Proposed Amendment to Regulations on Supply of Small Package Pharmaceutical Products

9 July 2008

Korea Food and Drug Administration

1. Amendment Reason

The regulations on the supply of small package pharmaceutical products shall be amended for the purpose of operating the current supply system more reasonably, preventing unnecessary stocks of pharmaceutical products and designing a better distribution plan. In order to do so, government-subsidized essential drugs and other low-cost medicines worth 50 Korean won or less shall be exempted from the requirement of supplying in a small package unit. Also, the small package products kept in stock in pharmacies and hospitals shall be included when calculating the necessary supply of these products for the pharmacies and hospitals. In addition, the information on the output of small package products and their supplier names shall be available to the businessmen concerned.

2. Summary

A. The amendment (Article numbers, names etc.) of the Act referred in this Proposal shall be reflected in Article 1, Article 2.1 and 2.3, Article 3.2, Article 4, Article 5.2, Article 6.1 and Article 6.3.

B. The package unit shall be reasonably adjusted in accordance with the currently accepted standard (Article 2.3.B).

(1) The current regulations say '30 tablets/capsules' but a smaller package unit than this is generally accepted as a small package unit, therefore it shall be adjusted as '30 tablets/capsules or less'.

C. The government-subsidized essential drugs and other low-cost medicines worth 50 Korean won or less shall be exempted from the requirement of supplying in a small package unit (Article 3.4 and 3.5)

(1) The government-subsidized essential drugs and other low-cost medicines worth 50 Korean won or less shall be exempted from the requirement of supplying in a small package unit on concerns over a possible halt in production due to the increased costs by small package production.

D. The supply amount of pharmaceutical products in small packages shall be calculated including the products already kept in stock (Article 4)

(1) The current regulatory requirement puts a burden on pharmaceutical manufacturers or importers by ordering them to provide pharmacies and hospitals with more than 10 % of annual pharmaceutical supply as a small package unit without considering the actual demand of each pharmaceutical product.
(2) Therefore, a plan that allows the number of products already kept in stock to be included in the calculation of the supply amount of small package products shall be prepared.

E. Those who are licensed to manufacture or import pharmaceutical products shall submit a quarterly report regarding the information on the output (or imported amount) of small package items, wholesaler names etc. to the head of the authorities

concerned. The head of the authorities concerned shall allow the businessmen concerned to have access to this report (Article 7 and 8).

(1) This is to prevent unnecessary stocks of small package products and to facilitate their distribution.

F. Those who are given access to the reports including profit reports shall keep the information strictly confidential and refer to the reports only for the business purpose (Article 9).

3. Enforcement Date

This Proposal shall be enforced as of the date of announcement.

Korea Food and Drug Administration Notification No. 2008-123
Regulations on Supply of Small Package Pharmaceutical Products (Korea Food and Drug Administration Notification No. 2006-46, 4 October 2006) shall be amended and notified as described below in accordance with Article 38 and 42 of Pharmaceutical Act and Article 43 and 51 of Enforcement Regulations of the same Act.

9 July 2008
Commissioner of the Korea Food and Drug Administration

Proposed Amendment to Regulations on Supply of Small Package Pharmaceutical Products

Regulations on Supply of Small Package Pharmaceutical Products shall be amended as follows:

In Article 1:-
(1) 'Article 31.1 and Article 34. 4' shall be replaced with 'Article 38 and Article 42';
(2) 'Article 40.1.21 and Article 46.1 of Enforcement Regulation of the same Act' shall be replaced with 'Article 43 and Article 51 of Enforcement Regulation of the same Act';
(3) ' Pharmaceutical manufacturers' shall be replaced with 'those who are licensed to manufacture pharmaceuticals or have reported pharmaceutical manufacturing (hereinafter referred to as 'those who are licensed for pharmaceuticals')'.

'Pharmaceutical manufacturers' in Article 2.1 and 2.3, Article 3, Article 4, Article 5.2, Article 6.1 and 6.3 shall be replaced with 'those who are licensed for pharmaceuticals'.

In Article 2.3.B, '30 tablets/capsules' shall be replaced with '30 tablets/capsules or less'.

In Article 3 and Article 5.1, '1' shall be replaced with 'one'.

In Article 3.2, ‘Minister for Health and Welfare’ shall be replaced with ‘Minister for Health, Welfare and Family Affairs’. Also, ‘pharmaceuticals supply/non-supply list and maximum supply cost table’ shall be replaced with ‘Pharmaceuticals Supply List and Maximum Supply Cost Table’.

In Article 3.3, ‘rare pharmaceuticals’ shall be replaced with ‘the rare pharmaceuticals designated in accordance with Regulations on Rare Pharmaceutical Designation provided by the Commissioner of Korea Food and Drug Administration’.

Article 3.4 and 3.5 shall be added as follows:

Article 3.4. The government-subsidized essential drugs chosen in compliance with the management of the government-subsidized essential drugs and the adjusted standard of maximum cost indicated on Attached Table 4 of Selection and Adjustment Standard of New Medical Technology designated by the Minister for Health, Welfare and Family Affairs

Article 3.5. The low-cost medicines that are indicated in Pharmaceuticals Supply List and Maximum Supply Cost Table designated by the Minister for Health, Welfare and Family Affairs and of which the maximum supply cost is 50 Korean won or less.

An exception shall be added to Article 4 as follows:

However, when calculating the supply amount, small package items already kept in stock shall be allowed to be included.

Article 7 shall be added as follows:

Article 7 (report of manufacturing and import) Those who are licensed for pharmaceutical products and importers shall submit a report, which shows the total output or imported amount of the pharmaceuticals required for small packages, the output or imported amount of small package products, the amount of small package products kept in stock and the small package product wholesalers’ names etc., to the president of the Korea Pharmaceutical Association or to the president of the Korea Drug Import and Export Association within one month after the end of each quarter.

Article 8 shall be added as follows:

Article 8 (access to reports etc.) 1. The head of the authorities concerned shall allow only those who opened pharmacies or medical centres (hereinafter referred as ‘Businessmen Concerned’) to have access to the reports submitted in accordance with Article 7 within two months after the end of each quarter. 2. In accordance with Article 8.1, easy methods for Businessmen Concerned to have access, such as access to websites of the authorities concerned, shall be provided.

Article 9 shall be added as follows:

Article 9 (prohibition of disclosure) In accordance with Article 8, those who have access to confidentiality regarding the business of those who are licensed for pharmaceutical products, importers and pharmaceutical wholesalers shall not disclose

any obtained information to a third party and shall use the information only for business purposes such as manufacturing and sale.

Subsidiary Act

Article 1 (enforcement date) This Proposal shall be enforced as of the date of announcement.

Comparison of Old and New Acts

Old (Current)	New (Proposed Amendment)
Article 1 (purpose) The purpose of the Regulations is to designate the supply methods as well as the types of pharmaceuticals, which are manufactured or imported by pharmaceutical manufacturers or importers in accordance with Article 31.1and Article 34.4 of Pharmaceutical Act and Article 40.1.21 and Article 46.1 of Enforcement Regulations of the same Act and need to be supplied in a small package unit such as individually wrapped tablets.	Article 1 (purpose) ---------- ---------- ---------- ---------- those who are licensed to manufacture pharmaceuticals or have reported pharmaceutical manufacturing (hereinafter referred to as 'those who are licensed for pharmaceuticals') ---------- ----------Article 38 and Article 42, and Article 43 and Article 51 of Enforcement Regulations of the same Act----------
Article 2 (definition) The terms used in the Regulations shall be defined as follows: 1. 'Package Unit' means a package unit manufactured/imported and supplied by pharmaceutical manufacturers/importers. 2. (omission) 3. 'Small Package Unit' means the following package units among the package unit supplied by pharmaceutical manufacturers/importers. A. (omission) B. In bottle: 30 tablets/capsules	Article 2 (definition) ---------- 1. ---------- ---------- those who are licensed for pharmaceuticals--. 2. (same as the current Regulations) 3. ----------those who are licensed for pharmaceuticals-------. A. (same as the current Regulations) B. In bottle: 30 tablets/capsules or less
Article 3 (targeted pharmaceuticals) The types of pharmaceuticals that pharmaceutical manufacturers/importers should supply in a small package unit shall be those in tablets and capsules. However,	Article 3 (targeted pharmaceuticals) -------- ---------- those who are licensed for pharmaceuticals---------- ----------

in case of 1 of the followings, it shall be exempted from this requirement. 1. (omission) 2. General pharmaceuticals not recorded in pharmaceuticals supply/non-supply list and maximum supply cost table designated by the Minister for Health and Welfare 3. Rare pharmaceuticals <Added> <Added> Article 4 (supply method) Pharmaceutical manufacturers/importers shall provide pharmacies and hospitals with more than 10 % of annual pharmaceutical supply as a small package unit in accordance with Article 2.3 <Exception added> Article 5 (exceptional case) 1. ----------1----------. 2. In accordance with Article 5.1, if pharmaceutical manufacturers/importers wish to be considered as an exceptional	----------one----------. 1. (same as the current Regulations) 2. General pharmaceuticals not recorded in Pharmaceuticals Supply List and Maximum Supply Cost Table designated by the Minister for Health, Welfare and Family Affairs 3. The rare pharmaceuticals designated in accordance with Regulations on Rare Pharmaceutical Designation provided by the Commissioner of Korea Food and Drug Administration 4. The government-subsidized essential drugs chosen in compliance with the management of the government-subsidized essential drugs and the adjusted standard of maximum cost indicated on Attached Table 4 of Selection and Adjustment Standard of New Medical Technology designated by the Minister for Health, Welfare and Family Affairs 5. The low-cost medicines that are indicated in Pharmaceuticals Supply List and Maximum Supply Cost Table designated by the Minister for Health, Welfare and Family Affairs and of which the maximum supply cost is 50 Korean won or less. Article 4 (supply method) Those who are licensed for pharmaceuticals----------. However, when calculating the supply amount, the small package items already kept in stocks shall be allowed to be included. Article 5 (exceptions) 1. ----------one----------. 2. ---------- Those who are licensed for pharmaceuticals----------

case, they shall submit a request form and necessary proof material to the Commissioner of the Korea Food and Drug Administration for the acknowledgement. 3. (omission) Article 6 (cooperation etc.) 1. If the president of the Korea Pharmaceutical Association or the president of the Korea Pharmaceutical Wholesalers Association asks to increase the supply amount of the corresponding pharmaceuticals above the level decided in Article 4, pharmaceutical manufacturers/importers shall actively cooperate to do so. 2. For the smooth supply of the pharmaceuticals in a small package unit, the Commissioner of Korea Food and Drug Administration may encourage or advise pharmaceutical manufacturers/importers and organizations concerned to increase the supply amount of small package products. 3. In accordance with Article 6.2, the pharmaceutical manufacturers/importers who were encouraged or advised by the Commissioner of Korea Food and Drug Administration shall endeavour to perform as encouraged or advised unless there is a specific reason not to do so. <Added>	---------- ---------- ---------- ---------- ----------. 3. (same as the current Regulations) Article 6 (cooperation etc.) 1---------- ---------- ---------- ---------- ---------- ---------- ---------- - those who are licensed for pharmaceuticals----------. 2. ---------- ---------- ---------- ---------- those who are licensed for pharmaceuticals ---------- ----------. 3. ---------- those who are licensed for pharmaceuticals ---------- ---------- ---------- ---------- ----------. Article 7 (report of manufacturing and import) Those who are licensed for pharmaceutical products and importers shall submit a report, which shows the total output or imported amount of the pharmaceuticals required for small packages, the output or imported amount of small package products, the amount of small package products kept in stock and the small package product wholesalers' names etc., to the president of the Korea Pharmaceutical Association or to the president of the Korea Drug Import and Export Association within one month after

<Added>	the end of each quarter. Article 8 (access to reports etc.) 1. The head of the authorities concerned shall allow only those who opened pharmacies or medical centres (hereinafter referred as 'Businessmen Concerned') to have access to the reports submitted in accordance with Article 7 within two months after the end of each quarter. 2. In accordance with Article 8.1, easy methods for Businessmen Concerned to have access, such as access to websites of
<Added>	authorities concerned, shall be provided. Article 9 (prohibition of disclosure) In accordance with Article 8, those who have access to confidentiality regarding the business of those who are licensed for pharmaceutical products, importers and pharmaceutical wholesalers shall not disclose any obtained information to a third party and shall use the information only for business purposes such as manufacturing and sale.