中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Our ref.: FHB/H/24/24
Your ref: LS/B/19/16-17

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14 July 2017

Mr Bonny LOO
Assistant Legal Adviser
Legal Service Division
Legislative Council Secretariat
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Mr LOO,

Re: Chinese Medicine (Amendment) Bill 2017 ("the Bill")

I refer to your letter dated 15 June 2017 which seeks our clarification on issues related to the Bill. Our response to the issues raised in your letter is set out in the Annex of this letter.

Yours sincerely,

(Mr James LAM)
for Secretary for Food and Health

Encl.

c.c. Department of Justice (Attn: Ms Mandy NG)
Department of Health (Attn: Dr Edwin TSUI)
Clerks to Bills Committee on the Chinese Medicine (Amendment) Bill 2017

Chinese Medicine (Amendment) Bill 2017

The Administration's response to the issues raised by the Assistant Legal Advisor of the Legislative Council

Clause 3 – proposed long title of the Chinese Medicine Ordinance (Cap.549)

(a) **Long title:** The amended long title provides for the regulation of activities or matters relating to Chinese medicines ("CM"). We have used "including" to list some examples of what activities or matters this covers. The recall of CM is not in itself a regulated activity or matter, but a measure employed to facilitate the regulation of the sale of CM. Therefore, we think the amended long title is wide enough to encompass recall and it is not necessary to explicitly spell it out in the long title.

Clause 4 – proposed Part XIVA of Cap. 549

(b) **Comparison table:** Please refer to Appendix for details.

Clause 4 – proposed new sections 138C and 138D of Cap. 549

(c) **Fitness for human use:** The application of the proposed new sections include both external use (such as cream and plaster) and internal use (such as tablets and capsules). As such, "unfit for use by human beings" would be wide enough to cover both scenarios.

Clause 4 – proposed new sections 138E, 138H and 138I of Cap. 549

(d) **Recall action:** The way in which the recall is to be conducted will be covered by "action required under the order" provided for under the proposed new section 138E(d).

(e) **Order number:** For administrative purpose, every Chinese medicine safety order ("CMSO") made under the proposed new section 138B(1), variation order made under the proposed new section 138H(1) and revocation order made under the proposed new section 138I(1) will have an order number. All the specified forms will have a blank designated for the order number. As for "the order number of the CMSO" to which a variation or revocation order relates, it is made a requirement to be stated in section 138H(2)(b) and 138I(2)(b) respectively because an order number of the CMSO is necessary to identify the subject order of the variation or revocation order. We do not see the need to stipulate the order

number in the proposed new section 138E.

(f) **Variation or revocation order:** Based on various factors, such as subsequent test results and professional judgment, the Director of Health ("the Director") may revoke a CMSO, or vary the length of the order period, the manner of disposal, etc. As the circumstances in which a CMSO has to be varied or revoked may vary from one case to another, it may not be practical to set out all of the grounds that would entitle the Director to vary or revoke a CMSO. Nevertheless, the variations made are expected to be reasonable and should not be such that the varied CMSO will be inconsistent with the restrictions or requirements under Cap. 549. Furthermore, revocation of a CMSO would release the person against whom the original CMSO is directed from onerous obligations, the need for setting out the grounds for revocation in the legislation may not be necessary.

(g) **Suspension of order:** The grounds for the Director making a CMSO are all related to CM with public health risk. It is unlikely to suspend a CMSO when there is reasonable ground to believe the CM has posed public health risk. Nevertheless, we may apply section 46(a) of the Interpretation and General Clauses Ordinance (Cap. 1) should such unlikely event arises. It is noted that section 46(a) of Cap.1 provides that where any Ordinance confers power upon any person to make, grant, issue or approve any order, such power shall include power to amend or suspend such order. Section 2 of Cap. 1 further provides that save where the contrary intention appears, the provisions of Cap. 1 shall apply to any other Ordinance in force. As it does not appear that there is such a contrary intention in Cap. 1 or in Cap. 549, section 46(a) of Cap.1 shall apply and the Director will have the power to suspend a CMSO even though such power is not explicitly provided in Cap. 549.

Clause 4 – proposed new sections 138K of Cap. 549

(h) **Failure/refusal to comply with order:** The proposed new section 138K makes it an offence for "a person bound by a CMSO" to fail or refuse to comply with a requirement of the order. The person who commits such an offence is liable to a fine at level 6 fine and to imprisonment for 2 years. We do not consider it appropriate to introduce under the proposed section 138K a separate offence similar to that under section 146(3) of Cap. 549 which will apply to "any person" (as opposed to "a person bound by a CMSO") who willfully delays or obstructs a recall which in effect will expand the scope of the proposed section 138K by making those who are not "bound" by any CMSO to comply with the requirement of a related order to recall of the questionable medicine. If we make it an offence for "any person" to willfully delay or obstruct a recall, there are bound to be enforcement difficulties. For example, a retailer upon whom a CMSO has been served may have sold the questionable medicine to a number of sub-

retailers (including their friends and relatives). It would be impracticable (if not virtually impossible) for law enforcement agencies to trace all these sub-retailers for the purpose of initiating prosecution. Nevertheless, if a retailer to whom the CMSO is not specifically addressed refuses or fails without reasonable excuse to return the product concerned to the wholesaler or manufacturer, the Director may issue another CMSO to that particular retailer to prohibit sale and recall of the product concerned.

Clause 4 – proposed new sections 138L of Cap. 549

(i) **Reasonable excuse:** The following are examples of what would constitute "a reasonable excuse" –

- The product concerned has already been consumed by consumers.
- The product concerned was damaged and disposed of by the retailer.
- The product concerned was found in a retailer after the recall action was completed. However, the above retailer was not a customer of the person bound by the CMSO and the latter can provide evidence showing that the product found in the above retailer is a counterfeit product.

(j) The statutory defences in the existing section 156 of Cap. 549 fall outside the scope of the Bill. If it is necessary to review section 156, it should be taken forward in the context of a separate legislative exercise.

Clause 5 – proposed section 141 of Cap. 549

(k) **Legal recourse by aggrieved persons:** The proposed section 141 of Cap. 549 provides appeal mechanism for a person who has been served with a CMSO or variation order. A person who has been served with a revocation order is unlikely to be aggrieved by this order, appeal mechanism for revocation order is hence not provided. Moreover, the decision of a revocation order by the Director would not affect the right of a person aggrieved by the revocation order (such as a competitor or a member of the public whose initial complaint prompted the making of the CMSO now revoked by the Director) to appeal against the Director's decision such as by way of judicial review.

(l) **Finality clause:** The finality provision concerned was modelled on Pharmacy and Poisons Ordinance (Cap. 138) when the Chinese Medicine Bill was being drafted in 1999. We note that the relevant finality provision in Cap. 138 has already been repealed in 2008. In this regard, the Administration will introduce a Committee Stage Amendment (CSA) to amend the Bill with a view to repealing the finality provision in section 141 of Cap. 549.

Clause 6 – proposed section 159 of Cap. 549

(m) **Serving notice:** It should be noted that the coverage of the amended section 159 of "a notice or order required to be served or given (however described) under the Ordinance" is no different from the coverage of the existing section 159. Section 159 is not intended to apply to all forms of communication. For example, the service of a summons to witness under section 100 of Cap. 549 and section 21 of Cap. 549C are respectively provided for under those sections. Section 35 of Cap. 549C and Part IV of Cap. 549D which the Bill seeks to repeal merely concern the proof of service. The repeal of these provisions would mean that the service of "a notice or other communication" covered by those 2 provisions can no longer be proved by a sworn statement. After the repeal, the service of all documents under the Ordinance would have to be proved in court in the same way.

(n) **Serving notice on partnership/unincorporated association:** A partnership or unincorporated association is not a legal entity. In case a CMSO which involves a partnership or unincorporated association has to be issued, the Director may specify in the CMSO the partners or the major officers of the unincorporated association who will be bound by the order. The CMSO may then be served on such partners and officers as an individual (or in the case of a partner which is a body corporate, as a body corporate). A separate provision for service on a partnership or unincorporated association is therefore not strictly necessary.

(o) **Serving notice on individuals and body corporates:** The difference between these modes of service reflects the policy that the requirements for delivering a notice or order differs between an individual and a body corporate. For service on an individual, the requirement is more stringent in that the individual must receive the notice or order personally. For service on a company or body corporate, the requirement is that the notice or order is dispatched by a person to an officer who receives it for the company or body corporate.

Clause 8 to 10 – proposed sections 11(i), 16(1)(q) and 20(g) of Cap. 549F

(p) **Grounds for product recall:** The function of the amended sections 11(i), 16(q) and 20(g) of Cap. 549F is to require the licence holder to set up and maintain a system of control to enable the rapid and, so far as practicable, complete recall of CM. Such a system should be able to accommodate not only recalls ordered by the Director under section 138B(1)(b) on grounds listed under section 138D, but also recalls done in other circumstances, for example, recalls initiated by the licence holder on a voluntary basis. As such, these sections do not provide for the circumstances or grounds on which recall is to occur. The Chinese Medicines Board ("CMB") under the Chinese Medicine Council of Hong

Kong would be informed of the suggestion of the Assistant Legal Adviser to consider whether the circumstances or grounds for recall should be set out in the relevant practicing guidelines or recall guidelines ("the Guidelines").

(q) **Involvement of multiple manufacturers:** In the scenarios illustrated, A, B and C may all be directed by the Director under section 138B(1)(b) of Cap. 549 to recall intermediate products or proprietary Chinese medicines ("pCms") which were sold to another. The proposed section 16(1)(q) of Cap. 549F is the requirement imposed on a manufacturer regarding the system of control that it must set up and maintain to enable the rapid and, so far as practicable, complete recall of specified products as defined in section 16(2) of Cap. 549F. As such, whilst A, B and C all have a duty to recall intermediate products or pCms which were sold to another, only A is required to set up and maintain a system to enable the recall of intermediate products generated by A, as intermediate products generated and sold by A fall within the definition of "specified products"

(r) **Amendments to Guidelines:** The CMB will amend the Guidelines to reflect the changes sought to be made by the Bill. The amendments would include the definition of recall, and the grounds for setting up and maintaining a recall system. The amended Guidelines should take effect after the Bill is passed. The administrative procedure for seeking endorsement from the CMB to amend the Guidelines may take one to two weeks.

(s) **Pharmacy and Poisons Ordinance (Cap. 138):** Cap 138 does not apply to the sale, manufacturing, dispensing or compounding of Chinese herbal medicines ("Chms") or pCms as defined in Cap. 549 and only applies to pharmaceutical products or pharmaceutical products containing any Chms or pCms or other materials of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose as active ingredients (see section 37 of Cap. 138). As the present amendment exercise is only to impose further control on CM but not pharmaceutical products, the amendment of Cap. 138 to provide for the power to recall a pharmaceutical product will not fall within the scope of the present amendment exercise (as set out in the long title of the Bill). The Pharmacy and Poisons Regulations (Cap. 138A) provide that a licensed wholesale dealer or manufacturer should set up a recall system in the event of a pharmaceutical product (or substance) is found to be dangerous or injurious to health. Cap. 138A do not provide statutory authority for the Director to recall pharmaceutical substances or products. However, according to the Code of Practice for Holder of Wholesale Dealer Licence and the Code of Practice for Licensed Manufacturers and Registered Authorized Persons which were issued by the Pharmacy and Poisons Board under section 4B of Cap. 138, the Department of Health may instruct or initiate a recall of pharmaceutical products in the events of defective products or suspected quality defects. Contravention of

the relevant codes of practice may result in disciplinary actions under Cap. 138A.

Chinese text

(t) Our view is that the two expressions "回收" and "收回" have different meanings. In the context of our proposed legislation, the meaning of "recall" is to request the return of something. According to 《現代漢語詞典》, "收回" means "把發出去或借出去的東西取回來". Examples of the usage of "收回" as the Chinese rendition of "recall" in the context of retrieving problematic products in legislation include: section 30(1)(c) of the Food Safety Ordinance (Cap. 612), section 72H(1) of the Patents Ordinance (Cap. 514), section 36A(6)(b) of the Pharmacy and Poisons Regulation (Cap. 138A), section 12(2) of the Toys and Children's Products Safety Ordinance (Cap. 424) and section 21 of the Consumer Goods Safety Ordinance (Cap. 456). On the other hand, "回收" is often used in relation to taking back or collecting waste as it has a meaning of 把物品 (多指廢品或舊貨) 收回利用, e.g. "推行產品回收計劃，規定製造商、進口商、批發商或零售商回收若干產品，以作妥善的廢物處理" (section 2(2)(a) of the Product Eco-responsibility Ordinance (Cap. 603)). Hence, it is considered that "收回" is more suitable in the context of our Bill.

(u) "致送" is used in sections 138F, 138H and 138I in relation to a CMSO for consistency with the existing rendition of "addressed to" under Cap. 549. Please see section 56(2) of Cap. 549 and section 26 of Cap. 549C.

(v) Upon review, "確立" is the preferred Chinese expression for "establish" in this context of the proposed new section 138L. The Administration will introduce a CSA to amend the Chinese text of the Bill accordingly.

(w) In the present context, using "當日起計的第三日" is direct and the policy intention is clear from the wording. As we are not familiar with the actual policy intention or consideration behind the drafting of section 166(2)(a) of the Competition Ordinance (Cap. 619), we will refrain from speculating the reason for the difference in drafting between that Cap. 619 and Cap. 549.

Appendix

Relevant provisions of the Chinese, Australian and Canadian statutes

		Mainland China – 《藥品召回管理辦法》	Australia – 《Therapeutic Goods Act 1989》	Canada – 《Food and Drugs Act》	Proposed sections of the new Part XIVA of the Chinese Medicine (Amendment) Bill 2017
(i)	types of medicinal or therapeutic products subject to recall	藥品 **第二條** 在中華人民共和國境內銷售的藥品的召回及其監督管理，適用本辦法。	Therapeutic goods **Section 30EA(1)** – The Secretary may, in writing, impose requirements, relating to therapeutic goods, on a person if: (a) any of the circumstances referred to in the second column of an item in the following table occur in relation to the goods; and (b) the person is referred to in the third column of that item.	Therapeutic product **Section 21.3(1)** – If the Minister believes that a therapeutic product presents a serious or imminent risk of injury to health, he or she may order a person who sells the product to: (a) recall the product; or (b) send the product, or cause it to be sent, to a place specified in the order **Section 21.3(3)** - Subject to subsection (5), no person shall sell a therapeutic product that the Minister orders them, or another person, to recall.	Chinese medicine or related product (means a herbal medicine, a proprietary Chinese medicine or an intermediate product) **Section 138B** – The Director may, by order in writing, do either or both of the following – (a) Prohibit the sale of a Chinese medicine or related product; (b) Direct that a Chinese medicine or related product that has been sold be recalled and specify the way in which, and the period within which, the recall is to be conducted.

(ii)	grounds for prohibiting sale and/or directing recall	**第二十五條** 藥品監督管理部門經過調查評估，認為存在本辦法第四條所稱的安全隱患(指由於研發、生產等原因可能使藥品具有的危及人體健康和生命安全的不合理危險)，藥品生產企業應當召回藥品而未主動召回的，應當責令藥品生產企業召回藥品。必要時，藥品監督管理部門可以要求藥品生產企業、經營企業和使用單位立即停止銷售和使用該藥品。	**Section 30EA(1) -** 1. The goods do not conform with a standard applicable to the goods 2. The manufacturing principles have not been observed in the manufacture of the goods 3. The goods are supplied in contravention of subsection 19B(1), (2) or (4), 19D(1) or 42E(1) or section 42EA 4. The goods appears to the Secretary that: (a) the quality, safety or efficacy of the goods is unacceptable; or (b) in the case of registered goods — the presentation of the goods is not acceptable; or (c) in the case of listed goods — the presentation of the goods is unacceptable 5. the manufacturer did not hold a licence that was in force 6. The registration or listing of the goods has been	**Section 21.3(1)** - A therapeutic product presents a serious or imminent risk of injury to health.	**Section 138C Grounds for prohibiting sale** (a) for a Chinese herbal medicine, if the Director has reasonable grounds to believe that — (i) the medicine has been sold or distributed in contravention of section 109(2) or 111(2); (ii) the medicine is dangerous or injurious to health, or unfit for use by human beings; or (iii) the order is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health; (b) for a proprietary Chinese medicine, if the Director has reasonable grounds to believe that — (i) the medicine has been sold in contravention of section 119(1), 143 or 144; (ii) the medicine has been

			suspended under this Part 7. The registration or listing of the goods has been cancelled under this Part		sold or distributed in contravention of section 134; (iii) the medicine has been manufactured in contravention of section 131; (iv) the medicine is dangerous or injurious to health, or unfit for use by human beings; or (v) the order is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health; and (c) for an intermediate product, if the Director has reasonable grounds to believe that — (i) the product is dangerous or injurious to health, or unfit for use by human beings; or (ii) the order is necessary to prevent or reduce a possibility of danger to public health, or to

					mitigate any adverse consequence of a danger to public health. **Section 138D Grounds for directing recall** The Director may make an order under section 138B(1)(b) only if — <u>(a)for a Chinese herbal medicine, if the Director has reasonable grounds to believe that —</u> (i) the medicine has been sold or dispensed in contravention of section 109(1) or 111(1); (ii) the medicine has been sold or distributed in contravention of section 109(2) or 111(2); (iii) the medicine is dangerous or injurious to health, or unfit for use by human beings; or (iv) the order is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse

					consequence of a danger to public health; (b)for a proprietary Chinese medicine, if the Director has reasonable grounds to believe that — (i) the medicine has been sold in contravention of section 119(1), 143 or 144; (ii) the medicine has been sold or distributed in contravention of section 134; (iii) the medicine has been manufactured in contravention of section 131; (iv) the medicine is dangerous or injurious to health, or unfit for use by human beings; or (v) the order is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health; and

					(c)for an intermediate product, if the Director has reasonable grounds to believe that — (i) the product is dangerous or injurious to health, or unfit for use by human beings; or (ii) the order is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health.
(iii)	types of persons bound by a recall order	**第二十五條** 藥品生產企業、經營企業和使用單位	**Section 30EA(1)** – The person in relation to whom the goods are included in the Register or the person supplying the goods.	**Section 21.3(1)** – A person who sells the product.	**Section 138F –** A particular person or particular persons.
(iv)	variation, revocation and appeal	Variation and revocation: **第二十八條** 經過審查和評價，認為召回不徹底或者需要採取更為有效的措施的，藥品監督管理部門可以要求藥品生產企業重新召回或者擴大召回范圍。 **第三十八條** 藥品監督管	Variation and revocation: No provision Appeal: Yes **Section 60 - Review of decisions**	Variation and revocation: No provision Appeal: No provision stipulated in the Food and Drug Act.	Variation and revocation: Yes **Sections 138H and 138I** Appeal: Yes **Sections 141(1A) and 141(1B)**

		理部門及其工作人員不履行職責或者濫用職權的，按照有關法律、法規規定予以處理。 Appeal : No provision stipulated in《藥品召回管理辦法》			
(v)	sanctions and penalties for non-compliance	**第三十一條** 藥品生產企業違反本辦法第二十五條規定，拒絕召回藥品的，處應召回藥品貨值金額3倍的罰款；造成嚴重後果的，由原發證部門撤銷藥品批準證明文件，直至吊銷《藥品生產許可證》。 **第三十二條** 藥品生產企業違反本辦法第十六條規定，未在規定時間內通知藥品經營企業、使用單位停止銷售和使用需召回藥品的，予以警告，責令限期改正，並處 3 萬元(人民幣)以下罰款。 **第三十三條** 藥品生產企業違反本辦法第十九條、第二十四條第二款、第二十八	**Section 30EC** - Criminal offences for non-compliance with requirements (1) A person commits an offence if: (a) the person does an act or omits to do an act; and (b) the act or omission breaches a requirement imposed on the person under section 30EA; and (c) the act or omission has resulted in, or will result in, harm or injury to any person. Penalty: Imprisonment for 5 years or 4,000	**Section 31.2** – Every person who contravenes and order made under any of sections 21.1-21.3 is guilty of an offence and liable (a) On conviction by indictment, to a fine not exceeding (CAD)$5,000,000 or to imprisonment for a term not exceeding two years or to both; and (b) On summary conviction, for a fist offence, to a fine not exceeding (CAD)$250,000 or to imprisonment for a term not exceeding six months or to both and, for a subsequent offence, to a fine not exceeding (CAD)$500,000 or to	**Section 138K –** If a person bound by a Chinese medicine safety order fails or refuses to comply with a requirement of the order, the person commits an offence and is liable to a fine at level 6 (i.e. HK$ 100,000) and to imprisonment for 2 years

		條第二款規定，未按照藥品監督管理部門要求採取改正措施或者召回藥品的，予以警告，責令限期改正，並處 3 萬元(人民幣)以下罰款。 **第三十四條** 藥品生產企業違反本辦法第二十二條規定的，予以警告，責令限期改正，並處 3 萬元(人民幣)以下罰款。 **第三十五條** 藥品生產企業有下列情形之一的，予以警告，責令限期改正；逾期未改正的，處 2 萬元(人民幣)以下罰款： （一）未按本辦法規定建立藥品召回制度、藥品質量保證體係與藥品不良反應監測係統的； （二）拒絕協助藥品監督管理部門開展調查的； （三）未按照本辦法規定提交藥品召回的調查評估報告和召回計劃、藥品召回進展情況和總結報告的；	penalty units, or both. Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A. Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA. (2) A person commits an offence if: (a) the person does an act or omits to do an act; and (b) the act or omission breaches a requirement imposed on the person under section 30EA; and (c) the act or omission is likely to result in harm or injury to any person. Penalty: 2,000 penalty units.	imprisonment for a term not exceeding 18 months or to both. **Section 31.4** - A person who knowingly or recklessly causes a serious risk of injury to human health in contravening another provision of this Act or the regulations, as it relates to a therapeutic product, or an order made under any of sections 21.1 to 21.3 is guilty of an offence and liable (a) on conviction on indictment, to a fine the amount of which is at the discretion of the court or to imprisonment for a term not exceeding five years or to both; and (b) on summary conviction, for a first offence, to a fine not exceeding (CAD)$500,000 or to imprisonment for a term not exceeding 18 months or to both and, for a subsequent offence, to a fine not exceeding (CAD)$1,000,000	

		（四）變更召回計劃，未報藥品監督管理部門備案的。 **第三十六條** 藥品經營企業、使用單位違反本辦法第六條規定的，責令停止銷售和使用，並處 1000 元(人民幣)以上 5 萬元以下罰款；造成嚴重後果的，由原發證部門吊銷《藥品經營許可證》或者其他許可證。 **第三十七條** 藥品經營企業、使用單位拒絕配合藥品生產企業或者藥品監督管理部門開展有關藥品安全隱患調查、拒絕協助藥品生產企業召回藥品的，予以警告，責令改正，可以並處 2 萬元(人民幣)以下罰款。	Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA. (3) Subsection (2) is an offence of strict liability. Note: For strict liability, see section 6.1 of the *Criminal Code*. (4) A person commits an offence if: (a) the person does an act or omits to do an act; and (b) the act or omission breaches a requirement imposed on the person under section 30EA. Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.	or to imprisonment for a term not exceeding two years or to both.	

			Section 30ECA - Civil penalty for non-compliance with requirements A person contravenes this section if: (a) the person does an act or omits to do an act; and (b) the act or omission breaches a requirement imposed on the person under section 30EA. Maximum civil penalty: (a) for an individual— 5,000 penalty units; and (b) for a body corporate — 50,000 penalty units.		
(vi)	any defence available	No provision	**Section 30EA(4)** - A requirement to recover therapeutic goods under this section does not apply to therapeutic goods that cannot be recovered because they have been administered to, or applied in the treatment of, a person.	**Section 31.3** – Due diligence is a defence in a prosecution for an offence under this Act, other than an offence under section 31.4.	**Section 138L –** (1) It is a defence for a person charged under section 138K to establish that the person had a reasonable excuse for the failure or refusal. (2) The person is to be taken to have established that the person had a reasonable excuse for the failure or refusal if – (a) Sufficient evidence is

					adduced to raise an issue that the person had such a reasonable excuse; and (b) The contrary is not proved by the prosecution beyond reasonable doubt.