# Written evidence submitted by Jazz Pharmaceuticals (DRU0054)

## ABOUT JAZZ PHARMACEUTICALS

1. At Jazz Pharmaceuticals (Jazz), our purpose is to innovate to transform the lives of patients and their families. We are focused on developing life-changing medicines for people with serious diseases — often with limited or no options — so they can live their lives more fully.

2. Jazz has a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in two key therapeutic areas: neuroscience and oncology. Within neuroscience, Jazz focuses on sleep disorders (currently narcolepsy, cataplexy and obstructive sleep apnoea), epilepsy, multiple sclerosis, essential tremor and movement disorders, PTSD, autism and schizophrenia. Jazz's oncology portfolio and pipeline is in blood cancers – including acute myeloid leukaemia (AML), acute lymphoblastic leukaemia (ALL) and veno-occlusive disease (VOD) – solid tumors such as lung and urothelial cancer, alongside focused research in precision oncology and targeted therapies.

3. As announced on 5 May 2021, Jazz acquired GW Pharmaceuticals (GW), a UK-based world leader in the science, development and commercialisation of cannabis-based medicines. Much of what is known about the medical uses of cannabis was discovered by GW – we have led the way in understanding cannabinoid science and how, if harnessed correctly, it has the potential to improve the lives of patients and their families. This work over the last two decades was recognised with a 2021 Queen's Award for Enterprise in Innovation.

4. The UK is home to a significant proportion of Jazz's growing and manufacturing operations, as well as our critical innovation and R&D capabilities. We are committed to maintaining our presence and preserving and investing in our UK-based capabilities in R&D, innovation, growing and manufacturing, In the last five years, we have invested £470m in R&D and £114m in manufacturing facilities in the UK. Jazz employs more than 1,000 employees in the UK, representing a third of our global workforce.

5. Whilst we appreciate this inquiry focuses on illegal drug use and its impact on society and the economy, within its remit is consideration of the UK's legislative framework on drugs, including the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 (MDR). Having developed two regulatory approved cannabis-based medicines in the UK – Sativex (nabiximols) and Epidyolex (cannabidiol) – which are subject to controlled drug restrictions, and established a strong working relationship with the Home Office over a 20-year plus period to enable this work, we believe we are well-placed to comment constructively on a small range of questions posed by the Committee. In addition, our work in navigating controlled drug regulations in 40+ markets around the world also equips us with insights which we believe it helpful to share with the Committee.

## CONSULTATION RESPONSE

### THE UK DRUG FRAMEWORK

**How effective is the UK drug framework in today's society?**

6. Jazz strongly believes that policy making, including controlled drug issues, should be guided by careful analysis of all available evidence with the safety of patients and the

protection of the general public front of mind. For this reason, we welcome the Home Affairs Committee's examination of this important issue.

7. Jazz is supportive of the current scheduling of non-regulatory approved cannabis-based products (legally known cannabis based products for medicinal use in humans / CBMPs) – their move from Schedule 1 to 2 of the Misuse of Drugs Regulations 2001 (MDR) in 2018 allows for legitimate Research and Development (R&D) for medical purposes, whilst ensuring appropriate protections remain in place for patients and the general public.

8. High-quality R&D using CBMPs, including Randomised Controlled Trials (RCTs), followed by robust assessments of their safety and efficacy and subsequent approval by medicines regulators such as the MHRA, is critical if we are to unlock the medical potential of the cannabis plant in a way which protects patients and is meaningful for both patients and Healthcare Professionals (HCPs).

9. We draw the Committee's attention to the Advisory Council on the Misuse of Drug's (ACMD) November 2020 assessment of the impact of this rescheduling and its accompanying recommendations, including the need for increased public understanding of the benefits/risks of cannabis-based products.

10. Two of Jazz's regulatory approved medicines – Sativex (nabiximols) and Epidyolex (cannabidiol) – are subject to the MDR, sitting in schedules 4 part 1 and 5 respectively, following scientifically-based recommendations from the ACMD on their 'low abuse potential' and 'low risk of diversion', and Home Office-led legislative changes.

11. We believe this lower level of scheduling when compared to recreational cannabis and CBMPs is appropriate given the extensive body of evidence supporting their use within approved medical indications and the considerable controls and protections they are subject to as part of their regulatory Marketing Authorisations, for example, pharmacovigilance, and appropriate labelling for the prescriber and patient.

12. We are supportive of the Home Office's approach to defining controlled substances – that is, that any quantity of controlled substances present in a material (e.g. ∆9-THC, THCV and CBN) makes it "controlled" in the UK – which makes it very easy for Jazz to determine the status of its materials and products. In theory, if enforced, it could also help to protect consumers from accessing products containing controlled substances which they do not intend to consume, for example, in CBD-containing products. The Home Office approach is, however, different to the approach in the US and many countries in the EU where a percentage weight / weight of the controlled substance (typically 0.3%) is used to define "controlled" versus "uncontrolled". The lack of alignment between the UK and other markets internationally does create some supply chain challenges for Jazz.

13. Jazz is also supportive of the UK's approach to licensing UK facilities to produce, possess and supply controlled substances, in particular the approach to control cannabis cultivation through the use of 'Industrial Hemp' and 'greater than 0.2% THC' licences for growing sites.

**Does the current framework, or a particular aspect of the framework, need to be reformed?**

14. In order to encourage and incentivise the development of more regulatory approved cannabis-based medicines and ensure minimal supply chain disruptions for HCPs and patients, we believe it is important for a prompt reassessment of scheduling by the ACMD to take place following a medicine's approval (for example, a set 90-day window), followed by

fast-tracked secondary legislation to enact any recommended changes and the automatic communication of rescheduling decisions across the healthcare community.

15. When rescheduling medicines such as our own, we believe it is important for careful consideration to be given to the legal definition of the product to ensure all current and future formulations sit within the same schedule. Jazz continues to face challenges in this regard, with the exact same formulation of our regulatory approved medicines Epidyolex (cannabidiol) and Sativex (nabiximols) sitting in three different schedules in the MDR 2001 – schedules 2, 1, 5 (cannabidiol) and 4.2 (nabiximols). This creates unnecessary complication and confusion for researchers, prescribers and patients, and means some forms of our medicines are subject to the same restrictions as recreational cannabis.

16. One area which we believe worthy of further political and regulatory action is CBD-containing consumer products and their controlled cannabinoid content, most notable THC. We welcome the ACMD's recent recommendations on appropriate levels of controlled substances (∆9-THC, THCV and CBN and the cannabinoid ∆9-THCA-A) within consumer products and hope this will ultimately result in more decisive action by the Home Office and other bodies such as the Food Standards Agency (FSA) to protect consumers from illegal, and potentially harmful, levels of controlled substances. The Food Safety Authority of Ireland (FSAI) has taken decisive action in this area – recalling 90 different CBD-containing products since 2019 despite enforcement technically not being within its remit.

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