立法會
Legislative Council

Ref : CB2/PL/HS

LC Paper No. CB(2)2325/08-09
(These minutes have been seen by the Administration)

Panel on Health Services

Minutes of special meeting
held on Tuesday, 31 March 2009, at 10:45 am
in the Chamber of the Legislative Council Building

Members present	:	Dr Hon Joseph LEE Kok-long, JP (Chairman) Dr Hon LEUNG Ka-lau (Deputy Chairman) Hon Fred LI Wah-ming, JP Hon Andrew CHENG Kar-foo Hon Albert CHAN Wai-yip Hon Audrey EU Yuet-mee, SC, JP Hon Vincent FANG Kang, SBS, JP Hon Cyd HO Sau-lan Hon CHAN Hak-kan Hon IP Kwok-him, GBS, JP
Members absent	:	Hon Albert HO Chun-yan Hon Alan LEONG Kah-kit, SC Dr Hon PAN Pey-chyou
Public Officers attending	:	Items I-II Dr York CHOW, SBS, JP Secretary for Food and Health Mr Patrick NIP Deputy Secretary for Food and Health (Health) 1 Dr P Y LAM Director of Health Item I Dr Gloria TAM Deputy Director of Health

Mr Anthony CHAN
Chief Pharmacist
Department of Health

Dr W L CHEUNG
Director (Cluster Services)
Hospital Authority

Ms Anna LEE
Chief Pharmacist
Hospital Authority

Mr Raymond WONG
Chief Manager (Business Support Services)
Hospital Authority

Item II

Dr Thomas TSANG
Controller, Centre for Health Protection
Department of Health

Clerk in attendance : Miss Mary SO
Chief Council Secretary (2) 5

Staff in attendance : Ms Maisie LAM
Senior Council Secretary (2) 7

Ms Sandy HAU
Legislative Assistant (2) 5

Action

I. Regulation and control of pharmaceutical products in Hong Kong
(LC Paper Nos. CB(2)1168/08-09(01) and (02), FS23/08-09, CB(2)1185/08-09(01) and CB(2)1221/08-09(01))

Secretary for Food and Health (SFH) and Director of Health (D of Health) briefed members on the measures to be taken by the Administration to review and enhance the existing regime for the regulation and control of pharmaceutical products in Hong Kong, in the light of the recent incidents concerning pharmaceutical products, details of which were set out in paragraphs 33-35 of the Administration's paper (LC Paper No. CB(2)1168/08-09(01)). SFH and D of Health supplemented as follows -

Action

(a) as an immediate measures, the Department of Health (DH) had already completed inspection to all the 25 local manufacturers. No irregularities had been identified. DH had also written to all local manufacturers, wholesalers and retailers of drugs last week to remind them of their responsibility, including the compliance with the requirements of the law. In addition, DH would hire 10 more pharmacists to strengthen inspection to manufacturers, wholesalers and retailers of drugs and the sampling of drugs for analysis. Apart from reviewing its drug procurement system, the Hospital Authority (HA) had carried out a comprehensive inspection on all existing drugs in HA hospitals and clinics. HA had also instructed its staff at various levels to increase vigilance on expired drugs so as to ensure drug safety. HA would also implement seven initiatives to strengthen the procurement and management of pharmaceutical products in public hospitals;

(b) to ensure the safety and quality assurance of drugs, work was underway to (i) enhance the identification and control of microbiological hazards by local manufacturers through the establishment of a robust microbiological vigilance system with standards set by DH for microbiological testing; (ii) examine how the governance and internal audit system of local manufacturers could be improved by, say, requiring professional personnel to undergo Good Manufacturing Practices (GMP) training periodically and the engagement of external auditor; and (iii) strengthen the overall monitoring of drugs;

(c) although Hong Kong adopted the GMP guidelines promulgated by the World Health Organization (WHO), whilst other countries such as the United States (US), the European Union (EU) and Australia had drawn up their national GMP guidelines which were recognised to be of a standard higher than the WHO guidelines, the GMP used by local drug manufacturers should not be considered as substandard as the WHO GMP was recognised worldwide to be an effective quality assurance system for ensuring that products were consistently produced and controlled according to quality standards appropriate to the products' intended use; and

(d) DH's investigation on the recent drug incidents, outlined in paragraph 31 of the Administration's paper, was in the final stage. Findings of the investigation would be forwarded to the Department of Justice to decide whether to initiate prosecution against the manufacturers and importers concerned.

2. Director (Cluster Services), HA (Director (CS), HA) next briefed members on the seven initiatives that would be implemented by HA to strengthen its procurement of drugs as follows -

Action

(a) HA would approach manufacturers to introduce microbiology testing as a prerequisite to the procurement for high risk drug items and for the provision of batch release reports on delivery of drug products;

(b) within HA, sample testing would be enhanced to include a wider range of drugs and microbiology testing based on risk levels;

(c) drug suppliers would be required to provide additional standard information for drug delivery documentation to enable more effective physical checking of goods received;

(d) HA would work with DH to enhance the access to key additional registration details, including pack sizes to strengthen checking on regulatory compliance;

(e) the Pharmaceutical Information Technology Systems at HA would be enhanced by moving progressively towards introducing bar coding, automatic check for what was ordered, automatic track and trace drugs to the point of issue, and prevention of dispensing expired items;

(f) HA would consider introducing multi-source supply for high volume and high risk drugs to ensure the availability of back up and alternative supply under emergency situation; and

(g) a Drug Quality Assurance Office would be established to monitor quality and to oversee the implementation of the above initiatives.

Compensation

3. Mr Fred LI said that several extremely immuno-compromised patients, who were prescribed the Allopurinol tablets produced by a local manufacturer, the Europharm Laboratoires Co. Ltd. (Europharm), recently died from gastrointestinal mucormycoisis. Mr LI asked whether, and if so, when HA would compensate the family members of these deceased patients, having regard to the fact that The University of Hong Kong had announced on 6 March 2009 that four batches of Allopurinol tablets produced by Europharm were contaminated with Rhizopus microsporus.

4. Mr Albert CHAN said that it was unfair that families of the deceased patients had to undergo legal proceedings to obtain compensation from Europharm and HA. The Administration should provide compensation to the families of these patients if a loss adjuster so appointed confirmed that there was sufficient evidence that errors were made by Europharm and HA.

Action

5. SFH responded that reports of the patient cases of gastrointestinal mucormycoisis had been submitted to the Coroner. To his understanding, death inquests would be held to find out the cause of these deaths. Should the Coroner's Court decide that the deaths were caused by the consumption of the fungal contaminated Allopurinol, appropriate legal action could be taken by HA and the family members concerned alike. Director (CS), HA supplemented that there were cases whereby claims for compensation from HA were resolved by out-of-court settlement through mediation.

6 Ms Cyd HO opined that it should be made mandatory for pharmaceutical manufacturers to take out product liability insurance to ensure that victims of problem drugs would be compensated for any injuries caused.

7. SFH responded that he believed all pharmaceutical manufacturers had purchased product liability insurance. SFH, however, pointed out that it was more effective to enhance the existing regulatory regime to prevent drug incidents from occurring.

Monitoring of drugs

8. Mr Fred LI said that the fact that Allopurinol manufactured by Europharm was contaminated with Rhizopus microsporus, which could cause mucormycosis in humans, demonstrated that monitoring of drugs was less stringent than that of food in Hong Kong. Mr LI further cited a recent news article on a drug manufacturer packaging drugs in the lift lobby and stairways. Mr LI then asked about the number of prosecution taken against local drug manufacturers in the past five years.

9. D of Health responded as follows -

(a) all pharmaceutical manufacturers must meet the licensing requirements before they could obtain a licence from the Manufacturing Licensing Committee of the Pharmacy and Poisons Board. Since 2002, compliance with GMP had become an additional important licensing condition. As a result, the number of licensed pharmaceutical manufacturers had dropped from some 50 prior to 2002 to 25 at present;

(b) overseas literature on the occurrence of fungal contaminated Allopurinal was rare. DH's investigation revealed that during the production process of Allopurinal at Europharm, there was prolonged storage of granules prior to tabletting. Prosecution action might be instigated against Europharm if it was found that these granules were no longer safe for tabletting but Europharm had used them nevertheless knowingly;

Action

(c) licensed pharmaceutical premises of manufacturers were monitored by means of GMP inspections conducted by two inspectors of DH once or twice a year, each inspection lasting one or two days. During inspections, all different GMP aspects would be audited for compliance and checked against a checklist and samples of drugs would be selected for analysis to ensure quality. If there was minor noncompliance with any licensing conditions, the manufacturer was instructed to remedy the situation and verbally reprimanded. For other serious noncompliance, the Manufacturing Licensing Committee might revoke the licence or suspend it for such period as it saw fit. In recent years, only one manufacturer had been prosecuted for possession of unregistered cough medicine intended for sale in Hong Kong. As inspections were carried out in the presence of the manufacturers, work was underway to see how monitoring of the production process by manufacturers could be strengthened through other means; and

(d) as regards the case concerning a GMP manufacturer packaging drugs in the lift lobby of its office, DH's investigation revealed that the company did not violate any GMP process as the company was merely loading pharmaceutical products already packaged in their containers. Nevertheless, this would be an area which the Task Force set up under DH to comprehensively review the existing control of the drug supply chain, as well as the control of drugs, would look into.

10. In response to Mr LI's further enquiry on the measures to enhance the safety of pharmaceutical products in the medium to long term, SFH said that possible new measures to be implemented ahead of the completion of work by the Review Committee, referred to paragraphs 33-36 of the Administration's paper, could include requiring microbiological testing in the manufacturing of high risk drug items.

11. Mr CHAN Hak-kan suggested the following measures to restore public confidence on the supply of pharmaceutical products in Hong Kong -

(a) conducting unannounced inspections to licensed pharmaceutical premises of manufacturers and to retailers of pharmaceutical products for taking of samples of drugs for testing, prior to completion of work by the Review Committee; and

(b) making it mandatory for doctors and players in the drug supply chain to report adverse drug reaction cases to DH.

12. D of Health responded that the additional 10 pharmacists to be recruited would mainly be deployed to carry out inspection to manufacturers, wholesalers and retailers of drugs and the sampling of drugs for analysis, most of which

Action

would be done unannounced. D of Health further said that at present, some 4 500 drug samples were taken yearly from all levels of the drug supply chain for analysis and institution of prosecutions against offenders. Whether, and if so, how many more drug samples should be taken for analysis would be studied by the Task Force referred to in paragraph 9(d) above. D of Health, however, pointed out that from a public health perspective, a more effective way to ensure the safety of pharmaceutical products was by exercising quality control at the upstream of the drug supply chain, i.e. the manufacturers. This was in line with the spirit of GMP which emphasised that the assessment of good quality should be based on scrutiny of the manufacturing process and not by testing of the pharmaceutical products produced.

13. On making it mandatory for doctors and players in the drug supply chain to report adverse drug reaction cases to DH, SFH said that more studies needed to be made on its feasibility. D of Health supplemented that under the Hong Kong Poison Control Network, HA would refer cases whereby patients were suspected to have been affected by the consumption of harmful products to DH for follow-up investigation. In addition, importers of pharmaceutical products were required to report to DH any adverse drug reaction reports. DH would also survey reports on product recalls and safety alerts in the websites of other regulatory authorities, and recall of pharmaceutical products at various levels would be made where necessary.

14. Ms Audrey EU wondered whether the reason why only one prosecution was instigated against local pharmaceutical manufacturers was because HA had all along been relying on a single supplier for certain drug items. Ms EU asked whether a manufacturer producing drugs contaminated with Rhizopus microsporus had breached the law; and if so, why no prosecution had yet been instigated against the manufacturer.

15. D of Health advised that under the Public Health and Municipal Services Ordinance (Cap. 132), any person intending to sell any drug intended for use by human but unfit for that purpose would be guilty of an offence. The maximum penalty upon conviction was a fine of $50,000 and six months' imprisonment. In addition, the Pharmacy and Poisons Ordinance (Cap. 138) (PPO) stipulated that any manufacturer who failed to comply with the licensing requirements, except for the compliance with GMP licensing requirement, would on conviction be subject to a maximum penalty of $100,000 and two years' imprisonment. As regards the incident of fungal contaminated Allopurinol, DH's investigation was in the final stage. Prosecution would be instigated if there was sufficient evidence that Europharm had breached the law.

16. Mr Andrew CHENG opined that the reasons why the recent drug incidents happened were due to inadequate manpower of DH to perform inspection and surveillance on the drug supply chain and that the GMP used in Hong Kong was less stringent than that used in countries such as Singapore, Australia and US. To better protect public health, Mr CHENG urged DH to increase the number of pharmacists, raise the standard of GMP, make non-

Action

compliance of GMP licensing requirement an offence under PPO, and introduce a demerit point system to ensure GMP compliance. As many drugs used in Hong Kong were manufactured in the Mainland, Mr CHENG asked whether, and if so, what measures would be taken by the Administration to ensure their safety and efficacy.

17. SFH and D of Health responded as follows -

(a) raising the standard of GMP was one of the major areas to be covered by the Review Committee, summaries of which were outlined in paragraph 35(a)-(e) of the Administration's paper;

(b) the fact that GMP in countries such as US, EU and Australia was recognised to be of a standard higher than GMP in Hong Kong should not be taken to mean that GMP in Hong Kong was substandard, as GMP used in Hong Kong followed exactly the GMP guidelines promulgated by WHO. The reason why GMP in US, EU and Australia was recognised to be of a higher standard was because manufacturers in these countries also produced new/patent drugs which required more detailed and rigorous quality requirements, whereas local manufacturers only produced off-patent generic drugs.;

(c) to enhance safety and quality assurance of drugs, plan was in hand to make certain GMP aspects governing high risk manufacturing process more comprehensive;

(d) effective penalty system to ensure GMP compliance, which might include a demerit point system capable of proportionate penalty ranging from for example written warnings, announcement of serious noncompliance cases, suspension or termination of licences, would be considered by the Review Committee; and

(e) all imported drugs must be GMP certified by the corresponding overseas authorities. The GMP used in the Mainland was comparable to, if not better than, the GMP used in Hong Kong. Should Hong Kong decide to require manufacturers to introduce microbiological testing for high risk drugs, compliance of such GMP requirement would be imposed on all imported drugs, including those from the Mainland.

18. Mr Albert CHAN urged the Administration to set up a dedicated office to enhance drug safety, as had been done for food safety, as suggested by the Society of Hospital Pharmacists of Hong Kong in its submission to the Panel (LC Paper No. CB(2)1185/08-09(01)). In the meantime, HA should establish a rigorous drug testing programme to ensure patients' safety. In view of staff shortage at DH's Pharmaceutical Service, Mr CHAN further said that HA

Action

should make available its results of drug sample testing to DH to obviate the need of DH to conduct sample on the same drugs as many drugs procured by HA were also offered for sale in the private sector.

19. SFH pointed out that although drugs procured by HA were also available in the marketplace, it was still necessary for DH to conduct sample testing on the drugs as these drugs might be of different batches. Director (CS), HA also said that one of the initiatives to be launched by HA to enhance drug safety within HA was to enhance its sample testing to include a wider range of drugs and conduct microbiology testing based on risk levels. The testing results would be made available to DH for reference.

20. Ms Cyd HO noted from paragraph 35(d) of the Administration's paper that the Review Committee would review the checklist used by DH inspectors when conducting inspections with a view to yielding measurable and accountable audit results. Ms HO requested DH to provide the existing checklist and the revised checklist, as well as a paper setting out the differences between these two checklists when they became available. D of Health agreed.

Admin

21. The Chairman asked whether the Administration would consider requiring local pharmaceutical manufacturers to engage external auditors to ensure they conformed to GMP standards. SFH agreed to consider.

Manpower

22. Ms Audrey EU noted that of the 50 pharmacists of DH's Pharmaceutical Service, 28 were responsible for the inspection of 25 manufacturers, 240 importers/exporters, 860 wholesalers, and 3 800 retailers in Hong Kong, as well as the sampling of some 19 500 registered pharmaceutical products for analysis and conducting investigation on some 600 complaint cases and some 100 drug poisoning incidents annually. In the light of this, Ms EU questioned whether recruiting 10 more pharmacists to enhance inspection and surveillance of pharmaceutical products was adequate.

23. D of Health responded that DH would further consider the need for additional pharmacists in the course of the review on regulation of pharmaceutical products in Hong Kong.

24. Mr CHAN Hak-kan hoped that DH would recruit more pharmacists to provide more job opportunities to local pharmacy graduates.

25. SFH responded that there should be no great difficulty for local pharmacy graduates to secure jobs as pharmacists, as there was greater demand for pharmacists in private hospitals and clinics and HA also had plan to recruit more pharmacists.

Action

26. Ms Cyd HO said that DH should provide training to its inspectors on a regular basis to remind them to be vigilant in carrying out inspections on the premises of pharmaceutical traders. D of Health responded that taking the opportunity of the commissioning of a consultancy study on the enhancement of regulation of pharmaceutical products in Hong Kong, DH would enlist the overseas expert to conduct training to the existing and the newly recruited inspectors.

Conclusion

27. In closing, the Chairman said that the Administration should take into accounts the views expressed by members in its review on regulation of pharmaceutical products, and to revert to the Panel once the Review Committee came up with improvement measures that could be implemented in the short term.

Admin

II. Inclusion of pneumococcal conjugate vaccine in the Childhood Immunisation Programme

(LC Paper Nos. CB(2)1007/08-09(01), CB(2)1168/08-09(03) and (04), CB(2)1185/08-09(02), CB(2)1194/08-09(01) and CB(2)1221/08-09(02))

28. SFH briefed members on the inclusion of Pneumococcal Conjugate Vaccine (PVC) in the Childhood Immunisation Programme (CIP) and the provision of free pneumococcal vaccination for children aged below two years under a Catch-up Programme, details of which were set out in the Administration's paper (LC Paper No. CB(2)1007/08-09(01)).

29. Ms Audrey EU said that the Civic Party welcomed the inclusion of PCV in the CIP. Ms EU urged that the publicity programme to be launched by the Administration later this year would also target Mainland children aged below two years born to Hong Kong parent(s). Ms Cyd HO raised a similar view.

30. SFH responded that many Mainland young children born to Hong Kong parents regularly came to Hong Kong to receive vaccinations under CIP at the Maternal and Child Health Centres (MCHCs) of DH. Nevertheless, to ensure that parents of young children living in the Mainland were well aware of the provision of PCV injection service at MCHCs starting from 1 September 2009, publicity would be made to all hospitals and clinics providing obstetric services in both the public and private sectors. Controller, Centre for Health Protection (Controller, CHP) supplemented that publicity could also be made at boundary control points. CHP had met with members of concern groups on child immunisation and solicited their advice to ensure smooth implementation of the new arrangements.

31. In response to Ms Audrey EU's enquiry on whether kindergartens and nurseries could require that all young children must first be vaccinated before

Action

admission, Controller, CHP advised that there was no law requiring that children must receive childhood vaccines under CIP. Controller, CHP, however, pointed out that the overall vaccination coverage rates of CIP remained high at over 90%.

32. Dr LEUNG Ka-lau noted that children born between 1 September 2007 to 30 June 2009 inclusive would be eligible to receive free PCV under a one-off Catch-up Programme to be launched at MCHCs starting from 1 September 2009 to 31 March 2011. To this end, the Administration was actively exploring the feasibility to recruit extra manpower, such as staff members of the Auxiliary Medical Service (AMS), to provide inoculation service under the Catch-up Programme. Dr LEUNG expressed concern about whether staff members of AMS had the knowledge and skill to provide such service.

33. SFH pointed out that many staff members of AMS were healthcare professionals. Controller, CHP supplemented that staff members of AMS had all along been rendering assistance to DH in protecting public health. The fight against SARS in 2003 was a case in point. In the present case, staff members of AMS would be required to attend and pass a training course on providing vaccine injection to young children before they would be assigned to provide inoculation service under the Catch-up Programme at MCHCs.

34. Dr LEUNG further asked the Administration whether consideration could be given to subsidising parents to receive PCV vaccination at the private sector for their children. This should not incur significant additional cost, as doing so would reduce the workload of MCHCs. Mr IP Kwok-him expressed similar view.

35. SFH responded that as most newborns in Hong Kong received their vaccinations under CIP at MCHCs, it was more straightforward and consistent if provision of PCV injection service was provided at MCHCs. To do otherwise which inevitably delay the provision of the service. This view was shared by paediatricians in the private sector. SFH further said that engaging the private sector participating in PCV injection service might be more appropriately launched following the implementation of the territory-wide electronic healthcare record sharing system.

36. Mr Andrew CHENG welcomed the inclusion of PCV in CIP, and urged the Administration to take every step to ensure its smooth implementation. Mr CHENG further said that he did not have strong view about subsidising parents to receive PCV vaccination at the private sector for their children, but was concerned that to do so would greatly delay the provision of the new service.

37. Mr IP Kwok-him asked about the measures to prevent health workers at MCHCs from injecting wrong number of doses of vaccine to children under the Catch-up Programme. Controller, CHP advised that clear guidelines in this

Action

regard would be drawn up. Mr IP further said that another way to prevent errors from occurring was to raise parents' knowledge about the number of doses of vaccine required for children of different age groups under the Catch-up Programme.

38. There being no other business, the meeting ended at 12:45 pm.

Council Business Division 2
Legislative Council Secretariat
31 July 2009