

將處方藥轉類為非處方藥的世界規範 與民眾自己用藥(Self-Medication)

2015年2月11日

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醫師公會全聯會顧問

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世界衛生組織對**Self-Medication**的指引

It has become widely accepted that **self-Medication** (自己用藥) **has an important place in the health care system** (健康照顧體系). Recognition of the responsibility of individuals for their own health and awareness that professional (醫師專業) care for minor ailments (微恙，不是minor disease!) is often unnecessary have contributed to this view.

Drug regulatory (食物藥品管理署) **and** health authorities (衛服部的醫事司) have to consider the types of medicinal products for which **reclassification** (共同負責轉類) is **appropriate, safe and rational in the interest of public health.** (為公眾健康利益)

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推動「自己用藥」 Self-Medication 的基礎條件

Improvements in people's general knowledge, level of education and socioeconomic status in many countries form a reasonable basis for successful self-medication. New drugs with specific pharmacological action, such as histamine H₂-receptor antagonists (第二型抗組織胺), nonsteroidal anti-inflammatory compounds (非類固醇抗炎藥) (NSAID) and nicotine preparations for cessation of smoking, have been successfully reclassified from prescription to non-prescription status in many countries.

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民眾「自己用藥」是求醫行為的轉變-屬醫事司的權責

- 症狀 > 求醫 > 醫師診斷 > 處方 (醫師告知用藥意義、用法、應注意事項、出現不良反應的應對) > 藥師調劑並且指導用藥 (藥師依據處方無法瞭解醫師給藥的適應症和意義，如果病人有疑問，應告知向醫師詢問，不可以隨意答覆，更不可以批評!)
- 症狀 > 求醫 > 沒有診斷 (頭痛、肌肉酸痛、頭暈、便秘等)，醫師處方僅緩解症狀
- 醫師告知病人以後可自行購買非處方藥服用
- 輕微症狀 (aches, pains and itches) > 民眾自己購買非處方藥使用：「自己用藥」 Self-Medication
- 病人原有疾病復發，自行購買原診治醫師處方的非處方藥使用：「自己用藥」 Self-Medication

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文明先進國家民眾的求醫問題和台灣現況

- 求醫不易，需要預約等待
- 醫師診察費不便宜
- 檢驗費用更是昂貴
- 民眾教育知識水準高，能自行判斷是否求醫或購買非處方藥，「自己用藥」
- 衛服部醫事司考慮台灣的醫療常態，「自己用藥」的優缺點和利弊，評估台灣是否現在要努力推動民眾「自己用藥」，需要慎重考慮
- ★食藥署負責審查將處方藥轉類為非處方藥，並且發給非處方藥販售許可證，規範販售地點(不只是篩選)

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推行「自己用藥」的優缺點和利弊

優點和利益

- 方便病人迅速緩解症狀
- 節省醫療資源和費用

缺點和弊病

- 病人誤判，延誤診治，危及生命: 直腸癌誤以為是痔瘡，口腔癌誤以為是普通口腔炎，肺炎、肺結核和肺癌誤以為是普通咳嗽
- 病人誤用或濫用非處方藥，產生不良後果

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緩解氣喘發作的 β -激動藥噴劑



英國民眾自己購買

isoproterenol 噴劑使用，導致氣喘死亡率突然上升，稱之為氣喘矛盾(asthma paradox)。檢討後認為當時不需處方即可從藥房購得，病人過度依賴噴劑，並且用藥過量。

1. Page CE. An explanation of the asthma paradox. Am Rev Respir Dis 1993; 147: S29-S32.
2. Burney PGJ. Asthma mortality in England and Wales: evidence for a further increase, 1974-1984. Lancet 1986;2:323-36.

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食藥署推動「自我藥療」(Self-Medical Treatment) 層級超越「自己用藥」

食品藥物管理署(簡稱為食藥署)宣稱順應世界文明先進國家的潮流(應遵守世界規範)，推動「自我藥療」(self-medical treatment)計畫，第一梯次篩選出13種處方藥品，轉類為指示用藥(文明先進國家無此項目，只有非處方藥)，宣布自今年六月民眾不需醫師處方，即可自行至藥局直接購買指示藥(尚未完成審查、核准、發給販售許可證!)，超越醫事司的職權。

世界規範和指引

- "Guidelines for the Regulatory Assessment of Medicinal Products for use in **Self-Medication**"
World Health Organization. Dept. of Essential Drugs and Medicines Policy, **2000** Geneva :
<http://apps.who.int/iris/handle/10665/66154>
- **ADVICE FOR AMERICANS ABOUT SELF-CARE**
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration and the Consumer Healthcare Products Association

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Guidelines for the Regulatory Assessment of Medicinal Products for use in Self-Medication

Self-care consists of the health activities and health-related **decision-making of individuals**, families, friends, colleagues at work, and so on. It includes **self-medication**, non-drug self-treatment, social support in illness, and first aid in everyday life.

The reclassification of medicinal products from sale on prescription only to nonprescription (over-the-counter, or OTC) sale is of great current interest in many countries.

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Guidelines for the Regulatory Assessment of Medicinal Products for use in Self-Medication

Regulatory assessment of a change from prescription to non-prescription status should be based on medical and scientific data on safety and efficacy of the compound and rationality in terms of public health.

The purpose of the present Regulatory assessment of a change from prescription to non-prescription status should be based on medical and scientific data on safety and efficacy of the compound and rationality in terms of public health.

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Definition of Medicinal Products for Self-Medication

Those medicinal products which do not require a medical prescription and which are produced, distributed and sold primarily with the intention that they will be used by consumers on their own initiative and responsibility, when they consider such a use appropriate. The term “over-the-counter (OTC) medicines” ~ is widely used to describe this class of product. (不是指示藥!也不叫作輕症藥!) The **packing, package size, labelling and product information** (package insert, leaflet, directions folder or other accompanying text) will generally be designed and written to ensure appropriate self-medication.!!!(必須在審查後發給新的販賣許可證)

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如何將處方藥轉類為非處方藥？

The initiative for the review of prescription products or any new product that might reasonably be released for self-medication(篩選品項) has generally been taken by the pharmaceutical industry in the form of documented proposals to national drug regulatory authorities. (由廠商主動向食藥署提出申請，不是由食藥署擅自改類，因為有醫療爭議、刑事和民事賠償的責任)。Occasionally, such authorities have themselves taken steps to reclassify medicinal products to make them available for self-medication.

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文明先進國家的作為

- 尊重生產廠商的權利、責任和義務
- 生產廠商擁有最完整的不良反應報告
- 萬一發生差錯時，廠商負全責

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VIOXX
You May Be Entitled To Compensation...

The Arthritis and acute pain medication, VIOXX, was recently withdrawn from the market after a study confirmed concerns that it raises the risk of heart attack and stroke.

If you were taking VIOXX and suffered any of the following symptoms or injuries, call for information about your legal rights:

- Heart Attack
- Stroke
- Deep Vein Thrombosis
- Pulmonary Embolism
- Kidney Failure

Call Toll Free Now for Your Free Information Packet
1-888-376-2234

Don't Be Left Out

- 美國Merck藥廠製造的抗炎鎮痛藥 (NSAID)
- 1998年美國核准上市銷售
- 2004年發現會增加心肌梗塞和中風的危險，藥廠主動停止銷售
- Merck花費約新台幣1500億元和解求償訴訟
- 食藥署能承擔這個責任嗎？

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從非處方藥轉類為處方藥

In some cases, moreover, products have been changed back from self-medication to prescription drug status because new safety issues have arisen. (前述**isoproterenol**噴藥事件) This underlines the fact that it is of **crucial importance** carefully to monitor the use of medicinal products and postmarketing data on adverse effects to be able to respond adequately and quickly to possible harmful developments.(由製造廠商負責)

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食藥署只篩選尚未審查核定

食藥署宣稱篩選的依據是：

- 一. 十大醫藥先進國已有三國作為非處方藥達一年以上；
 - 二. 在國內使用達10年以上，無嚴重不良反應通報
 - 三. 用於緩解輕微疾病(醫學上沒有這種名稱，感冒和流行性感冒是輕微疾病嗎?)或症狀緩解。
- 請問：要三條件全部具備或是只有一個條件即可？

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食藥署建議改類為指示藥的品項

| 品項 | 使用途徑 | 評論 |
|------------|------|--|
| Aspirin | 口服 | 81 mg 製劑是Bayer產品，標示是pain reliever，不是心血管疾病用藥；100 mg 製劑應比照標示 |
| Cetirizine | 口服 | 屬racemic form的落伍老藥，不宜推薦，可考慮純化的levo-cetirizine |

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請教醫師，不是由藥師指示

- Check with **your doctor** (不是訓練良好，能幹的美國藥師或臨床藥師) before taking products containing aspirin if you're taking a prescription blood thinner (抗血凝藥) or if you have diabetes or gout.

• **ADVICE FOR AMERICANS ABOUT SELF-CARE**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration and the Consumer
Healthcare Products Association★

Access + Knowledge = Power

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| | |
|---|---|
| <div> Drug Facts Active ingredient (in each tablet) Aspirin 81 mg (NSAID)*.....Pain reliever *nonsteroidal anti-inflammatory drug </div> <div> Purpose Pain reliever </div> <div> Uses ● for the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief. ● ask your doctor about other uses for Bayer Safety Coated 81 mg Aspirin ★ </div> <div> Warnings Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness. Allergy alert: Aspirin may cause a severe allergic reaction which may include: ● hives ● facial swelling ● asthma (wheezing) ● shock Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you ● are age 60 or older ● have had stomach ulcers or bleeding problems ● take a blood thinning (anticoagulant) or steroid drug ● take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ● have 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed Do not use if you are allergic to aspirin or any other pain reliever/fever-reducer Ask a doctor before use if ★ ● stomach bleeding warning applies to you ● you have a history of stomach problems, such as heartburn ● you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ● you are taking a diuretic ● you have asthma ★ Ask a doctor or pharmacist before use if you are taking a prescription drug for ● gout ● diabetes ● arthritis Stop use and ask a doctor if ★ ● an allergic reaction occurs. Seek medical help right away. ● you experience any of the following signs of stomach bleeding: </div> | <div> Drug Facts (continued) ● feel faint ● vomit blood ● have bloody or black stools ● have stomach pain that does not get better ● pain gets worse or lasts more than 10 days ● redness or swelling is present ● new symptoms occur ● ringing in the ears or a loss of hearing occurs </div> <div> If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ★ </div> <div> Directions ● drink a full glass of water with each dose ● adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor ● children under 12 years: consult a doctor </div> <div> Other information ● save carton for full directions and warnings ● store at room temperature </div> <div> Inactive ingredients black iron oxide, brown iron oxide, carnauba wax, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer type C, polysorbate 80, powdered cellulose, propylene glycol, shellac, sodium lauryl sulfate, triacetin, triethyl citrate </div> <div> Questions or comments? 1-800-331-4536 (Mon - Fri 9AM - 5PM EST) or www.bayeraspirin.com 負責廠商電話 </div> <div> Made in Spain Bayer HealthCare LLC Consumer Care P.O. Box 1910 Morristown, NJ 07962-1910 USA Bayer and the Bayer Cross are registered trademarks of Bayer. </div> |
|---|---|

食藥署建議改類為指示藥的品項

品項

使用途徑

評論

Triamcinolone 口內膏

國人咀嚼檳榔口腔黏膜潰爛或罹患口腔癌人數不少，應求醫，不宜自己用藥

Clotrimazole 陰道栓劑

Miconazole 陰道栓劑

美國婦女求醫時，家醫科或內科醫師必要時都會執行陰道內診，因此，美國婦女瞭解陰道狀況，當陰部搔癢時，可以自己購買使用，台灣醫療常態不宜改類成非處方藥

食藥署建議改類為指示藥的品項

Azelastine 鼻用噴液劑

Triamcinolone 鼻用噴液劑

Ketotifen 點眼液劑

Benzydamine 口腔噴劑

Loratadine 口服

Fexofenadine 口服

Omperazole 胃腸用藥

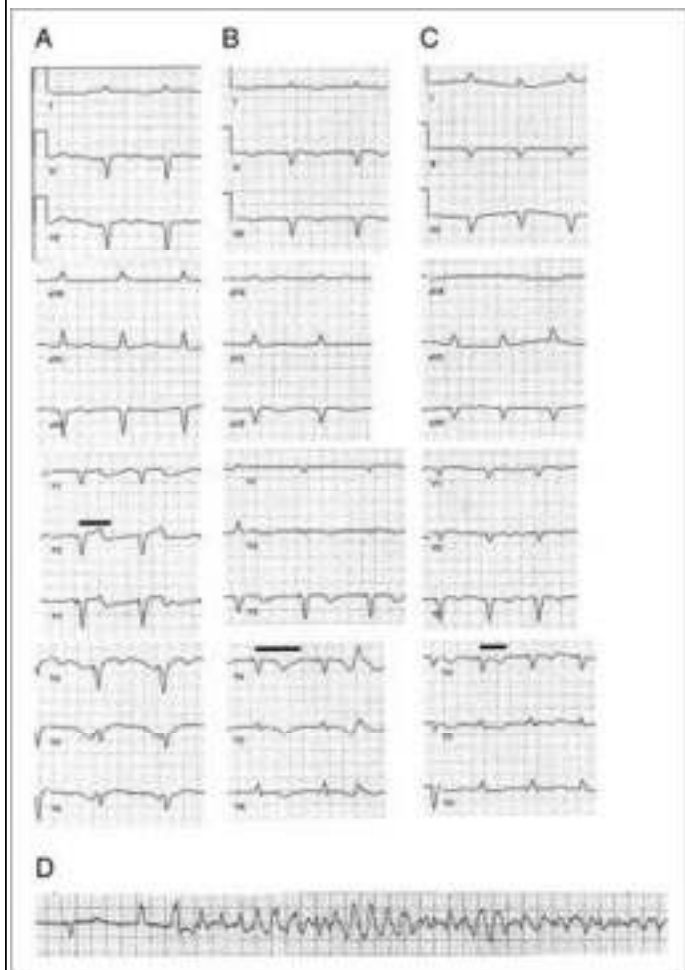
Pantoprazole 胃腸用藥

請食藥署提出十大醫藥先進國列為非處方藥的製劑實物連同仿單(必要篩選依據)送交「處方藥轉類非處方藥專案委員會」審查。

Famotidine (Gaster) 是安全嗎？

- Famotidine (Gaster) 是日本山之內藥廠生產的第二型抗組織胺(H₂-blocker)
- 在國內使用超過十年以上，沒有重大不良反應的報告

不是所有的抗組織胺都是安全的



A) Baseline 12-lead ECG: paced ventricular rhythm with QTc of 439 ms.

B) After **famotidine (Gaster)** was started, the QTc increased to 618 ms and episodes of TdP (多型態心室速動) were recorded (D).

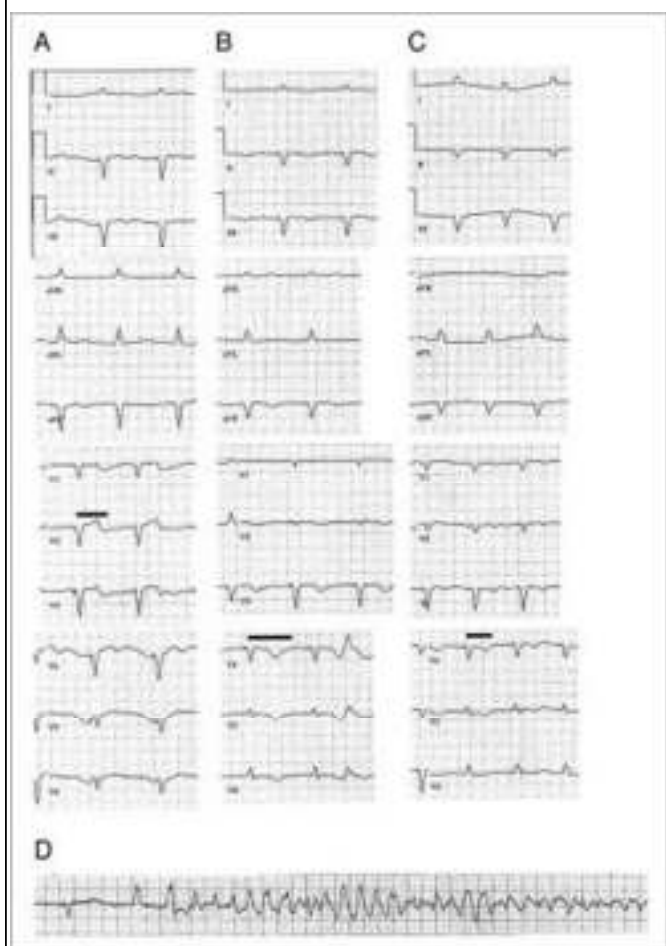
C) The ECG 4 days after cessation of famotidine (QTc of 445 ms).

Overlying, horizontal bars, the QT interval. The American Journal of Cardiology Volume 93 • Number 10 • May 15, 2004

←

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抗組織胺也會致人於死



A) Baseline 12-lead ECG.

B) ECG taken after **famotidine** was started: the QTc increased from 466 to 596 ms.

C) ECG recorded 5 days after cessation of famotidine (QTc of 451 ms).

D) Illustrative example of TdP.

Overlying, horizontal bars, the QT interval. The American Journal of Cardiology Volume 93 • Number 10 • May 15, 2004

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Characteristics of Self-Medication

Self-medication involves the use of medicinal products by the consumer to treat self recognized disorders or symptoms (消費者自我評估決定，不是藥師指示!), or the intermittent or continued use of a medication prescribed by a physician for chronic or recurring diseases or symptoms.(香港腳、念珠球菌陰道炎復發) In practice, it also includes use of the medication of family members, especially where the treatment of children or the elderly is involved.

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In order to use a non-prescription product safely and effectively, **the consumer must perform a number of functions normally carried out by a physician treating a patient with a prescription drug.** These functions include accurate recognition of the symptoms, setting of therapeutic objectives, selection of a product to be used, determination of an appropriate dosage and dosage schedule, taking into account the person's medical history, contraindications, concomitant diseases and concurrent medications, and monitoring of the response to the treatment and of possible adverse effects. (民眾自主自己用藥，世界衛生組織沒有要求醫師或藥師指示民眾用藥)

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In the case of non-prescription medicinal products (非處方藥), all of the information required to permit safe and effective use must come from **the labelling material** (必須特別設計仿單，與處方藥不同!)，patient information texts, the individual's previous personal experience, various sources of information in the media, advertising, and advice (是建議，不是指示) given by health care professionals.

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從處方藥設計(非轉類)非處方藥範例

- 美國第二型抗組織胺(H_2 -blocker) Ranitidine (Zantac) 醫師處方藥每錠含量150 mg，治療使用適應症是治療消化性潰瘍，使用劑量是每日300 mg。
- 設計非處方藥的Ranitidine (Zantac)項目，每錠含量只有75 mg，藥品仿單(package insert)沒有治療消化性潰瘍的適應症，只寫明緩解腹部不適症狀，使用劑量是每日150 mg，而且有警語：「若服用兩週症狀沒有消失，應立即求醫」，不是單純的將醫師處方藥150 mg的Ranitidine (Zantac) 直接改列為非處方藥。

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Pharmacists in particular can play a key role in giving advice to consumers (只提供建議或勸告，不是評估也不是指示，藥師的正當業務除調劑以外，可以說明藥劑，教導使用方法和注意不良反應以及如何對應，不可以指示用藥或不用藥!!!) on the proper and safe use of medicinal products intended for self-medication. It is important, therefore, to take this role into account both in their training and in practice.

醫師公會全聯會的聲明與建議一

- 支持衛服部為公眾健康利益的適當、安全和合理的政策－依據世界衛生組織和文明先進國家的指引，推動「民眾自己用藥」政策，不是食藥署的「民眾自我藥療」。
- 民眾自己用藥，衛服部醫事司負責決定是否可行，食藥署負責評估審查處方藥轉類為非處方藥，發給非處方藥販賣許可證，因此，建議衛服部整合辦理。
- 建議衛福部聘請專家和社會人士組織「處方藥轉類非處方藥專案委員會」，負責審查民眾「自己用藥」和「將處方藥轉類為非處方藥」事宜。

醫師公會全聯會的聲明與建議二

- 建議衛服部可公告通知廠商，接受廠商將處方藥轉類為非處方藥的申請，其要件是：
 - 一. 原研發廠商在其本國已取得非處方藥許可證
 - 二. 非原研發廠商在藥品專利過期後，已有十大醫藥先進國轉類為非處方藥
 - 三. 申請時，應附上非處方藥產品完整樣品。
- 世界衛生組織和文明先進國家都沒有指示藥的藥品類別，台灣已經醫藥分業，不應該有指示藥存在，如果經審查通過，應可將處方藥轉類為非處方藥，不可以稱為指示藥。

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美國民眾對聯邦政府食物藥品管理局的信任度

- Playing “Kick the FDA” — Risk-free to Players but but Hazardous to Public Health.
- Alastair J.J. Wood, M.D. N Engl J Med 2008; 358:1774-1775 April 24, 2008
- Public opinion polls show that confidence in the FDA fell from 80% in the 1970s to 36% in 2006.
- 經費預算: 2007年15億7千萬美元
- 人員編制: 2007年 7,856人

台灣食藥署

- 經費預算: ?
- 人員編制: ?
- 民眾信任度: ???

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醫師公會全聯會的聲明與建議三

- 呼籲衛福部重視食藥署人才缺乏，經費不足，目前應以食品安全為優先處理項目，不宜從事非其職責的民眾「自己用藥」。美國FDA有許多醫師負責審查管理藥物安全 (Section of Drug Safety)，應比照2003年SARS流行時的措施，迅速網羅優秀醫師進入疾病管制署(CDC)，努力修法聘請優秀醫師進入食藥署服務。
- 非處方藥應該比照文明先進國家，讓民眾能在大賣場 (COSCO)、便利商店 (Seven-Eleven)和旅館賣店購買到，才能達成方便民眾「自己用藥」的目的。

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醫師公會全聯會的聲明與建議四

- 建議衛福部聘請藥學、臨床藥學、藥理學、臨床藥理學和藥政管理專家，以及台灣藥學會、台灣醫學會、醫師公會全聯會、醫師公會全聯會和社會民眾(大學、中學和小學學歷各一人)，組織「處方藥轉類非處方藥專案委員會」，負責審查將處方藥轉類為非處方藥事宜。
- 建議衛福部組織包括各級醫師公會代表的考察團，考察新加坡、香港和日本的藥政管理，特別是「藥物安全」和「將處方藥轉類為非處方藥」的作業制度，訪問當地的醫師和藥師團體，聽取意見。

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敬請指正

感謝聆聽