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Public Citizen Comments Regarding the Draft Guideline on Implementation of Patent Linkage for Pharmaceutical Products in Malaysia

Thank you for the opportunity to provide written comments to the National Pharmaceutical Regulatory Agency regarding the proposed implementation of the patent linkage mechanism in Malaysia.¹

Public Citizen is a nonprofit consumer advocacy organization with over one million members and supporters. Public Citizen's Access to Medicines Program works with partners across the United States and around the world to make medicines available for all through tools in policy and law.

We understand that the Patent Linkage Guideline (hereinafter the "Guideline") aims to implement Malaysia's commitments under the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) to provide a notification mechanism to patent holders, opportunity to seek legal remedies, and procedures to resolve patent disputes before marketing of an allegedly infringing pharmaceutical product.² We also understand that the Guideline's objective is to balance regulatory efficiency with patent protection while ensuring continued access to medicines.³ However, Public Citizen is concerned that the Guideline as currently proposed will adversely impact access to affordable medicines in Malaysia.

CPTPP provides two options for implementing "patent linkage." The first option provides that a Party must either create a system to provide notice to a patent holder or allow for notification prior to the marketing of a competing product, or a product for an approved use, claimed under a patent. A Party also needs to provide adequate time and opportunity for a patent holder to seek remedies. The second option provides for a "hard" linkage system which prevents generics companies from receiving marketing approval during the patent term unless by consent or acquiescence of the patent holder. To comply with the CPTPP, Malaysia only needs to provide a notification system and availability of judicial remedies.

The Guideline goes beyond the minimum requirements in the CPTPP, proposing a system that requires a 45-day hold on a registration decision for a generic application containing a list of patents and pending patents and an automatic 12-month suspension of approval if the patent holder initiates court action within the 45-day period. This would allow patent holders to block the registration of generic medicines for marketing approval, even for spurious patents.

¹ <https://upc.mpc.gov.my/main/user/view-consultations/232>

² CPTPP, Article 18.53

³ <https://upc.mpc.gov.my/main/user/consultations/documents/view/consultations/documents/Vx0gJAiuAMcSRiigxHGEAzV319QVXeKfrPDF875.pdf>

Evidence shows that patent linkage delays generic entry and can facilitate abuse, since the financial benefits to patent holders of deterring generic market entry may outweigh the risks of penalties. For example, a study by Mexico’s Federal Economic Competition Commission found the patent linkage system encourages legal disputes and abuse by patent holders seeking to delay competition. The Commission found that generic drugs entered the market on average two years after patent expiration, indicating barriers to competition and lost savings as spending is maintained on higher-priced patented products.⁴ Additionally, the U.S. Federal Trade Commission has noted the harmful impacts of improperly listed patents within the U.S. “hard” linkage system, stating that “[w]hen [the] stay [on approval of a generic application] is triggered by a patent that is improperly filed and does not meet the statutory listing criteria, the stay may improperly delay consumer access to a competing product that might reduce prices, improve quality and access, or both. Given the high cost of many drugs, even a short delay in competition can have enormous consequences for consumers in accessing cost-effective medications.”⁵ Notably, the European Commission strictly prohibits patent linkage systems, finding that linkage creates unnecessary delays in generics market entry and unjustifiably blocks healthy competition and access to affordable medicines.⁶

We urge you to withdraw the proposed Guideline and to pursue meaningful consultations with civil society experts and patient organizations on the implementation of Article 18.53 of the CPTPP.

Sincerely,

Peter Maybarduk
Access to Medicines Director
pmaybarduk@citizen.org

⁴ https://www.cofece.mx/wp-content/uploads/2017/11/Studies-drugmarkets_vF-BAJA.pdf

⁵ <https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-files-amicus-brief-outlining-anticompetitive-harm-caused-improper-orange-book-listings>

⁶ <https://www.medicinesforeurope.com/wp-content/uploads/2021/03/Medicines%20for%20Europe%20Position%20Paper%20On%20Patent%20Linkage%20-%20May%202019.pdf>