Fourth Meeting of the Business Facilitation Advisory Committee

Agenda Item 2 : Improvements Made to the Pharmaceutical Product Registration System

Purpose

This paper updates Members on the improvement measures implemented in the pharmaceutical product registration system.

Background

2. The subject was previously discussed at the meetings of the Business Facilitation Advisory Committee (BFAC) held on 14 February, 26 June and 9 November 2006 respectively.

3. To protect public health, all pharmaceutical products are required to be registered under the Pharmacy and Poisons Ordinance (PPO) (Cap. 138) before they can be sold in Hong Kong. Applications for registration are assessed by the Pharmacy and Poisons Board (the Board) on the basis of the safety, efficacy and quality of the pharmaceutical products concerned. The Department of Health (DH) provides executive and scientific support to the Board.

4. In 2005 and 2006, 3 846 and 3 873 applications for registration of pharmaceutical products were processed respectively. DH strives to complete the registration process within five months and this target was met in 97% of the cases.

5. Among all applications processed in 2005 and 2006, 51 and 78 of them respectively concerned pharmaceutical products that contained new chemical entities. Such cases are more complicated and require longer processing time. They have to be supported by two Certificates of Pharmaceutical Product [1] (CPPs) issued by reference countries. After DH's

[1] A Certificate of Pharmaceutical Product is issued by the drug regulatory authority of a country to show that the drug concerned is registered in that country.

initial review of the clinical and technical documents and verification of the CPPs, the Registration Committee of the Board will examine the application to determine if the pharmaceutical product concerned meets the requirements of safety, efficacy and quality. After that, the Poisons Committee of the Board will consider how the pharmaceutical product should be classified to control its sale, taking into account scientific and social considerations. Subject to the Board's endorsement, amendment regulations will be introduced into the Legislative Council to effect sale control on the new pharmaceutical products.

6. In the past few years, the Administration has introduced various measures to expedite the registration process. For cases involving new chemical entities, the time taken from the submission of a full application with all supporting documents to the point where the registration certificate is ready for collection has reduced by more than 20% from around 7 months in early 2005 to around 5.5 months by end 2006.

Improvement Made

7. The Board and DH maintain close dialogue with the pharmaceutical trade, and are committed to facilitating the trade as far as possible, while upholding the fundamental objective of ensuring the safety, efficacy and quality of pharmaceutical products in Hong Kong. In this regard, a number of improvement measures have been introduced to the registration system.

Approval Procedures

Approval Cycles of the Board

8. With effect from January 2007, the Board increased the number of approval cycles from four to five per year. This allows more occasions for submission of applications. As in the past, the deadline for submitting applications and supporting documents is clearly announced to the trade to facilitate their planning. In addition, the Board began to deliberate on the recommendations of the Poisons Committee by circulation of papers instead of formal meetings.

Two CPPs Requirement

9. While two CPPs are required to support an application for registration of a pharmaceutical product that contains new chemical entities, DH, since July 2005, has started to accept any official evidence showing the approval of a pharmaceutical product in a reference country, for example, a certified true copy of the CPP or an approval letter.

10. The Registration Committee of the Board has also reviewed the requirement for two CPPs and decided that such requirement should be maintained, having regard to international practices and previous cases where products registered in one country only have to be withdrawn soon after the emergence of serious side effects, before they are registered in a second country. BFAC noted at its meeting on 9 November 2006 that it was common for pharmaceutical product regulatory authorities which adopt the secondary review approach to require two or even three CPPs before approving a pharmaceutical product.

Early Start of the Assessment by DH

11. Since December 2004, DH starts the initial review of an application even if only one CPP is available at the time of application. Two CPPs are ultimately required before the Board gives its final approval. But the new arrangement enables an early start of the assessment by DH.

12. There has also been a suggestion that the Board should consider an application supported by only one CPP and give in-principle approval where appropriate. The Board could then go through the remaining parts of the registration process quickly when the second CPP is available. However, this suggestion is considered not feasible. According to past experience, in around 25% of all cases, the details of the CPP granted by the second country were different from those in the first CPP. Such cases would then require re-consideration of the approval-in-principle previously given. It is considered that the substantial abortive work likely to be involved would undermine the efficiency of the Board.

Legislative Process

13. The legislative process introduces transparency and public scrutiny into the registration system. At present, the amendment regulations to effect sale control of pharmaceutical products with new chemical entities are subject to positive vetting by the Legislative Council. The Administration has considered the option of changing the current positive vetting procedure to negative vetting procedure, but found that such a change would not shorten the time for completing the legislative process. As we understand, the trade in general agrees with our assessment.

14. To ensure that the review by the Legislative Council can proceed as quickly as possible, the Board collaborates closely with the Health, Welfare and Food Bureau (HWFB) and the Department of Justice in preparing the relevant legal instruments. The schedule of the approval cycle is carefully worked out to ensure timely introduction of legislative amendments and to avoid the Legislative Council's holiday breaks.

15. HWFB also introduced a new arrangement in end 2006 whereby preparatory work for law drafting is started immediately after the Poisons Committee made a recommendation, but before the Board considers and endorses it.

Collection of the Registration Certificates

16. Previously the signing of undertaking by the trade is done after the completion of the legislative process. On the recommendation of BFAC, with effect from January 2007, the signing of the undertaking is advanced to the time when the submitted documents are being reviewed by DH. On the day of gazettal of the amendment regulations, DH informs the applicants to collect the registration certificate. Upon payment of the registration fees, the applicant can collect the registration certificate immediately. It is up to the applicant to decide when to collect the certificate.

Communication with the Trade

17. DH has been organizing two rounds of briefings for the trade each year since 2004. Specific requirements for registration are explained in the

briefing sessions. The trade can raise questions and seek clarifications at the sessions. The trade in general finds such sessions useful. DH is reviewing the scope and frequency of these sessions with a view to providing more opportunities for exchanges.

Conclusion

18. The Board and DH have all along maintained close dialogue with the pharmaceutical trade and introduced many useful measures in recent years to make the registration system more user-friendly and to shorten the processing time. Since the subject of pharmaceutical product registration system was first examined by the Retail Task Force of BFAC in 2005, the Administration has introduced a number of measures which bring convenience to the trade and reduce the processing time from 7 months to 5.5 months by end 2006, representing a 20% reduction. With the additional measures taking effect in end 2006 and in the beginning of 2007, the Administration expects the processing time to further reduce by at least 3 weeks. We will continue to listen to the views of the trade and put in our best efforts to facilitate them as far as possible while ensuring the safety, efficacy and quality of pharmaceutical products and protecting the public health.

Health, Welfare and Food Bureau
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