Written evidence from Gilead Sciences

Executive summary

- Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercialises innovative medicines in areas of unmet medical need. Gilead's portfolio of products and pipeline of investigational drugs includes treatments for HIV/AIDS, liver diseases, cancer, inflammatory and respiratory diseases, and cardiovascular conditions. For 30 years, Gilead has focused on the development of antiretroviral therapy to treat HIV/AIDS, helping transform HIV infection from a fatal and debilitating disease into a chronic, manageable condition.1

- Human immunodeficiency virus (HIV) is a virus that damages the cells in your immune system, thereby reducing its ability to fight everyday infections and disease.2 If left untreated, it can develop into acquired immune deficiency syndrome (AIDS), the umbrella term for a group of potentially fatal infections and illnesses that can take hold after the immune system has been weakened.2

- HIV is most commonly transmitted through unprotected sex. Because of this, sexual health services are central to the prevention, diagnosis and treatment of HIV.

- Gilead has worked with sexual health services across the world to ensure that people who are diagnosed with HIV have access to the most appropriate treatment as quickly and securely as possible. We therefore welcome the opportunity to provide a written submission to this inquiry, which has come at a time of significant change in the demographic of the HIV population. It is vital that services are able to respond to these changes and provide the best care to people living with HIV (PLWHIV).

- Our submission focuses on the following areas:
  
  - Recent trends in HIV
  - The commissioning and delivery of sexual health services
  - Health inequalities faced by black and minority ethnic people living with HIV

- Gilead welcomes the recent progress in reducing HIV transmission and limiting the detrimental impact that HIV can have on a person’s life. This is testament to expanded HIV testing and the effectiveness of HIV treatments. However, there remain significant challenges confronting the HIV community in the UK:
  
  - Late diagnosis rates remain high and have increased amongst black African heterosexual men
  - Cuts to local authority budgets pose a risk to the recent progress that has been made in tackling the HIV epidemic
  - Fragmentation of HIV services continues to detrimentally impact diagnosis and the delivery of HIV care
  - There exist concerning disparities in the way that different racial groups, particularly Black Ethnic Minority people, experience and interact with the health system

- Sexual health services must play a role in overcoming these challenges. However, action from Public Health England (PHE), NHS England, and Government will also be necessary if the issues are to be definitively addressed.
This submission contains a number of recommendations for action. Gilead would welcome the opportunity to work further with the Committee to explore how these could be implemented in practice.

1. Recent trends

1.1 Gilead welcomes the progress that has been made towards eliminating HIV transmission and reducing the detrimental impact that HIV can have on a person’s life.

1.2 Diagnosis, treatment and mortality

1.2.1 The decrease in new infections in recent years is welcome, and illustrates the effectiveness of treatment and regular testing. Between 2015 and 2017 there was a 28% decline in the number of people newly diagnosed with HIV, and a 31% decline in new diagnoses among gay, bisexual, and other men who have sex with men (MSM) – the first fall within this group in over thirty years.3

1.2.2 Mortality rates have also improved. In 2016 the overall mortality rate among PLWHIV aged between 15 and 59 was comparable, for the first time, to that of the general population – 1.22 per 1,000 people compared to 1.63 per 1,000.4

1.2.3 Improved access to treatment and an expansion of HIV testing have contributed to these successes. We explore each in turn below:

- **Improved access to antiretroviral therapy and rapid intiation of ART** – Antiretroviral therapy (ART) works by preventing the HIV virus from replicating in the body and allowing the immune system to repair itself.2 By reducing the viral load to undetectable levels,2 successful ART prevents HIV from damaging the immune system and makes a person’s HIV untransmittable to sexual partners.5 In 2017, 98% of PLWHIV in the UK received ART (compared to 84% in 20106) and 97% of those receiving treatment were virally suppressed.3 It is therefore welcome that in 2018 NHS England introduced a commissioning policy of starting ART immediately after diagnosis, irrespective of the degree of damage to the individual’s immune system.7

- **Expanded HIV testing** – Expanded testing and the implementation of more effective testing techniques, such as repeat HIV testing among higher risk MSM, has three key benefits: reducing the number of people unaware of their positive HIV status; shortening the amount of time in which people are unaware of their infection; and enabling rapid access to effective treatment.4 In ‘steep fall’ sexual health clinics in London (clinics where diagnosis rates have drastically lowered over the last three years), high levels of testing, when coupled with rapid initiation of treatment, led to a 32% reduction in HIV diagnoses amongst MSM between 2014 and 2015.8 As such, the fact that HIV testing rates in the general services of high prevalence areas increased by 17% between 2014 and 2016 is a welcome development.9

- **Pre-Exposure Prophylaxis (PrEP) national trial** – PrEP has been shown to be an effective HIV prevention measure.10 The fact that an implementation trial is underway is welcome, but given existing evidence of the effectiveness of PrEP, we do not believe it necessary to establish the efficacy of the treatment. We are also concerned that in a number of clinics trial places are over subscribed, limiting the number of high risk individuals able to access PrEP in England.

1.2.4 To build upon these positive developments, we recommend that:

- Mechanisms are put in place to ensure that adherence to the new policy of immediate ART for treatment of HIV is monitored.
The testing techniques used in the ‘steep fall’ clinics, particularly high volume and high frequency testing of MSM, are replicated across the UK.

1.2.5 However, despite this progress, there remain challenges within HIV care that must be addressed. In particular, late diagnosis continues to be of critical concern, with 43% of people diagnosed at a late stage of infection in 2017. This is concerning given the high rate of mortality in the first year of diagnosis among those who are diagnosed late (26.1 per 1,000 population aged 15 to 59 years). It remains a particularly significant problem for heterosexual men and women and black heterosexual African men. In 2017, 60% of heterosexual men and 47% of heterosexual women were diagnosed late. Between 2015 and 2017 late diagnosis rates for black African heterosexual men actually increased from 59% to 69%.

1.2.6 Sexual health services alone are not responsible for reducing late diagnoses, but they are part of the solution. For instance, the Sophia Forum has found that 27% of women with HIV felt that there were missed opportunities to test earlier for HIV. Going forward, it must be a priority for sexual health services to expand testing among hard-to-reach groups in order to accelerate reductions in late diagnosis for every subset of the HIV-infected population.

1.3 Living with HIV

1.3.1 Due to the transformation of HIV from a fatal virus into a long-term, manageable condition, PLWHIV now have a normal life expectancy if diagnosed early and treated with ART. Consequently, the HIV population is ageing, with 38% of PLWHIV accessing care aged 50 or above, compared with 17% in 2007. This presents new challenges, namely the greater prevalence and earlier onset of certain comorbidities, primarily cardiovascular disease, bone fragility, and cancer.

1.3.2 Every service involved in HIV diagnosis and care must be adequately equipped to meet the changing needs of the HIV population. Regular health assessments for PLWHIV are an important factor in achieving this, enabling comorbidities to be promptly identified and treated. However, there are shortfalls in the current implementation of health assessments. The most recent audit of the British HIV Association (BHIVA) guidelines found that only 44.9% of people on ART had their 10-year cardiovascular disease risk calculated in the last three years, despite BHIVA guidelines stating that this should be performed within 3 years in all those taking ART. In addition, only 16.7% of PLWHIV over 50 had their fracture risk assessed in the last three years.

1.3.3 Sexual health services must inform PLWHIV, whatever their age, of the wider health complications associated with HIV at the point of diagnosis, as well as their entitlement to regular health assessments from clinical HIV services and their primary care provider.

2. The commissioning and delivery of sexual health services

2.1 Reconfiguration of sexual health services

2.1.1 The financial pressures on local authorities have significantly impacted funding for sexual health services. In November 2017, the British Medical Journal reported that 114 of 147 authorities had reduced spending on sexual health services in the previous three years, with annual reductions ranging from 0.4% to 23%. Meanwhile, demand for sexual health services is growing, with the latest figures showing that there has been a 13% increase in yearly attendances to clinics between 2013 and 2017.

2.1.2 HIV services have been affected by this situation. The National Aids Trust estimated that in 2015 just £10 million was spent on HIV prevention and testing in local authorities with a high prevalence of HIV, compared to £55 million in 2001/2002 and £38 million in 2005/2006. Evidence indicates that this has led to reduced access to HIV prevention and testing services:
• The British Association for Sexual Health and HIV Services (BASSH) has cited anonymised instances where genitourinary medicine (GUM) clinics were prevented from extending their opening hours because of commissioners’ concerns about the cost of such a move.\textsuperscript{19}

• 56 Dean Street, a prominent sexual health clinic in London, announced it has been forced to reduce the number of timeslots at its Express clinic from 350 per day to 75 as part of a new contract.\textsuperscript{20} In 2017 it announced that patients who contacted the clinic would no longer be seen within 48 hours, for which reductions in local authority budgets were cited as the reason.\textsuperscript{21}

2.1.3 We believe that cuts to sexual health services threaten to undermine recent progress in combatting the HIV epidemic. The forthcoming transition towards business rate retention presents a further challenge to funding for these services. We therefore urge the Government and PHE to require local authorities to set out how current funding for HIV prevention and testing will be maintained once the public health grant is abolished and business rate retention introduced from 2020/2021.

2.2 Fragmentation of HIV care and sexual health services

2.2.1 Prior to 2012, HIV clinics operated within or beside sexual health or GUM clinics, as the majority of HIV diagnoses were picked up through routine sexual health check-ups. Close proximity and partnership between HIV and sexual health services meant people diagnosed with HIV could transition smoothly and efficiently from one to the other.

2.2.2 However, the 2012 Health and Social Care Act weakened the relationship between HIV clinics and sexual health clinics. While the commissioning of sexual health services was transferred to local authorities, HIV clinical services remained with NHS England. In some cases, HIV and sexual health services have been either physically separated or discontinued, causing disruption to patient care and making it harder to keep PLWHIV in the care pathway.\textsuperscript{19}

2.2.3 There is also fragmentation within responsibility for HIV testing, which falls to both local authorities (as part of their broad responsiblities for prevention), CCGs (through GPs), and NHS England (through secondary care clinical services). The absence of a clear strategy that delineates these groups’ responsibilities has been detrimental. The Halve It Coalition has reported that GPs, aware of the transfer of testing responsibilities to local authorities, have become disincentivised to offer tests.\textsuperscript{19} This is concerning given that black African men, for reasons associated with stigma and embarrassment,\textsuperscript{22} are less likely to get tested at a sexual health clinic than men who have sex with men (MSM).\textsuperscript{18}

2.2.4 The forthcoming NHS ten-year plan presents an opportunity to tackle this fragmentation of services. We recommend that, in line with the APPG on HIV and AIDS’ report ‘HIV the Puzzle’, PHE should urgently develop a whole-service specification for HIV and sexual health to ensure there is clear, consistent advice available to local authorities, CCGs and NHS England.

2.2.5 Fast Track Cities

2.2.6 In 2018 the London Mayor, PHE, NHS England and the London local authorities signed up to make the capital a ‘Fast Track City’.\textsuperscript{23} This entails a commitment to:\textsuperscript{24}

• End new HIV infections in the capital by 2030
• Put a stop to HIV-related stigma and discrimination
• Stop preventable deaths from HIV-related causes
2.2.7 The city is also examining opportunities for collaboration between the statutory bodies responsible for HIV prevention and treatment, alongside community organisations, as well as the private sector.

2.2.8 The Fast Track city initiative presents an opportunity to address the fragmentation of HIV care and to develop support for quality of life indicators for people living with HIV. It is therefore welcome that Manchester authorities have also announced their intention to join the initiative.24

3. Health inequalities faced by black and minority ethnic (BME) people living with HIV

3.1 In 2018 Gilead commissioned a polling exercise with PLWHIV to further develop understanding of the gap in the way that different racial groups experience HIV care, the findings of which outlined the alarming disparities between BME PLWHIV and other racial groups in their interaction with the health service:25

- While 49% of non-BME PLWHIV felt informed about their condition, their treatment and how both affect daily life, only 33% of the BME group felt the same
- Just 47% of BME PLWHIV felt able to ask questions of their HCP when discussing HIV treatment change, compared to 82% of non-BME PLWHIV
- While 91% of the non-BME cohort indicated that they were generally getting on well with their treatment, the figure was just 75% amongst BME PLWHIV

3.2 These findings and the significantly higher rates of late diagnosis in black African men point to racial inequalities in the provision of HIV care. Sexual health service must help address these disparities, given that they are the first point of contact for PLWHIV. As such, we recommend that sexual health services:

- Provide all people diagnosed with HIV with information on the importance of appropriate treatment regimens and the impact that treatment will have on their everyday life
- Ensure support and information on HIV is tailored to the individual’s circumstances
- PHE should investigate the causes of late diagnosis in black African men

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