CHAPTER 11 SUMMARY OF RECOMMENDATIONS

Overview

11.1 This chapter gives a summary on all the recommendations and concludes the work of the Review Committee.

Summary of Recommendations

11.2 The Review Committee has made a total of 75 recommendations as follows. Recommendations which can be implemented with existing resources are marked with an "＊" while recommendations which will be implemented when new resources are available are marked with an "＃".

Regulation of Drug Manufacturers

Recommendation 1# – to upgrade Hong Kong's current GMP licensing standards by a phased approach to PIC/S standards over a period of fours years. (paragraphs 3.15 – 3.16 above)

Recommendation 2# – to require imported drugs to comply with the same standards once local drugs attained the PIC/S standards. (paragraph 3.17 above)

Recommendation 3# – to strengthen the control of the use of Active Pharmaceutical Ingredients (APIs) and contract laboratories by local manufacturers. (paragraph 3.18 above)

Recommendation 4* – to strengthen the experience requirement for existing APs from at least one year of relevant working experience to at least three years; and for the heads of production and quality control from at least one year to at least two years for pharmacy degree holders and from at least two years to at least three years for holders of higher diploma in pharmacy-related subjects. (paragraph 3.19 above)

Recommendation 5# – to draw up a set of qualification requirements of Authorized Persons (APs), to establish a licensing or listing scheme and to liaise with the universities for offering a structured training programme for APs. (paragraph 3.20 above)

Recommendation 6# – to empower the Pharmacy and Poisons Board to maintain an AP register and remove any AP from the register should he be found incompetent to perform the AP role. (paragraph 3.22 above)

Recommendation 7* – to increase the number of inspections to local manufacturers. While most of the inspections to manufacturing premises should remain announced, some unannounced inspections should be introduced. Further, one of the two inspectors in the inspection team should be retained for subsequent inspections to facilitate effective follow-up on irregularities identified. (paragraph 3.25 above)

Recommendation 8# – to set up a multi-disciplinary GMP inspection team with professionals of other related disciplines like biochemists, chemists, engineers, microbiologists, etc. for effective auditing of manufacturers with diversified production environment. (paragraph 3.27 above)

Recommendation 9# – to develop structured, practical and continuous training programmes for all levels of players in the GMP system including DH inspectors, APs, production and quality control heads, and other workers. (paragraph 3.28 above)

Recommendation 10* – to state in the licensing conditions that local manufacturers should either (a) appoint the AP as a board member; or (b) invite the AP to attend board meetings and allow the AP to speak and have his remarks put on record where safety, efficacy and quality issues of products are concerned. This recommendation should be put on trial for two years and then reviewed. (paragraphs 3.29 – 3.32 above)

Recommendation 11# – to introduce a code of practice to govern the conducts of the manufacturers and the APs. (paragraph 3.33 above)

Recommendation 12* – to require all local manufacturers to adopt the enhanced microbiological monitoring model covering raw materials, granules, finished products and stability studies. (paragraphs 3.34 – 3.39 above)

Pre-market Control of Drugs

Recommendation 13# – to require BABE studies as registration requirement for pharmaceutical products to enhance quality of generic drugs. The implementation should be by phases starting in April 2010. It will begin with antiepileptic drugs, which have a narrow therapeutic index where a comparatively small difference in the absorption of the drug by the human body may lead to undesirable consequences. (paragraph 4.14 above)

Recommendation 14* – to replace the term "Poison 毒藥", as required to be labelled on pharmaceutical products classified as poisons, with other terms to alleviate the unnecessary concern of consumers that the products might be harmful and unsuitable for use or consumption. (paragraph 4.15 above)

Recommendation 15* – to delete the phrase "to be marketed for use within Hong Kong" on the certificate of registration of pharmaceutical products. (paragraph 4.16 above)

Recommendation 16* – to extend the validity of clinical trial certificate from not more than two years to not more than five years. (paragraph 4.17 above)

Recommendation 17# – to shorten the time-frame for processing applications for registration of pharmaceutical products, change of particulars of registered products and clinical trials by 40% - 50%. (paragraph 4.18 above)

Regulation of Importers/Exporters and Wholesalers

Recommendation 18# – to require all wholesalers of non-poisons to be subject to inspection and licensing control. (paragraphs 5.17 – 5.18 above)

Recommendation 19# – to require all wholesalers to keep transactions records of all pharmaceutical products, including Part II poisons and non-poisons in the same manner as for Part I poisons, and to require wholesalers to keep samples of each batch of drugs handled to facilitate investigation when needed. (paragraphs 5.19 – 5.20 above)

Recommendation 20* – to require both primary and secondary packaging be carried out by a licensed manufacturer. (paragraphs 5.21 – 5.22 above)

Recommendation 21* – to introduce a code of practice for importers/exporters and wholesalers detailing their roles and responsibilities, including the requirement of batch release certificate, the reporting of adverse drug reactions, proper storage and transportation of drugs, etc. (paragraphs 5.23 – 5.24 above)

Recommendation 22# – to strengthen the monitoring of importers/exporters and wholesalers by means of more frequent and more detailed inspections, especially after the introduction of a code of practice. (paragraphs 5.25 – 5.26 above)

Recommendation 23# – to set up a dedicated team of pharmacist inspectors to advise C&ED staff on pharmaceutical imports at various ports of entry. (paragraphs 5.27 – 5.28 above)

Recommendation 24# – to set up a record and tracking system by requiring EL applicants to produce the ILs of the imported drugs to be re-exported. (paragraph 5.29 above)

Recommendation 25# – to prescribe in the licensing conditions for ILs for the products for re-export that the importer should not sell unregistered imported drugs in Hong Kong and must re-export the products within a specified period of time, say one year. (paragraph 5.30 above)

Recommendation 26# – to conduct a joint review with C&ED to determine a new weekly quota for post-shipment consignment checks of licences which should be a statistically significant sample size of the ILs and ELs population. (paragraph 5.31 above)

Recommendation 27# – to require exporters who chose to export products by mail to clear their products at designated post offices. DH should include the requirement in the ELs and discuss with C&ED for the introduction of a daily quota on outgoing mail parcels of drugs for verification of content and endorsement by C&ED. (paragraph 5.32 above)

Recommendation 28# – to develop an electronic record system among DH, C&ED and TID to facilitate the tracking of imported and exported drugs. (paragraph 5.33 above)

Regulation of Retailers

Recommendation 29# – to require all retailers of non-poisons to be subject to licensing and inspection control. (paragraphs 5.49 – 5.50 above)

Recommendation 30# – in the longer term after taking into account the market operating conditions and the availability of sufficient pharmacists, to require the presence of a registered pharmacist whenever an ASP is open for business. Heightened enforcement actions should be taken against those non-pharmacists who violate and interrupt the pharmacists' performance of their duties at ASPs. (paragraphs 5.51 – 5.54 above)

Recommendation 31* – to require all Part I Poisons be stored in locked receptacle in the premises of an ASP and that only the pharmacist should hold the key to the locked receptacle. (paragraphs 5.55 – 5.56 above)

Recommendation 32* – to add a provision in the Pharmacy and Poisons Ordinance for the issuance and revision of the code of practice for ASPs in order to give a legal status to the code to enhance monitoring on the operation of ASPs; and to introduce a code of practice for LSPs which should enjoy the same legal status as the code for ASPs. (paragraphs 5.57 – 5.58 above)

Recommendation 33* – to give the Pharmacy and Poisons Board the authority to revoke the licence of an ASP at any time after the ASP has been convicted of serious drug offence. (paragraphs 5.59 – 5.60 above)

Recommendation 34* – to tighten the licensing conditions for the refusal or renewal of ASP or LSP applications. DH should evaluate what type of drug offences should be included based on their public health impact. (paragraphs 5.61 – 5.62 above)

Recommendation 35# – to strengthen the monitoring of ASPs and LSPs by means of more frequent and more detailed inspections. (paragraphs 5.63 – 5.64 above)

Recommendation 36* – to require ASPs and LSPs to purchase drugs from licensed traders only. (paragraphs 5.65 – 5.66 above)

Recommendation 37* – to require that all orders for drugs to have written records. (paragraphs 5.67 – 5.73 above)

Recommendation 38* – to require ASPs to sell pharmaceutical products in their original packing, save in the case of a doctor prescription drug which is required by law to be dispensed in exact quantity in accordance with the prescription and in the case of pharmacist dispensing drugs to patients according to their need with proper labelling. (paragraphs 5.74 – 5.75 above)

Recommendation 39* – to require ASPs and LSPs to keep all the supporting documents including drug orders and sales invoices related to every purchase of all pharmaceutical products, and the documents should be kept as long as the expiry date of the pharmaceutical product concerned for DH's inspection if necessary. (paragraphs 5.76 – 5.77 above)

Regulation of Drug Procurement

Recommendation 40# – both DH and HA to conduct post-delivery surveillance including microbiological and chemical testing to ensure drug quality. (paragraph 6.14(a) above)

Recommendation 41* – both DH and HA to require the suppliers to provide additional information, such as pack size and registration number, etc. in the delivery documents to enable more effective physical checking and verification if drugs received are legally conforming. (paragraph 6.14(b) above)

Recommendation 42# – both DH and HA to provide additional training to staff and monitor the workflow in the repacking activities in drug dispensing to minimize errors. (paragraph 6.14(c) above)

Recommendation 43* – to impose a new requirement on suppliers to keep samples of each batch of drugs that are still within the expiration period to facilitate investigation when needed. (paragraph 6.14(d) above)

Recommendation 44# – to upgrade DH's central inventory monitoring computer system to enhance the traceability of drugs. (paragraph 6.14(e) above)

Recommendation 45# – DH to enrich the database of registered pharmaceutical products so as to provide more detailed information to the public on registration details of products, e.g. pack-size, labelling, legal classification, etc. (paragraph 6.14(f) above)

Recommendation 46* – HA to require suppliers to provide evidence that their products are either registered or are exempted from registration under the law. (paragraph 6.14(g) above)

Recommendation 47* – HA to require suppliers to provide microbiological test results for high risk drug items and batch release certificates on all drugs supplied to HA to ensure safety and quality. (paragraph 6.14(h) above)

Recommendation 48* – HA to use multiple sources for supply of high risk products with high usage volume. (paragraph 6.14(i) above)

Recommendation 49# – HA to establish a Drug Quality Assurance Office to enhance quality monitoring of products, performance management of manufacturers and suppliers and quality incident management as well as to monitor the implementation of all improvement initiatives. (paragraph 6.14(j) above)

Recommendation 50# – HA to enhance the current electronic system, such as exploring the use of RFID, bar coding, wireless data transmission, etc. to enable product traceability and effective stores management. (paragraph 6.14(k) above)

Recommendation 51* – HA to require suppliers to provide drugs in suitable pack sizes as far as possible to reduce the need for repacking. (paragraph 6.14(l) above)

Recommendation 52* – DH to issue a set of guiding principles on drug procurement for the private medical sector and encourage private hospitals, MCOs and private medical practitioners in solo or joint practices to follow this set of guiding principles as far as practicable. (paragraphs 6.26 – 6.27 above)

Recommendation 53* – DH to encourage private hospitals to develop an automated inventory management system and bar-coding system for pharmaceutical products. (paragraphs 6.28 – 6.29 above)

Pharmacovigilance

Recommendation 54* – to establish a pharmacovigilance advisory body to review DH assessments of the ADR reports received, advise DH on action on specific cases, serve as an editorial advisory board of the pharmacovigilance bulletin and assist DH in the promotion of pharmacovigilance activities. (paragraph 7.16 above)

Recommendation 55[#] – DH to set up a dedicated team to promote pharmacovigilance work among professionals, education institutions and the industry; handle ADR reports received; disseminate information; and support the pharmacovigilance advisory body. (paragraph 7.17 above)

Recommendation 56* – DH to publish a regular pharmacovigilance bulletin for distribution to all doctors, dentists and pharmacists, and a user-friendly version of the bulletin for reference of the general public. (paragraph 7.18 above)

Recommendation 57[#] – DH to include an ADR report form in mails to doctors and pharmacists, enhance DH website such that doctors and pharmacists could subscribe and receive emails from DH on ADR as soon as they become known, encourage the use of electronic reporting of ADRs, and develop additional electronic interface for dentists and pharmacists to facilitate ADR reporting. (paragraph 7.19 above)

Recommendation 58[#] – DH to publish guidelines for the drug industry on their responsibilities to report ADRs, to educate and encourage them to report ADRs and to develop a culture of awareness of pharmacovigilance. (paragraph 7.20 above)

Recommendation 59* – to require the drug industry to report any actions taken by overseas drug regulatory authorities on any drugs as a consequence of safety issues and require manufacturers to inform DH if they have committed to the request of European Union or United States to develop an EU Risk Management Plans (RMP) or US Risk Evaluation and Mitigation Strategies (REM) as a condition for approving a new drug. (paragraph 7.21 above)

Recommendation 60* – DH to review ADR reports within three working days. (paragraph 7.22 above)

Recommendation 61* – DH to establish liaison with overseas health authorities for exchange of ADR information as well as providing training on pharmacovigilance to staff. (paragraph 7.23 above)

Recommendation 62# – DH to review the progress and effectiveness of the development and implementation of the improved pharmacovigilance measures in two years' time. (paragraph 7.24 above)

Recommendation 63# – DH to continue the heightened surveillance against high risk products sold in the market and set up a dedicated team of pharmacists to handle increased sampling of high risk products. (paragraph 7.25 above)

Recommendation 64* – to adopt a risk-based approach in drug recall and public communication. Specifically DH should revise the recall guidelines to include the different stages of recall procedures, the classification of the recall, the level of the recall, the strategy of the recall including the dissemination of information to the public, the responsibilities of the trade including refund, and the monitoring of all follow up actions, including the effectiveness of the recall. (paragraphs 7.26 – 7.27 above)

Recommendation 65* – DH to inform the Consumer Council on every drug recall incident at consumer level to widen the dissemination network of the drug recall message. (paragraph 7.28 above)

Recommendation 66* – DH to add a refund mechanism in the recall guidelines requiring manufacturers and wholesalers to provide refund details to consumers at retail level in the event of drug recall. (paragraphs 7.29 – 7.30 above)

Risk Communication

Recommendation 67# – to set up a dedicated, multi-disciplinary team to oversee education and training. The team should collaborate with and co-ordinate efforts of the academia, Consumer Council and relevant professional

bodies in the provision of education and training programmes on drug safety. (paragraphs 8.12 – 8.13 above)

Recommendation 68[#] – to continue organizing seminars with additional focus on quality control for the management at different levels of the drug supply chain as well as front-line staff. (paragraphs 8.14 – 8.15 above)

Recommendation 69[#] – to enhance the content of "Compendium of Pharmaceutical Products" on DH website to provide more information about each registered drug. (paragraphs 8.16 – 8.17 above)

Recommendation 70[#] – to set up a designated website on drug safety to provide a better platform for information dissemination and exchange. (paragraphs 8.18 – 8.19 above)

Recommendation 71* – to establish a working group to work out the prototype of the enhanced website and its contents. (paragraph 8.19 above)

Recommendation 72[#] – to require that more information on drugs and patient-oriented advice be provided along with drugs dispensed to patients at hospitals or clinics. (paragraphs 8.20 – 8.21 above)

Penalty System

Recommendation 73* – to include more aggravating factors in the facts of the case submitted to the Court to reflect the seriousness of the offence concerned for the Court to impose an appropriate sentence. (paragraph 9.11(a) above)

Recommendation 74* – to amend the Pharmacy and Poisons Ordinance to include provision for the Court to order the convicted person to pay the analytical costs incurred by the Government to increase the deterrent effect. (paragraph 9.11 (c) above)

Manpower Requirements

Recommendation 75[#] – to expand DH's Pharmaceutical Service into a dedicated office on drugs to strengthen DH's regulatory role in enhancing drug safety. In the long run, consideration will be given to expanding the office to be a "Centre for Drug Safety". (paragraphs 10.5 – 10.11 above)

Way Forward

11.3 The Review Committee has now completed its task. The Review Committee is pleased that the Government has accepted all its recommendations. In particular, the establishment of a dedicated office on drugs and the raising of Hong Kong's GMP licensing standards to PIC/S standards will become major milestones in the enhancement of Hong Kong's drug safety standard.

11.4 The next step is for the Government to join hands with the pharmaceutical sector in implementing the recommendations. The Food and Health Bureau will oversee the policy issues, introduce the necessary legislative amendments and seek the required resources, while DH, HA and the pharmaceutical sector will be responsible for implementation of the recommendations. The Review Committee would like to appeal to the pharmaceutical sector that it is their primary responsibility to practise to their highest professional standards and strive for continuous service improvement. With the joint efforts of all parties, the Review Committee is confident that the standards of the pharmaceutical industry in Hong Kong will be enhanced and public confidence on the use of drugs will be raised.

11.5 The Chairman of the Review Committee would like to thank all the members of the Committee, the pharmaceutical sector, the medical sector, patient groups and the consumer representative for their contributions to the deliberations of the Review Committee. Members have been most generous with their time and they contributed constructively to all discussions and debates at the meetings in this comprehensive review resulting in a total of 75 recommendations. The Food and Health Bureau and the Department of Health look forward to working with all stakeholders to implement these recommendations under the same spirit of cooperation.

Review Committee on
Regulation of Pharmaceutical Products in Hong Kong
Food and Health Bureau
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