August 23, 2013

Risks of the US TPP Proposal for the Sustainability of Japan’s NHI Drug Pricing System

At the Trans-Pacific Partnership negotiations, the United States has proposed a series of measures which could significantly weaken Japan’s National Health Insurance (NHI) drug pricing system. These measures are proposed in an annex to the TPP “Transparency” chapter. A leaked copy of that proposal is available on the Public Citizen website. This memo reviews the mechanisms Japan uses to contain pharmaceutical costs, the potential changes to this system that the US proposal may require, and the consequences of those changes.

Since 1961, Japan has provided universal health coverage. According to 2010 OECD health data, Japan spent much less on health care as a percentage of GDP than the United States, which did not have universal health coverage – 9.6% compared to 17.7%. In significant part, this is because Japan, like many OECD countries, uses effective cost containment mechanisms for pharmaceutical expenditures.

The U.S. TPP Proposal

The Office of the U.S. Trade Representative aims to restrict these cost containment mechanisms by proposing the following requirements:

- Basing reimbursement rates on “competitive market-based pricing” or the “value of the patented or generic pharmaceutical products” (subparagraphs X.3(d)).
- Limiting the use of international reference pricing (subparagraphs X.3(d)).
- Introducing an “independent appeal or review right” (subparagraph X.3(i)); and
- Heightening “procedural transparency” standards (subparagraphs X.3(b), (c), (g), (h), and (k)).

1 Public Citizen’s Global Access to Medicines Program, August 2013, contact bklic@citizen.org, mkim@citizen.org or pmaybarduk@citizen.org
5 Subparagraph X.3(d) also requires “transparent and verifiable” grounds for determining reimbursement prices.
6 The leaked TPP text does not explicitly use the term “international reference pricing.” However, as discussed in detail below, in view of the U.S. pharmaceutical companies’ long-term campaign to challenge governments’ drug price control mechanisms, (manifest in the EHI agenda and industry comments regarding Japan’s joining the TPP), the language “in the Party’s territory” may be interpreted as aiming to restrict international reference pricing, which is a tool used by many OECD countries including Japan.
This memo analyses provisions, X.3(d) and X(i), which some academics and non-governmental organizations consider especially problematic.

**Context: U.S. Objectives**

In recent years, the U.S. patent-based pharmaceutical industry has increasingly criticized pharmaceutical reimbursement programs in many countries. The U.S. pharmaceutical industry has pushed the U.S. Trade Representative to aim to curb pricing policies through trade agreements and bilateral pressure.

**ECONOMIC HARMONIZATION INITIATIVE:**

Since November 2010, the U.S. and Japan have been engaged in a discussion of certain trade and economic-related policies under a bilateral Economic Harmonization Initiative (EHI). The EHI covers a range of topics, among them intellectual property, transparency, medical devices and pharmaceuticals. In the EHI, the U.S. made quite specific proposals to change pharmaceutical pricing in Japan. The EHI is non-binding, but indicates U.S. objectives and priorities. The discussions in the EHI shed light on how USTR and the U.S. industry seek specific interpretations of key terms. This could be used to influence interpretation of provisions in binding agreements such as the TPP (despite the otherwise vague nature of some of these provisions). These include the perpetuation of new “premium pricing” (described below), which is currently applied on a trial basis, the elimination or restriction of repricing for market expansion, and the elimination or restriction of Foreign Price Adjustment (FPA) rule and the Foreign Average Price (FAP) rule as follows:

**U.S.-Japan EHI: 2011 U.S. Agenda Topics**

**MEDICAL DEVICES AND PHARMACEUTICALS**

**Pharmaceuticals and Other Issues**

*New Premium Pricing:* Accelerate elimination of the drug lag and boost incentives for research and development by implementing the new innovation premium on a permanent basis and removing the ceiling for the premium.

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7 Subparagraph X.3(c) requires taking more inputs from the pharmaceutical companies in deciding reimbursement prices; subparagraphs X.3(b) and (g) require the government to give detailed information supporting its decision on reimbursement prices to the pharmaceutical companies; subparagraphs X.3(h) and (k) require the member countries to make public written information related to reimbursement decisions and committee membership.


Repricing for Market Expansion: Encourage companies to introduce their most successful products in Japan by eliminating or, at minimum, amending the Repricing for Market Expansion Rule so that it does not punish such products.

Foreign Price Adjustment (FPA) Rule: Ensure fairness in Japan’s implementation of pricing policies by revising the FPA Rule to ensure that products are treated equally regardless of whether the Japanese price is lower or higher than the foreign price.

Medical Devices

Foreign Average Price (FAP) Rule: Promote the timely introduction and stable supply of medical devices in Japan by eliminating FAP, or if that is not possible, ensuring stability in the rules and practices used to calculate FAP.

INDUSTRY TARGETS JAPAN’S PHARMACEUTICAL PRICING:

The international pharmaceutical industry and business groups see the TPP negotiations as a means to subject Japan’s pharmaceutical pricing system to further constraints, supplementing the EHI. In the TPP, obligations may potentially be enforceable under investor-state dispute settlement (ISDS).

PhRMA comments on Japan’s joining TPP: “The issues that are now being discussed in the EHI – including pharmaceutical pricing reform and reimbursement-related matters, pharmaceutical regulatory reform, and preventive health care and vaccines – should continue to be a subject of these EHI and other bilateral discussions and consultations alongside the TPP negotiations (including any parallel bilateral negotiations conducted as part of that agreement).”

US-Japan Business Council comments: “In that many of the most important bilateral U.S.-Japan issues pertaining to pricing and product approval for pharmaceuticals and medical devices will not be covered specifically in the TPP negotiations, the USJBC urges USTR to pursue U.S. industry objectives to the fullest extent possible in the parallel bilateral negotiations, as well as the Economic Harmonization Initiative. Collaboration and alignment on these issues between the U.S. and Japanese industries is extensive, and continued progress through government-to-government consultations will enhance mutually beneficial innovation and further growth in both economies.”

Novartis’ comments: “Through the “New Growth Strategy,” approved in January 2012, Japan has resolved (at least on a pilot basis) to take steps to eliminate the domestic “drug lag” by improving the clinical trial environment and accelerating domestic review timelines for new pharmaceuticals. The new premium pricing system is aimed at encouraging innovation and drug discovery by moderating the downward pressure on drug reimbursement levels imposed by regulators. The TPP negotiations could help to reinforce these emerging practices by introducing criteria for more transparency by regulators when determining initial prices at which drugs will be listed in the national formulary, and thereafter, tightening criteria for subsequent pricing and reimbursement review and modifications. Ensuring that there is a domestic appeal process for government pricing and reimbursement will also be critical. TPP negotiators should ensure that Japan is

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14 PhRMA, supra note 8.
willing to **address these issues as part of the TPP discussions** in determining Japan’s readiness for participation in the TPP.”

**American Council of Life Insurers’ comments**: “[T]he United States and Japan agreed to engage in bilateral negotiations to address non-tariff measures … According to the exchange of letters between Ambassador Sasae and Acting USTR Marantis and accompanying USTR “fact sheet,” the **parallel bilateral process** is expected to address issues that “are not fully addressed in the TPP negotiations” and will be completed by the end of TPP negotiations. …It is vitally important, however, to include concrete legally binding Japanese commitments … and, to the extent possible, that those commitments be included in the TPP itself so disputes can be handled under the TPP dispute settlement mechanism.”

**Analysis of TPP Provisions**

**NHI PRICING: ENTRY OF NEW DRUGS AND GENERIC DRUGS IN THE NHI PRICE LIST**

**JP Practice**: In Japan, the Ministry of Health, Labour and Welfare (MHLW) establishes government reimbursement prices for pharmaceuticals. The Minister sets rates and reimbursement coverage by consulting with the Central Social Insurance Medical Council (CSIMC). In 2000, a Drug Price Organization was established under the CSIMC, to provide expert advice on pricing. Japan established the National Health Insurance (NHI) Drug Price List (“NHI Price List”) and reimburses any drugs listed.

When a new drug is launched in Japan, determination of the reimbursement price depends on whether a similar drug exists on the market. If a similar drug exists, the new drug’s price is determined by taking into consideration the similar drug’s price (“comparison-based pricing method”). If the new drug is proved to be innovative or more useful when compared to other drugs, a value-based approach applies premiums up to 120% for the new drug. On the other hand, if no similar drug exists, the new drug’s price is determined by taking into consideration manufacturing cost, operating profits, distribution costs, administration costs, and consumption tax (“cost-based pricing method”). In this cost-based method, average operating profit (as of 2013, 19.1%) is adjusted in the range of between -50% and +50% depending on the innovativeness, efficacy and safety of a new drug compared to existing drugs.

In case of a generic drug, the calculation of reimbursement prices differs depending on whether the generic is the first generic or not. If the drug is the first generic, the price is set at 70% of the original drug price. If there is already another generic on the market, the price is set at the lowest price among the existing generics.

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17 ACLI, supra note 9.

18 Gordon G. Liu et al., *Evidence-Based Decision-Making on Medical Technologies in China, Japan, and Singapore*, 12 Value in Health (Supplement 3) S12, S16 (2009).


20 Id.


**US Proposal:** The proposed paragraph X.3(d), would require the government either to base reimbursement rates on "competitive market based pricing," or alternatively, to "appropriately recognize the value of the patented or generic" pharmaceuticals.

X.3(d) "[A] Party shall ensure that the Party's determination of the reimbursement amount for a pharmaceutical product or medical device has a transparent and verifiable basis consisting of competitive market-derived prices in the Party's territory, or an alternative transparent and verifiable basis consisting of other benchmarks that appropriately recognize the value of the patented or generic pharmaceutical products or medical devices at issue."

**Analysis:** The leaked TPP text does not define the term "competitive market-derived prices." Given the Japanese government's price control measures and its role in setting prices, the U.S. would likely argue that the current NHI pricing does not meet the competitive market standard. In the U.S., pharmaceutical companies largely can set the price of drug products. Although participation in federal or state buying programs, which use rebates and discounts, would impose restrictions on pharmaceutical companies' pricing, the U.S. International Trade Commission reports that as of 2000, such programs accounted for only 13 percent of the U.S. market. The U.S. pharmaceutical industry has long complained about price intervention by governments of other countries, claiming that foreign governments' use of price control stifle competition (an odd argument for those products otherwise subject to the owners' monopoly pricing) and hinder innovation by reducing revenue that could be reinvested in R&D.

In understanding the implication of the alternative basis for reimbursement referencing to "the value of the patented or generic" pharmaceutical products, the changes of the languages from the AUSFTA text to the KORUS text and TPP Annex need careful analysis. The textual changes are deemed to reflect a USTR desire to prevent the spread and introduction of "health technology assessment" in many countries, which is a tool to reduce reimbursement rates. The AUSFTA text (Annex 2-C Art.1(d)) requires "the value of innovative pharmaceuticals" be based either on the competitive market price or "the objectively demonstrated therapeutic significance of a pharmaceutical." In contrast, the KORUS text (Art.5.2(b)) and TPP Annex require the alternative basis for reimbursement to appropriately

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24 Tetsuji Yamada et al., Pharmaceutical Price Control Policy, Pharmaceutical Innovation, and Health Durability, The Open Pharmacoeconomics & Health Economics Journal, 34, 39-40 (2010), http://www.benthamscience.com/open/topharmej/articles/V002/34TOPHARMEJ.pdf. This article states that in Japan, pharmaceutical prices are set by the government, and so the Japanese pharmaceutical market is not a purely competitive market; Todd Tucker, supra note 22. The author analyzed the risks of the proposed pricing standards in the TPP annex to the U.S. healthcare policies, in particular several pharmaceutical purchase programs run by the federal government, which utilize certain price control methods. In the two WTO cases examined by the author, the government's predominance in the market was found to give the government market power and exercise of such market power was found to distort price. The author warns that the government's use of price control mechanisms could be interpreted to run afoul of a competitive market price standard under the TPP proposal.


26 Id., at 1-11.
recognize “the value of the patented (in the TPP Annex also “or generic”) pharmaceutical products or medical devices.”

These textual changes may reflect U.S. determination to override through trade negotiations South Korea government’s healthcare reform of December 2006, which implemented health technology assessment (HTA). While there are various definitions of HTA, one widely accepted definition is “a multidisciplinary field of policy analysis, studying the medical, economic, social and ethical implications of development, diffusion and use of health technology.” In essence, the HTA is used to assess economic value of a therapy. To address the growing concerns of increasing pharmaceutical expenditures, countries including the U.K., Germany, France, Canada, Australia and South Korea adopted HTA in making decisions for reimbursement of drugs. South Korea introduced the Positive List System and separated reimbursement review into two stages—the reimbursement decision by the Health Insurance and Review Assessment service (HIRA) and the price negotiation between the National Health Insurance Corporation (NHIC) and drug manufacturers. HIRA makes a reimbursement decision by assessing whether drugs meet decision criteria including clinical benefit, cost-effectiveness, and budget impact etc. The introductions of these more rigorous systems in South Korea lead to a more selective listing and decreases in listing rates.

Japan has been slow in adopting the HTA, and economic value assessment is only partially, or not officially implemented in reimbursement decisions. However, the Central Social Insurance Medical Council (CSIMC) put the introduction of the HTA on the agenda since 2012, and began discussions for the possible adoption of the HTA for 2014 fee schedule revision. The patent-based pharmaceutical industry in Japan has been expressing strong antipathy against the introduction of the HTA, pointing out possible drawbacks of the HTA such as impeding patients’ access to innovative drugs, delaying in the drug listing and burdening manufacturers with additional submission of cost-effective evidence. As South Korea’s experience shows that the obligations under the KORUS causes the tension with the operation of the HTA, the obligations under the TPP Annex, which require basing reimbursement rate on either the competitive market price or appropriate value of the patented or generic drugs would likely make Japanese government face the same kind of uncertainty in implementing the healthcare policy.

28 Adrian R. Levy et al., International Comparison of Comparative Effectiveness Research in Five Jurisdictions, Pharmacoconomics 28(10), 813, 815 (2012).
30 Id.
30 Dong Mun Ha et al., A Comparative Analysis of the Impact of a Positive List System on New Chemical Entity Drugs and Incrementally Modified Drugs in South Korea, Clinical Therapeutics 33(7), 926, 927 (2011). In the previous drug listing system, a negative list system (NLS), most drugs were automatically listed for reimbursement; Isao Kame, Value-Based Approaches to Healthcare Systems and Pharmacoconomics Requirements in Asia, Pharmacoconomics 28(10), 831, 832, 2010. Under the PLS, the HIRA determines that the listing is appropriate only for drugs which are proven to be economically and therapeutically valuable.
31 Sung Eun Park et al., Evaluation on the first 2 years of the positive list system in South Korea, Health Policy 104, 32, 33 (2012).
33 Isao Kamae, Value-Based Approaches to Healthcare Systems and Pharmacoconomics Requirements in Asia, Pharmacoconomics 28(10), 831, 832 (2010); The 2010 new pricing system introduces a premium for new drugs on a trial basis. In determining an application of premiums, pharmacoeconomic studies are taken into consideration. PhRMA supports the utilization of the HTA to reward innovations in this way, but resists its application as a cost containment tool. See Pharma Japan, May 14, 2012, Interview with Alfonso G. Zulueta of PhRMA; Pharma Japan, Dec. 7, 2012, Ex-JPMA Secretary General Expresses Hope for Globalization of Domestic Pharma; Pharma Japan, May 14, 2012, Greater Concern than Hope about HTA: Mr Zulueta of PhRMA.
International Reference Pricing

- **JP Practice:** Another method the Japanese government employs to contain the prices of new drugs is international reference pricing. For pharmaceuticals, Japan introduced the Foreign Price Adjustment (FPA) Rule to reduce reimbursement prices. In setting a new drug price, Japan uses “average foreign price adjustment” by taking into account price of the same product in foreign countries (U.S., U.K., Germany, and France). When the base price of the new drug is substantially higher or lower than the foreign comparator countries’ prices in the bracket, the price is adjusted to make the price difference between Japan and those countries smaller. If the calculated drug price according to either the comparison-based pricing method or cost-based pricing method is higher than the average foreign price by more than 1.5 fold, the price is lowered. Japan may exclude the highest foreign price (frequently the U.S.) in calculating the average if the highest foreign price is more than five times the lowest price. Conversely, if the calculated price is lower than the average foreign price by more than 0.75 fold, the price is increased (maximum price increase is two-fold).

Similarly, for medical devices, the MHLW fixes the maximum reimbursement price for medical devices and uses the Foreign Average Price (FAP) rule to reduce reimbursement for devices. Except for the U.S., all three other comparator countries, i.e., U.K., Germany and France, use cost containment policies to keep health care costs low.

- **US Proposal:** The proposed paragraph X.3(d), which requires the use of competitive market based price “in the Party's territory,” could be read to call for the elimination of international reference pricing.

X.3(d) “[A] Party shall ensure that the Party's determination of the reimbursement amount for a pharmaceutical product or medical device has a transparent and verifiable basis consisting of competitive market-derived prices in the Party's territory, or an alternative transparent and verifiable basis consisting of other benchmarks that appropriately recognize the value of the patented or generic pharmaceutical products or medical devices at issue.”

- **Analysis:** The U.S. pharmaceutical industry has been complaining Japan’s use of international reference pricing comparing the prices of those countries. In the parallel bilateral EHI, the U.S. industry specifically demands the elimination of the FPA and FAP rules. These

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35 One article suggests a definition of reference pricing as follows: “a system for determining the maximum reimbursement amount for approved categories of pharmaceutical products prescribed by physicians.” William Looney, The Costs and Consequences of Reference Pricing: A Flawed Experiment in Drug Payment Reform, PhRMA 6-7 (1999), cited in U.S. ITC report. Reference pricing can be classified into two types: international reference pricing and therapeutic class reference pricing. U.S. DOC, supra note 3, at 4 (“Reference pricing determines sales prices based on the prices in other countries or relative to existing therapies in the same country. Since reference pricing controls the reimbursement level and not the manufacturer’s price, governments often view this method as less restrictive than price controls.”); Many countries including Germany, the Netherlands, Sweden and Denmark have introduced reference pricing since the early 1990s. U.S. ITC, supra note 7, at 2-12.
36 JPMA Appendix, supra note 15, at 11.
38 Id. at 9.
reference pricing is an effective tool in reducing pharmaceutical purchase costs by cutting back the price if the price is more than 1.5 times than the average foreign prices. Restriction or limitation on the use of reference pricing would hinder Japanese government’s effort to keep drug prices low.

**REPRICING: Price Revisions and Repricing by Market Expansion**

- **JP Practice:** In addition to the cost control mechanisms used in determining the new drugs’ prices, the Japanese government also uses effective cost containment approaches to control the prices of drugs already on the market. These methods include biennial drug price revision and repricing by market expansion.

  Every two years reimbursement prices are revised to adjust for the difference between the actual market prices and the reimbursement prices. For drugs already on the market, this biennial price revision has worked as an effective tool to keep reducing prices. For example, in 2008, the drug price revision rate was -5.2%.

  Another effective method to cut the prices of existing drugs already on the market is repricing based on market expansion. When a drug’s sale exceeds the original forecast by more than two times and the annual sales exceed 15 billion yen, the drug price is subject to downward repricing for market expansion. And, the market expansion re-pricing also applies if an additional indication is added after the original listing.

  Since 2010, Japan has implemented a new premium system on a trial basis for drugs protected under patents. The biennial price revision regularly cuts the prices of the patented drugs. However, under the new premium system, the prices of the patented drugs are maintained during the patent protection period. Trial premium pricing scheme applies the six premium rates with ceilings.

- **Analysis:** The U.S. pharmaceutical industry has been trying to remove the downward pressure on reimbursement price by price revisions. In particular, it has been resisting market expansion repricing by arguing that this punishes innovative drugs and discourages research and development of new drugs or new indications. The U.S. pharmaceutical industry targets “permanent” implementation of the new premium system and removal of the

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40 JPMA Appendix, supra note 15, at 9.
41 JPMA, supra note 18, at 204; the revision of new reimbursement price is calculated as follows: New price= weighted average value of market price in survey x (1+consumption tax rate) + current reimbursement price x R/100. R means a reasonable adjustable zone, which is intended to take into account the differences in actual market prices. As of 2010, it is set at 2%. See JPMA, supra note 18, at 211, Table 7.
42 Id. at 213.
43 Id. at 203.
44 Id.
45 JPMA Appendix, supra note 15, at 19.
47 JPMA, supra note 18, at 206.
48 USTR, 2013 National Estimate Report on Foreign Trade Barriers 218-19, http://www.ustr.gov/sites/default/files/2013%20ENTE.pdf (criticizing Japan’s reimbursement policies for failing to reward innovative medical technology, in particular expressing concerns about Japan’s application of FAP rule); Novartis’ comments, supra note 12 (“The new premium pricing system is aimed at encouraging innovation and drug discovery by moderating the downward pressure on drug reimbursement levels imposed by regulators.”)
ceilings. If Japan discontinues the new premium pricing scheme after the trial period, it could be a ground for the pharmaceutical companies’ complaint that the Japanese government fails to appropriately recognize the value of the patented drugs.

The requirement of “in-country competitive market prices” imposed by subparagraph X.3(d) could limit the Japanese government’s use of all these cost containment policies, which have been successful in keeping prices low while providing affordable universal health care to all citizens of Japan. It is also unclear how much more flexibility the member country would have under the alternative standard.

INDEPENDENT APPEAL OR REVIEW

- **JP Practice:** To assure transparency, the pricing formulas and procedures for calculation of drug prices have been made public. Furthermore, in the pricing decision process, the pharmaceutical companies are given hearing opportunities. A hearing is held at the first meeting on pricing, where the drug manufacturer has an opportunity to provide its opinion. Once a notice of calculated drug price is made, the drug manufacturer may submit a dissenting opinion for further consultation with the Drug Pricing Organization (“appeal of dissatisfaction”). In this case a second meeting is held, giving the drug manufacturer another opportunity to be heard before a final decision on the NHI price is made.

- **US Proposal:** Subparagraph X.3(i) requires the member countries to provide an opportunity of “independent appeal or review” of decisions on reimbursement prices to the pharmaceutical companies.

X.3(i) “[A] Party shall make available an opportunity for independent appeal or review of recommendations or determinations relating to reimbursement for pharmaceutical products or medical devices.

- **Analysis:** A new obligation on Japan would be unreasonable because even the U.S. pharmaceutical industry generally considers Japan’s drug pricing system fair and transparent. The NHI pricing process is fundamental to maintaining Japan’s practice of universal health care with affordable medical options for all its citizens.

The NHI pricing procedure already provides an opportunity to appeal to the drug pricing organization. If the drug manufacturer is dissatisfied with the pricing draft after its first meeting with the pricing organization, the NHI pricing procedures allow a submission of dissenting opinion and hearing before the drug pricing organization.

Like many other key terms in the TPP annex, the term “independent appeal or review” is not defined in the US-proposed TPP Annex. Several authors who have provided detailed analyses of the TPP provisions’ impact on public health policies have expressed concerns that this independent appeal right could be used by the pharmaceutical companies as litigation threats, which would hamper the government’s use of price control measures. One analysis further pointed out that

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50 PhRMA, supra note 8; Tracy Haller, supra note 12.
51 JPMA, supra note 11, at 204, 215-16.
52 Id.
53 Id. at 215-16, see Fig.20. Reimbursement Pricing Flow-sheet for New Drugs; JPMA Appendix, supra note ##, at 15.
54 Todd Tucker, supra note #, at 3 “Since the TRIPS, drug companies have trained their sights on techniques that governments employ to reduce the cost of public drug benefit programs, both in the United States and abroad. They have used U.S. courts to challenge aspects of state Medicaid drug programs. When the challenges failed, they pushed extreme
the appeal right goes beyond the U.S. practice, which gives great deference to the agency’s decisions and provides limited standing to pharmaceutical companies over the pricing decisions.\textsuperscript{55}

Further, the comparable terms in the previously concluded free trade agreements, the Australia-U.S. Free Trade Agreement (AUSFTA) and the Korea-U.S. Free Trade Agreement (KOURS), which are considered as the benchmarks for the U.S. efforts in the TPP negotiations, could shed light on how USTR and U.S. industry want the term to be interpreted in the TPP context. In the AUSFTA, Annex 2-C requires an independent review process (Annex 2-C Art.2(f)).\textsuperscript{56} But the side letter narrowed the obligation so that review only applies to listing decisions, not to pricing.\textsuperscript{57} The implementation of this obligation is that independent review process under the AUSFTA does not remake a decision of the Pharmaceutical Benefits Advisory Committee (PBAC), but rather “serves essentially as an independent quality assurance mechanism.”\textsuperscript{58}

KORUS Chapter 5 reflects an increasingly ambitious U.S. approach to pushing U.S. industry’s agenda in trade agreements.\textsuperscript{59} For example, the TPP Annex resembles that of KORUS in extending its scope to medical devices (in contrast, the AUSFTA Annex 2-C covers only pharmaceutical products). While the texts regarding the independent review process are similarly drafted in KORUS and AUSFTA, side letters clarified the obligations of Australia and Korea, which is narrowed in AUSFTA Annex 2-C (not covering pricing) while broadened in KORUS Chapter 5 (covering pricing). In the TPP Annex, the independent review process specified in the draft expressly covers pricing determinations (“relating to reimbursement for pharmaceutical products or medical devices”).\textsuperscript{56} And in the implementation of KORUS, a side letter requires establishment of an independent review body, rather than an independent review process, whose members are not employees or members of the central government healthcare authorities with the listing or reimbursement determinations. This obligation only applies to Korea, not to the U.S., because most U.S. drug purchase programs are carved out from the obligations of proposals in the negotiations for the U.S. FTAs with Australian and Korea aimed at creating new means to challenge government drug pricing policies, and the TPP language is yet more extreme”; Sean Flynn, Margot E. Kaminski, Brook K. Baker, and Jimmy H. Koo, Public Interest Analysis of the US TPP Proposal for an IP Chapter, PIJIP Research Paper Series, Paper 21, 52-53 (2011), \url{http://digitalcommons.wcl.american.edu/research/21} (expressing concerns that the independent appeal right would likely pose litigation threats to governments’ pricing policies).

\textsuperscript{55} Todd Tucker, supra note #, at 14, “In the case of all of the U.S. programs evaluated in this memo, pharmaceutical companies have limited ability to appeal the reimbursement decisions of the federal, private or state agencies...Pharmaceutical companies have a very difficult time even gaining standing in administrative or judicial courts to have their grievances about pricing heard. The TPP Annex seems to be an effort to grant appeal and standing rights to pharmaceutical companies where none exist currently.”

\textsuperscript{56} AUSFTA Annex 2-C Art 2(f) includes requirement to “make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.”

\textsuperscript{57} The side letter to Annex 2-C to the AUSFTA, available at \url{http://www.dfat.gov.au/fta/ausfta/final-text/letters/02_pbs.pdf}.


\textsuperscript{59} and in abandoning the reference to “the objectively demonstrated therapeutic significance” and adopting the reference to “the value of the patented or generic pharmaceutical products or medical devices.”


\textsuperscript{58} Todd Tucker, supra note #, at 14, “In the case of all of the U.S. programs evaluated in this memo, pharmaceutical companies have limited ability to appeal the reimbursement decisions of the federal, private or state agencies...Pharmaceutical companies have a very difficult time even gaining standing in administrative or judicial courts to have their grievances about pricing heard. The TPP Annex seems to be an effort to grant appeal and standing rights to pharmaceutical companies where none exist currently.”

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Paragraph X.3 through interpretation tools.\textsuperscript{61} Already there is a tension surrounding the interpretation of the role of independent review as the U.S. pharmaceutical industry is complaining that Korea has not fully implemented the obligation to establish an independent review system.\textsuperscript{62} While the Korean government takes the position that the application of the independent review is limited to drugs classified as “essential medicines,” the U.S. industry claims that companies should be allowed to challenge reimbursement determinations on all drugs.\textsuperscript{63} Furthermore, while the Korean Ministry of Health and Welfare has interpreted independent review decisions as merely non-binding recommendations, which do not have the capacity to overturn original decisions, it also expresses concern that there is a great chance of future disputes over the meaning and scope of the independent review process.\textsuperscript{64}

As shown in the implementation of KORUS, the independent review process would likely be an interpretative minefield. Unnecessary litigations and undue burdens on administrative proceedings could undermine the flexibility of domestic health policies. An additional independent appeal and review right to the pharmaceutical companies will likely delay NHI pricing decisions and have a negative impact on maintaining Japan’s health care system.

\textbf{Conclusion}

In the U.S., increased health care costs create a huge financial burden on many households. For example, a 2007 study, which surveyed five U.S. states, finds that 62\% of all bankruptcies are attributed to medical expenses.\textsuperscript{65} Moreover, even with the higher healthcare expenditure of the U.S. in comparison with other OECD countries, the quality of health care of the U.S. is assessed to be not better than other countries.\textsuperscript{66}

The proposed TPP “Transparency” annex would help multinational pharmaceutical companies interfere with the NHI pricing system. Investor-state dispute settlement (ISDS), which under the TPP provides investors broad grounds to sue states for large sums, compounds these dangers, and could be used to threaten the maintenance of Japan’s current universal health care system.

\textsuperscript{61} The obligations are limited to listing and pricing by “central level of government,” which exempt private and state programs, and second, footnotes provide exemp upon government procurements.


\textsuperscript{63} Id.; For “essential medicines,” the National Health Insurance Corporation (NHIC) makes “determinations” on reimbursement rates without negating companies. For other drugs, the NHIC negotiates with drug companies before setting the final prices. The Korean government interprets the independent review process applicable to only “determinations,” not mere “negotiations.” PhRMA Special 301 Submission 2013, 119-120, http://www.regulations.gov/#documentDetail;D=USTR-2012-0022-0030--Comment.

\textsuperscript{64} D.J. Kim et al., \textit{The Chances and Challenges of the Free Trade in Healthcare Sector-Based on the KORUS FTA,} 215-16 (2012), The Korean Institute for Health and Social Affairs (KIHASA) (S.Kor.), https://www.kihasa.re.kr/html/jsp/english/public/view.jsp?bid=30&ano=627. In reaching a conclusion that the term “review process” means merely an advisory function of recommending reconsideration to the original decision authority, rather than the authority to overturn the original decision, the KIHASA report found five bases: (i) the U.S. original claim that the authority to overturn the original decision should be expressly included in the agreement has not been reflected in the final agreement; (ii) the same language “an independent review process” is used in the AUSFTA, but Australia does not allow the independent review process to overturn the original decision; (iii) the term “appeal” is not used in the text; (iv) in view of the significance of overturning the original decision, finding such an authority from the texts which do not expressly allow that authority is too attenuated; and (v) the original decision can be challenged in judicial or administrative appeal.
