



香 港 執 業 藥 劑 師 協 會

THE PRACTISING PHARMACISTS ASSOCIATION OF HONG KONG

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8th January 2010

Dear Legislative Council Health Panel Members,

On behalf of The Practising Pharmacists Association of Hong Kong, we would like to draw your kind attention that we are of the view that the Recommendations of the Review Committee may not be able to meet the objective of enhancing the existing regulatory regime to a level required to protect the health and safety of the citizens of a modern and world-class city of Hong Kong.

Firstly, The Practising Pharmacists Association of Hong Kong, representing the majority view of community pharmacists that will be responsible for the implementation of the recommendation of "Requiring a registered pharmacist to be present whenever the ASP is open for business ", objects to the recommendation as it may have no value in enhancing public safety. We are of the view that the Review Committee is unrealistic and impractical to propose such a measure as the ultimate solution to solve the increasingly serious public safety issues of illegal activities (sale of counterfeit drugs, illegal sale of prescription drugs, sale of cough medicine for abuse, etc) conducted in retail pharmacies. (see news clips).

Without the concurrent implementation of measures to tighten the licensing requirements of Authorized Seller of Poisons to a more restricted level of requiring pharmacists to be owners or major shareholders, pharmacists (currently with an employee status) lack the actual power to exercise full control of the operations of the pharmacy and cannot be reasonably expected to prevent the illegal activities performed by the non-pharmacist employer and other staff working in the pharmacy. We would like to highlight that it is not the role of the pharmacist practising in Hong Kong or in other countries to perform law enforcement activities to remedy serious problems, posing public safety risks, caused by the government's outdated and relaxed requirements in awarding licenses to non-pharmacists to own and operate pharmacies. The role of the pharmacist across the world is to provide clinical services in the form of dispensing, counseling, and drug risk management to serve patients. The role of the owners of the pharmacy business is to ensure for the high levels of corporate governance of the business, to control the lawful business activity performed by their staff, and to assure for the reliability and quality of drug products which they procure, store, and sell to the public.

If Hong Kong were to seriously address the issues existing in the community pharmacy sector

to protect the health of our citizens, we recommend to tighten the current licensing requirements of pharmacies to have the restriction of ownership of retail pharmacies to pharmacists (a practice adopted by many developed countries such as Australia, New Zealand, Canada, Korea, Egypt, France, Germany, Italy, Spain, and other European Union countries(see table of countries) in order to effectively achieve the purpose of safeguarding public health.

We would like to draw to your attention a recent European Union High Court ruling on restriction of ownership of pharmacies by pharmacists, in May 2009, where it is deemed that restriction of pharmacies to pharmacists is justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality and over-rides free trade considerations. It is highlighted that non-pharmacist owners, who by definition lack training, experience, and responsibility, do not provide the same safeguards as pharmacist owners and may represent a risk to public health, in particular to the reliability and quality of the supply of drugs at the retail level. (attached European Union Court Judgement, paragraph 39)

Community pharmacists agree with the view of the European High Court that restriction of ownership of pharmacies to pharmacists is necessary to provide quality services and reliable drug products to the public and any lesser restriction, such as rules designed to provide professional independence to pharmacists, is likely "not to be observed in practice."

Furthermore, we are of the view that implementation of the above-mentioned recommendation will not add any value to enhancing levels of drug safety but will incur unnecessary additional costs in pharmacist manpower.

Since Hong Kong has no separation of prescribing from dispensing (SPD), like other advanced countries, prescription volumes are extremely low and does not justify the consumer need and extra financial costs for additional pharmacy opening hours. Therefore, without the business to support additional pharmacist manpower costs, we fear that the small independent pharmacies may be forced to close business and community pharmacy business will soon be monopolized by large chain pharmacy stores. This situation works to the detriment of the society by reducing consumer choice in healthcare product range, pricing, and services (similar to the case of the supermarket business).

We believe it is important to take note that the legislative requirement of pharmacies in advanced countries (USA, UK, Canada) that the pharmacist do not have to be present whenever the store is open for business. The pharmacy department may close and stop the dispensing services before the rest of the store close for business. Hong Kong currently has the same practice model where the dispensary section is allowed to be closed and all dispensing

services ends after the pharmacist leaves while the store can remain open to sell non-poison medicines, Chinese medicines, and other sundry products. We are of the view that this practice need not be changed to continue to provide convenience to customers and to allow for a sustainable and flexible operating business environment.

Please find attached the hundreds of petition letters from the community pharmacy sector for your reference to support the above views. (see petition letter files)

Secondly, community pharmacists responsible for the implementation of the recommendation to require written records of drug orders objects to the recommendation due to the fact that it is a professional right of a pharmacists to place orders in either verbal or written form and of the fact the mandatory written order is not a generally accepted pharmacy practice to enhance drug safety in major countries such as USA, UK, Australia, New Zealand, Canada, etc. Community pharmacists are of the view that the recommendation wastes valuable manpower resources which should be used to provide quality care to patients. However, community pharmacists are disappointed that our recommendation to require pharmacy workers to have a minimum F7 education and appropriate training, to perform high quality pharmacy duties, has not been accepted.

Thirdly, we are disappointed that our recommendation to require wholesalers of drug products to employ pharmacists to ensure for the safe storage, handling, distribution of drugs, in line with practices of developed countries such as Australia and Singapore, has not been accepted.

Finally, we support the establishment of a Drug Safety Center but requests that the role of Head of CDS has solid training and experience in drugs, drug management, and drug safety. We recommend that the candidate have a registered pharmacist qualification as a basic requirement with public health/ medical experience as an addition qualification.

Thank you for your kind support to enhance drug safety to the required level for the best interests of Hong Kong people.

Yours faithfully,

Yours faithfully,



Iris Chang
President

The Practising Pharmacists Association of Hong Kong

Email: president@ppa.hk

世界各地對社區藥房藥劑師擁有權的法例要求

Ng2

	藥劑師擁有權	法例要求*
澳洲	有	<p>《2001年藥劑師註冊法令》 藥房擁有權 第139B條 – 關於藥房業務擁有權的限制 任何人不得擁有藥房業務除非— (a) 該人是一名註冊人；或 (b) 該法團的所有董事及所有股東均為註冊人；或 (ba) 該法團的 - (i) 董事及股東由註冊人及註冊人的親屬組成；及 (ii) 大多數股份由註冊人持有；及 (iii) 有表決權股份只由註冊人持有；或 (c) 該友好團體在本條例生效日期當日於本州或其他州份經辦藥房業務；或 (d) 該友好團體是由不少於兩個在本條(c)款所述的友好團體合併組成；或 (e) 該公司是 Mater Misericordiae Health Services Brisbane Limited ACN 096 708 922。</p>
奧地利	有	<p>選取自《2009 國際藥學聯合會 全球藥劑報告》(2009 FIP Global Pharmacy) 版權屬國際藥學聯合會所有© 2009年</p>
加拿大	有	<p>加拿大藥物及藥房規例 – 第142條 藥房擁有權 第142(1)條 法團不得擁有或經辦藥房業務除非該法團的大多數董事為藥劑師。 第142 (2)條 法團不得擁有或經辦藥房業務除非該法團的每個股份類別均由藥劑師持有及以藥劑師的名義登記。</p>
乍得	只能由藥劑師擁有	<p>選取自《2009 國際藥學聯合會 全球藥劑報告》(2009 FIP Global Pharmacy) 版權屬國際藥學聯合會所有© 2009年</p>

丹麥	只能由藥劑師擁有	選取自《2009 國際藥學聯合會 全球藥劑報告》(2009 FIP Global Pharmacy) 版權屬國際藥學聯合會所有© 2009年
英國	有	根據於 1968 年的藥品法第四部份- 社區藥房的登記及擁有人必須為下列人士 1. 藥劑師； 2. 合伙人，當中全部人必需是藥劑師（在蘇格蘭，則至少一位合伙人是藥劑師） 3. 由註冊公司，如有限公司。 另外，藥房可以聘請一藥劑師代表，當該藥劑師不肯逝世、破產或身體殘障時能確保藥房能繼續運作。
埃及	只能由藥劑師擁有	選取自《2009 國際藥學聯合會 全球藥劑報告》(2009 FIP Global Pharmacy) 版權屬國際藥學聯合會所有© 2009 年
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伊拉克	只能由藥劑師擁有	選取自《2009 國際藥學聯合會 全球藥劑報告》(2009 FIP Global Pharmacy) 版權屬國際藥學聯合會所有© 2009年
意大利	只能由藥劑師擁有	選取自《2009 國際藥學聯合會 全球藥劑報告》(2009 FIP Global Pharmacy) 版權屬國際藥學聯合會所有© 2009年
尼日利亞	只能由藥劑師擁有	選取自《2009 國際藥學聯合會 全球藥劑報告》(2009 FIP Global Pharmacy) 版權屬國際藥學聯合會所有© 2009年
紐西蘭	只能由藥劑師擁有	紐西蘭藥物及醫療儀器安全監管機構 (New Zealand Medicine and Medical Devices Safety Authority)

	或 藥劑師付出大部分 資金、受藥劑師監管	
南韓	只能由藥劑師擁有	選取自《2009 國際藥學聯合會 全球藥劑報告》(2009 FIP Global Pharmacy) 版權屬國際藥學聯合會所有© 2009年
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敘利亞	只能由藥劑師擁有	選取自《2009 國際藥學聯合會 全球藥劑報告》(2009 FIP Global Pharmacy) 版權屬國際藥學聯合會所有© 2009年
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英國	有	《1968年醫藥法令》第四部 - There are restrictions on ownership of community pharmacies. Retail premises must be registered and owned by a pharmacist, a partnership of pharmacists (in Scotland one or more partners must be a pharmacist) or by a “body corporate” – for example a limited company. In addition, a representative of the pharmacist may carry on the business in the event of death, bankruptcy or disability.
津巴布韋	只能由藥劑師擁有 或 藥劑師最少有 51%	選取自《2009 國際藥學聯合會 全球藥劑報告》(2009 FIP Global Pharmacy) 版權屬國際藥學聯合會所有© 2009年

*如中英文條款有所差異，一切以英文版本為準。

參考資料:

1. 澳洲：[http://www.pharmacyboard.qld.gov.au/Information for Pharmacists/Ownership legislation.pdf](http://www.pharmacyboard.qld.gov.au/Information%20for%20Pharmacists/Ownership%20legislation.pdf)
2. 紐西蘭：<http://www.medsafe.govt.nz/Profs/PharmLicence/guidelines.asp#Executive>
3. 英國：<http://www.rpsgb.org.uk/pdfs/consdoc1170.pdf>
4. 其他國家：<http://www.fip.org>

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香港藥業藥劑師協會在社區藥房設立流感資訊站，由註冊藥劑師解答市民有關流感的查詢。



香港藥業藥劑師協會在社區藥房設立流感資訊站，由註冊藥劑師解答市民有關流感的查詢。



區國維(左二)呼籲市民切勿亂服特敏福及樂感清，以免病毒出現抗藥性。

豬流感冒全球迅速擴散，本港亦陷入防疫恐慌，市民紛紛搶購抗流感藥，有藥房竟趁機大發橫財，在顧客未能出示醫生紙下仍照搬出售「特敏福」，更將售價由每盒（十粒裝）三百多元抬至兩倍半至八百五十元。香港藥業藥劑師協會指出，藥房售賣特敏福須憑醫生處方，呼籲市民出現流感徵狀應先求診，由醫生處方抗流感藥物，不應自行購買及盲目服藥，以免引起副作用及出現抗藥性。

因應豬流感冒疫情逼近，港人近日四出搜購抗流感藥及口罩等防疫用品。本報記者昨晚視察角處多間藥房，並以顧客身份到其中一間標明是政府註冊藥房，詢問有否特敏福及樂感清出售，店員稱有售賣特敏福，並直言因疫情緊張，每盒十粒售價由五百多元炒到近八百五十元，限買三盒，更強調毋須醫生紙也可購買。

不過，該店員與記者先落一半訂，數小時後再來取貨。「唔可以即時畀到你，要同醫生搵貨，放心有單有據，唔係假家」，他更稱，前日一日內已售出廿盒，若記者「買就要趁手」。記者其後再到另一藥房查詢，店員表示每盒特敏福售價已加至五百多元，但就要有醫生紙才可購買。

毋須儲存售賣紀錄

據業內人士指，特敏福零售價每盒介乎二百至三百五十元之間，樂感清每盒約二百五十元。他又透露，醫生行內有藥物「拆家」與藥房相熟，藥房可向「拆家」大量買藥，又毋須儲存售賣紀錄，避免衛生署發現，而且價錢較直接向廠家取貨為低，再以市面零售價轉售圖利。現時市場對特敏福需求大，這些拆家途徑向藥房供應特敏福。

胡亂服用有副作用

她呼籲市民切勿自行購買該兩種藥，以免引起副作用對藥物出現抗藥性，而胡亂服用亦可引起嚴重副作用，如特敏福可引起作嘔、腹痛、甚至神志不清等，樂感清則可引起氣管炎及氣管收窄，有心臟及氣管問題人士不宜服用。

全港近五百間社區藥房的藥劑師，昨日免費為市民提供流感諮詢服務，評估市民有否流感徵狀及查閱外症紀錄，如發現懷疑個案，會建議患者即時求醫，亦會為一般流感患者提供用藥指引，藥劑師指，有關服務會持續至豬流感冒危險過去為止。

而香港醫院藥劑師學會教育總監崔俊明則認為，當局應定出用藥指引，規定哪類病人才可使用抗病毒藥物。他又指，本港一旦出現豬流感冒個案，都會在公立醫院治療，藥廠在此非常時期，應只將抗病毒藥供應給公立和私家醫院。

口罩愈搶愈貴 一日抬價七成

口罩及消毒用品亦是市民搶購目標，有藥房近千盒的口罩在數小時內大堆售罄，消毒洗手液亦被搶清，盡快補貨應付需求，強調口罩無加價。不過，有市民投訴萬寧大埔中心分店出售一款四個裝口



本報記者勞須藥劑師查詢詳情，即趕從新界一間藥房購得「偽麻黃鹼」藥丸。



香港執業藥劑師協會今日會向四百名會員發出書面通知，勸喻提高警惕，不要大量購買「偽麻黃鹼」。

內地人一箱箱狂掃「偽麻黃鹼」 製冰毒原材料 港藥房賣斷市

港府聲稱要嚴打青少年濫毒，但本港卻淪為不法分子搜購冰毒原材料的天堂。本報獲悉，可供提煉冰毒的偽麻黃鹼「偽麻黃鹼」(Pseudoephedrine)，近月出現需求異常情況，部分地區藥房出現掃貨潮，本港藥房業界及藥劑師協會月前已發現此情況，但由於本港未有跟隨內地監控公眾購買同類藥物數量，香港執業藥劑師協會遂自行把關，上週口頭勸同業提高警惕，不要一次過大量出售該藥，今日更會向四百多同業發出書面通告。

偽麻黃鹼近月在本港多區藥房斷市，業界消息指，自上月起有人聘用內地人來港掃貨，「一箱箱」地購入該藥，估計每箱多達一千粒以上，以每粒售價幾毫子計，轉售最

少可賺一倍利潤。有藥房職員向本報稱，以往在港售賣偽麻黃鹼毋須醫生處方，不少水貨客大量入貨，運往內地用以提煉毒品。港九藥房總商會有限公司理事長劉愛國指出，偽麻黃鹼是提煉冰毒原料，一般來自俄羅斯及印度，因原料充分及價格便宜，內地販毒集團會用以製冰毒，但近日有指印俄兩地供貨減少，最近「一年半載」業界確傳出有人在本港藥房大批搜購純偽麻黃鹼。

藥劑師已獲勸喻警惕

他續指，一般藥房每次最多只可購入含該藥成分的偽麻藥丸二百至五百粒，但搜購者打算一箱箱購入，故得悉有人嘗試圖直接向藥廠取貨，但未知最後是否成功。海關消息，海關關中在口岸檢獲少量偽麻黃鹼，但未收大量被偷運至內地的情報。

執業藥劑師協會會長鄭綺雯證實，最近接獲同業通知，指近月開始有人在藥房掃偽麻黃鹼，最初以近口岸的上水等區藥房為主，其後各區也出現此情況，有顧客更「有幾多買幾多」。

她不清楚顧客身份，但鑑於該藥可用作製冰毒用途，故上週她已口頭勸喻同業提高警惕，不要大量出售，該會今日會向同業發出通告，她坦言：「惟有自己把關。」

根據《藥物業及毒藥條例》，偽麻黃鹼屬毒藥列表第一部毒藥，即不用醫生處方，但需藥劑師監控出售，但法例無規定每次可賣的數量，而是交藥劑師自行專業判斷。有藥劑師透露，出售該藥不用登記買家身份資料，僅需查詢病源，藥劑師通常會處方一星期用約廿至卅粒藥丸；被問及若有不法分子化整為零到多間藥房掃貨，他指惟有靠同行互報消息。

通鼻塞用 醫院無購入

香港醫院藥劑師學會教育總監霍俊明指，純偽麻黃鹼只用於通鼻塞，必須要加入抗組織胺等其他成分，才可治療傷風及過敏感，醫院並無購入。他建議衛生署規定藥房營業時必須有藥劑師駐守，並研究規定市面不能出售偽麻黃鹼藥物，只能出售該成分的複方藥物。

衛生署發言人稱，偽麻黃鹼及該成分的藥物同樣需藥劑師監售，市民若發現有人違法未經藥劑師出售該藥，可向該署或警方舉報，應例者最高罰款十萬元及監禁兩年。至於監管問題，發言人稱，該署每年最少巡在藥房兩次，調查藥物出售紀錄，留意是否有異常情況，如有需要亦會加密巡查。

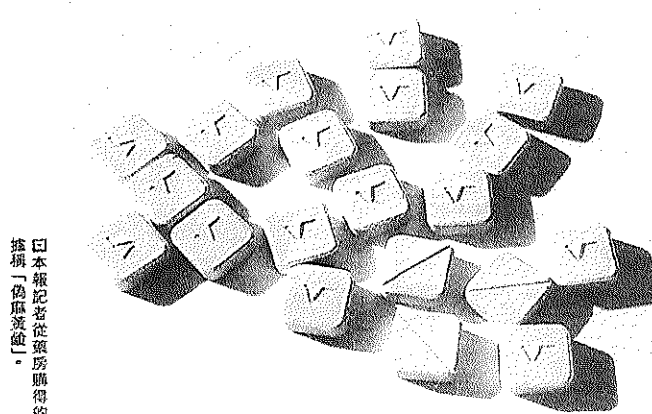
聞記者盧怡安、蔣淑儀



因劉愛國指有傳言，內地有人大批大批從本港搜購偽麻黃鹼。



因鄭綺雯表示上週已口頭通知會員留意有人大批購入偽麻黃鹼藥物的情況。



日本報記者從藥房購得的「偽麻黃鹼」。





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JUDGMENT OF THE COURT (Grand Chamber)

19 May 2009 (*)

(Freedom of establishment – Article 43 EC – Public health – Pharmacies – Provisions restricting the right to operate a pharmacy to pharmacists alone – Justification – Reliability and quality of the provision of medicinal products to the public – Professional independence of pharmacists)

In Joined Cases C-171/07 and C-172/07,

REFERENCES for a preliminary ruling under Article 234 EC from the Verwaltungsgericht des Saarlandes (Germany), made by decisions of 20 March and 21 March 2007 respectively, received at the Court on 30 March 2007, in the proceedings

Apothekerkammer des Saarlandes,

Marion Schneider,

Michael Holzapfel,

Fritz Trennheuser,

Deutscher Apothekerverband eV (C-171/07),

Helga Neumann-Seiwert (C-172/07)

v

Saarland,

Ministerium für Justiz, Gesundheit und Soziales,

joined party:

DocMorris NV,

THE COURT (Grand Chamber),

composed of V. Skouris, President, P. Jann, C.W.A. Timmemans, K. Lenaerts, J.-C. Bonichot and T. von Danwitz, Presidents of Chambers, J. Makarczyk, P. Küris, E. Juhász, G. Arestis, J. Malenovsk (Rapporteur), L. Bay Larsen and P. Lindh, Judges,

Advocate General: Y. Bot,

Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 3 September 2008,

after considering the observations submitted on behalf of:

- the Apothekerkammer des Saarlandes, Ms Schneider, Mr Holzapfel, Mr Trennheuser and Deutscher Apothekerverband eV, by J. Schwarze, assisted by C. Dechamps, Rechtsanwalt,**
- Ms Neumann-Seiwert, by H.-U. Dettling, Rechtsanwalt,**
- Saarland and the Ministerium für Justiz, Gesundheit und Soziales, by W. Schild, acting as Agent, assisted by H. Krüninger, Rechtsanwalt,**
- DocMorris NV, by C. König, assisted by F. Diekmann, Rechtsanwalt,**
- the German Government, by M. Lumma and C. Schulze-Bar, acting as Agents,**

- the Greek Government, by E. Skandalou, acting as Agent,
 - the French Government, by G. de Bergues and B. Messmer, acting as Agents,
 - Ireland, by D. O'Hagan, acting as Agent, assisted by A. Collins SC and N. Travers BL,
 - the Italian Government, by I.M. Braguglia, acting as Agent, assisted by G. Fiengo, avvocato dello Stato,
 - the Netherlands Government, by Y. de Vries, acting as Agent,
 - the Austrian Government, by C. Pesendorfer and T. Kr II, acting as Agents,
 - the Polish Government, by E. Ośniecka-Tamecka and M. Kapko, acting as Agents,
 - the Finnish Government, by J. Himmanen and A. Guimaraes-Purokoski, acting as Agents,
 - the Commission of the European Communities, by E. Traversa and H. Kr mer, acting as Agents,
- after hearing the Opinion of the Advocate General at the sitting on 16 December 2008,
- gives the following

Judgment

- 1 These references for a preliminary ruling relate to the interpretation of Articles 43 EC and 48 EC and the principles of Community law
- 2 The references were made in two actions, brought by the Apothekerkammer des Saarlandes (Saarland Pharmacists' Association), Ms Schneider, Mr Holzapfel, Mr Trennheuser and Deutscher Apothekerverband eV (German Pharmacists' Association) (C-171/07) and Ms Neumann-Seiwert (C-172/07) against Saarland and the Ministerium für Justiz, Gesundheit und Soziales (Ministry for Justice, Health and Social Affairs; 'the Ministry'), concerning national legislation which allows only persons who have the status of pharmacist to own and operate pharmacies.

Legal context

Community legislation

- 3 Recital 26 in the preamble to Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255, p. 22) states:

'This Directive does not coordinate all the conditions for access to activities in the field of pharmacy and the pursuit of these activities. In particular, the geographical distribution of pharmacies and the monopoly for dispensing medicines should remain a matter for the Member States. This Directive leaves unchanged the legislative, regulatory and administrative provisions of the Member States forbidding companies from pursuing certain pharmacists' activities or subjecting the pursuit of such activities to certain conditions.'

- 4 That recital repeats, in essence, the 2nd recital in the preamble to Council Directive 85/432/EEC of 16 September 1985 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy (OJ 1985 L 253, p. 34) and the 10th recital in the preamble to Council Directive 85/433/EEC of 16 September 1985 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the field of pharmacy (OJ 1985 L 253, p. 37). Those two directives were repealed with effect from 20 October 2007 and replaced by Directive 2005/36.

National legislation

- 5 Paragraph 1 of the Law on Pharmacies (Gesetz über das Apothekenwesen) in the version published in BGBl. 1980 I, p. 1993, as amended by the regulation of 31 October 2006 (BGBl. 2006 I, p. 2407) ('the ApoG'), provides as follows:

'(1) The obligation in the public interest to ensure proper provision of medicinal products to the public shall be incumbent on pharmacies.

(2) A person who wishes to operate a pharmacy and up to three branch pharmacies requires a licence from the competent authority.

(3) The licence shall cover only the pharmacist to whom it is granted and the premises identified in the licence

certificate.'

6 Paragraph 2 of the ApoG provides:

'(1) A licence is to be granted, on application, if the applicant:

1. is German within the meaning of Article 116 of the Basic Law (Grundgesetz), a national of one of the other Member States of the European Union or of another State party to the Agreement on the European Economic Area ...;

2. has full legal capacity;

3. possesses a German licence to practice as a pharmacist;

4. has the trustworthiness required to operate a pharmacy;

...

7. is not physically unfit to manage a pharmacy properly;

...

(4) A licence to operate several public pharmacies is to be granted, on application, if:

1. the applicant fulfils the conditions under subparagraphs 1 to 3 above in respect of each of the pharmacies applied for;

2. the pharmacy and branch pharmacies to be operated by him are in the same district ("Kreis") or town or in neighbouring districts or towns.

(5) The provisions of this Law shall apply mutatis mutandis to the operation of several public pharmacies, subject to the following requirements:

1. the operator is required to manage one of the pharmacies (main pharmacy) personally;

2. for each further pharmacy (branch pharmacy), the operator is required to designate in writing a pharmacist as the responsible person who must fulfil the obligations as laid down in this Law and in the pharmacy operation rules applicable to pharmacy managers.

...'

7 Paragraph 7 of the ApoG states:

'The licence shall oblige the holder to manage the pharmacy personally on his own responsibility. ...'

8 Paragraph 8 of the ApoG is worded as follows:

'A number of persons may operate a pharmacy together only in the form of a civil law partnership or commercial partnership; in such cases, each partner requires a licence. ...'

9 Paragraph 13(1) of the ApoG states:

'Following the death of the licence holder, his heirs may entrust the running of the pharmacy to a pharmacist for a maximum of 12 months.'

10 Under Paragraph 14 of the ApoG, hospitals have the choice of obtaining their supplies of medicinal products from an internal pharmacy, that is to say, a pharmacy on the premises of the hospital concerned, from the pharmacy of another hospital or from a pharmacy outside hospital premises. A licence to operate an internal pharmacy is granted if the hospital demonstrates inter alia that it has recruited a pharmacist who fulfils the conditions laid down in subparagraphs 1 to 4, 7 and 8 of Paragraph 2(1) of the ApoG.

The main actions and the questions referred for a preliminary ruling

11 DocMorris NV ('DocMorris') is a public limited company established in the Netherlands whose business includes the selling of medicinal products by mail order. By decision of 29 June 2006, the Ministry granted it, with effect from 1 July 2006, a licence to operate a branch pharmacy in Saarbrücken (Germany), subject to a condition requiring it to recruit a pharmacist who would be entrusted with managing the pharmacy in question personally and on his own responsibility ('the decision of 29 June 2006').

12 On 2 and 18 August 2006, the claimants in the main proceedings brought actions before the Verwaltungsgericht des Saarlandes (Administrative Court, Saarland) for annulment of the decision of 29 June 2006.

13 In those actions, they submitted that the decision of 29 June 2006 is contrary to the ApoG because it infringes the 'Fremdbesitzverbot', that is to say the principle, as resulting from subparagraph 3 of Paragraph 2(1) in conjunction with Paragraphs 7 and 8 of the ApoG, under which the right to own and operate a pharmacy is restricted to pharmacists alone ('the rule excluding non-pharmacists').

14 The Ministry, supported by DocMorris, contended that the decision of 29 June 2006 is valid because the Ministry was obliged to disapply the abovementioned provisions of the ApoG on the ground that they infringe Article 43 EC which guarantees freedom of establishment. In their submission, a capital company lawfully operating a pharmacy in a Member State does not have access to the German pharmacy market and such a restriction is not necessary for achieving the legitimate objective of protection of public health.

15 In those circumstances, the Verwaltungsgericht des Saarlandes decided to stay proceedings and to refer to the Court for a preliminary ruling the following questions, which are drafted in identical terms in both Case C-171/07 and Case C-172/07:

(1) Are the provisions concerning freedom of establishment for capital companies (Articles 43 EC and 48 EC) to be interpreted as precluding [the rule excluding non-pharmacists], as provided for by subparagraphs 1 to 4 and 7 of Paragraph 2(1), the first sentence of Paragraph 7 and the first sentence of Paragraph 8 of the [ApoG]?

(2) If the first question is answered in the affirmative:

Having regard in particular to Article 10 EC and to the principle of effectiveness of Community law, is a national authority entitled and obliged under Community law to disapply national provisions if it regards as contrary to Community law even if there is no clear breach of Community law and it has not been established by the Court of Justice ... that the relevant provisions are incompatible with Community law?

16 By order of the President of the Court of 1 June 2007, Cases C-171/07 and C-172/07 were joined for the purposes of the written and oral procedure and the judgment.

Consideration of the questions

Question 1

17 By its first question, the national court asks whether Articles 43 EC and 48 EC preclude national legislation, such as that at issue in the main actions, which prevents persons not having the status of pharmacist from owning and operating pharmacies.

Preliminary observations

18 First, it is clear, both from the case-law of the Court and from Article 152(5) EC and recital 26 in the preamble to Directive 2005/36, that Community law does not detract from the power of the Member States to organise their social security systems and to adopt, in particular, provisions intended to govern the organisation of health services such as pharmacies. In exercising that power, however, the Member States must comply with Community law, in particular the provisions of the Treaty on the freedoms of movement, including freedom of establishment. Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of those freedoms in the healthcare sector (see, to this effect, Case C-372/04 Watts [2006] ECR I-4325, paragraphs 92 and 146, and Case C-169/07 Hartauer [2009] ECR I-0000, paragraph 29).

19 When assessing whether that obligation has been complied with, account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved. Since the level may vary from one Member State to another, Member States must be allowed discretion (see, to this effect, Case C-322/01 Deutscher Apothekerverband [2003] ECR I-14887, paragraph 103; Case C-141/07 Commission v Germany [2008] ECR I-0000, paragraph 51; and Hartauer, paragraph 30).

20 Second, neither Directive 2005/36 nor any other measure implementing the freedoms of movement guaranteed by the Treaty lays down conditions governing access to activities in the pharmacy field that specify the category of persons who are entitled to operate a pharmacy. Consequently, the national legislation must be examined in the light of the provisions of the Treaty alone.

21 Third, the regime applicable to persons entrusted with the retail supply of medicinal products varies from one Member State to another. Whereas, in certain Member States, only self-employed pharmacists can own and operate pharmacies, other Member States accept that persons not having the status of self-employed pharmacist may own a pharmacy while entrusting its management to employed pharmacists.

Existence of a restriction on freedom of establishment

22 According to settled case-law, Article 43 EC precludes any national measure which, even though it is applicable without

discrimination on grounds of nationality, is liable to hinder or render less attractive the exercise by Community nationals of the freedom of establishment that is guaranteed by the Treaty (see, in particular, Case C-19/92 Kraus [1993] ECR I-1663, paragraph 32, and Case C-299/02 Commission v Netherlands [2004] ECR I-9761, paragraph 15).

23 Legislation which makes the establishment in the host Member State of an economic operator from another Member State subject to the issue of a prior authorisation and allows self-employed activity to be pursued only by certain economic operators who satisfy predetermined requirements, compliance with which is a condition for the issue of that authorisation, constitutes a restriction within the meaning of Article 43 EC. Such legislation deters or even prevents economic operators from other Member States from pursuing their activities in the host Member State through a fixed place of business (see, to this effect, Hardauer, paragraphs 34, 35 and 38).

24 The rule excluding non-pharmacists constitutes such a restriction because it allows only pharmacists to operate pharmacies, denying other economic operators access to this self-employed activity in the Member State concerned.

Justification of the restriction on freedom of establishment

25 Restrictions on freedom of establishment which are applicable without discrimination on grounds of nationality may be justified by overriding reasons in the general interest, provided that the restrictions are appropriate for securing attainment of the objective pursued and do not go beyond what is necessary for attaining that objective (see Hardauer, paragraph 44).

26 In the main actions, first, the national legislation at issue applies without discrimination on grounds of nationality.

27 Second, the protection of public health is one of the overriding reasons in the general interest which can justify restrictions on the freedoms of movement guaranteed by the Treaty such as the freedom of establishment (see, inter alia, Hardauer, paragraph 46).

28 More specifically, restrictions on those freedoms of movement may be justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality (see, to this effect, Deutscher Apothekerverband, paragraph 106, and Commission v Germany, paragraph 47).

29 Third, it must be examined whether the rule excluding non-pharmacists is appropriate for securing such an objective.

30 It is important that, where there is uncertainty as to the existence or extent of risks to human health, a Member State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent. Furthermore, a Member State may take the measures that reduce, as far as possible, a public-health risk (see, to this effect, Case C-170/04 Rosengren and Others [2007] ECR I-4071, paragraph 49), including, more specifically, a risk to the reliability and quality of the provision of medicinal products to the public.

31 In this context, attention is to be drawn to the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods (see, to this effect, Case C-369/88 Delattre [1991] ECR I-1487, paragraph 54).

32 Those therapeutic effects have the consequence that, if medicinal products are consumed unnecessarily or incorrectly, they may cause serious harm to health, without the patient being in a position to realise that when they are administered.

33 Overconsumption or incorrect use of medicinal products leads, moreover, to a waste of financial resources which is all the more damaging because the pharmaceutical sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied (see by analogy, with regard to hospital treatment, Case C-385/99 M Ier-Faur and van Riet [2003] ECR I-4509, paragraph 80, and Watts, paragraph 109). There is a direct link between those financial resources and the profits of businesses operating in the pharmaceutical sector because in most Member States the prescription of medicinal products is borne financially by the health insurance bodies concerned.

34 In the light of those risks to public health and to the financial balance of social security systems, the Member States may make persons entrusted with the retail supply of medicinal products subject to strict requirements, including as regards the way in which the products are marketed and the pursuit of profit. In particular, the Member States may restrict the retail sale of medicinal products, in principle, to pharmacists alone, because of the safeguards which pharmacists must provide and the information which they must be in a position to furnish to consumers (see, to this effect, Delattre, paragraph 56).

35 In this connection, given the power accorded to the Member States to determine the level of protection of public health, it must be accepted that Member States may require that medicinal products be supplied by pharmacists enjoying genuine professional independence. They may also take measures which are capable of eliminating or reducing a risk that that independence will be prejudiced because such prejudice would be liable to affect the degree to which the provision of medicinal products to the public is reliable and of good quality.

36 In this context, three categories of potential pharmacy operators must be distinguished, namely natural persons having the status of pharmacist, persons operating in the pharmaceutical products sector as manufacturers or wholesalers, and persons neither having the status of pharmacist nor operating in that sector.

37 It is undeniable that an operator having the status of pharmacist pursues, like other persons, the objective of making a

profit. However, as a pharmacist by profession, he is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint. His private interest connected with the making of a profit is thus tempered by his training, by his professional experience and by the responsibility which he owes, given that any breach of the rules of law or professional conduct undermines not only the value of his investment but also his own professional existence.

- 38 Unlike pharmacists, non-pharmacists by definition lack training, experience and responsibility equivalent to those of pharmacists. Accordingly, they do not provide the same safeguards as pharmacists.
- 39 A Member State may therefore take the view in the exercise of its discretion referred to in paragraph 19 of the present judgment, that, unlike the case of a pharmacy operated by a pharmacist, the operation of a pharmacy by a non-pharmacist may represent a risk to public health, in particular to the reliability and quality of the supply of medicinal products at retail level, because the pursuit of profit in the course of such operation does not involve moderating factors such as those, noted in paragraph 37 of the present judgment, which characterise the activity of pharmacists (see by analogy, with regard to the provision of social welfare services, Case C-70/95 *Sodemare and Others* [1997] ECR I-3395, paragraph 32).
- 40 It is therefore permissible for a Member State inter alia to assess, in the exercise of that discretion, whether such a risk exists in the case of manufacturers and wholesalers of pharmaceutical products on the ground that they might compromise the independence of employed pharmacists by encouraging them to promote the medicinal products which they produce or market themselves. Likewise, a Member State may determine whether operators lacking the status of pharmacist are liable to compromise the independence of employed pharmacists by encouraging them to sell off medicinal products which it is no longer profitable to keep in stock or whether those operators are liable to make reductions in operating costs which may affect the manner in which medicinal products are supplied at retail level.
- 41 In their observations lodged before the Court, *DocMorris* and the Commission of the European Communities also submitted that in the main actions the rule excluding non-pharmacists cannot be justified in the general interest because that objective is pursued in an inconsistent manner.
- 42 As to those submissions, it is apparent from the Court's case-law that national legislation is appropriate for securing attainment of the objective relied upon only if it genuinely reflects a concern to attain that objective in a consistent and systematic manner (see Joined Cases C-338/04, C-359/04 and C-360/04 *Placanica and Others* [2007] ECR I-1891, paragraphs 53 and 58; Case C-500/06 *Corporaci n Demoest tica* [2008] ECR I-0000, paragraphs 39 and 40; and *Hartlauer*, paragraph 55).
- 43 In this context, it is to be observed that the national legislation does not exclude the operation of pharmacies by non-pharmacists absolutely.
- 44 First of all, Paragraph 13(1) of the ApoG provides, by way of exception, that the heirs of a pharmacist who do not themselves have the status of pharmacist may operate the pharmacy which they have inherited for a maximum of 12 months.
- 45 However, this exception proves justified having regard to protection of the legitimate property rights and interests of the members of the deceased pharmacist's family. It must be found that the Member States may take the view that the interests of a pharmacist's heirs are not such as to jeopardise the requirements and guarantees flowing from their respective legal systems which operators who have the status of pharmacist must meet. In this context, account is to be taken especially of the fact that throughout the transitional period a qualified pharmacist must be responsible for operating the inherited pharmacy. Therefore, the heirs cannot, in this specific context, be equated with other operators who do not have the status of pharmacist.
- 46 It should also be noted that the effects of this exception are only temporary since the heirs must transfer the rights to operate the pharmacy to a pharmacist within 12 months.
- 47 This exception is thus designed to enable the heirs to assign the pharmacy to a pharmacist within a period which does not prove unreasonable and it may thus be regarded as not presenting a risk to the reliability and quality of the provision of medicinal products to the public.
- 48 Next, nor can such a risk result from the fact that hospitals may operate internal pharmacies. The latter are intended to provide medicinal products not to persons outside those hospitals but to the hospitals in which they are established. Thus, hospitals which operate such pharmacies are not, in principle, capable of affecting the general level of reliability and quality in the provision of medicinal products to the public as a whole. Furthermore, having regard to the fact that those hospitals provide medical care, there are no grounds for assuming that they would have an interest in making a profit to the detriment of the patients for whom the medicinal products of the pharmacies which they house are intended.
- 49 Finally, although the national legislation allows pharmacists to operate up to three branches of a single pharmacy, such a possibility is subject to a number of conditions which are intended to safeguard public health requirements. First of all, the pharmacist concerned is himself responsible for the branches' operation and he therefore determines their general commercial policy. Those branches are thus also presumed to be operated from a professional viewpoint, the private interest connected with the making of a profit being tempered to the same extent as in the case of the operation of pharmacies which are not branches. Next, those branches must be located within a specified geographical radius in order to ensure a sufficient presence in the branches of the pharmacist operating them and actual supervision by him. Last, the pharmacist operating the branches must designate, for each branch, a responsible pharmacist, who must ensure that legal obligations are complied with and that the management of the branch concerned conforms to the general

commercial policy determined by the pharmacist operating the branches.

- 50 Since the operation of the branches is subject to those conditions, the legislation at issue in the main actions cannot be regarded as inconsistent.
- 51 In view of all the foregoing, it must be found that the legislation at issue in the main actions is appropriate for securing attainment of the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality and, therefore, that public health is protected.
- 52 Fourth, it must be examined whether the restriction on freedom of establishment goes beyond what is necessary for attaining that objective, that is to say whether there are measures restricting the freedom guaranteed by Article 43 EC less which would enable the objective to be attained just as effectively.
- 53 DocMorris and the Commission have submitted before the Court that that objective could be attained by less restrictive measures, such as an obligation that a pharmacist be present in the pharmacy, an obligation to take out insurance or a system of adequate controls and effective penalties.
- 54 However, having regard to the discretion which the Member States are allowed, as referred to in paragraph 19 of the present judgment, a Member State may take the view that there is a risk that legislative rules designed to ensure the professional independence of pharmacists would not be observed in practice, given that the interest of a non-pharmacist in making a profit would not be tempered in a manner equivalent to that of self-employed pharmacists and that the fact that pharmacists, when employees, work under an operator could make it difficult for them to oppose instructions given by him.
- 55 The Commission has not put forward, apart from general considerations, anything to show what the specific system would be that would be capable of ensuring – with the same effectiveness as the rule excluding non-pharmacists – that those legislative rules are observed in practice notwithstanding the considerations set out in the previous paragraph of the present judgment.
- 56 Nor, contrary to DocMorris's and the Commission's submissions, can the risks to the independence of the profession of pharmacist be excluded with the same effectiveness by the means consisting in the imposition of an obligation to take out insurance, such as insurance for vicarious civil liability. While that measure might enable the patient to obtain financial reparation for any harm suffered by him, it operates after the event and would be less effective than the rule excluding non-pharmacists in that it would not in any way prevent the operator concerned from exerting influence over the employed pharmacists.
- 57 Accordingly, it has not been established that another measure that restricts the freedom guaranteed by Article 43 EC less than the rule excluding non-pharmacists would make it possible to ensure just as effectively the level of reliability and quality in the provision of medicinal products to the public that results from the application of that rule.
- 58 Consequently, the national legislation at issue in the main actions proves appropriate for securing attainment of the objective pursued by it and does not go beyond what is necessary for attaining that objective. It must therefore be accepted that the restrictions flowing from the national legislation may be justified by that objective.
- 59 This conclusion is not called into question by the judgment in Case C-140/03 Commission v Greece [2005] ECR I-3177, upon which Saarland, the Ministry, DocMorris and the Commission rely, where the Court ruled that the Hellenic Republic had failed to fulfil its obligations under Articles 43 EC and 48 EC by enacting and maintaining in force national provisions under which the establishment by a legal person of an optician's shop was subject *inter alia* to the condition that authorisation for the establishment and operation of that shop had to have been granted to a recognised optician who was a natural person and the person holding the authorisation to operate the shop had to hold at least 50% of the company's share capital and participate at least to that extent in the profits and losses of the company.
- 60 Given the particular nature of medicinal products and of the medicinal-product market, and as Community law currently stands, the Court's findings in Commission v Greece cannot be transposed to the field of the retail supply of medicinal products. Unlike optical products, medicinal products prescribed or used for therapeutic reasons may none the less prove seriously harmful to health if they are consumed unnecessarily or incorrectly, without the consumer being in a position to realise that when they are administered. Furthermore, a medically unjustified sale of medicinal products leads to a waste of public financial resources which is not comparable to that resulting from unjustified sales of optical products.
- 61 In view of all the foregoing, the answer to the first question is that Articles 43 EC and 48 EC do not preclude national legislation, such as that at issue in the main actions, which prevents persons not having the status of pharmacist from owning and operating pharmacies.

Question 2

- 62 Given the reply to the first question, there is no need to answer the second question.

Costs

- 63 Since these proceedings are, for the parties to the main proceedings, a step in the actions pending before the national

court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Grand Chamber) hereby rules:

Articles 43 EC and 48 EC do not preclude national legislation, such as that at issue in the main actions, which prevents persons not having the status of pharmacist from owning and operating pharmacies.

[Signatures]

*** Language of the case: German.**

敬啟者：

藉悉委員會「藥房在所有營業時間內均須藥劑師在場」建議，我們社區藥劑師特此致函委員會表達對此建議看法。我們認為香港執業藥劑師協會比起其他藥劑師或藥劑師組織更能代表正在社區執業的藥劑師，提出我們的主流意見，而且更能代表將會執行委員會所建議監管零售商政策的藥劑師。因此香港執業藥劑師協會的提議應比起這些現時不是在社區執業或不能代表我們主流意見的藥劑師或藥劑師組織更受委員會的重視。這些藥劑師組織拒絕聆聽大部份藥劑師的訴求，我們覺得他們的提議只可被視為他們個人意見或在未曾與我們尋求共識下對現時社區藥房處境的看法。

鑑於現時社區藥劑師並不能真正監控藥房的運作，我們作為將會執行委員會所建議監管零售商政策的藥劑師，反對單以「藥房在所有營業時間內均須藥劑師在場」的建議，作為社區藥劑師為市民提供更專業服務和加強對藥物儲存及供應的控制的唯一措施。

我們對保障公眾利益義不容辭，但是我們認為委員會亦須顯示其徹底處理造成現時對公眾安全造成風險的處境根本原因的決心，即除上述建議外，更須實行以下措施。否則我們將否決上述建議。

1. **收緊獲授權毒藥銷售商發牌條件：**跟隨其他先進國家的做法(如澳洲、紐西蘭、加拿大、德國、西班牙、意大利、韓國等)，只有藥劑師能夠持有藥房擁有權。只有如此，藥劑師才可以真正監控藥房的運作，從而為市民提供更專業的服務和加強對藥物儲存及供應的控制。
2. **提供合適營商環境：**推行公私營合作(即社區藥房為所有公立醫院門診病人配藥)和實施醫藥分家，以確保社區藥房具有足夠的生意額支付「藥房在所有營業時間內均須藥劑師在場」所需的開支。

我們敦促委員會考慮到歐洲最高法院對於在零售商層面提高藥物安全以保障公眾健康所作出的結論(見附錄)，並希望委員會能夠明瞭除了實行「藥房在所有營業時間內均須藥劑師在場」的建議，更要作出治本的轉變，以解除現時政策對公眾安全所造成之風險。

我們重申不能接受委員會只推行「藥房在所有營業時間內均須藥劑師在場」的措施。我們懼怕這會誤導公眾，令他們以為只要有社區藥劑師在場就能夠確保市民用藥方面的安全，但作為顧員的我們實際上對藥物儲存及供應的藥物是否可靠和高品質的監控卻是有限。

敬希委員會慎重考慮以上建議及盡早賜覆為荷！

(中文譯本祇供參考，如中、英文兩個版本有任何抵觸或不相符之處，請以英文版本為準。)

此致

香港藥物監管制度檢討委員會成員

藥劑師姓名

二〇〇九年十二月二十六日

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1/7/2010

Letter for ASP

Please sign and return to PPA by fax 3003 0112 before 29 Dec 2009.

敬啟者：

我們強烈反對藥物監管制度檢討委員會（下稱「委員會」）的建議，要求所有獲授權毒藥銷售商（下稱「藥房」）在開放營業的每一日，所有時間均須有註冊藥劑師在處所內。在沒有醫藥分家的情況下，非連鎖式經營、獨立營運的藥房是沒有可能增加營業額以支付因委員會要求而增加的藥劑服務。

因此，我們認為委員會提出的建議，是變相強迫所有非連鎖式經營、獨立營運的藥房結業，是等如讓連鎖式經營的藥房壟斷整個行業。

此致

藥物監管制度檢討委員會

二零零九年十二月廿六日

歐盟法院於2009年6月裁定公眾安全和確保藥物質量凌駕於「自由貿易」的考慮，因此建議所有歐洲國家的社區藥房不應由非具備藥劑師資格的人士持有。

摘錄於醫藥期刊 'UK Pharmaceutical Journal'

的報告，歐盟最高法院近期的判決為支持歐洲國家內的藥房之擁有權只限由藥劑師持有。

首先，歐洲最高法院的結論為公民的健康比企業自由和資金自由流動(即是自由貿易)更為重要。

請注意以下備註是關於藥房如果由非具備藥劑師資格的人士所擁有對公眾健康所造成的風險，以及藥劑師作為僱員的難處。

「基於確保提供公眾的藥物是可靠和具備良好質量的考慮，限制由藥劑師持有藥房的擁有權也是合於情理的。」

此外，法院亦斷定藥物是有別於一般商品。報告指出「法院表示注意到藥物由於具有治療效力，因此不可跟其他商品相並論。」

再者，判詞強調各會員國可根據以上理由而決定，是否應該限制只由藥劑師擁有藥房。「會員國行使自由決定權時，可從由非藥劑師營運藥房時對公眾健康造成風險的角度考慮，特別是零售供應的層面上能否保證藥物的可靠性和質量。」

判詞繼續指出，「會員國自行決定時可考慮到，如果實行此限制，或不會再有減少對確保藥劑師的專業獨立的管制規例和刑罰情況出現。

這是因為非藥劑師人士在經營藥房時對賺取盈利的考量跟自行擁有藥房的藥劑師有所不同；而藥劑師若受僱於老闆之下，很難反對僱主的指示。」

(中文譯本祇供參考，如中、英文兩個版本有任何抵觸或不相符之處，請以英文版本為準

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