

## NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	<b>Member to Agreement notifying:</b> <u>REPUBLIC OF KOREA</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b> Ministry of Health and Welfare <b>Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b>
3.	<b>Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
4.	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Pharmaceuticals
5.	<b>Title, number of pages and language(s) of the notified document:</b> Amendment of "Pharmaceutical law enforcement regulation" 58 pages, in Korean)
6.	<b>Description of content:</b> When applying for approval of manufacture or importation of a pharmaceutical product, the following documents should be submitted.  1. Gene combinant medicine, cell culture medicine, biological product, cell treatment remedy & gene treatment remedy: documents to prove it compatible with GMP & biological GMP  2. Raw medicine for listing-up <ul style="list-style-type: none"><li>- documents on facilities for manufacture &amp; quality control;</li><li>- document on physio-chemical properties and stability;</li><li>- document to prove it compatible with GMP or equal (or over) to GMP;</li><li>- document on certificate of analysis on raw medicine.</li></ul> Re-examination can be exempted when:  3. The number of subject pool for surveillance is too small to satisfy the requirement for re-examination.

<b>7.</b>	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> Health
<b>8.</b>	<b>Relevant documents:</b> Ministerial Decree of Health and Welfare 208 (2002.1.12)
<b>9.</b>	<b>Proposed date of adoption:</b> 12 January 2002  <b>Proposed date of entry into force:</b> -6.1) 1 January 2003 -6.2) 1 July 2002 -6.3) 12 January 2002
<b>10.</b>	<b>Final date for comments:</b>
<b>11.</b>	<b>Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:</b>  International Cooperation Division Office of Planning and Management Ministry of Health and Welfare 1 Jungang-Dong Kwacheon-City Kyoungi-Do 427-760 Republic of Korea  Telephone: +82-2-2110-6152/3 Fax: +82-2-504-6418