Iðnaðarnefnd Alþingis
Alþingi
150 Reykjavík

Reykjavík, 5. desember 2005

Vegna umsagnar um frumvarp til laga um breytingu á lögum nr 17/1991, um einkaleyfi.
Þingskjal 380

Frumtök, samtök framleiðenda frumlyfja eru þeirrar skoðunar að fyrirliggjandi lagafrumvarp samrýmist alþjóðaheimildum en mikið veltur á hvernig lögin verða útfærð í reglugerð. Sú reglugerð verður á afdráttarlausan hátt að taka tillit til samþykktar aðalráðs WTO og yfirlýsingar forseta ráðsins. Þar kemur m.a. fram að auðkenna verður sérstaklega öll lyf sem framleidd eru í skjóli þessarar sérstöku heimildar, framleiðsluna skal tilkynna til TRIPS ráðsins og að framleiðslan má ekki vera í hagnaðarskyni eða neyðarheimildin nýtt sem forsenda viðskipta- og iðnaðarstefnu þess lands sem nýtir sér neyðarleyfið. Einnig á að leita samninga við handhafa einkaleyfis og ekki á að binda upphæð þóknunar í reglugerð, heldur á að skoða hvert tilvik sérstaklega.

Frumtök leggja til eftirfarandi breytingu á b.lið frumvarpsins:

b. Við bætist ný málsgrein sem orðast svo:
Nauðungarleyfi er aðallega veitt til að fullnægja eftirspurn hér á landi. Heimilt er þó að veita nauðungarleyfi vegna lyfja til útflutnings til þróunarríkja eða ríkja sem stríða við alvarlegan heilbrigðisvanda í samræmi við ákvörðun aðalráðs Alþjóðaviðskiptastofnunarinnar frá 30. ágúst 2003, ***og í ljósi yfirlýsingar forseta aðalráðsins,*** um samninginn um hugverkarétt í viðskiptum og heilbrigði almennings. Slík nauðungarleyfi verða þó aðeins veitt að uppfylltum nánar tilgreindum skilyrðum í reglugerð sem samræmist fyrrgreindri ákvörðun aðalráðsins ***og yfirlýsingar forseta þess.***

Virðingarfyllst,
f.h. stjórnar Frumtaka, Samtaka framleiðenda frumlyfja,

Hjörleifur Þórarinsson,
formaður

Hjálagt: Yfirlýsing forseta aðalráðs Alþjóðaviðskiptastofnunarinnar frá 30. ágúst 2003. (The General Council Chairperson's statement).

WTO NEWS: 2003 NEWS ITEMS

30 August 2003
INTELLECTUAL PROPERTY
The General Council Chairperson's statement

On 30 August 2003, the General Council approved a decision to make it easier for countries in need to import cheaper generic medicines made under compulsory licensing if they are unable to manufacture the medicines themselves. A separate statement by General Council chairperson Carlos Pérez del Castillo, Uruguay's ambassador, was designed to provide comfort to those who feared that the decision might be abused and undermine patent protection. Below is the statement:

> Press release: Decision removes final patent obstacle to cheap drug imports
> The decision

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> Supachai Panitchpakdi's speeches

The General Council has been presented with a draft Decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This Decision is part of the wider national and international action to address problems as recognized in paragraph 1 of the Declaration. Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented. I would like to emphasize that this Statement is limited in its implications to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.

Second, Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision. In this regard, the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. It is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals.

In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programmes. "Best practices" guidelines that draw upon the experiences of companies are attached to this statement

for illustrative purposes. Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.

Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably:

- To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.
- In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.
- Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.
- If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilise the good offices of the Director General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.

Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

In addition, as stated in footnote 3 to paragraph 1(b) of the Decision, the following Members have agreed to opt out of using the system as importers: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers.

As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.