Mr. J.P. Nadda
Minister of Health & Family Welfare
C wing, Nirman Bhavan
New Delhi, India
Phone: +91 11 23061647
Email: jp.nadda@sansad.nic.in ; gargd@ias.nic.in

Dr. G. N. Singh
Drug Controller General
Central Drugs Standard Control Organization
FDA Bhavan, New Delhi
Phone: 91-11-23236975, E mail: dci@nic.in

Mr. Chandrashekar Ranga
Deputy Drugs Controller (India), CDSCO
FDA Bhavan, ITO, Kotla Road,
Phone: 91-11-23212074, E mail: rcs.ddci@yahoo.in

Dr. Jagdish Prasad
Director General of Health Services
Room Number 446A, Nirman Bhavan
New Delhi, Email: dghs@nic.in

Shri B.P. Sharma
Secretary, Department of Health and Family Welfare
Chairman Apex Committee, Clinical Trials on New Chemical Entities
Email: secyhfw@gmail.com

Subject: Requesting waiver for local clinical trials on new direct-acting antivirals for hepatitis C treatment

Dear Minister Nadda, Dr. Singh, Shri. Ranga, Dr. Prasad and Shri Sharma,

We, the undersigned patient groups and organizations working on hepatitis C care and treatment access, would like to acknowledge the efforts of the Government of India, especially the Apex Committee, Clinical Trials on New Chemical Entities, for waiving the need for a local clinical trial on sofosbuvir in December 2014.

This concrete and bold step has allowed many of us and our friends and colleagues around the world to access Indian generic sofosbuvir legitimately with successful treatment outcomes. We can assure you, had it not been for the waiver of the local clinical trial requirement by the Government of India, most if not all of these individuals would not have been able to treat their hepatitis C infections.

It is consequently with much concern that we learned of the Subject Expert Committee (SEC) recommendation during its recent 14th meeting to require the implementation of local clinical trials as part of the review and approval process for the direct-acting antiviral medicines daclatasvir and ledipasvir (the latter as a co-formulation with the previously approved sofosbuvir). We strongly believe that this requirement would substantially delay the availability of these medicines to patients who are in need of better treatment options.

Daclatasvir was already approved for treatment of hepatitis C across genotypes 1, 2, 3 and 4 by the European Medicines Association (EMA) in June 2014[1] and by the United States Food and Drug Administration (US FDA) for genotype 3 in July 2015.[2]

When administered with sofosbuvir in previous clinical trials, the drug combination has demonstrated sustained virological responses at week 12 for 98% of previously untreated genotype 1 patients as well as 98% of patients who failed previous therapies, 92% of patients with genotype 2 infection, and 89% of those with genotype 3 infection.[3] The European Commission decided to reduce the treatment period using daclatasvir with sofosbuvir for treatment of genotype 3 to 12 weeks,[4] with recent studies showing a sustained virological response of 96% for patients with genotype 3 infection without cirrhosis.[5]

The European Commission's decision has important implications both for India and the region. It also provides an alternative regimen to pegylated interferon and ribavirin in combination with other direct-acting antivirals, which can be inappropriate for many people at more advanced stages of liver disease. Most countries in the region also have reported infections predominantly with genotype 1 and 3. In Thailand, the prevalence of genotype 1 is 31% and of genotype 3 is 41%; in Pakistan, it is 12% for genotype 1 and 79% for genotype 3; and in India, it is 30% for genotype 1 and 67% for genotype 3.[6]

The clinical trial data that have been used for earlier approvals by regulators such as the EMA and the US FDA demonstrate that sufficient evidence has already been gathered on the efficacy of these direct-acting antivirals. Beyond efficacy is the ability to shorten the duration of treatment and improve hepatitis C cure rates, which is what daclatasvir has been proven to do while being pan-genotypic in its coverage and having almost no major side effects.

A requirement for new local clinical trials would unnecessarily delay the introduction of medicines that could have a massive impact on the treatment of hepatitis C infection. We urge you to recognize the immediate need for these medicines, which would already be supported by existing research data and approvals by stringent regulatory authorities. If the requested waiver is approved by the Government of India and its respective committees, these medicines will reach the hands of treatment providers and patients much more faster. They represent the hope for a cure for millions of people across the globe, but this hope can only be a reality if access to treatment is rapidly expanded through the scale of generic production that India can offer.

Sincerely yours,

1) AIDS ACCESS Foundation, Thailand
2) AIDS Care China, Hong Kong SAR

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[1] Europeans Medicines Agency, Press Release, European Medicines Agency recommends approval of Daklinza in chronic hepatitis C, June 27,2014, http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/06/news_detail_002133.jsp&mid=WC0b01ac058004d5c1

[2] United States Food and Drug Administration, Press release, FDA approves new treatment for chronic hepatitis C genotype 3 infections, July 24,2014, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm455888.htm

[3] M. S. Sulkowski, et al. (January 2014) Daclatasvir plus Sofosbuvir for Previously Treated or Untreated Chronic HCV Infection, The New England Journal of Medicine.

[4] Bristle Myers Squibb, Press Release, Updated Label for Daklinza (daclatasvir) for the 12-week Treatment of Non-cirrhotic Patients with Chronic Hepatitis C Genotype 3 Approved by the European Commission, September 10, 2015, http://news.bms.com/press-release/updated-label-daklinza-daclatasvir-12-week-treatment-non-cirrhotic-patients-chronic-he

[5] D.R. Nelson, et al. (April 2015), All-Oral 12-Week Treatment with Daclatasvir Plus Sofosbuvir in Patients With Hepatitis C Virus Genotype 3 Infection: ALLY-3 Phase III Study, Hepatology.

[6] J.P Messina, et al. (January 2015), Global Distribution and Prevalence of Hepatitis C Virus Genotypes, Hepatology

3) Asia Pacific Network of People Living with HIV and AIDS (APN+), Thailand
4) Asian Network of People who Use Drugs (ANPUD), Thailand
5) Cambodian People living with HIV Network (CPN+), Cambodia
6) Center for Supporting Community Development Initiatives (SCDI), Vietnam
7) Community Network for Empowerment (CoNE), India
8) Delhi Drug Users Forum (DDUF), India
9) Delhi Network of Positive People (DNP+), India
10) Foundation for AIDS Rights (FAR), Thailand
11) Hepatitis Coalition of Nagaland (HepCoN), India
12) Indian Drug Users Forum (IDUF), India
13) Indonesian AIDS Coalition (IAC), Indonesia
14) Lawyers Collective, India
15) Malaysian AIDS Council, Malaysia
16) National Association of People Living with HIV in Nepal (NAPN+), Nepal
17) Ozone Foundation, Thailand
18) Perssaudaraan Korban Napza Indonesia (PKNI), Indonesia
19) Positive Malaysian Treatment Access and Advocacy Group (MTAAG), Malaysia
20) Thai AIDS Treatment Action group (TTAG), Thailand
21) Thai Network of People Living with HIV/AIDS (TNP+), Thailand
22) TREAT Asia/amfAR, Thailand
23) Union C, Nepal
24) Vietnam Network of People Living with HIV (VNP+), Vietnam
25) Vietnam Network of People who Use Drugs (VNPUD), Vietnam

For further information, please contact Giten Khwairakpam at giten.khwairakpam@treatasia.org or at +66 2 663 7561