



Patient Group Submission Form

The Scottish Medicines Consortium (SMC) is committed to working in partnership with patient groups to capture patient and carer experiences, and use them to inform decision-making.

Before you make a submission

You are required to complete a patient group partner registration form before you make a submission. The registration form requests general information about your organisation. It only needs to be completed once (and annually updated) and should save you time with any further submissions to SMC. If you have not already completed a registration form, please do this before you make your submission.

You will find it helpful to read our *Guide for Patient Group Partners*, which gives details about the type of information you need to capture in the submission form. **Please read this before you make your submission and use it to help you complete each question.**

You can find the registration form and *Guide for Patient Group Partners* in the [Public involvement](#) and [Making a submission](#) sections of our website.

Contact us

If you have any more questions after reading the guide, the SMC Public Involvement Team can support you throughout the submission process. You can email us at:

his.smcpublicinvolvement@nhs.scot

Please do not hesitate to get in touch, as we are here to help you.

Name of medicine:

Cabotegravir prolonged-release suspension (Vocabria®) and Rilpivirine prolonged-release suspension (Rekambys®)

Indication: (what the medicine is used for)

Vocabria® long-acting injection and Rekambys® long-acting injection are to be used in combination for the treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral treatment without present or past evidence of viral resistance to, and no prior virological failure on similar antiretroviral therapies.

Submission date:

29/07/2021

Name of organisation making submission:

Waverley Care

Who is the main contact for submissions to SMC?

Name:

Murray Cheek

Position held in organisation:

Policy and Public Affairs Officer

Email address:

murray.cheek@waverleycare.org

Phone number:

0131 558 1425

Postal address:

Waverley Care Milestone, 113 Oxfangs Road North, Edinburgh EH14 1EB

Summary of key points

Please summarise the key points of your submission which you would like to emphasise to SMC Committee – bullet points may be helpful.

(See P11 of *A Guide for Patient Group Partners*)

300 words maximum

In response to the SMC's invitation to submit a Patient Group Submission for Cabotegravir and Rilpivirine, Waverley Care issued a questionnaire to service users to gather their views. Through this process, and wider experience of our work, we note:

- While advances in treatments have transformed HIV into a manageable, long-term health condition, many people continue to face poor health and wellbeing linked to their diagnosis.
- HIV stigma and discrimination remain widespread - this not only has a damaging impact on the health and wellbeing of people living with HIV, but also undermines efforts to reduce transmission.
- The availability of a range of HIV treatment regimens is essential, allowing people living with HIV to work with their clinicians to find the option that works for their circumstances.
- The proposed new treatment, involving 2 injections every two months, has significant scope to support improved quality of live for people living with HIV by: supporting improved adherence; reducing fear of disclosure; removing the need to take treatment around meal schedules; overcoming issues associated with dysphagia; supporting people with no fixed abode to access treatment; and as an option for people with cognitive difficulties. See Q4 for further details.
- The disadvantages identified by service users who responded to our questionnaire were largely related to circumstances that could be discussed in consultation with clinicians (see Q6). The fact that the proposed new treatment would be in addition to, rather than replacing existing treatments also means that the disadvantages could be easily overcome.
- By making it easier to adhere to treatment, the approval of the proposed new treatment would not only support people living with HIV to manage their condition more effectively, but also support efforts to reduce new transmissions thanks to U=U (See Q2 and Q7 for further information on U=U). Alongside the moral imperative to pursue these goals, it would also result in savings linked to the lifetime treatment costs of new HIV patients.

Please provide details of any individuals who have had a significant role in preparing your submission and who have an interest to declare.

(See P11 of *A Guide for Patient Group Partners*)

300 words maximum

This submission has been compiled by Murray Cheek (Policy and Public Affairs Officer), and Michael Marr (Facilities Manager) on behalf of Waverley Care. Michael is a member of the UK HIV Treatment Advocacy Network (www.ukcab.net).

In April 2021, representatives of ViiV Healthcare provided a briefing session, open to all Waverley Care staff, covering the Cabotegravir and Rilpivirine long-acting treatment regimen.

Although not related to the medicines under consideration in this submission, Waverley Care has also received funding from ViiV Healthcare in the past two years as detailed on our Patient Group Partner Registration Form.

This has comprised £10,000 to support our HIV Street Support project, which provides community-based support in Glasgow city centre for people who inject drugs. The project is part of our response to the ongoing HIV outbreak affecting this population in Glasgow city centre.

Please tell us how you gathered information about the experiences of patients and carers to help inform your submission.

(See P11 of *A Guide for Patient Group Partners*)

300 words maximum

Following notification of the opportunity to submit a Patient Group Submission, we reviewed the information submitted by ViiV Healthcare.

A brief summary of this information was produced, alongside a short questionnaire for Waverley Care services users, allowing them to provide their feedback.

Staff assisted in circulating the questionnaire by contacting service users directly. In total, 17 service users provided their feedback to the questionnaire.

1. How does this condition affect the day-to-day lives of people living with it?

(See P11 of *A Guide for Patient Group Partners*)

500 words maximum

Today in Scotland, advances in HIV treatment mean that it is now a manageable long-term health condition.

However, a significant proportion of people living with HIV continue to face significant challenges to their physical and mental health and wellbeing, often fuelled by stigma, discrimination and wide-ranging health inequalities.

HIV continues to attract high levels of stigma and discrimination, often linked to outdated knowledge and attitudes about the condition, who it affects and how it is transmitted. This stigma and discrimination exists at a personal, community and clinical level, and will often result in people becoming socially isolated and unable to access support.

A diagnosis has the potential to significantly strain relationships with family and friends, and to result in people being discriminated against and shunned by their communities. This stigma also acts as a disincentive to test for the wider community, preventing more people from knowing their HIV status and therefore accessing treatment that can manage the condition and help to reduce transmission.

HIV continues to disproportionately affect specific populations in Scotland, including gay, bisexual and all men who have sex with men, people from African communities and people who inject drugs. Many of the people we work with require support linked to wider health and social inequalities affecting people both within these populations and where they intersect. That can include a wide range of issues including:

- homophobia
- racism
- addiction
- alcohol use
- homelessness
- poor mental health
- poverty
- immigration

2. How well do medicines which are currently available in NHSScotland help patients manage this condition? (See P12 of *A Guide for Patient Group Partners*)

500 words maximum

There are currently a range of well tolerated HIV medications available on the NHS in Scotland which are administered as daily tablets in a variety of combinations.

If taken as prescribed the treatments are highly effective at controlling HIV levels in the body and preventing ill health.

In addition, there is now scientific consensus that a person living with HIV, who is on treatment and who achieves and maintains an undetectable viral load cannot pass HIV on to sexual partners. This is known as U=U or Undetectable=Untransmittable.

For HIV treatments to be effective, they have to be taken according to a well-defined routine that considers time of day, whether to take with food, and interactions with other medications. If a person is unable to adhere to treatment as prescribed, it will limit its effectiveness, and make it less likely that the person will reach an undetectable viral load.

Finding the correct combination of treatments can be a time consuming process discussed between patient and clinician. In addition to how the body responds to particular treatments, patients may need to try different regimens to fit in with their routine. For this reason, it is desirable to have a range of treatment options to ensure that all patients can find an option that fits with their circumstances.

Many people that we work with often struggle to adhere to treatment, in part citing the difficulties of maintaining a mix of daily tablets.

3. Have you been able to consult with patients who have used this medicine?

(See P12 of *A Guide for Patient Group Partners*)

Yes

No

4. Would this medicine be expected to improve the patient's quality of life and experience of care, and if so, how?

(See P12 of *A Guide for Patient Group Partners*)

500 words maximum

1. Adherence:

A number of people highlighted challenges they face linked to adherence:

- "Sometimes I forget to have taken it then have to get up in the middle of night or go on holiday and forget them which means they have to send them"

- "Disruption to daily life caused by Covid ... [and in general] any disruption or change in daily life tends to lead to forgetting doses"

Many service users believed the proposed treatment would help to improve their adherence:

- "It would be improving the quality of my life ... as I don't need to take to many tablets and as I sometimes forget to take them that will help me to be regular with my medication"

- "It would make me feel less anxiety problems of remembering to take them"

2. Stigma and Fear of Disclosure:

A number of people highlighted that daily medication raised the risk of having their HIV status disclosed to others:

- "I have concerns that someone finding medication and knowing my HIV status without my consent. Lack of space is an issue not kept in a locked cupboard"

- "... when I'm with my friends in my house I always hiding my medicine so not to see them"

- "I always not taking my medication on the right time because I don't want my friends to see"

A number of people highlighted that the proposed treatment would increase privacy:

- "I would not have to remember when to take my meds, especially when I am around people who do not know that I have HIV"

- "Think it will be easier to take my HIV treatment as prescribed and also Think it would give me greater privacy about my health and wellbeing"

One person commented on the impact of daily treatment as a regular reminder of their HIV status:

- "It would mean also spending less time thinking and stressing about taking the meds thus less time thinking about why I have to take them"

In many cases we are working with service users who have not disclosed their HIV status to their families. In cases where these individuals live with family members, keeping their diagnosis secret can cause significant stress. While we would always want to support people to be able to disclose to loved ones, the easier it is on people until they do this, the better. Less frequent, regular injections would benefit this group.

3. Interaction with Food:

The absorption of current HIV medications can be affected by food in the stomach, so many service users are currently required to fit medication around their diet.

- "Taking daily meds when I have to take them in the morning, I cannot eat breakfast, and sometimes that makes them difficult to get down without boaking"

The proposed treatment would help to overcome this particular challenge:

- "Every two monthly injections would mean I wouldn't have to worry about eating when I really don't want to"

4. Dysphagia (swallowing difficulties):

Although we did not gather specific views, we have supported individuals who face significant difficulty with swallowing tablets. In some cases, the requirement to take two doses of tablets on a daily basis has caused significant trauma. We have seen cases where older service users have had to move to paediatric formulations of treatment due to swallowing difficulties. Two-monthly injections would represent a huge and daily improvement in quality of life for people in these circumstances.

5. Accessing Treatment:

Although we didn't manage to gather specific views from individuals, we know that accessing current HIV treatments on a regular basis is more difficult for people who are homeless or have no fixed address. As a result of their circumstances, it can be difficult to access local pharmacies to pick up prescriptions (e.g. because they are moving between accommodation regularly), and they do not necessarily have somewhere where they can store medication safely. The proposed medication would help to alleviate this, by linking treatment in with pre-existing appointments with HIV clinics.

6. HIV and Ageing:

With improved effectiveness of HIV treatment, we are now seeing a cohort of people living with HIV into older age. In cases where individuals face cognitive difficulties, adhering to daily treatment may be challenging, and regular injections as part of routine, but less frequent HIV clinic visits would prove beneficial.

5. What kind of impact would treating a patient with this medicine have on the patient's family or carers? (See P13 of *A Guide for Patient Group Partners*)

500 words maximum

Although we did not specifically identify benefits to family members of carers linked to the proposed new treatment option, we would envisage the following benefits:

- Support to access appointments - many of our service users rely on family to support them to access appointments and pick up prescriptions. Moving to two-monthly injections would make this support easier to provide for many.

- Improving knowledge and challenging stigma - lifelong daily treatment is a very visible indicator of a person's HIV status, reinforcing that they are living with an illness. A move to less intrusive treatments can prompt discussion with family and friends, helping to increase understanding of the effectiveness of HIV treatments at managing the condition and preventing onward transmission - therefore challenging HIV stigma.

6. Are there any disadvantages of the new medicine compared to current standard treatments? (See P13 of *A Guide for Patient Group Partners*)

500 words maximum

The responses we received identified potential disadvantages to the proposed new treatment. However, these were linked to specific individual circumstances that would form part of a discussion between patient and clinician, to assess whether two-monthly injections were the right treatment option for them.

Given that the proposed new treatment would be in addition to, rather than replacing, existing daily treatments, we do not believe there would be any disadvantages to making it available.

1. Already managing well on treatment

Some people responding to our questionnaire highlighted that they were managing well on existing treatment and that moving regimens could potentially disrupt their routine

- "Think it might disrupt your daily routine"
- "I manage ok and have to take 8 other pills every morning so two more don't make a difference"
- "After the regime of pills over the last 20 years the current ones are no problem"
- "No [benefit to the new treatment] really unless the injections have no side effects or nasty wee extras guaranteed!"

2. Challenges for people in remote/rural areas

Different individuals identified that they only access their HIV clinic on a six-monthly basis, and highlighted concerns about more regular appointments:

- "at present I do the [journey to] my clinic twice a year, that would increase"
- "It's usual that because of work commitments I can't make a 6 month appointment so ask for a few extra pills to see me through to the date. If I had to attend a clinic every 2 months this would be massively disruptive to my life, painful for my arm, and provoke anxiety if I felt I wasn't being covered"

7. Is there any additional information you think may be useful for the SMC committee to consider? (Optional)

500 words maximum

Today in Scotland, we have access to a range of effective HIV treatments that have transformed HIV into a manageable long-term health condition.

We believe that having a wide range of potential treatment options is in the best interest of patients, as it allows them to work with their clinician to find a combination of treatments that works for their circumstances.

Among the key considerations that patients and clinicians have to consider when assessing treatment options is how practical is it for the individual to adhere to treatment. In the sections above, we have highlighted service users' views on a range of potential benefits to the proposed treatment in terms of aiding adherence.

Alongside the role of adherence in supporting individuals to take control of their HIV and health, we also need to consider the role of treatment adherence in the wider context of HIV prevention. Supporting people to adhere to treatment means more people can reach and maintain an undetectable viral load - meaning they cannot pass HIV on to sexual partners (U=U).

We believe that the proposed new treatment would be a valuable addition to the existing HIV treatment landscape that would aid treatment adherence and support efforts to reduce new transmissions.

Alongside the clear moral imperative to both support people living with HIV, and to reduce new infections, it is worth noting the economic case. In the UK, the most recent estimates of the lifetime cost of managing HIV range from £73,000 to £404,300. Reducing the number of new infections can therefore lead to significant savings over time.

8. Do you consent for a summary of your submission to be included in the Detailed Advice Document for this medicine?

Yes

No

Thank you for completing this form.

The Public Involvement Team is available to advise you on how to complete this form to ensure the patient and carer experience is fully captured, to help inform the SMC decision making process.

If you have any questions about completing this form, please email it to:

his.smcpublicinvolvement@nhs.scot