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## **Pharmaceutical Patents and Variety Protection Remain Challenges Nearing Conclusion of EPA with EU (2)**

In the negotiations for the Comprehensive Economic Partnership Agreement (CEPA, IEU-CEPA) with the European Union (EU), which the Indonesian government is aiming to conclude as soon as possible, Indonesian and European civil society groups are concerned about the EU's demands for stronger intellectual property rights. They point out that the EU's proposal to extend the patent period for medicines could lead to delays in generic drug market entry and higher drug prices, while stricter protection of new plant varieties could lead to a reduction in the rights of small-scale farmers to handle seeds. The issue of intellectual property rights, where there is a gap in views between developed and emerging countries, is an unavoidable theme in achieving a soft landing in the CEPA negotiations.

The IEU-CEPA negotiations, launched in July 2016, have been held 20 times by July this year, including virtual meetings. During the negotiation process, the EU side submitted draft articles of the CEPA as a basis for discussion, and published summaries after each meeting. According to the Indonesian government, the negotiations are 90% complete, but the details of what has been agreed upon so far have not been made public.

In this context, Indonesian and European civil society groups and non-governmental organizations (NGOs) have criticized the IEU-CEPA for not making the negotiation process public, and have warned of the negative aspects that Indonesia would suffer if it were to conclude the agreement.

According to Indonesia for Global Justice (IGJ), a civil society group that raises issues surrounding free trade, major concerns include the EU's proposal to apply "TRIPS Plus", an expansion of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the requirement to ratify the International Convention for the Protection of New Varieties of Seed Plants (UPOV) 1991, which strengthens intellectual property rights for new plant varieties.

Limited access to affordable medicines

Agung, a health program officer at the IGJ, points out that the IEU-CEPA negotiations are discussing TRIPS-plus clauses, which clearly include provisions such as extending the patent protection period for pharmaceuticals and banning parallel imports, raising concerns that this could have a negative

impact on access to medicines.

The EU's initial draft text proposed extending the patent protection period for pharmaceuticals, while stating that intellectual property rights would be in line with the TRIPS system. The text left the specific extension period blank, stating that negotiations would be held.

Indonesia's patent law stipulates that the protection period for a patent is 20 years from the date of application, but the examination period is said to take about five years, which means that the effective protection period will be shortened. The EU is thought to be proposing patent extension to prevent this.

The IGJ points out that the extension of patent periods, etc., may result in delays in the start of generic production in Japan, and that even if generics are sold in other countries, they may not be able to be imported into Japan while the patent for the original drug is still valid.

According to Arni Rismayanti, Chair of the Indonesian Pulmonary Hypertension Foundation (YHPI), the brand-name version of the pulmonary hypertension drug "Ambrisentan" in developed countries costs 60 million rupiah (approximately 548,300 yen) per month, but a generic version imported from India costs just 2.5 million rupiah. Another pulmonary hypertension drug, "Macitentan" costs 31 million rupiah per month for the brand-name version, but only 1.5 million rupiah per month for the generic version.

Indonesian economists have also been urging caution in extending pharmaceutical patents. Mohammad Faisal, Executive Director of Center of Reform on Economics (CORE) Indonesia, said, "The extension of patent rights will limit opportunities for innovation to develop and expand Indonesia's pharmaceutical industry and reduce dependency on drug imports".

"This needs to be taken into account in the negotiations to ensure people's access to health services is not undermined", said Dafydd, chief economist at Bank Central Asia (BCA), the largest private bank in Indonesia.

The EU is the largest importer of medical supplies, including pharmaceuticals, by country/region, so the focus is on whether the negotiations will reach a soft landing.

Concerns over the reduction of rights for small-scale farmers

Another issue that domestic and international civil society groups have been concerned about in the IEU-CEPA negotiations is the ratification provision of the UPOV 1991 Convention. The Convention provides for intellectual property rights aimed at promoting the development of new varieties, and stipulates that breeders of new varieties are given exclusive rights if they register the variety with the authorities. The EU, in the draft text it submitted during the negotiation process, clearly stated that it would protect varieties in accordance with the UPOV 1991 Convention, and called on the Indonesian side to ratify the Convention.

The UPOV 1991 Convention requires that farmers, for example, license the cultivation of registered varieties, harvest them, and then collect seeds to reproduce (breed) and sell them. As an exception, it stipulates that private, non-commercial self-cultivation of seeds is permitted.

While the treaty benefits global companies involved in seed development, countries in the Global South with abundant genetic resources are concerned that the rights of their farmers, who have historically preserved and exchanged seeds, will be narrowed, and are therefore reluctant to join. 62 countries, regions, and organizations have ratified the UPOV 1991 Treaty, and even if the UPOV 1978 Treaty before the treaty was revised is included, only 79 countries, regions, and organizations have joined UPOV.

For example, member countries of the Trans-Pacific Partnership (CPTPP) are required to ratify the 1991 UPOV Convention, but five of the 11 member countries (Malaysia, Brunei, New Zealand, Mexico and Chile) have yet to ratify it.

Kartini (Asia Program Coordinator) of GRAIN, an international non-profit organization that supports small farmers, points out that “More than 90% of farmers in Indonesia are small-scale farmers, and they obtain seeds in various ways, such as saving seeds for the next planting and exchanging them with neighboring farmers when necessary”. She says that if Indonesia joins the UPOV 1991 treaty, the standardization and privatization of seeds will progress, and there is a possibility that laws will be amended to make common agricultural practices such as exchange illegal.

### **Government denies joining UPOV**

Approximately 90 domestic and international organizations, including GRAIN and IGJ, are calling on the government, including President Joko Widodo, to reject the EU’s proposal to join the 1991 UPOV Treaty in the IEU-CEPA negotiations in 2022.

Furthermore, in December 2023, Michael Fakhri, a special rapporteur on the right to food appointed by the United Nations Human Rights Council, will issue a letter to the Indonesian government requesting an explanation of measures to protect farmers' rights regarding developments surrounding Indonesia's accession to the 1991 UPOV Convention in the IEU-CEPA negotiations.

Fakhri pointed out that the treaty's exception to the rule of "private and non-commercial" home-seeding is an unrealistic definition that ignores important practices such as local seed exchange and sharing of harvests among families.

In response, the Indonesian government replied in February 2012 that it was taking note of a strong proposal from the EU to join the 1991 UPOV treaty. It explained that although Indonesia has a Plant Variety Protection Law with content similar to UPOV, it maintains its position of not joining the treaty in order to secure policy space to protect the seed systems and plant genetic resources of small farmers.

Kartini from GRAIN said, "We strongly urge the government not to join the UPOV 1991 Treaty and not to sign the IEU-CEPA too soon". Faisal from CORE also opposed rushing to reach a settlement under the current administration saying, "We should not make major policy decisions that will have long-term effects before the transition to a new administration".