

**Judgment 28/2011**

**Law Officers of the Crown v Robert Andre Le Billon  
– Court of Appeal (File No. 429)  
- 15<sup>th</sup> September, 2011**

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**Misuse of Drugs (Bailiwick of Guernsey) Law 1974 and Import and Export (Control) (Guernsey) Law, 1946 – appeal against acquittal – importation of mephedrone – appeal against acquittal – importation of a medicinal product – appeal allowed.**

**THE COURT OF APPEAL OF GUERNSEY**

The 15<sup>th</sup> day of September, 2011 before The Hon Michael Jacob Beloff, QC presiding, Michael Scott Jones QC and Clare Patricia Montgomery QC

**THE LAW OFFICERS OF THE CROWN**

**(Appellants)**

**-v-**

**ROBERT ANDRE LE BILLON**

**(Respondent)**

In the matter of the appeal, with leave, against the acquittal of Robert Andre Le Billon by the Magistrates Court on 2<sup>nd</sup> day of December 2010;

THE COURT, having on the 12<sup>th</sup> day of September 2011 heard Crown Advocate C G Dunford, and Advocate C J Green, ALLOWED the appeal, and this day GAVE JUDGMENT in the attached terms.

J TORODE  
Registrar of the Court of Appeal

**IN THE COURT OF APPEAL OF GUERNSEY**

**CRIMINAL APPEAL 429**

**Before:** **The Hon Michael J Beloff QC Presiding**  
**Michael Scott Jones QC**  
**Clare Montgomery QC**

**Between:** **THE LAW OFFICERS OF THE CROWN** **Appellants**  
**and**  
**ROBERT ANDRE LE BILLON** **Respondent**

**Advocate C G Dunford represented the Appellants**  
**Advocate C J Green represented the Respondent**

**JUDGMENT**

**Montgomery JA:**

1. This is the judgment of the Court.
2. This is an appeal by the Prosecution against the acquittal of the Respondent brought with the leave of the Court of Appeal given under section 7(1) of the Magistrate's Court (Criminal Appeals) (Guernsey) Law, 1988. Under section 28 of the Court of Appeal (Guernsey) Law 1961 the Court has full power to determine any questions necessary to be determined for the purpose of doing justice in the case before it.
3. As well as the power to determine the questions of law that arise in this appeal, the Court of Appeal has the same power as the Royal Court to quash the acquittal and to remit the case for rehearing (see section 6(3) of the Magistrate's Court (Criminal Appeals) (Guernsey) Law, 1988). However Advocate Dunford properly accepted that in the particular circumstances of this case it would be unjust to quash the acquittal or to remit the case for rehearing irrespective of the views we come to as to the relevant questions of law that arise on this appeal.
4. The Respondent was charged with three charges of importing a medicinal product into Guernsey, namely 4-Methylmethcathinone (otherwise known as mephedrone), in contravention of the Import and Export (Control) (Guernsey) Law, 1946, as amended and the Import and Export of Goods (Control) (Guernsey) Order, 1990, as amended.
5. The mephedrone was imported by the Respondent in three separate consignments in October 2009. The Respondent intended to sell the mephedrone for human consumption in Guernsey. By October 2009 mephedrone had not been classified as a dangerous drug and no official information had been published in Guernsey dealing with its pharmacological properties.
6. Mephedrone has since been classified as a dangerous drug of Class B under the Misuse of Drugs (Bailiwick of Guernsey) Law, 1974. Scientific evidence was called at the Respondent's trial that established beyond doubt that mephedrone was a substance that might be used in human beings

with a view to modifying physiological functions by exerting a pharmacological action. As its classification in Class B demonstrates, mephedrone is a substance that poses a considerable threat to human health.

7. On 2 December 2010, the Magistrate, Philip Robey Esq., (“the Magistrate”) determined a submission of no case at the close of the prosecution case in favour of the Respondent. He held that mephedrone was a medicinal product and the offences charged were strict liability offences on which a sufficient evidential case had been established.

8. However the Magistrate went on to hold, in accordance with what he perceived to be common law principles that the criminal law governing the importation of mephedrone had to meet “requirements of reasonability, certainty and accessibility.” The Magistrate cited the words of Professor Glanville Williams that: “The citizen must be able to ascertain beforehand how he stands with regard to the criminal law; otherwise to punish him for breach of that law is purposeless cruelty” (Criminal Law: The General Part (2<sup>nd</sup> Edition), 1961, page 575).

9. The Magistrate described the requirements of reasonable certainty and accessibility in these terms: “Was Mr Le Billon able to foresee to a degree that was reasonable in the circumstances the consequences which his three importations of Mephedrone between 13 October and 1 November 2009 might entail? ... Was he able to foresee at that time to a degree that was reasonable in the circumstances that Mephedrone could fall within the definition of a medicinal product?”

10. The Magistrate held that, since there was no published information from the authorities of Guernsey that identified the pharmacological effects of mephedrone in October 2009, there was nothing available from the authorities of the Respondent’s: “own jurisdiction to enable him to judge whether mephedrone was or was not a medicinal product. Nothing therefore was available from the authorities of his own jurisdiction to enable him to ascertain whether the importation of mephedrone was liable or was not liable to render him subject to prosecution.”

11. The Magistrate concluded that this state of affairs was “at odds” with the provisions of Article 7(1) of ECHR (no punishment without law). He therefore sought to interpret the legislation in a way that he considered would be consistent with Article 7(1) and to that end read into the definition of medicinal product words that would require the properties of the substance to be “established as at the date of importation” so that they might be known at the time of importation.

12. On this basis the Magistrate held that Advocate Green’s submission on behalf of the Respondent succeeded as mephedrone had not been established, as at the date of the importation, as having a pharmacological, immunological or metabolic action on human physiological functioning. He did so with a “heavy degree of reluctance.” Not guilty verdicts were entered in respect of each of the charges on this basis.

13. On 8 June 2011 John Russell Finch Esq., Judge of the Royal Court (“the Royal Court”) dismissed the prosecution appeal to the Royal Court holding that on the facts the Magistrate had been correct to reach the conclusion that he did. The Royal Court accepted that the decision in *Cantoni v France* [1990] ECHR 17862/9 established that the requirement for legal certainty under Article 7 might be satisfied where the individual could know from the wording of the relevant provision, and, if need be, with the assistance of the court’s interpretation of it, what acts and omissions would make him criminally liable.

14. The Royal Court quoted the decision in *Cantoni* at paragraph 35: “The court recalls that the scope of the notion of foreseeability depends to a considerable degree on the content of the text in issue, the field it is designed to cover and the number and status of those to whom it is addressed. A law may still satisfy the requirement of foreseeability even if the person concerned has to take appropriate legal advice to assess, to a degree that is reasonable in the circumstances, the consequences which a given action may entail. This is particularly true in relation to persons carrying on a professional activity, who are used to having to proceed with a high degree of caution when

pursuing their occupation. They can on this account be expected to take special care in assessing the risks that such activity entails. With the benefit of appropriate legal advice, Mr Cantoni, who was, moreover, the manager of a supermarket, should have appreciated at the material time that, in view of the line of case-law stemming from the Court of Cassation and from some of the lower courts, he ran a real risk of prosecution for unlawful sale of medicinal products.”

15. The Appellant drew attention to the words “real risk” and argued before the Royal Court that the Magistrate’s Court should have assessed not whether the Respondent could have foreseen that mephedrone was a medicinal product but rather whether there was the real risk that mephedrone would be so identified.

16. The Royal Court held that the “thin ice” principle (a phrase taken from the speech of Lord Morris in *DPP v Kneller* [1973] AC 435: “Those who skate on thin ice can hardly expect a sign which will denote the precise spot where they may fall in “) could not trump Article 7. The Royal Court held that Article 7 was an absolute right from which no derogation was possible in agreement with Professor Ashworth; see Ashworth: Principles of Criminal Law, OUP 6<sup>th</sup> Edition at page 76.

17. Although the Royal Court accepted that Article 7 did not preclude criminal penalties being imposed for conduct that fell in an area where it was reasonably foreseeable that a development of the law might lead to criminal sanctions being imposed, it held that, as in *Cantoni v France*, this would only arise where the courts had earlier “adopted a clear position” on the matters at hand. The Royal Court held that *Cantoni* and other “real risk” cases were based on facts which were different from those in the appeal. It held that a “real risk” of a particular outcome only saved a law from violating Article 7 where there had been a reasonably foreseeable development of the law, or a clear line of accessible judicial decisions.

18. We have some doubts as to the approach of the Royal Court given the statement by the European Court of Human Rights in *Cantoni v France* at paragraph 31-32 acknowledging that; “it is a logical consequence of the principle that laws must be of general application that the wording of statutes is not always precise. One of the standard techniques of regulation by rules is to use general categorisations as opposed to exhaustive lists. The need to avoid excessive rigidity and to keep pace with changing circumstances means that many laws are inevitably couched in terms which, to a greater or lesser extent, are vague. The interpretation and application of such enactments depend on practice (see, among other authorities, *Kokkinakis v Greece* judgment of 25 May 1993, Series A no. 260-A, p. 19, para. 40). Like many statutory definitions, that of ‘medicinal product’ ... when the legislative technique of categorisation is used, there will often be grey areas at the fringes of the definition. This penumbra of doubt in relation to borderline facts does not in itself make a provision incompatible with Article 7, provided that it proves to be sufficiently clear in the large majority of cases. The role of adjudication vested in the courts is precisely to dissipate such interpretational doubts as remain, taking into account the changes in everyday practice.”

19. However, as is clear from the passages of the judgments of the Magistrate and the Royal Court set out above, both the courts below accepted the argument developed by Advocate Green for the Respondent that the requirements of legal certainty under Article 7 required the Respondent to reasonably have foreseen, at the time of the importation, that mephedrone might constitute a medicinal product and was thus prohibited from importation into Guernsey following the coming into force on 7 April 2009 of the Import and Export of Goods (Control) (Guernsey) (Amendment) Order, 2009 Guernsey SI 2009 No. 15 (the 2009 Amendment).

### **Legal certainty**

20. We consider that the appropriate starting point from which to consider any argument on legal certainty is the language of the law itself.

21. Article 3(1) of the Import and Export (Control) (Guernsey) Law, 1946 as amended (the 1946 Law) regulates the import and export of goods in Guernsey:

“If any goods (a) are imported ... in contravention of an order made under this Law ... the goods shall be deemed to be prohibited goods and shall be forfeited and the importer ... of the goods or the agent of any of them shall be liable in addition to any penalty under any other enactment to fine not exceeding level 4 on the uniform scale to imprisonment for a term not exceeding 2 years or to both.”

22. Schedule 1 to the Import and Export of Goods (Control) (Guernsey) Order, 1990 is the order made under the 1946 Law which identifies goods that are subject to prohibition or restriction from importation. The 2009 Amendment added as item 19 in the list contained in Schedule 1:

“A medicinal product as defined by article 1 of the Council Directive 2001/83 EEC (“the 2001 Directive”) as from time to time amended or re-enacted (with or without modification) except – (a) for a medicinal product in respect of which a United Kingdom marketing authorisation is in force, or (b) where the import of the medicinal product is for such amount as is for the personal use only of the importer.”

23. Article 1 of the 2001 Directive as amended defines a medicinal product as:

“(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis.”

24. Article 7 provides: “(1) No one shall be held guilty of any criminal offence on account of any act or omission which did not constitute a criminal offence under national or international law at the time when it was committed. Nor shall a heavier penalty be imposed than the one that was applicable at the time the criminal offence was committed.” It is common ground that Article 7 (1) includes a requirement that any offence should be clearly described by law.

25. The requisite standard governing certainty under Article 7 was summarised by the European Court of Human Rights in *Kafkaris v Cyprus* (2008) 49 EHRR 35 as follows:

“140. Furthermore, the term “law” implies qualitative requirements, including those of accessibility and foreseeability (see, among other authorities, *Cantoni v France* [1996] ECHR 17862/91 at para 29; *Coëme v Belgium* [2000] ECHR 32492/96 at para 51, 7 February 2002). These qualitative requirements must be satisfied as regards both the definition of an offence and the penalty the offence in question carries (see *Achour v France* (2006) 45 EHRR 9, [2006] ECHR 67335/01 (para 41)). An individual must know from the wording of the relevant provision and, if need be, with the assistance of the courts' interpretation of it, what acts and omissions will make him criminally liable and what penalty will be imposed for the act committed and/or omission (see, among other authorities, *Cantoni v France* [1996] ECHR 17862/91 at para 29). Furthermore, a law may still satisfy the requirement of “foreseeability” where the person concerned has to take appropriate legal advice to assess, to a degree that is reasonable in the circumstances, the consequences which a given action may entail (see, among other authorities, *Cantoni v France* [1996] ECHR 17862/91 at para 35; and *Achour v France* (2006) 45 EHRR 9, [2006] ECHR 67335/01 (para 54)).

141. The court has acknowledged in its case law that however clearly drafted a legal provision may be, in any system of law, including criminal law, there is an inevitable element of judicial interpretation. There will always be a need for elucidation of doubtful points and for adaptation to changing circumstances. Again, while certainty is highly desirable, it may bring in its train excessive rigidity and the law must be able to keep pace with changing circumstances. Accordingly, many laws are inevitably couched in terms which, to a greater or lesser extent, are vague and whose

interpretation and application are questions of practice (see, *mutatis mutandis*, *Sunday Times v UK* (1979) 2 EHRR 245, [1979] ECHR 6538/74 (para 49), and *Kokkinakis v Greece* (1993) 17 EHRR 397, [1993] ECHR 14307/88 (para 40)). The role of adjudication vested in the courts is precisely to dissipate such interpretational doubts as remain (see, *mutatis mutandis*, *Cantoni v France* [1996] ECHR 17862/91). Article 7 of the convention cannot be read as outlawing the gradual clarification of the rules of criminal liability through judicial interpretation from case to case, “provided that the resultant development is consistent with the essence of the offence and could reasonably be foreseen” (see *SW v UK* (1995) 21 EHRR 363, [1995] ECHR 20166/92 (para 36), and *Streletz v Germany* (2001) 33 EHRR 751, [2001] ECHR 34044/96 (para 50)).”

26. We have also considered the masterly summary of the Strasbourg jurisprudence contained in the speech of Lord Bingham of Cornhill in *R v Goldstein; R v Rimmington* [2006] 1 AC 459 at paragraph 35: “The effect of the Strasbourg jurisprudence on this topic has been clear and consistent. The starting point is the old rule *nullum crimen, nulla poena sine lege* (*Kokkinakis v Greece* (1993) 17 EHRR 397, para 52; *SW and CR v United Kingdom* (1995) 21 EHRR 363, para 35/33): only the law can define a crime and prescribe a penalty. An offence must be clearly defined in law (*SW and CR v United Kingdom*), and a norm cannot be regarded as a law unless it is formulated with sufficient precision to enable the citizen to foresee, if need be with appropriate advice, the consequences which a given course of conduct may entail (*Sunday Times v United Kingdom* (1979) 2 EHRR 245, para 49; *G v Federal Republic of Germany* (1989) 60 DR 256, 261, para 1; *SW and CR v United Kingdom*, para 34/32). It is accepted that absolute certainty is unattainable, and might entail excessive rigidity since the law must be able to keep pace with changing circumstances, some degree of vagueness is inevitable and development of the law is a recognised feature of common law courts (*Sunday Times v United Kingdom*, para 49; *X Ltd and Y v United Kingdom* (1982) 28 DR 77, 81, para 9; *SW and CR v United Kingdom*, para 36/34). But the law-making function of the courts must remain within reasonable limits (*X Ltd and Y v United Kingdom*, para 9). Article 7 precludes the punishment of acts not previously punishable, and existing offences may not be extended to cover facts which did not previously constitute a criminal offence (*ibid.*). The law may be clarified and adapted to new circumstances which can reasonably be brought under the original concept of the offence (*X Ltd and Y v United Kingdom*, para 9; *G v Federal Republic of Germany*, pp 261-262). But any development must be consistent with the essence of the offence and be reasonably foreseeable (*SW and CR v United Kingdom*, para 36/34), and the criminal law must not be extensively construed to the detriment of an accused, for instance by analogy (*Kokkinakis v Greece*, para 52).”

27. Judged by these standards, we cannot agree with the reasoning of the Magistrate or that of the Royal Court to the effect that the relevant provisions of the Guernsey laws were insufficiently clear so as to be invalid or to lack legal certainty. The language used in the 2009 Amendment and the 2001 Directive is intelligible and precise. The scope of the prohibition under the law is not in any doubt. Any individual would know from the definition of medicinal product in the 2001 Directive that the 2009 Amendment made it an offence for a person to import into Guernsey any substance which might be administered to human beings with a view to modifying their physiological functions by exerting a pharmacological action if the substance was not the subject of a United Kingdom marketing authorisation or otherwise exempt from the prohibition (for example because the importation was for personal consumption or the subject of an open general license).

28. Any doubt that might exist as to the pharmacological characteristics of a substance does not, in our judgment, give rise to any legal uncertainty as to the scope of the offence. What is uncertain in such a case is not the law but the facts. Article 7 does not establish any principle of factual certainty.

29. In this case the relevant uncertainty was not what the law was but whether, on scientific analysis, mephedrone might prove in fact to be covered by the 2009 Amendment. This is a factual and not a legal uncertainty. For this reason we do not consider the offences charged violated Article 7 or any cognate common law principle.

30. Insofar as the width of the 2009 Amendment might be argued to produce an overbroad prohibition on importation, catching goods that might be pharmacologically active although not intended by the importers for human consumption (for example volatile solvents in household products such as paint thinner), we consider that any complaint of overbreadth is to be treated as distinct from uncertainty. The intended breadth of a law may be clear yet its application may be overbroad. Cases on overbreadth support the proposition that in order to justify the width of the offence it must be shown that there is a need for a law of that width and that its width is not disproportionate to the legitimate object which the law seeks to achieve. There is therefore no basis in either authority or principle for using the proportionality test as a criterion of legal certainty, see the decision of the Court of Final Appeal in *HKSAR v Mo Yuk Ping* [2007] 12 HKPLR 406 at paragraph 87-89.

31. Insofar as the law is overly broad, we consider that the existing powers of the prosecution to determine whether a prosecution is in the public interest, coupled with the limited powers of the courts to review such a decision (see *Sharma v Brown-Antoine* [2007] 1 WLR 780 at paragraph 14 (5)) and the undoubted power of the court to reflect oppressive prosecution practices by appropriate sentencing dispositions (such as imposing absolute or conditional discharges) are sufficient to guard against unfairness.

### **Strict Liability**

32. The only circumstances in which uncertainty as to the prohibition on the importation of a particular substance could lead to an acquittal would be if offences under Article 3 of the 1946 require proof of a mental element such as proof of knowledge of the prohibition.

33. The Appellant submits that offences under Article 3 of the 1946 Law are strict liability offences and require no proof of any mental element. The Appellant argues that, if a substance imported for commercial purposes is objectively established to be an unauthorised medicinal product at the point of importation, it is irrelevant that the importer did not know the pharmacological characteristics of the substance or that it was a medicinal product.

34. The modern law on strict liability is expressed in a number of decisions of the House of Lords and Privy Council: *Lim Chin Aik v The Queen* [1963] AC 160, *Sweet v Parsley* [1970] AC 132, *Gammon (Hong Kong) Ltd v Attorney-General of Hong Kong* [1985] AC 1 and *B (a minor) v Director of Public Prosecutions* [2000] 2 AC 428.

35. The relevant propositions for the purposes of our analysis were identified by Lord Scarman in *Gammon* at p. 14:

1. There is a presumption of law that mens rea is required before a person can be held guilty of a criminal offence.
2. The presumption is particularly strong where the offences are “truly criminal” in character.
3. The presumption applies to statutory offences, and can be displaced only if this is clearly or by necessary implication the effect of the statute.
4. The only situation in which the presumption can be displaced is where the statute is concerned with an issue of social concern, and public safety is such an issue.
5. Even where a statute is concerned with such an issue, the presumption of mens rea stands unless it can also be shown that the creation of strict liability will be effective to promote the objects of the statute by encouraging greater vigilance to prevent the commission of the prohibited act.

36. Thus the position of principle from which any analysis of strict liability must proceed is that there is a presumption of *mens rea*. The supposition that a provision which is silent on the issue of *mens rea* nevertheless incorporates a mental element is a reflection of the philosophy that the criminal law should only be invoked against those who have acted in a blameworthy fashion, see *Sweet v Parsley* [1970] AC 132.

37. However, as Lord Scarman's propositions in *Gammon* make clear, this presumption is rebuttable. The presumption is liable to be displaced either by the words of the statute creating the offence or by the subject matter with which it deals. Both must be considered.

38. The words of Article 3 of the 1946 Law on their face appear to exclude any mental element because the offence is not defined by reference to what someone does but by what happens and the provisions of the 1946 Law appear to the Court to be directed at regulation rather than at conduct that can be regarded as truly criminal.

39. True it is, as Advocate Green submits, that the unlawful importation of certain goods may be regarded as more morally blameworthy than others (for example the importation of mephedrone in this case was characterised by the Magistrate as “truly despicable”). However looking at the 1946 Law as a whole we consider that offences connected with the general regulation of export and import are more regulatory than criminal.

40. We are fortified in this view by the decision of the English Court of Appeal in *R v Mathudi* [2003] EWCA Crim 697 which reached a similar conclusion in relation to certain English import regulations.

41. Furthermore it is clear that the 1946 Law and the Orders made under it, restricting the importation of certain goods, are concerned with issues of social concern and public safety. The restrictions on the importation of knuckle dusters (for example) and unauthorised medicinal products are designed to ensure the safety of the people of Guernsey. In relation to emerging drugs of concern such as mephedrone there are significant public health implications that engage the safety of the public.

42. The fact that offences under Article 3 of the 1946 Law are punishable by up to 2 years imprisonment does not affect the analysis. In *Gammon*, the Privy Council noted that: “there is nothing inconsistent with the purpose of the [provision] in imposing severe penalties for offences of strict liability” ([1985] 1 AC 1 at 17). Courts have been prepared to impose strict liability in the context of offences with similar and indeed, more severe, maximum penalties (see *R v Brockley* (1994) 99 Cr App R 385—under s. 11(1) of the *Companies Directors Disqualification Act 1986*, the offence of holding directorship while an undischarged bankrupt is an offence of strict liability—the maximum penalty is two years' imprisonment; *R v Mathudi* [2003] EWCA Crim 697—under Regulations 21 and 37 of the *Products of Animal Origin (Import and Export) Regulations 1996* the offence of importing any product of animal origin—the maximum penalty is two years' imprisonment; *R v Zahid* [2010] EWCA Crim 52—under s 5 of the *Firearms Act 1968*, offence of possession of ammunition or firearms is an offence of strict liability—the maximum penalty is five years' imprisonment).

43. In our judgment the real issue that arises is whether the possible imposition of strict liability will be effective to promote the objects of the statute by encouraging greater vigilance to prevent the commission of the prohibited act. In this regard we have been considerably assisted by the analysis conducted by Scott Baker LJ in *R v Mathudi* [2003] EWCA Crim 697 at paragraphs 18-20 where he observed: “A person who chooses to be an importer takes upon himself the obligation of ensuring that any importation complies with the relevant regulations. The subject-matter of the regulation with which the court is concerned relates to a particular activity (importation) involving the potential dangers to which we have referred. Citizens have a choice in whether or not they choose to participate in such an activity. Those who do may, as Lord Diplock said in *Sweet v Parsley* at p 163, place on themselves an obligation to take whatever measures may be necessary to prevent the prohibited act. .... Strict liability imposes a clear black and white obligation on importers. It is up to them to ensure that they contract with consignors that they can trust who do not take risks on lax procedures. ... It seems to us that strict liability is inevitably going to make the regulation more effective.”

44. We consider this analysis applies with equal force in this case. A person who chooses to import for sale to others in Guernsey a substance that may be a medicinal product, faced with strict liability, is more likely to take on himself the burden of establishing the nature of the substance before he imports it in order to avoid liability. If he cannot discharge that burden he has the freedom to choose not to import.

45. Strict liability importation offences thus serve to strengthen the likelihood that importers will take precautions in the light of their clear obligations under Guernsey Law. The imposition of strict liability encourages vigilance and dissuades importers, who might be otherwise relatively unconcerned about the contents of their consignments and the possibility that they may transpire to be consignments of potentially potent drugs.

46. Accordingly we conclude that the offences under Article 3 of the 1946 Law were strict liability offences and required no proof of any mental element. Once the mephedrone imported for commercial purposes by the Respondent was objectively established to have been an unauthorized medicinal product at the time it was imported, it was irrelevant that the Respondent did not and even could not know the pharmacological characteristics of the substance.

47. The argument that unfairness may result if a person is strictly liable for an importation when he had no means of knowing that the importation is prohibited is met by reference to the duty of any prosecutor to consider whether a prosecution is in the public interest.

### **Therapeutic purpose**

48. Advocate Green ventilated an argument before us that mephedrone could not be a medicinal product by function within the meaning of the 2001 Directive because it had no beneficial or therapeutic effect and could never have the function of treating and preventing disease. He relied in advancing this argument on only two authorities.

49. The first was the opinion of Advocate General Geelhoed delivered on 3 February 2005 in *HLH Warenvertriebs GmbH v Germany: C-211/03, C-299/03 and C-316/03 to C-318/03*. The Advocate General observed at paragraph 30 and 80 that: “30. The case-law shows that the notion of the 'presentation' of a product should be given a broad interpretation. It includes not only products presented for treating or preventing disease within the meaning of the medicinal products directive, but also products that create the impression in the averagely well informed consumer that they possess such therapeutic or prophylactic properties. Products to which the definition is applied by virtue of their 'function' must first be subjected to a detailed technical and scientific investigation. In its case-law the Court has mentioned the following criteria which may be taken into consideration in determining whether a product is covered by this part of the definition: the pharmacological properties of the product concerned in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail. ... 80 The pharmacological effect of a product is one of the factors that must be investigated in assessing whether a product has a significant influence on the metabolism and can affect the actual functioning of the organism and thus, in the language of the second subparagraph of Article 1(2) of Directive 2001/83, may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings. The risks associated with the use of the product constitute one of the factors which may be taken into account in determining whether or not it is a medicinal product. *However, this factor is not decisive. At least one demonstrable 'therapeutic effect' must also be present. The therapeutic efficacy must always be investigated in relation to the risk associated with the use of the product.*” (emphasis added)

50. Advocate Green also relied on the decision of the ECJ in *European Commission v Germany: C-319/05* [2008] 1 CMLR 943 at paragraph 61 and 64: “61 Contrary to the definition of medicinal product by presentation, whose broad interpretation is intended to protect consumers from products which do not have the effectiveness they are entitled to expect, the definition of medicinal product by function is designed to cover products whose pharmacological properties have been

scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions. ... 64. In those circumstances, and in order to preserve the effectiveness of that criterion, it is not sufficient that the product has properties beneficial to health in general, *but it must strictly speaking have the function of treating or preventing disease.*” (emphasis added)

51. We found these citations of limited value. We certainly do not consider that they support the argument about legal certainty which was the primary reason for their citation.

52. Advocate Green however also suggested that it was legitimate to have regard to the opinion of the Advocate and to the decision of the ECJ in relation to the 2001 Directive in construing the definition of medicinal product in the 2009 Amendment. We are inclined to agree with this as a general proposition, although any reference to views expressed by the ECJ must be subject to the recognition that the Guernsey legislation imported part only of the definition section of the 2001 Directive and not the wider scheme of the Directive which is associated with the industrial production and marketing authorisation of medicinal products.

53. Accordingly, insofar as ECJ cases involve the construction of the 2001 Directive as a whole, they must be viewed with caution. Both the cases cited by Advocate Green require the application of this approach. The particular cases are also subject to the need for additional caution because they are concerned with the interpretation, not merely of the 2001 Directive but also other related Directives regulating the production and authorisation of food stuffs and other products (such as Directive 2002/46) and deal with the problems associated with borderline products, seeking to explain why products might fall within or without the various definitions.

54. More importantly we do not consider that the authorities cited can be relied on as requiring, as an element of the Article 3 offence, in the case of a substances alleged to be a medicinal product by function, proof of therapeutic benefit or use against disease.

55. There is no specific language in either of the cases that would permit us to ignore the plain words of paragraph (b) in the definition of medicinal product in the 2001 Directive which refers to: *“any substance or combination of substances which may be used in or administered to human beings ... with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action ...”*

56. The cases do not make any explicit statement that the part of paragraph (b) set out above in italics is to be ignored. In our judgment the words in that part of paragraph (b) fall to be construed according to their natural meaning. They do not mandate a definition that requires proof of therapeutic or beneficial effect.

57. So far as the particular cases are concerned, it is to be observed that the opinion of Advocate General Geelhoed was not adopted by the ECJ in its decision in the relevant case, see *HLH Warenvertrieb and Orthica* [2005] ECR I-5141.

58. Paragraph 64 of the decision of the ECJ in *European Commission v Germany* has to be understood in the light of the submission by the Commission set out at paragraphs 18 – 19 to the effect that: “Where a product which is claimed to be a medicinal product does nothing more than a conventional foodstuff, it is clear that its pharmacological properties are insufficient for it to be accepted as a medicinal product. ... A product which has no more effect on the body than a foodstuff has not reached the threshold above which it must be regarded as a medicinal product by function. In other words, substances which do not have a significant effect on the body and strictly speaking modify the way in which it functions cannot be treated as medicinal products. The Commission takes the view that the product concerned might at best be regarded as a food supplement within the meaning of Article 2(a) of Directive 2002/46, that is to say as a foodstuff which is a concentrated source of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form.”

59. In our judgment, it is this argument that the Court was addressing and endorsing in paragraph 64. The Commission was not advocating and the Court did not mandate a narrowing of the definition of medicinal products by function to cover only those substances that have the function of treating or preventing disease. This would transpose part of the definition in Article 1(a) into Article 1(b) which would be at odds with the structure of the Article. Moreover paragraph 64 of the Court's judgment has to be read in the context of paragraph 61 which specifically tracks the language of Article 1 (b).

60. For these reasons we have concluded that mephedrone is a medicinal product by function within the meaning of the 2001 Directive even though it has no beneficial or therapeutic effect and does not have the function of treating and preventing disease.

### **Conclusion**

61. In the circumstances we propose to allow the appeal. However as already indicated we consider that it would not be just to remit the case for rehearing given the particular circumstances of the case. We accordingly do not quash the acquittals that would otherwise fall to be quashed in the light of the views that we have expressed in this judgment.