ACCESS CAMPAIGN
MEDECINS SANS FRONTIERES

Rue de Lausanne, 78
CP 116 - 1211 Geneva 2,
Tel: +41 (0) 22 849 84 05
Fax: +41 (0) 22 849 84 04

access@msf.org
www.msfaccess.org

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Richard Gonzalez
CEO and Chair of the Board
AbbVie Inc.
1 N. Waukegan Road
North Chicago, IL 60064

Re: Supply of glecaprevir/pibrentasvir for people with hepatitis C

Dear Mr Gonzalez,

I write on behalf of Médecins Sans Frontières/Doctors Without Borders (MSF), an international medical humanitarian organisation, to urge AbbVie to make glecaprevir/pibrentasvir (G/P) accessible for people with hepatitis C in low- and middle-income countries (LMICs) and MSF medical projects.

G/P is a pan-genotypic hepatitis C treatment that is particularly important for those in need of retreatment. G/P offers a shorter retreatment alternative and is crucial for people who have failed multiple direct-acting antiviral (DAA)-containing regimens. These individuals are left with limited salvage options and thus urgently need access to G/P to avoid the risk of complications such as hepatocellular carcinoma and/or life-threatening liver failure.

Since 2018, MSF has made numerous requests to AbbVie to enable the procurement of G/P.[1] Still, G/P remains out of reach for many people with hepatitis C in LMICs. This seriously affects the care of people living with hepatitis C who are critically ill.

A number of barriers impede access to G/P for people with hepatitis C in LMICs:

- AbbVie has failed to set up a G/P compassionate use program for people with hepatitis C in LMICs where the medicine is not yet registered and introduced in domestic treatment protocols.
- AbbVie's G/P price in high-income countries is too high to allow for importation from these countries.
- AbbVie has not filed for registration of G/P in many LMICs, expecting that generic companies entering into AbbVie's voluntary license with the Medicines Patent Pool (MPP) as sub-licensees would file for approval in these countries. This has not happened.
- AbbVie's restrictive voluntary licensing agreement with the MPP in 2018 has failed to boost generic production, registration and supply. Nearly three years later, access to generic G/P remains a challenge given India's designation as a 'manufacturing only' country in the license, meaning licensee manufacturers cannot make the medicine available to people in India. Only one generic company, Mylan (now Viatris), has shown interest in manufacturing G/P, and they have not provided a clear timeline of when their generic version will be available.[2] Brazil, China, Colombia, Kazakhstan, Mexico, Russia, and Turkey – countries with generic production capacities and home to almost 40% of people living with hepatitis C globally – are also not included in the territory of the voluntary license. MSF's license analysis shows that in at least 21 LMICs excluded from the MPP license, patents on pibrentasvir and/or glecaprevir are a barrier to access.[3]

After months of exchanges, we still do not know how to procure this medicine. Early this year, MSF requested that AbbVie provide a practical option to procure G/P for people in our medical project in Pakistan, where AbbVie has

delayed submitting the medicine for regulatory approval. AbbVie still has not offered a price to MSF for LMICs or a concrete route for procurement.

Months later, in June, AbbVie suggested a donation of G/P instead of submitting a sustainable procurement solution and presented this as the only supply option. MSF strives to provide equal access to quality medical care, and donations from commercial corporations do not offer a sustainable, long-term solution for improving access or supply.

We would like to reiterate the requests we made to AbbVie in October 2019:[1]

1. Establish a compassionate use program for people with hepatitis C for whom other pan-genotypic regimens have failed in all LMICs where G/P remains unregistered and unavailable.
2. Expedite registration of G/P in LMICs.
3. Offer G/P at an affordable price (in line with other pan-genotypic regimens' prices) for people in MSF's projects in Pakistan and people in LMICs.
4. Expand the territory of the G/P voluntary licensing agreement with MPP to ensure generic companies have sufficient incentive to develop and supply this essential treatment.

We hope AbbVie will urgently work to provide a timely, sustainable and affordable supply of G/P for people in LMICs. We would appreciate the opportunity to discuss possible solutions for access in LMICs on a call at your earliest convenience.

Sincerely,

Dr Sidney Wong
Executive Co-Director, MSF Access Campaign
Médecins Sans Frontières/Doctors Without Borders (MSF)

Cc.
Charles Gore, Executive Director, Medicines Patent Pool
Dr Meg Doherty, Director, Global HIV, Hepatitis and STI Programmes, WHO
Dr Philippe Duneton, Executive Director, UNITAID
Robert Matiru, Director of Operations, UNITAID
Marisol Touraine, Chair, Executive Board, UNITAID
Catherine Dauphin, Policy Advisor to the Board Chair, UNITAID
Kenley Sikwese, Board Member, UNITAID
Rohit Malpani, Board Member, UNITAID
Ashok Kumar Gupta, Chairperson, Competition Commission of India
Sangeeta Verma, Member, Competition Commission of India
Bhagwant Singh Bishnoi, Member, Competition Commission of India
S. Ghosh Dastidar, Secretary, Competition Commission of India

[1] MSF. Open letter to AbbVie on access to critical hepatitis C treatment – glecaprevir/pibrentasvir (G/P). 2019 Oct 2. https://msfaccess.org/open-letter-abbvie-access-critical-hepatitis-c-treatment-glecaprevirpibrentasvir-gp
[2] MPP. Glecaprevir/pibrentasvir. Licence agreement. 2018 Nov. https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p/ (Viatris is a company established by a merger of two other companies, Mylan and Upjohn. MPP's website still names Mylan as the partner.)
[3] MSF. MSF Access Campaign analysis of the MPP Licence Agreement with AbbVie for glecaprevir/pibrentasvir (G/P). 2019. Available from: https://msfaccess.org/msf-access-campaign-analysis-mpp-licence-agreement-abbvie-glecaprevirpibrentasvir-gp