



DAC BEACHCROFT

LIABILITY FOR CANNABIS-BASED PRODUCTS

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INTRODUCTION

- Cannabis-based medicines - the new regime since 1 November 2018
- CBD, the Food Standards Agency and “Novel Foods”
- POCA, Shares and Listings
- Cannabis and the UK product liability framework

CANNABIS-BASED MEDICINES IN THE UK

- Prior position: no legal basis for prescription
- The Alfie Dingley and Billy Caldwell cases
- Summer 2018: a review of the law
- 1 Nov 2018: “cannabis-based products for medicinal use”
 - prescribed by consultants for named patients
 - treated as “unlicensed medicines”/“specials”
- 2019: NICE draft guidance and NHS England review
 - concern expressed that a lack of evidence of safety and effectiveness of medical cannabis
 - recommendations for further research – echoing House of Commons Committee call
 - Sativex not recommended for MS as not cost-effective

CBD, THE FSA AND "NOVEL FOODS"

- CBD oil is widely available in the UK today
- Estimated to be over 1,000 vendors
 - major retail chains
 - independent producers
- No bespoke regulation currently, so need to consider various regulatory regimes
 - Misuse of Drugs – no more than 0.2% THC in seeds, European catalogue, no more than 1mg THC in bottle
 - Medicines – "medical claims" and "medical effect" tests
 - Food – safety testing, labelling requirements and "novel foods"

CBD, THE FSA AND "NOVEL FOODS" (2)

- "Novel food" – a food, of any kind, not consumed widely in the EU before May 1997
- Recent developments on EU/UK level have resulted in CBD oil being classified as a "novel food"
- Awaiting further guidance from FSA as to what this will mean for the industry – "reasonable and proportionate" approach promised
- Guidance expected in September 2019 and understood that a representative of a well-known UK CBD company is assisting with preparation of the guidance

POCA, SHARES AND LISTINGS

- Concerns around Proceeds of Crime Act 2002
 - receipt in UK of proceeds of “unlawful activity”
 - dividends or interest paid by overseas entities
- Understanding has evolved in last 12 months or so
 - US companies – virtually impossible to list in London
 - Canadian companies – concerns re recreational cannabis
 - Non-US medical businesses, and CBD businesses, should generally be feasible – but always depends on specific facts

PRODUCT LIABILITY ISSUES

- Consumer Protection Act 1987 implemented the Product Liability Directive (85/37/EEC)
 - a product is defective when it does not provide the safety which a person is entitled to accept, taking all circumstances into account
 - the manner in which, and purposes for which, the product has been marketed, its get-up, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product;
 - what might reasonably be expected to be done with or in relation to the product
 - the time when the product was supplied by its producer to another.
- This is the standard for all products whether general consumer goods like plugs and kettles and cars or cutting edge, life-saving technologies like medicines, medical devices or blood products

PRODUCT LIABILITY ISSUES (2)

- A body of case law was expected but instead, after 30 years since implementation, there have been three key cases, all at first instance:
 - *A v National Blood Authority [2001] All ER 289*, the Hepatitis C litigation – strict liability confirmed for blood products that transmitted hepatitis C
 - *Wilkes v DePuy International Limited [2016] EWHC 3096* - an artificial hip component that fractured was not defective
 - *Gee and others v Depuy International Limited [2018] EWHC 1208 (QB)* - 300 claimants alleged adverse reaction to metal wear debris from Pinnacle Ultamet hip but "inherent propensity" of a metal on metal artificial hip to shed metal debris in the course of normal use was not a defect

PRODUCT LIABILITY IMPLICATIONS FOR CANNABIS-BASED PRODUCTS

- An area of constant change – so needs to be kept under review
- If a product does not comply with the applicable regulatory regime and causes harm, this may well lead to the conclusion that it is “defective”
- Could be claims for physical and mental injury – and even addiction
- Claimant may pursue strict liability claim against manufacturer – may be easier than claim against prescribing physician
- Overseas cases may teach us something but the legal systems are not the same
- We expect the courts to apply the “known” to the “new” – cannabis shouldn’t be treated differently just because it is cannabis



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