Alder Hey Children's NHS
NHS Foundation Trust

Reference Number: FOIAH2425/241

From: Private Individual

Date: 12 August 2024

Subject: Information and Advice regarding Epidiolex and the addition of THC containining medicines for treatment of epilepsies

Q1 All correspondence, both verbal and written information from Professor Geoffrey Guy, GW Pharmaceuticals and its subsidiaries, now under Jazz Pharmaceuticals, covering the period from 2014 to 2024. My inquiry specifically pertains to guidance and insights regarding the use of medicinal cannabis products, including THC, in treating children with treatment-resistant epilepsy.'

A1 Please see attached document: FOI 241 Response

Date	Comments
Nov /Dec 2018 (Enquiry 56291)	GW Pharma advised launch of an early access programme facilitated by Durbin. Less restrictive than compassionate access programme.
6/12/2018 (Enquiry 56415) Request to GW Pharma to confirm ethanol content of Epidiolex	(= 10% v/v)
20/11/2018 (Enquiry 56357) Request to GW Pharma for confirmation of product expiry date	We were advised 'clinical trial supply had 28 day expiry whereas compassionate access stock is 12 weeks from opening'.
31/12/2018 (Enquiry 56475) We contacted GW Pharma for information on adverse effects concomitant use of chloral hydrate and Epidiolex.	They supplied a safety document.
1/10/2019 (Enquiry 57394) Contacted GW Pharma to confirm likely date for UK availability following EU approval. We were advised	There is no timescale at present for availability of licensed product or any information regarding ordering process. To continue current practice at this time.'
29/10/2019 (Enquiry 57528) Request to GW Pharma for advice on whether Epidyolex can be administered via an enteral feeding tube.	Outside the product licence however they offer some advice GW phase III trials of DS and LGS have used only oral administration, though gastrostomy (G) tube administration was allowed by some IRBs in the open-label extension trial following discussion with a medical monitor. Adherence to the following guidance is recommended{Pharmaceuticals, 2016 #17502}: Administer CBD-OS in gastric feeding tube slowly. Flush with15-30 mL of water. Tubes made of polyvinyl chloride (PVC) are not recommended, as they may harden after 9 doses. Avoid using G-tube or nasogastric tube with low dose administration. Note: jejunostomy tube not appropriate. Ultimately, the route/method of administration is a clinical decision to be made by the treating physician.
4/2/2022 (Enquiry 64550) Email and personal communication with local representative from Jazz Pharmaceuticals (who by now have acquired GW Pharma) confirming, at that time	'funding for Epidyolex for Dravet Syndrome and Lennox Gastaut Syndrome is via NHSE who has advised it may be prescribed and dispensed only by 33 designated specialist centres in England. Prescribing following initiation ay a specialist centre cannot be continued by a local hospital. Paediatric centres in the NW area approved to prescribe Epidyolex included Alder Hey, Preston and Manchester.'
10/2/2023 (Enquiry 65774) Contact with the medical science liaison officer at Jazz Pharmaceuticals following request from Alder Hey consultant to establish whether the dose of Epidyolex can be safely increased more rapidly than is recommended in the product information.	'The rate limiting step for dose increase is not actually the cannabidiol dose, but the potential for AEs – notably GI disturbance such as diarrhoea (due to the oily base). Clinical studies suggest Epidyolex is better tolerated with a gradual dose / volume increase. As you mention, it is also important to monitor LFTs. A faster rate of increase would be outside of the product licence; however, as an in-patient with such a severe condition and who is being closely monitored, it may be a reasonable action in order to achieve a therapeutic level more quickly. Unfortunately there is no specific advice on how this could/should be done.'
23/2/2023 (Enquiry 65886) Contacted Jazz Pharma re: abnormal liver function possibly associated with Epidyolex. GW Pharma advised we contact a named specialist in Newcastle.	Information exempted under Section 40: Personal data. Providing this information would likely identify individuals involved, as the response contains confidential patient information