19 December 2019

PHARMAC
PO Box 10254
The Terrace
Wellington 6143

Dear Lindsay Ancelet,

Submission of feedback on PHARMAC's comment on competing the INSTI market for the treatment of HIV

We are writing in response to a comment made in the May 2019 Anti-Infective Subcommittee minutes and the August 2019 PTAC minutes which states that PHARMAC are considering a competitive process for the integrase strand transfer inhibitors (INSTI) market for the treatment of HIV. We understand that this would involve dolutegravir (DTG) and raltegravir (RAL), and consequently, some patients may be switched, however both medications are intended to remain available to specific patient groups.

We would like to thank you for acknowledging the New Zealand AIDS Foundation (NZAF) as an important stakeholder representing people living with HIV, and for the opportunity to work together on advancing the best outcome for people living with HIV. We believe that we bring an important community perspective to the table, with HIV treatment an important component of our combination prevention and public health focus, which empowers people living with HIV to adhere to treatment and for their treatment needs to be met in order for them to flourish. Our Policy and Science team consults with international best practice guidelines and research in order to ensure all of our work is informed by evidence. Nevertheless, we would like it noted that NZAF is just one part of a wider HIV sector who work with and represent people living with HIV, and would encourage PHARMAC to engage more widely with organisations such as Positive Women and Body Positive, alongside seeking feedback from the wider public and people living with HIV as part of the consultation on competing the INSTI market.

The NZAF can see some important benefits to competing the INSTI market in driving down treatment costs. We understand that approximately 1143 patients currently use dolutegravir, while only approximate 359 use raltegravir[1]. According to our calculations based on the pharmaceutical list prices[2], we believe these two agents currently account for about 78% of the current total treatment costs for HIV medications, though we are aware that prices across all classes are lower and subject to confidential PHARMAC rebates. We have seen the effects of the high cost of this treatment with Immigration New Zealand denying many visas for people living with HIV, who cannot meet the low cost threshold for what is considered an acceptable standard of health.

Nevertheless, the NZAF have some significant concerns about the decision to restrict access to another agent in an environment that already has limited antiretroviral availability and where there already

[1] *Ministry of Health. 2019. Pharmaceutical data web tool (data extracted from the Pharmaceutical Collection on 26 March 2019). Wellington: Ministry of Health*
[2] *PHARMAC. 2019. Online Pharmaceutical Schedule – December 2019. Retrieved from: https://www.pharmac.govt.nz/wwwtrs/ScheduleOnline.php*

are unmet needs. Clinicians in New Zealand are guided by the ASHM antiretroviral guidelines, yet they are unable to choose agents flexibly as many drugs are not locally funded. We are concerned that the competing of the INSTI market may further result in New Zealanders not receiving clinically defined excellent care. Our main concerns surrounding the proposed competing process are:

1) It is unclear whether the preferred agent indication would only apply to treatment naïve patients or be a forced switch for all currently using INSTIs. The NZAF cannot support switching for non-clinical reasons in PLHIV who are tolerating their regimes well, as this could impact on their adherence, sense of stability and may be a cause of stress and concern. The NZAF expect that both agents remain available, and that the option of switching is presented to those who prefer it.
2) New Zealand is a relatively small market, and we are concerned that the restriction may result in losing availability of the second INSTI due to companies withdrawing. We are unaware of the competing process details, but we would expect an assurance that both currently available agents remain in supply, regardless of the process outcome.
3) The NZAF believe that if PHARMAC is to select the preferred agent, there needs to be a wide degree of flexibility allowed for prescribing clinicians. The highly individualised nature of selecting the optimal agent for each patient may be hard to account for with stringent criteria in the context of rapidly changing clinical evidence base. For example, recent research[3] has indicated that certain INSTI + backbone combinations may be associated with more weight gain and cardiovascular risk increase than others, yet new research is emerging rapidly. Clinicians should have the liberty to respond to the emerging scientific data by personalising the combinations to optimally suit their individual patients. While there may be benefits to the generally wider use of dolutegravir due to its high genetic barrier[4], as is already the case in New Zealand, raltegravir remains more appropriate in certain clinical scenarios (e.g. with persons of childbearing potential, certain drug-drug interactions, and others).
4) Internationally, there are four INSTIs in current use, and we believe that if the market is to be competed, then there would be a benefit from broader competition and widening access to other INSTIs, i.e. bictegravir and elvitegravir, both of which are already Medsafe approved in combination with other agents.

Thank you for taking the time to consider our feedback, and we look forward to hearing from you.

Yours sincerely,

Jason Myers
Chief Executive

[3] *Hill A. Are new antiretroviral treatments increasing the risks of clinical obesity? 17th European AIDS Conference, Basel, abstract ML1, 2019.*
[4] *Update of recommendations on first- and second-line antiretroviral regimens. Geneva, Switzerland: World Health Organization; 2019 (WHO/CDS/HIV/19.15).*