Generic Medicines Industry Association Pty Ltd

ABN 19 096 009 540

PO Box 222
Pymble BC
NSW 2073

30 January 2009

Korea FTA Taskforce
Department of Foreign Affairs and Trade
RG Casey Building
Barton
ACT 0221

**Australia – Republic of Korea Free Trade Agreement**

Please find attached a submission by the Generic Medicines Industry Association (GMiA) outlining some barriers that currently face our members seeking to export generic medicines into Korea.

The Generic Medicines Industry Association is the peak body for suppliers of generic medicines in Australia. It comprises six member companies that provide approximately 95% of generic medicines in the Australian domestic market. Three of our members also have domestic manufacturing facilities and export markets that span the major global markets. Australia exports $3.9b of medicines each year and Korea is an important export market for medicines. Generic medicines account for at least 12% of Australia's medicines exports.

As the Australia – Republic of Korea Free Trade Agreement feasibility study found medicines were in Australia's top 15 merchandise exports to the Republic of Korea, by value, in 2006. Further, exports of medicines have shown the strongest growth of any major Australian manufacturing export to the Republic of Korea.

GMiA would urge the Australian government to raise the issues set out in the attached submission as part of the current discussions between Australia and the Republic of Korea on a possible bilateral Free Trade Agreement.

Please do not hesitate to contact me on 0432 500 308 or kate.lynch@gmia.com.au should you require any further information.

**Yours sincerely,**

**Kate Lynch**
**Chief Executive Officer**

**Generic Medicines Industry Association Submission to the Department of Foreign Affairs and Trade - Korea Free Trade Agreement Taskforce**

## Factors that delay, prevent or discourage generic entry to South Korea

| Market access hurdle | Korean/KFDA approach | Australia/TGA approach | US/FDA approach |
|---|---|---|---|
| Certificate of Pharmaceutical Product (CPP) | A generic application requires the inclusion of a Certificate of Pharmaceutical Product (CPP) from either the country of manufacture or a recognised 'Tier 1' market – meaning that the product must be approved in another major market before an application can be submitted in Korea. This requirement is only for foreign-produced product. Locally-manufactured product is not subject to the same requirements.<br><br>Therefore local generic manufacturers are able to enter the Korean market approximately 12 – 18 months earlier than a foreign-sourced product. | Generic application is submittable without need for a CPP | Generic application is submittable without need for a CPP |
| GMP Certification | From 2009, KFDA require that production facility must be inspected by KFDA – even if the facility has been inspected by another regulatory agency and GMP certificate granted.<br><br>This requirement is in addition to the need for CPP, which is essentially a 'double up' of GMP assessment. | Mutual Recognition Agreement between TGA and several EU markets allows for an EU-granted GMP certificate to be accepted by the TGA. TGA also accept the US-FDA's Establishment Inspection Report (EIRs) along with key supporting documentation from audits by Pharmaceutical Inspection Cooperation Scheme (PIC/s) regulators and New Zealand Medsafe | FDA has historically performed their own site inspections. However they are now showing some willingness to collaborate with European agencies for joint inspections. |

| Market access hurdle | Korean/KFDA approach | Australia/TGA approach | US/FDA approach |
|---|---|---|---|
| API | API plant inspection must be carried out by the KDFA, regardless of an inspection by any other authority. This can delay approval and add additional cost to the application (approx USD20,000, depending on site/destination). | API is assessed as part of finished product application (full manufacturing details must be submitted). Site inspection by the TGA is not a requirement, as TGA accepts GMP certification from MRA regulators; TGA also accept most countries GMP certifications or an acceptable rating on FDA FACT's database with key supporting documentation from audits by PIC/s regulators. | API assessed as part of finished product application (full manufacturing details must be submitted) OR as separately approved DMF |

| Market access hurdle | Korean/KFDA approach | Australia/TGA approach | US/FDA approach |
|---|---|---|---|
| Hospital product tendering | The requirement for foreign sourced products to have the Certificate of Pharmaceutical Product (CPP) not only typically delays market entry by 12-18 months, it also has reduces the attractiveness of the product in the hospital market given Korea's reimbursement pricing practices outlined below. The system operates as an artificial trade barrier to foreign generic manufacturers due to the higher price given to (a) innovators (even after patent expiry) and (b) Korean generic manufacturers (due to their lack of CPP requirement). Such trade barriers create a strong disincentive for investment by foreign generic companies in Korea, limits competition in the Korean generic pharmaceutical market, thereby increasing costs within the Korean health system itself.<br><br>The reimbursement price of a new chemical entity is normally based on the 65% of the USA "Red Book" price. The reimbursement price applied to a generic is dictated by the order in which each generic obtains listing. The 'Group 1' listings - first 6 listings - are listed at a low discount off the innovator (reference) product. Then deeper discounts are applied to subsequent 'Group 2' and 'Group 3' listings.<br><br>Hospitals pharmaceuticals are normally tendered in Korea and the award is based on quality and best offered tender price. While hospitals pay the tender price, they claim the official reimbursement price through the reimbursement system and retain the difference to fund other hospital activities. Hence, hospitals profit most from the 'Group 1' generics. As foreign-sourced product requires a CPP for registration, which, the requirement for a CPP leads to foreign-sourced product often falling into the second, or sometimes third, grouping for reimbursement. The lower price makes such products unfavourable for hospitals. | 12.5% price discount applies to all products, including the innovator, following the approval of the first generic. All subsequent listings are afforded the same price. | Hospitals/GPOs pay the actual (competitive) market price – price not affected by order of entry. |
| Importation duties | Korean Government imposes an import tax of 8.0% on imported pharmaceuticals. This creates an 8% 'cost disadvantage' over locally-manufactured product. | Pharmaceuticals are exempt from importation duties. | Not applicable |

| Market access hurdle | Korean/KFDA approach | Australia/TGA approach | US/FDA approach |
|---|---|---|---|
| Listing Process | Each hospital requires its own listing, i.e. each hospital must separately approve each manufacturer of each molecule as an acceptable supplier despite the product being approved by KFDA. Consequently the time for a generic (whether local or foreign) to achieve broad adoption is delayed as each hospital must be convinced to adopt the new generic on a per-hospital basis. | No hospital-based listings are used. Once approved, the product is freely able to be sold in any hospital country-wide. | No hospital-based listings are used. Once approved, the product is freely able to be sold in any hospital country-wide. |