the person on chemoprophylaxis develops any other symptoms, he should immediately seek medical treatment of the medical practitioner who has prescribed the chemoprophylaxis.

It is reiterated that the intake of the above medicine should not in still sense of false security.



# Recommendation for empiric use of hydroxy-chloroquine for prophylaxis of SARS-CoV-2 infection

# Background:

Hydroxy-chloroquine is found to be effective against coronavirus in laboratory studies and in-vivo studies. Its use in prophylaxis is derived from available evidence of benefit as treatment and supported by pre-clinical data. The following recommendation for the use of hydroxy-chloroquine as a prophylactic agent against SARS-CoV-2 infection is based on these considerations, as well as risk-benefit consideration, under exceptional circumstances that call for the protection of high-risk individuals.

The National Taskforce for COVID-19 recommends the use of hydroxy-chloroquine for prophylaxis of SARS-CoV-2 infection for selected individuals as follows:

# Eligible Individuals:

- Asymptomatic healthcare workers involved in the care of suspected or confirmed cases of covin-19
- Asymptomatic household contacts of laboratory confirmed cases

#### Dose:

- Asymptomatic healthcare workers involved in the care of suspected or confirmed cases of COVID-19: 400 mg twice a day on Day 1, followed by 400 mg once weekly for next 7 weeks; to be taken with meals
- Asymptomatic household contacts of laboratory confirmed cases: 400 mg twice a day on Day 1, followed by 400 mg once weekly for next 3 weeks; to be taken with meals

# Exclusion/contraindications:

- The drug is not recommended for prophylaxis in children under 15 years of age.
- The drug is contraindicated in persons with known case of retinopathy, known hypersensitivity to hydroxychloroquine, 4-aminoquinoline compounds

# Key considerations:

- The drug has to be given only on the prescription of a registered medical practitioner.
- Advised to consult with a physician for any adverse event or potential drug interaction before initiation of medication
- The prophylactic use of hydroxychloroquine to be coupled with the pharmacovigilance for adverse drug reactions through self-reporting using the Pharmacovigilance Program of India (PvPI) helpline/app.
- If anyone becomes symptomatic while on prophylaxis he/she should immediately contact the health facility, get tested as per national guidelines and follow the standard treatment protocol.
- All asymptomatic contacts of laboratory confirmed cases should remain in home quarantine as per the national guidelines, even if they are on prophylactic therapy.
- Simultaneously, proof of concept and pharmacokinetics studies be taken up expeditiously.
   Findings from these studies and other new evidence will guide any change in the recommendation.