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Commentary

Coverage Decisions and the Court: A Public Health Perspective on Glucosamine Reimbursement in Thailand

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Abstract—Thailand achieves universal health coverage through the introduction of three benefit schemes: the Civil Servant Medical Benefit Scheme (CSMBS), Social Security Scheme, and Universal Coverage Scheme. The primary benefit package of these schemes includes all medicines referenced in the National List of Essential Medicines. However, the CSMBS pays for nonessential drugs (NEDs) for particular conditions.

The CSMBS's cost escalation prompted the Ministry of Finance to tightly control drug expenditure. In 2010, glucosamine—an NED—was prohibited from CSMBS reimbursement. Subsequently, a dispute was lodged at the Administrative Court by two CSMBS beneficiaries. The court ruled that glucosamine reimbursement should be reinstated in the CSMBS scheme based on two grounds: the Royal College of Orthopedic Surgeons of Thailand's clinical practice guidelines and an argument with reference to Article 78(8) of the 2007 Constitution mandating the state to provide appropriate benefits to government and state officials.

Our comments are based on two factors: (1) the integrity of evidence that the Court applied and (2) the ruling with reference to Constitution Article 78(8) as it conflicts with Article 51, which aims to ensure equal rights to health services by all citizens. Because court cases concerning health care coverage in Thailand may expand in the future, we call upon the public to discuss the following issue: whether the court should rule on the inclusion of particular interventions or whether it should focus on the integrity of the coverage decision-making process. Similar lessons can be drawn from the experiences of countries in Latin America and Europe. In any case, all concerned parties including the court should be equipped with a good understanding of the complexity of the country's health systems in either option.

Keywords: court, coverage decisions, glucosamine, health benefits, scientific evidence, Thailand

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BACKGROUND

In Thailand, the right to health services for all citizens is enshrined in Article 51^a of the 2007 Constitution. The entire

population is covered by three major benefit schemes, namely, the Civil Servants Medical Benefit Scheme (CSMBS), Social Security Scheme (SSS), and Universal Coverage Scheme (UCS).¹ The CSMBS, financed by general tax revenue, covers health services for government workers, pensioners, and eligible dependents (9% of the population). The SSS beneficiaries are private sector employees (16%) and the services are financed by employers, employees, and government contributions, and the tax-financed UCS covers the rest of the population. The National List of Essential Medicines (NLEM) is referenced by the three schemes as the basic package of drug benefits.² However, the CSMBS is the only scheme that pays for nonessential drugs (NEDs) for particular conditions. Moreover, nondrug benefits such as assistive devices, organ transplantations, and physical check-ups offered by the three schemes are different in terms of the types of items, quality, and prescribing and reimbursement conditions and have raised public concerns about fairness.

Although the number of CSMBS beneficiaries was kept constant due to the freeze on civil servant hiring, CSMBS expenditure had substantially increased from 26 billion THB (equivalent to 0.65 billion USD) in 2004 to 61 billion THB (equivalent to 1.8 billion USD) in 2009.^b Spending on medicines accounted for the largest proportion—up to 80% of outpatient bills.³ In response to this increase, in March 2010 the Thai Cabinet assigned the Ministry of Finance (MOF), the managing agency for the CSMBS, to contain the surge in spending. One of the measures approved by the Cabinet was to control outpatient drug reimbursements; for NED items, the prescriptions must be consistent with the indications and conditions recommended by health professional organizations.⁴ The MOF assigned an expert working group to target expensive and cost-ineffective NEDs with potential for being prescribed inappropriately. Through this process, reimbursement of an osteoarthritic drug, glucosamine, was banned in late 2010. However, in 2015 the Administrative Court ruled that coverage of this drug for CSMBS beneficiaries should be reinstated. This is the first case in Thailand in which a health benefit policy was overturned by the Court, and it may set precedence for similar court cases to follow. This article reviews the judicial arguments in the glucosamine coverage and proposes generic principles on the use of scientific evidence in the Court's ruling. It also discusses the current health system context in Thailand and experiences in other countries concerning the involvement of the courts in coverage policy.

POLICY DIRECTIONS ON CSMBS DRUG REIMBURSEMENT

The CSMBS coverage policy on medicines is developed by two institutions, namely, the MOF and the NLEM

subcommittee. The MOF has the legal mandate to regulate CSMBS reimbursements as stipulated in the Act Prescribing Criterion for Payment of Particular Expenditure under Budgetary Appropriation⁵—a law that aims to regulate public spending on particular items (including CSMBS expenditures) to be relevant to the current budget availability and the country's economic status. In addition, the NLEM subcommittee has been designated by the National Drug Systems Development Committee since 1981 to formulate the country's list of essential drugs.⁵ The NLEM development involves a wide range of stakeholders including over 20 disciplines of clinical specialists, representatives of the three health schemes, Ministry of Public Health departments, civil society organizations, and patient associations. The essential drug selection is based on evidence regarding the therapeutic effects, cost-effectiveness, budget implication, service delivery feasibility, financial burden on households, and ethical issues through deliberative discussion among members of the NLEM subcommittee and respective working groups.^{6,7} Just as important, since 2008, the disclosure and management of conflicts of interests to all involved in the NLEM deliberations and decisions has been strictly enforced.⁸

Following the MOF regulation in 1999, the CSMBS allowed for NED reimbursements at the hospital level on the conditions that (1) patients did not respond to or could not tolerate the side effects of essential drugs; (2) there was no item on the NLEM that was appropriate for patients with particular symptoms; or (3) the NED was more cost-effective than NLEM items.^{9,10} In addition, the prescribing of NEDs to individual patients had to be endorsed by a panel of three medical doctors in the prescribing hospitals, and the justification regarding these conditions was required to be submitted to the MOF as part of the drug reimbursement process.

REMOVAL OF GLUCOSAMINE FROM CSMBS BENEFITS AND REACTIONS

In 2010, the MOF working group reviewed drug utilization in the CSMBS and found that there were NEDs in nine therapeutic classes^c with the highest consumption that were likely to be prescribed inappropriately¹¹; these drugs were targeted in the reviews of safety, effectiveness, and value for money. Based on a comprehensive review, the working group recommended banning the reimbursement of symptomatic slow-acting drugs for osteoarthritis including glucosamine-containing products due to the lack of evidence on the clinical and cost-effectiveness. The working group reviewed appeal arguments and related evidence submitted by the Royal College of Orthopedic Surgeons of

Thailand (RCOST) and the Thai Rheumatism Association suggesting continuation of glucosamine coverage but ultimately maintained its recommendation.

By virtue of the Act Prescribing Criterion for Payment of Particular Expenditure under Budgetary Appropriation, the MOF issued a regulation in December 2010 to remove glucosamine from the CSMBS benefits; this prompted public debates both for and against the decision.¹² Crucially, the chairperson of the NLEM subcommittee insisted that the subcommittee had reviewed evidence on glucosamine in 2008 and that the drug was not included in the NLEM because it failed to meet the criteria for therapeutic benefits and value for money.¹³ Medical doctors and pharmacists who advocated for rational drug use supported the MOF policy and noted that evidence on the clinical effectiveness of glucosamine was inadequate. On the other end, opponents of the policy included orthopedists and CSMBS beneficiaries who had direct experience in prescribing and using glucosamine. Specialists maintained that many technically robust studies illustrated the clinical benefits and cost-effectiveness of glucosamine and also referred to RCOST's clinical practice guidelines (CPGs), which recommend the use of this drug for certain indications.¹⁴

THE COURT RULING AND HOW SCIENTIFIC EVIDENCE WAS INTERPRETED

In January 2011, two pensioners who were CSMBS beneficiaries brought the case to the Administrative Court.^d Representatives of RCOST, the Thai Rheumatism Association, the Comptroller General's Department (the CSMBS managing authority), and the MOF working group were invited to give their testimonies and related documents to the Court. Because glucosamine was a NED, the Court considered the recommendations by professional organization; that is, RCOST.^{15,e} With reference to RCOST's 2010 CPGs,¹⁶ there was no compelling evidence to support or oppose the use of glucosamine sulfate for the treatment of osteoarthritis; hence the recommendation of +/-.^f As also illustrated in the CPG, systematic reviews suggested that glucosamine could reduce pain and improve joint mobility; however, because factors included in the reviewed studies varied substantially, RCOST was of the view that the conclusions on efficacy and safety of the drug in this guideline might have been invalid.

As presented in the ruling documents, the Court interpreted that the recommendation "+/-" meant that RCOST could neither confidently recommend that the use of glucosamine was clinically appropriate and offered value for money in the Thai context nor confidently reject its use.¹⁵ The Court

also pointed out that RCOST assessed the clinical and cost-effectiveness of glucosamine by taking into account not only findings from international studies but also local empirical evidence on the disease, health benefit scheme, and economic status. Based on this, RCOST's opinion and recommendation of +/-^g was "not less compelling"¹⁵ than findings from the review by the MOF working group, which relied only on studies in other countries.

THE JUDICIAL JUSTIFICATIONS THAT BROUGHT GLUCOSAMINE BACK

After four years of judicial processes, in February 2015 the Court ruled that the MOF regulation to remove glucosamine from CSMBS coverage was unlawful and ordered the withdrawal of the regulation.¹⁵ The Court ruling document indicated that the prohibition of glucosamine reimbursement was inappropriate because it had resulted in critical consequences; that is, it completely diminished this particular benefit and also affected the benefits for government officials as stipulated by Article 78 of the Constitution (8).^h The Court's ruling was based on the following justificationsⁱ: (1) the evidence submitted by the MOF working group was not robust enough to conclude that glucosamine was clinically ineffective and cost-ineffective and (2) the Court considered that the reviews by the working group were inadequate because there were contradictory assertions from RCOST and the Thai Rheumatism Association, which are respected and competent professional organizations.

As also elaborated in the ruling document, a cost-utility analysis of glucosamine for the treatment of osteoarthritis in Thailand conducted during March-September 2012 suggested that glucosamine sulfate would be cost-effective if its price decreased to 2,800 baht per patient per year.¹⁵ The study recommended cost containment measures: lowering the price of glucosamine and conducting a cost-effectiveness analysis of locally manufactured products. The ruling document further suggested that there were other options to control CSMBS expenditure on glucosamine rather than terminating coverage for it; for example, employing RCOST's guidelines for glucosamine prescription, restricting glucosamine reimbursements to certain indications, and revising the indications for use of glucosamine (to be done by the CSMBS coverage committee).

DISCUSSION

Experiences in Australia, Europe, Latin America, and Africa suggest that court rulings on coverage policy, known as

“judicialization,” have been increasing.¹⁷ In many countries, the right to health has been enshrined as a constitutional provision. This results in the courts becoming involved because they are responsible for the interpretation of how to apply the Constitution. Judicialization involves scientific, social, economic, ethical, and legal aspects of priority setting and can result in both positive and negative impacts—including the extension of health benefits and at the same time paradoxically widening the access inequality gap. There is also debate on the courts' ruling in favor of access to health care for certain individuals versus the population. The latter concerns the opportunity costs and trade-offs involved; that is, the provision of certain interventions, especially high-cost services and treatments for rare diseases for certain groups of the population, may deplete the limited resources and impede the accessibility of essential interventions that address prevalent health problems in the rest of the population.¹⁸

In some countries, courts avoid intervening in the issues of resource allocation because they are aware of the limitation of their technical capacity and the potentially undesirable consequences due to the fiscal constraints in the health sector. For example, the South Africa Constitutional Court ruled that health coverage is the responsibility of an administrative institution, not a judicial one, because the decisions are determined by the availability of finite resources. In addition, priority setting across health needs and groups of constituencies, opportunity costs, equity, and solidarity should be taken into account.¹⁹ Courts in other settings intervene only in matters of fairness and transparency of priority setting procedures, as opposed to ruling on the subject under consideration; for example, ruling for or against the coverage of certain technology options.²⁰ It is worth noting that in some cases, patients as individuals or associations, supported by the drug industry, file lawsuits to force the government payment for extremely expensive products.²¹

Because the glucosamine coverage dispute in the CSMBS is the first case in Thailand where the judicial institution ruled over a health benefit policy and the judicialization of health benefits may expand due to consumers' and health professionals' increasing demands for high-cost technologies in light of health care resource constraints, we call upon concerned parties to discuss the appropriateness, relevance, and implications of different options for Court intervention in the future coverage decision. Given that courts in other countries have had notable experiences on similar issues, lessons learned from those settings will be helpful in informing the involvement of Thai courts in health coverage decisions. From a public health perspective, we argue that all parties

including the courts should have a thorough understanding of the country's health system context; the following issues should be considered for further deliberation.

First, because the CSMBS is a general tax-financed, non-contributory scheme, reimbursement of any services has consequences for the use of public resources shouldered by all taxpayers and not the CSMBS beneficiaries' contributions. Furthermore, although the CSMBS is a fringe benefit scheme for government officials, the savings from spending on unproven clinical benefits and cost-ineffective glucosamine could be used to purchase more cost-effective services. It is noteworthy that the CSMBS had overspent its annual budget allocation as a result of excessive use of NEDs and brand products.

Second, given that CPGs are developed by professional communities that include recommendations intended to optimize patient care,²² should the Court rely on such guidelines when it makes a determination for the case on coverage of controversial health technology? In our opinion, a CPG's recommendations leave the decision of patient treatment to professional judgments on a case-by-case basis. Therefore, these guidelines are not relevant for use as references to justify health benefits because resource allocation needs to take into account not only the clinical effects of health interventions but also the social, ethical, and economic implications at the population level.

The third issue also involves CPGs because the quality of such guidelines varies widely.^{22,23} Studies in developed and developing countries suggest that a large number of CPGs are of low quality or fail to meet standards in certain aspects.^{24–26} There are several challenges in developing good quality guidelines, such as inadequate information from domestic research, involvement of experts with conflicts of interests, limited expertise to evaluate evidence in relevant disciplines, no timely or regular revision schedule, and the lack of stakeholder participation.²⁷ It is therefore suggested that before following any recommendations, the guidelines should be evaluated by using internationally accepted tools such as the Appraisal of Guidelines for Research and Evaluation instrument.²⁸

Fourth, CSMBS's reimbursement of glucosamine and other NEDs involves two principles in conflict: (1) the right to health of individuals and (2) the right to health of the population; that is, the coverage of NEDs is recognized as an appropriate health benefit for government officials as specified in Article 78(8) of the Constitution, whereas the Article 51 provision that ensures equal right of all Thai citizens to receive appropriate, standard health

care treatments is not acknowledged. In this regard, it should be noted that the disparity between the three schemes in terms of benefit coverage, provider payment methods, and expenditure per capita has been on the country's policy agenda for a decade now. Because health equity, in addition to health improvement, quality, and efficiency, is one of the goals of Thailand's health system reforms, the harmonization of benefits is discussed in government committees and public forums.

Fifth, when any policy-making authorities are involved in health benefit decisions, the NLEM subcommittee is among the most respected institutions to seek advice on drug coverage. This is because its mandate was granted by the National Drug Systems Development Committee in addition to its integrity in fulfilling their objectives. In Thailand, the NLEM has long been developed as an integral part of the National Drug Policy because it provides cohesive directions for the research and development, manufacture, distribution, accessibility, and rational use of pharmaceuticals. In practice, the NLEM is utilized as a reference for drug coverage and also for different administrative regulations concerning drug procurement, reference pricing, and drug use evaluation in government facilities. Given the technical expertise, procedural integrity, management of competing interests, and experience on the appropriate management of stakeholder engagement, we argue that the NLEM subcommittee is one of the credible institutions to be consulted when determining judicial decisions on health benefits in the event that there are future court rulings on this matter.

Sixth, based on international experiences, a crucial message regarding the use of scientific evidence in courts is that despite the same set of literature used in their reviews, different experts may provide different results due to several factors.²⁹ Consequently, professional recommendations in the form of either expert testimony or CPGs vary in terms of validity and relevance. Because the courts have limited capacity in health policy and research, it should not rule on particular health benefits but rather acknowledge that some organizations or individual specialists are more competent and credible than others. Rather, it should focus on examining whether the coverage policy making and related evidence-generating processes conform to good governance principles.

Given that many low- and middle-income countries are moving toward universal health coverage where priority setting of health technologies becomes inevitable, the role of the courts in coverage policy is expanding. Although this commentary focuses on the public health dimension, lessons drawn from the Thai case study may be helpful for other

societies and stimulate further debates from a legal perspective. As we propose in this article, the court's involvement in coverage decisions should be publicly discussed by all concerned parties who are well informed about the health systems and policy context. As such, exchange of knowledge and ideas from different perspectives including those from the courts and legal experts should not be precluded.

DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

No potential conflicts of interest were disclosed.

NOTES

- [a] Article 51: A person shall enjoy an equal right to receive proper and standard public health service, and the indigent shall have the right to receive free medical treatment from State's infirmary. A person shall have the right to receive public health service provided by the State thoroughly and efficiently. A person shall have the right to receive proper eradication and prevention of harmful contagious diseases without charge in a timely manner.
- [b] Data from the Comptroller General's Department, Ministry of Finance.
- [c] (1) Anti-ulcerant/variceal bleeding, (2) nonsteroidal anti-inflammatory drugs/anti-osteoarthritis drugs, (3) antilipidemia drugs, (4) angiotensin converting enzyme inhibitors, (5) angiotensin-II receptor blockers, (6) anti-platelets, (7) glucosamine, (8) drugs affecting bone metabolism, and (9) anticancer drugs.
- [d] The Administrative Court is a judicially independent organization that is separate from the Court of Justice. The Court has the authority and is competent to consider and make official decisions about problems or disputed matters.
- [e] There were two Court ruling documents for particular cases issued on the same date. Because the main content is not different, only one document is cited in this article.
- [f] According to the guidelines, +/- means "neither recommend nor against" the practice.
- [g] The underlying principles for RCOST's guideline development include (1) safety, (2) efficacy, (3) effectiveness, (4) benefit to the population and society, and (5) efficiency.
- [h] Article 78: The State shall implement national administrative policy as follows: (8) To implement a plan for

providing appropriate benefits to government and state officials.

- [i] As illustrated in the Court's ruling document.

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