

社評

本港藥物生產安全已亮起紅燈

繼 港島瑪麗醫院五名癌症病人疑因服用毛霉菌「別嘌醇」不治後，昨日，屯門醫院證實一名五十歲血癌病人本月七日逝世，死後體內驗出毛霉菌，她生前曾接受「別嘌醇」治療。

毛霉菌本來並不是什麼罕見的「超級惡菌」，但可能已成為連奪六命的「殺手」，而已經證實受感染或可能受感染的病人數目尚未知「伊於胡底」。如此「霉菌殺人」事件，在中外醫學界相信也會引起關注，相比起一些重大突發醫療事故，此次發霉「別嘌醇」暴露出來的藥物安全問題存在的長期隱患，更令人感到不安。

事實是，事發至今已多日，衛生署和相關藥廠交代出來的原因，即「別嘌醇」材料混合後在二十五度室溫下放置了四、五日才拿去「打丸」，做法到底是否合乎安全生產要求，至今未見披露。

按說不要說是治病救人的藥物，就是一般食品，在室溫下放置四、五天也可能會發霉不能進食，何以該批原料竟會長時間擱置還照樣使用？

而更有甚者，「一藥未平、一藥又起」，繼歐化藥廠生產的發霉「別嘌醇」奪命後，昨日又揭出本港另一藥廠：「萬輝」藥廠生產的多款藥物，包括小童咳水、傷風素及鈣片等，日前因需要更改藥物有效期標籤而自市面全面回收。

如同藥物生產過程不可能容許有霉菌滋長一樣，已經推出市面發售的藥物要更改有效日期，也是一件不容忽視的大事。據解釋，「萬輝」藥廠回收該批藥物，是要將有效期標籤由三年改為兩年，因為藥物的藥效不能維持三年有效期。

當然，藥廠能主動回收是好事，但令人不解的是，藥物有效期標籤不是兒戲，為何可以「朝令夕改」，隨時一改就是一年？

對此，食物及衛生局局長周一嶽昨日解釋，「萬輝」的「改期」是因為該批藥物如果存放過久，質素會不那麼穩定，所以需要更改有效期，事件只是一個「品質問題」而不是安全問題。

那麼，市民和病人不能明白的是，既然如此，三年有效期的標籤當初又是如何制定的？而且，存放過久既然會影響質素，為何又會與安全無關？

對此，本港醫院藥劑師學會一名負責人指出，病人如使用過期藥物，藥效會下降五成至八成，雖未必會直接導致病情惡化，但治療被延誤，後果也可大可小。



本港藥物接二連三出事，醫衛當局對藥物生產的監督管理亟待加強 (林雨樂攝)

事實是，從「歐化」的發霉藥，到「萬輝」的過期藥，核心都在一個監管問題上。對此，周一嶽局長昨日強調，本港藥物生產是跟足「世衛」標準辦事的。此說不必懷疑。但問題可能恰恰在於：標準是有了，要求也是高的，但在執行上卻只是「依書直說」、「立此存照」而已，監管「力度」在書面文字層面多於實際運作層面，如此就有可能「高標準」下而出霉菌了！

看來，接二連三出現的問題，已經敲響了本港藥物生產安全的警鐘，醫衛當局肩負全港市民的健康和九成以上病人的生命安危，對藥物生產安全的要求和監督絕不能放鬆。看來，一個全面的檢討和修訂已事在必行。

2009/03/12 大公报社評

中文基本功

誰是「中國原子彈之父」？

大陸改革開放以前，香港和海外不時傳說：為中國製造第一顆原子彈的是錢學森。這有其國際和歷史因素。近代中國科技遠遠落後於西方；而錢學森於一九五五年回國以前，已是美國的火箭專家，且領導美國人研製火箭。到一九六四年中國「平地一聲雷」爆出原子彈來，不是錢學森，誰有此本領？二月五日，香港電台《國事家事關你事》的女主持人也是這麼說。

其實，扶助中國第一代原子物理學家成長的雖然姓錢，卻不是從美國歸來的錢學森，而是從法國歸來的錢三強。至於爆出中國第一顆原子彈的「元勳」則是鄧稼先。

鄧稼先此名，相信不少香港人聞所未聞。他是安徽懷寧人，生於一九二四年，比錢學森年輕十三歲，是與

楊振寧、李政道一輩人。一九四五年畢業於西南聯合大學，一九四八年留學美國，一九五〇年取得普渡大學物理學博士學位即返國（比錢學森返國早五年）。

他為中國的核物理研究「開山劈石」，其成果見於一九六四年爆了中國第一顆原子彈和一九六七年爆了中國第一顆氫彈，故有「兩彈元勳」之稱。

此後，鄧稼先繼續研究核武器的實戰化（包括導彈核武器），解決了不少關鍵問題。不幸因長期接觸核輻射，於一九八六年因患白血病逝世，年六十二歲。

美國人把製成第一顆原子彈的奧本·海馬稱為「原子彈之父」。我們是否可以把鄧稼先稱為「中國原子彈之父」呢？ 容若

五星級英文



家長語言直接影響孩子

黑楊 (yeung@harkyeung.com)

與家長最有趣的對話，對方是一對隱形家長。那天和幾個學生去參與前中央書院遺址的「想創日」，地點是蘇豪區的前荷李活道警察宿舍。活動內容之一是藝術工作者裝置的藝術宿舍，由每個藝術工作者用一個棄置了的宿舍單位去創作。其中一個藝術家在牆上寫上這些字眼：「生嚟又燒好過生你」、「吊起你嚟打」、「死女包」，此外還有些更加兒童不宜的說話。藝術工作者在描述作品時說，這是孩子邁向光明前的黑暗。

學生說他們對這件裝置藝術特別有印象，因為多次親歷其境。可以想像那些沒有被畫公仔畫出腸的情節：父母打罵孩子。

不少學生在學校打開英文課本，句句都是書面語，但回到家中，聽到句句都是責罵的說話。第一語言和第二語言在兩個完全沒有共通點的世界裡。最近「微調」的爭論又起，討論的人有多少真正了解學生面對的處境？雖然他們不少都是經過學第二語言的過來人，但今日多少人能真正掌握和運用第二語言？

（與父母對話·三）

社經「數」描

探索新路 調整支柱產業

「財爺」曾俊華最近發表財政預算案時表示，今年香港生產總值（GDP）將會是10年來首次負增長，有2-3%的收縮。同時，本地銀行經濟師亦預測香港今年首季GDP與去年同期比較下降4%，預計全年GDP會收縮1.8%。事實上08年第4季GDP已較前年同期下滑2.5%，創下自1999年以來的季度最大減幅，亦高於市場預期。

香港經濟的四大支柱是金融、物流、旅遊及專業服務；07年金融忽然成為最大支柱，如今金融海嘯之際，金融萎縮，香港經濟的四大支柱或要調整，以勞動比例，或在調整方面露端倪。現時人力在零售批發、酒店、旅遊、餐飲的佔40%；金融保險、房地產佔20%；通訊、電訊、物流、交通等佔8%；公共、社會服務佔約20%；另製造業7%，建造業3%，香港的支柱仍不離服務和金融，只不過是如何在專業服務的基礎上追求卓越，也許正是經濟結構調整的基本平台，要持續讓香港成為全球人均擁財百達150萬港元的地方，政府應有長遠策略去搞好人力資源及培訓。 專業教育培訓顧問 呂康

Editorial

Red alarm rung on drug production safety

Following the deaths of five cancer patients at Queen Mary Hospital of the suspected fungi-tainted gout drug allopurinol, Tuen Mun Hospital yesterday confirmed that fungi were found in the remains of a 50-year-old female cancer patient who died on 7 March and who had been treated with allopurinol.

The mucorales fungi are not rare "super germs" but they probably have become the "killer" of six people. And the number of patients confirmed and possibly infected still remains unknown. Such an incident of "fungi killing people" is bound to arouse the attention of medical circles at home and abroad. Compared with some major emergent medical accidents, the long-standing hidden problems relating to drug safety exposed by the tainted allopurinol are much more unnerving.

As a matter of fact, it was not until days after the incident did the Department of Health and the pharmaceutical manufacturer explain the cause of the contamination: that the raw materials for allopurinol, after being mixed, had been stored indoors at a temperature of 25 degrees Celsius for four or five days before being pressed into tablets. It remains unclear if such practice accords with requirements for safety in production.

Commonsense suggests that even normal foodstuff, let alone drugs for curing patients, would be contaminated by fungi after being left indoors at 25 degrees Celsius and become inconsumable. How is it that these raw materials were still used after being left this way for such a period of time?

What is even more unacceptable is that drug safety incidents seem to be occurring one after another. With the "killer" allopurinol incident still unresolved yet another is reported, also involving another Hong Kong manufacturer, Marching Pharmaceutical Ltd, which had earlier recalled a number of drugs including cold and cough medicines and calcium tablets for children, because they had been wrongly labeled.

Fungi contamination is not tolerated in drug production. Likewise, to recall marketed drugs for re-labeling is something that cannot be overlooked. It was said that Marching Pharmaceutical recalled the drugs in order to change their shelf life to two years from the three years previously labeled because the effective shelf-life of drugs do not go beyond three years from the date of manufacture.

Of course, it is a good thing for a drug producer to recall its products on its own initiative. But what is hard to understand is that labeling the shelf life of a drug is not a trifling matter. How is it that "the order issued in the morning is easily countermanded at night" with the shelf life shortened by one year?

Secretary for Food and Health Dr York Chow Yat Ngok explained that Marching Pharmaceutical had to re-label the drugs because their quality would become unstable after long storage. The incident thus involved "quality" rather than "safety".

If so, what citizens cannot understand is how the three-year shelf-life was set for the original labels, and how come safety is not in issue when the quality of a drug tends to become unstable after long storage.

On this, an official with the Society of Hospital Pharmacists pointed out that the effects of an out-of-date drug would be weakened by 50% to 80%. Although expired drugs might not necessarily directly worsen patients' conditions, they could cause a delay in treatment and the outcome could be very serious in certain cases.

As a matter of fact, from the Europharm's fungi-contaminated drug to Marching's out-of-date drugs, the heart of the matter lies in ineffective supervision. In regard to this, Secretary Dr York Chow yesterday stressed that drug manufacturing in Hong Kong fully complied with World Health Organisation (WHO) standards. This goes without saying. But the problem may exactly lie in the fact that while there are strict standards and requirements, their implementation in practice may just "follow the book" or "for the sake of keeping records". The strength of supervision is more on writing than on practical operation, thus making it possible for fungi to grow under such "high standards".

The fact that problems crop up one after another seems to ring the alarm bell for the safety of drug production in Hong Kong. Medical-care and health authorities shoulder the responsibility for the health of all Hong Kong citizens and the life and death of 90% of patients. In no circumstances can they slacken their regulation and supervision of drug production safety. A thorough review and revision (of the current system) is inevitable.

12 March 2009

Idiom:

(Do something) on one's own initiative - Do something on one's own idea, not at the suggestion or instruction of another person.

Examples:

- 1. Sally does nothing on her own initiative.
2. The suspect reported himself to the police on his own initiative.
3. Did you ask him to organise a meeting or was it on his own initiative?
4. A few medical doctors have lowered their charges on their own initiative.
5. We ought to send a team to help disaster relief on our own initiative.

通識記憶體

藥物註冊費2千 每年查藥廠2次

根據香港《藥劑業及毒藥條例》，所有藥物均須註冊，方可在本港出售。藥劑業及毒藥管理局受理藥物註冊申請時，會要求申請人提交其公司的商業登記證。銷售未註冊藥劑製品屬違法，一經定罪，最高可罰款10萬元及監禁2年。

《藥劑業及毒藥條例》規定，有關藥物獲准註冊後，只有持有由藥劑業及毒藥管理局屬下牌照委員會所發的「毒藥批發牌照」的公司才可進口和分銷該藥物。藥物如被取消註冊，或因公眾衛生理由而要回收，回收的責任便落在進口及分銷商身上。病人或醫生等人士可向批發商追討。

不過，多間老牌藥廠產品出事，包括歐化藥業的降尿酸藥物「別嘌醇」毛霉菌含量超標100倍，萬輝藥廠要回收小童咳藥水、傷風素及鈣片等216種藥品

，以及琪寶製藥供應未註冊糖尿病藥物給醫管局，令香港藥品安全信譽動搖。醫院藥劑師學會批評，現時衛生署藥物註冊門檻過低，只需2000多元，致使藥廠輕易即可註冊藥物。雖然該署已於1995年訂出藥物生產程序指引，但署方並無具體監察生產程序，致使不同藥廠可自行決定生產過程中，空氣及水的質素是否達到最高級別水平。限於人手，衛生署每年只巡查藥廠兩次，往往只審核文件。

學會呼籲盡快設立「藥物管理署」，專責處理及監督藥物註冊及檢測程序，同時收緊藥廠發牌要求，規定藥廠每年必須提交微生物報告，證明藥物含菌量合乎標準，確保藥物品質。有市民公開要求成立達國際水平的藥檢中心，重檢全港藥物。