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Business Perspectives on the EU-Korea FTA – The Next 5 years

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EU KOREA BUSINESS FORUM



- EU-KOREA FTA
- Healthcare market in Korea –Pharmaceuticals / Medical Device
- Achievements
- Future developments

- EU-KOREA FTA entered into force in July 2011
- EU's first trade deal with an Asian country
- Elimination of duties
- Also addresses non-tariff barriers to trade, including pharmaceutical and medical devices sectors
- Include provisions in areas such as intellectual property rights, transparency in regulation and sustainable development.
- Establish a specialised committees and working groups to monitor its implementation.
- Annual meeting of working group on Pharmaceuticals and Medical Devices

Pharmaceutical market in Korea

- Korea pharmaceutical market size: KRW 19.24 trillion in 2015
- The production of pharmaceuticals : KRW 16.97 trillion in 2015 (+3.4% from the previous year)
- Exports: KRW 3.33 trillion (+22% from the previous year), Imports: KRW 5.6 trillion (-5.1% from the previous year)
 - ✓ Biggest growth rate for exports in the last 5 years
 - ✓ Korea exports to Europe have multiplied - Hungary, Finland, Switzerland, France
 - ✓ Biomedicines are mainly contributed for exports in EU
 - ✓ Top Europe countries for imports – UK, Germany, Switzerland, France, Italy

* Sources: MFDS statistical data (2015)

Medical Device market in Korea

- Korea medical device market size: KRW 5.27 trillion in 2015
- The production of medical device : KRW 5 trillion in 2015 (+8.6% from the previous year)
- Exports: KRW 3.07 trillion (+5.2% from the previous year), Imports: KRW 3.33 trillion (-0.9% from the previous year)
 - ✓ Production growth rate has increased due to ageing population and filler plastic surgery
 - ✓ Korea exports to Europe countries - Germany, Italy, UK
 - ✓ Top Europe countries for imports – Germany, Switzerland, France, UK

* Sources: MFDS statistical data (2015)

- Increasing trade between EU and KOREA
- Use of tariff preferences under the FTA
- Revisions of regulations in line with FTA
- Activation of dialogue channel to follow-up implementation of FTA

Future developments

- Healthcare industry is focused as future growth engine by Korea government
 - ✓ Global top company
 - ✓ Global success of new blockbuster drugs
 - ✓ Open innovation
 - ✓ Support R&D

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- Outstanding market access and implement issues of FTA in pharmaceutical and medical devices sectors
- De facto preferential treatment to domestic companies

- Premium pricing for global innovation drugs
 - ✓ Ministry of Health & Welfare announcement on July 7, 2016
 - ✓ 'Global innovation drugs' will receive premium pricing when all of 3 criteria are satisfied
 - Approved in Korea for the first time in the world or provided social contribution as patient support programs
 - Developed by innovative pharmaceutical companies or global-local pharma contract for open innovation, exports
 - Clinical trial (phase 1 or above) is conducted in Korea

- Premium pricing scheme shall be fairly accessible to multinational corporation drugs
 - ✓ Still needs to be clarified
 - ✓ Transparent operating guidelines should be developed in consistent with EU-Korea FTA spirit
- Value of innovation drugs shall be properly recognized to secure patient access
- More foreign countries are adapting the drug pricings in Korea as reference so it make impact on launching innovative drugs in Korea

- Recognition of new technology
 - ✓ R&D investment for new technology of medical devices is essential
 - ✓ Technological convergence is expected to create a new field in the market (ex. U-Health with integrated IT Technology)
 - ✓ Proper recognition of the value of new technology shall be implemented

- Discrimination and Transparency
 - ✓ Korea government policies shall be fair and non-discrimination against to multination corporation and the decision makings should be transparent
- Regulatory cooperation
 - ✓ International provisions, practices and guidelines shall be considered
 - ✓ Engage in closer regulatory cooperation between international bodies



Thank you !