Background: Previous studies of health policies in Iran have not focused exclusively on the drug reimbursement process. The aim of this study was to describe the entire drug reimbursement process and the stakeholders, and discuss issues faced by policymakers. Methods: Review of documents describing the administrative rules and directives of stakeholders, supplemented by published statistics and interviews with experts and policymakers. Results: Iran has a systematic process for the assessment, appraisal, and judgment of drug reimbursements. The two most important organizations in this process are the Food and Drug Organization, which considers clinical effectiveness, safety, and economic issues, and the Supreme Council of Health Insurance, which considers various criteria, including budget impact and cost-effectiveness. Ultimately, the Iranian Cabinet approves a drug and recommends its use to all health insurance organizations. Reimbursed drugs account for about 53.5% of all available drugs and 77.3% of drug expenditures. Despite its strengths, the system faces various issues, including conflicting stakeholders’ aims, lengthy decision-making duration, limited access to decision-making details, and rigidity in the assessment process. Conclusions: The Iranian drug reimbursement system uses decision-making criteria and a structured approach similar to those in other countries. Important shortcomings in the system include out-of-pocket contributions due to lengthy decision making, lack of transparency, and conflicting interests among stakeholders. Iranian policymakers should consider a number of ways to remedy these problems, such as case studies of individual drugs and closer examination of experiences in other countries. Keywords: drug registry, drug reimbursement, health insurance, Iran, policymaking.

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Organization (FDO), and the Medical Services Insurance Organization (MSIO) enabled us to add some details about the reimbursement process. Finally, we used periodically released and publicly available statistics, especially drug sale statistics published by the FDO. The numbers and costs of drugs sold by drug distribution companies to pharmacies are available in these publications \[4\], which enabled us to generate an overview of the current situation in Iran.

Results

Health Insurance Systems

Major changes in the Iranian national health insurance system began in 1994 with the introduction of universal health insurance \[6\]. This policy contained a description of the role of each stakeholder in the health care sector, the financing of health insurance organizations (HIOs), the health services tariff policy, and the minimum health service package to be adopted by all HIOs. Since the introduction of this policy, Iran has had four major health insurers: the SSO, the MSIO, the Armed Forces Health Insurance Organization (AFHIO), and the Imam Khomeini Relief Foundation (IKRF) \[6\].

The SSO, established in 1953, is a nongovernmental organization that covers about 43% of the population. The insurees comprise wage earners and salaried workers, many self-employed personnel in different businesses, and many civil servants \[7\]. SSO provides two kinds of health care schemes: direct and indirect health care. Direct health care is provided to SSO beneficiaries through 69 hospitals (8550 hospital beds) and 275 clinics \[8\]. Beneficiaries can also receive indirect health care from other providers, including health centers (privately, government-owned, army) and charity organizations. SSO beneficiaries who are referred to direct health care do not have to make any payments or co-payments (unless they receive indirect health care) \[8\]. Besides health care services, the SSO provides other social services relating to pension payments, disability compensation, and unemployment insurance services. These long-term services account for two-thirds of annual SSO expenditures.

The MSIO is a governmental organization established in 1994 that insures about 41% of the population, comprising mainly civil servants, the self-employed, and rural populations. The MSIO provides only health insurance services and has variable financing. The activities of the MSIO are similar to the indirect health care provided through the SSO.

The two other HIOs, the AFHIO and the IKRF, respectively, cover almost 6% and 2.5% of the population. AFHIO beneficiaries include armed forces personnel and their families, while IKRF beneficiaries include people with physical disabilities and people with economic or social crises that are so severe that they are not self-sufficient \[9\]. In addition, there are 30 or so smaller health financing schemes for privileged members of society or large organizations (e.g., government ministries, municipalities, banks, and cooperatives), which provide coverage to their employees and their families \[10\].

Key points about the Iranian HIOs are as follows:

1. Governmental organizations involved in the health care system are supervised by different ministries in the government. The SSO and the MSIO are supervised by the minister of welfare and social security, the AFHIO is supervised by the minister of defense, while the IKRF falls under the direct supervision of the Iranian president.

2. The occupation held by the head of household is the most important factor that determines HIO enrollment, insurance premiums, and level of commitment of the HIO to reimburse health care services. In fact, most people cannot select their health insurer and insurance premiums are paid monthly by their employers. Only self-employed people can choose between the SSO and the MSIO.

3. According to some experts, some people may benefit through coverage by multiple health insurers while others may have no health insurance coverage at all. The number of people without any coverage is estimated to be up to 10% of the population. Although the socioeconomic proportions of uninsured people have not been investigated, the experts argue they are mostly young and poor people who are not eligible to register by the SSO, the MSIO, and the AFHIO and do not need health care services (because of being young). Moreover, some rich people would not be insured because they can easily afford to pay for health care services in the private sector.

4. The contents of the minimum benefit package of the four main health insurers are determined by the Supreme Council of Health Insurance (SCoHI), and all insurers are obliged to provide whatever is included in the package. By law, patients must make co-payments of 10% and 30% of the costs of inpatient and outpatient services, respectively. Insurers make direct payments to pharmacies on a monthly basis, and patients have to pay both co-payments and a dispensing fee. The dispensing fee (about €0.70 in 2011) is a fixed-rate fee for labeling and repackaging that is generally paid out of pocket for every prescription received. In addition to the minimum benefit package and co-payment rules, organizations can provide excess services to prevent catastrophic household health expenditures. They may cover some nonreimbursed drugs or decrease the patient’s share of financial contribution. The ratios of cost sharing in drug services provided by HIOs for diseases are given in Table 1. Cancer patients treated with nonreimbursed drugs receive financial support from HIOs using different approaches. For example, the SSO pays a limited yearly grant directly to patients. The MSIO compensates patients for the costs of the drug, the maximum amount being equal to the costs of pharmaceutically similar drugs that are reimbursed. The AFHIO covers all drug costs through obligatory supplementary insurance. Last, the IKRF covers 50% of the costs of all nonreimbursed drugs.

The Drug Registration Process in Iran

All new drugs (except orphan drugs, with a disease prevalence of 1 or less in 200,000 people) \[11\] must be registered by the Council to Consider and Compile Drugs (CCCD) before they can become available in Iran. This council is part of the FDO, which is responsible for drug policy, which, in turn, is supervised by the minister of health and medical education. All CCCD members are Ministry of Health and Medical Education employees, and most of them are clinicians or pharmacists. The first step in the registration of any new drug that is produced or imported is the completion of three to four drug registry forms (Fig. 1). The applicant (e.g., drug company, group of physicians, and specialist society) must prepare documents that address the following items: efficacy, safety and adverse events, comparative efficacy with similar drugs, approval history, contraindications, warnings, precautions, monitoring parameters, pharmacokinetics, patient compliance, and pharmacoeconomic studies \[12\]. The CCCD, however, may exclude one or more of these items on the basis of the kind of drug and the availability of data.

Applications fall into three categories: 1) new molecules, 2) new dosage forms, and 3) new salts or new forms of any drug if the base has already been approved by the CCCD. Suppose the drug erythromycin, with stearate as a salt in its formulation, is available on the market and approved by the CCCD. If a new
application of erythromycin contains a different salt (e.g., ethyl succinate), it will fall in the third category.

If the application involves a new molecule, consultation will be sought from the heads of medical and pharmaceutical societies, national research centers, and medical universities. Approval of the drug by other organizations (such as the Food and Drug Administration, the European Medicines Agency, and the Therapeutic Goods Administration) and its use in at least five countries (including the United States, European Union countries, or other countries with a gross domestic product similar to Iran’s) have an important role in the evaluation. Once a drug is approved, it is given a unique national code and can be distributed, prescribed, and used throughout the entire country. Patients using the drug, however, will have to pay 100% of the drug costs until the drug is added to the reimbursement list.

The Drug Reimbursement Process in Iran

The SCoHI is the organization that deals with drug reimbursement decisions in Iran. The Drug Benefit Package Review Committee (DBPRC) is part of the SCoHI and is responsible for drug assessment. All members and stakeholders of the SCoHI have a representative in this committee. On the basis of Iran’s rules, all the health services covered by HIOs should complete the reimbursement process. The main rule, as previously mentioned, is universal health insurance and one of the most important parts of this law is the appointment of the SCoHI as an important health insurance policy center. The members of this council are the minister of welfare and social security (who is also the chairman of the council), minister of health and medical education, minister of economic affairs and finance, vice president on strategic planning and control, CEO of the SSO, CEO of the MSIO, CEO of the AFHIO, president of the Islamic Republic of Iran Medical Council, chief of the IKRF, and two members of the Iranian Islamic Parliament (Health Commission and Budget Commission). The process of reimbursement of health services is described in section 10 of the Iran universal health insurance for health care law.

The end of drug registry by getting unique national code, entrance to the Iran Pharmacopeia and Iran Pharmaceutical market otherwise, the application is rejected. Applicants (drug companies, physicians, physician specialist societies, etc.) must complete a formal application and submit all the necessary documents. These documents contain information about the

<table>
<thead>
<tr>
<th>Diseases or indications</th>
<th>DBC</th>
<th>Outpatients</th>
<th>Inpatients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SSO</td>
<td>DHC</td>
<td>IHC</td>
</tr>
<tr>
<td>Cancers</td>
<td>14.8</td>
<td>100</td>
<td>85</td>
</tr>
<tr>
<td>Dialysis (all drugs)</td>
<td>3.4</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Hemophilia (all drugs)</td>
<td>1.3</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Thalassemia (all drugs)</td>
<td>0.9</td>
<td>100</td>
<td>70</td>
</tr>
<tr>
<td>Kidney transplant</td>
<td>9.4</td>
<td>100</td>
<td>90</td>
</tr>
<tr>
<td>Other organ transplants (immunosuppressives)</td>
<td>70.2</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Multiple sclerosis (interferon drugs)</td>
<td>9.4</td>
<td>100</td>
<td>90</td>
</tr>
</tbody>
</table>

Table 1 – The financial contribution of drug reimbursement services by main Iran health insurance organizations.

AFHIO, Armed Forces Health Insurance Organization; DBC, Drug Budget Contribution; DHC, Direct Health Care scheme at SSO; IHC, Indirect Health Care scheme at SSO; IKRF, Imam Khomeini Relief Foundation; MISO, Medical Insurance Services Organization; SSO, Social Security Organization.

† Drug budget contribution percentage based on IHC of SSO annual reports for outpatients February 10, 2011, to February 9, 2012.

†† AFHIO provides the basic and supplementary health insurance together.

‡ In addition to immunosuppressives, other necessary drugs based on kind of transplantation also covered by the SSO.

Fig. 1 – Overview of the drug registration process in Iran. CCCD, Council to Consider and Compilation Drugs; FDO, Food and Drug Organization; N, no; Y, yes.
The documentation route
Consultation route
Drug reimbursement order

**Fig. 2 – Overview of the drug reimbursement system in Iran (Stakeholders roles map).**

drug and its characteristics, the proposed price, the cost in each treatment period, a list of alternative drug therapies with an analysis of their advantages and disadvantages, and documentation of the clinical and economic aspects of the drug. This information is categorized into items, each of which contributes a certain number of points toward the application. The maximum possible score is 100 points. If the total score based on an initial evaluation performed by SCoHI’s experts is less than 50 points, the application is rejected. If the total score is 50 points or more, however, the application will be sent to all DBPRC members, who will be asked to provide comments on the new drug, including the probable effect that it will have on their budget. Once these comments are received, the DBPRC will start the assessment process. If a drug application receives more than 80 points and no significant objections from the council, it will be sent to the SCoHI with a positive vote. The final DBPRC decision will also consider the budget impact for the country as well as cost-effectiveness results from other countries. If it finds that rich countries have concluded that a drug is not cost-effective, then this new drug will be considered unlikely to be cost-effective in Iran. All documents are then sent to all stakeholders 2 weeks before a general meeting is held in which all stakeholders gather to discuss the application. The documents contain the following information:

1. Comparison of effectiveness with other drugs in the Iranian pharmacopeia that have similar therapeutic effects.
2. Estimated effect on the use of other drugs, which can help to estimate the overall effect of a drug on a health insurer’s budget.
3. Cost modeling for one therapeutic course in outpatient care and comparison with other drugs with the same therapeutic effects.
4. Average monthly increase in sales in the 6-month period before the reimbursement application.
5. Drug price in other countries with a gross domestic product similar to that of Iran’s.
6. Opinions and comments of certain departments of major medical universities (the choice of the department is based on the kind of drug).

All stakeholders will have 2 weeks to examine the information, after which a general meeting will be held. The first goal in the meeting is to reach consensus about whether or not to reimburse the drug. If consensus is not achieved, the members will vote for or against reimbursement. A negative reimbursement decision brings the process to an end because there is no opportunity to reapply for reimbursement. If the reimbursement decision is positive, however, a meeting is arranged with the drug company to negotiate the drug price. If the drug company is able to agree with the DBPRC about the price, the application for reimbursement will be accepted, otherwise it will be rejected. Once the price has been set, the DBPRC will release a document containing the following information:

1. Conditions of reimbursement (e.g., which specialists can prescribe the drug, which indication(s) the drug can be used for, and location of production [Iran or other country]). For example, rituximab is reimbursed only if it is prescribed by an oncologist to treat non-Hodgkin’s lymphoma and will not be reimbursed for other purposes (e.g., rheumatic disorders).
2. Dosage forms under reimbursement.
3. Whether or not HIOs need to set up a patient registry for the specific drug.
4. Assessment of reimbursement eligibility by a HIO before a patient purchases the drug.

The DBPRC will then send the positive results of its decision with the agreed prices to the chairman of the SCoHI (minister of welfare and social security), who will then provide a final summary of comments made during a meeting with the SCoHI. After this process of deliberation is completed, a report with SCoHI conclusions is sent to the Iranian Cabinet, which makes the final official decision. According to experts, the Cabinet has never rejected a drug approved by the SCoHI.
Overview of the Current Situation

Currently, there are 3530 international nonproprietary name national codes in Iran’s drug pharmacopeia [13] and 1800 international nonproprietary name national codes and 90 raw materials for some drugs produced by pharmacies are reimbursed [5]. Most vitamins, nutritional supplements, infertility drugs, and herbal extracts are not on the reimbursement list. Based on statistics provided by the FDO [4], over a 1-year period (February 10, 2011, to February 9, 2012), the expenditures of the drugs found on the reimbursement list are approximately 77.3% of the total expenditures of all drugs sold to pharmacies by distribution companies. The rest is paid by patients or supplemental insurance. Because no reliable report about expenditures of nonreimbursed drugs is available, we used sales reports to describe the results of the reimbursement process. The top 20 nonreimbursed drugs (based on the results of the previous report) are listed in Table 2. This list of drugs includes both essential and nonessential drugs, where drugs are considered nonessential if therapeutically equivalent drugs are already available on the market.

Although sales statistics cannot accurately describe overall drug use over long periods of time, it can at least help to estimate the costs of nonreimbursed patient expenses in various groups of diseases and changes in the use of nonreimbursed drugs. As seen in Table 2, because the exact date of presentation of application to the SCoHI is unknown, it is not possible to estimate the mean duration of the application process. It is known, however, that some applicants received a decision a couple of years after submitting their reimbursement application. This delay appears to be due to the screening of drugs by the SCoHI. Many controversial drugs seem to have been held back by bureaucratic barriers while less controversial ones easily passed this bureaucratic filter. However, there are 12 drugs with a “No Application” status, which usually reflects a situation in which the applicant is not entirely confident about gaining approval from the SCoHI because of incompatibility properties of its drugs and SCoHI expectations. In other cases, however, it is likely that some companies choose not to apply for reimbursement because they are sure their drugs will sell well in Iran without it.

Discussion

Drug reimbursement decision making is an important process in the health care sector and has an essential role in the efficient allocation of resources. Moreover, the expansion of health insurance schemes with affordable and comprehensive packages of basic services is a great aid in achieving health equity. Although Iran is a developing country with an economy that is transforming into a market-based economy, the Iranian state still plays a key role in the economy because it owns large public and quasi-public enterprises, which partially dominate the manufacturing and commercial sectors. The Iranian pharmaceutical market has undergone great growth in comparison with developing countries and the market is expanding quickly although a major share went to biotechnology drugs during the period 1977 to 2010 [14]. Therefore, as a middle-income country with total health expenditure in 2011 of 6% of the gross domestic product [15], evidence-based decision making and the appropriate use of available resources are of paramount importance. Although there is a process now in place to assess whether or not a new drug is eligible for reimbursement in Iran, previous studies have found that this process lacks efficiency in making quick and sound reimbursement decisions. This article’s approach was to go one step further by providing a more comprehensive view of the current situation, which enabled us to identify both the strengths and the shortcomings of the review process.

Our study revealed some strengths of the current process. The drug registration and reimbursement system in Iran basically uses the same decision-making criteria that are applied in many other countries, which include efficacy, safety, and economic considerations. The SCoHI has managed to eliminate some of the problems arising from a lack of therapeutic guidelines by drawing...
up restriction rules on the consumption of some reimbursed drugs based on their indications (see rituximab example above). The HIOs can provide not only an appropriate financial contribution, especially for high-risk patients, but also extended universal coverage in Iran. Improved planning in the area of reimbursement would help to improve this strength even further.

Table 2 – The top 20 nonreimbursement drugs based on sales in the period between February 10, 2011, and February 9, 2012 ($1 \approx 16000$ rials in 2011).

<table>
<thead>
<tr>
<th>Drug</th>
<th>Major indication</th>
<th>Drug sales of total nonreimbursement sales</th>
<th>FDO approval date</th>
<th>What is clear decision from SCoHI?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>%</td>
<td>€</td>
<td></td>
</tr>
<tr>
<td>Trastuzumab 440 mg vial</td>
<td>Certain breast cancers</td>
<td>3.0</td>
<td>18,269,992</td>
<td>Before 2008 No (4/2010)</td>
</tr>
<tr>
<td>Follitropin 75 IU ampule</td>
<td>Infertility</td>
<td>2.5</td>
<td>15,233,374</td>
<td>Before 2008 No application</td>
</tr>
<tr>
<td>Orlistat 120 mg capsule</td>
<td>Obesity</td>
<td>2.4</td>
<td>14,492,096</td>
<td>Before 2008 No application</td>
</tr>
<tr>
<td>Ibuprofen 400 mg pearl†</td>
<td>Moderate pain</td>
<td>2.3</td>
<td>13,498,195</td>
<td>Before 2011 No application</td>
</tr>
<tr>
<td>Pantoprazole 40 mg tablet†</td>
<td>Gastroesophageal reflux</td>
<td>2.2</td>
<td>13,050,840</td>
<td>Before 2008 No (4/2009)</td>
</tr>
<tr>
<td>Tamsulosin 0.4 mg capsule</td>
<td>Benign prostatic hyperplasia</td>
<td>2.2</td>
<td>12,907,345</td>
<td>Before 2008 No (6/2010)</td>
</tr>
<tr>
<td>Sildenafil citrate 100 mg tablet†</td>
<td>Erectile dysfunction</td>
<td>1.9</td>
<td>11,239,538</td>
<td>Before 2008 No application</td>
</tr>
<tr>
<td>Menotropins 75 IU FSH + 75 IU LH ampule</td>
<td>Fertility disturbances</td>
<td>1.8</td>
<td>10,809,738</td>
<td>Before 2011 No application</td>
</tr>
<tr>
<td>Vaccine-influenza virus killed</td>
<td>Protect against influenza virus</td>
<td>1.7</td>
<td>10,437,869</td>
<td>Before 2008 No application</td>
</tr>
<tr>
<td>Drospirenone/estradiol 3/0.03 mg tablet</td>
<td>Hormonal contraceptive</td>
<td>1.5</td>
<td>8,928,217</td>
<td>Before 2011 No application</td>
</tr>
<tr>
<td>Bevastizumab 400 mg/16 ml vial</td>
<td>Various cancers, colorectal, lung, breast,</td>
<td>1.4</td>
<td>8,303,165</td>
<td>Before 2011 No application</td>
</tr>
<tr>
<td></td>
<td>glioblastoma kidney, and ovarian</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salbutamol 100 mcg/dose 200 dose inhaler†</td>
<td>Relief of bronchospasm</td>
<td>1.3</td>
<td>7,900,956</td>
<td>20/11/2009 No application</td>
</tr>
<tr>
<td>Buprenorphine 2 mg sl tablet†</td>
<td>Moderate to severe chronic pain</td>
<td>1.3</td>
<td>7,624,896</td>
<td>Before 2005 Under study</td>
</tr>
<tr>
<td>Celecoxib 100 mg capsule</td>
<td>Osteoarthritis, rheumatoid arthritis, acute</td>
<td>1.2</td>
<td>7,245,080</td>
<td>Before 2000 No (4/2002)</td>
</tr>
<tr>
<td>Zoledronic acid 4 mg vial</td>
<td>Osteoporosis</td>
<td>1.1</td>
<td>6,707,129</td>
<td>Before 2008 Yes (wait for government cabinet)</td>
</tr>
<tr>
<td>Pantoprazole 20 mg tablet†</td>
<td>Gastroesophageal reflux</td>
<td>1.1</td>
<td>6,565,955</td>
<td>Before 2008 No (4/2009)</td>
</tr>
<tr>
<td>Celecoxib 200 mg capsule</td>
<td>Osteoarthritis, rheumatoid arthritis, acute</td>
<td>1.0</td>
<td>5,891,905</td>
<td>Before 2000 No (4/2002)</td>
</tr>
<tr>
<td>Prospan syrup†</td>
<td>Expectorant</td>
<td>0.9</td>
<td>5,678,314</td>
<td>Before 2011 No application</td>
</tr>
<tr>
<td>Acetaminophen/caffeine/ibuprofen 325/40/200 mg capsule†</td>
<td>Moderate pain</td>
<td>0.9</td>
<td>5,566,815</td>
<td>Before 2002 No application</td>
</tr>
<tr>
<td>Tramadol 100 mg tablet†</td>
<td>Moderate to severe pain</td>
<td>0.9</td>
<td>5,431,981</td>
<td>Before 2002 No application</td>
</tr>
</tbody>
</table>

FDO, Food and Drug Organization; FSH, follicle-stimulating hormone; IU, International Unit; LH, luteinizing hormone; SCoHI, Supreme Council of Health Insurance; sl, sublingual.

* When the exact dates were not accessible, we looked at the Iran pharmaceutical market and if the drug was accessible in each year, we used “Before that year” to describe the FDO approval date.

† There are some others dosage forms in Iran reimbursement list.
Price negotiation, budget impact, and priority for drug coverage are important activities in the process of drug reimbursement. The drug reimbursement process in Iran can be described as a shared responsibility process because the decision-making process is distributed between two ministries with different interests. The Ministry of Health and Medical Education is expected to ensure patient access to useful drugs, while the Ministry of Welfare and Social Security must try to maximize health insurance coverage with a limited budget. The two ministries therefore have goals that can conflict with each other. In addition, the SCoHI must consider the recommendations of many stakeholders when making reimbursement decisions. These two factors of conflicting aims and many decision makers may complicate the goal of independent decision making. This not only might challenge the societal goals of drug reimbursement but also cause other problems such as delayed decisions. One consequence of a prolonged reimbursement process is an increase in out-of-pocket payments by patients, who will have to pay for a drug until it is deemed reimbursable. Some HIoIs may therefore use supplemental insurance or decrease other services to help patients needing expensive nonreimbursed drugs.

One issue in the current system is that periodical reports by the SCoHI and the FDO are not publicly available. The reasons for approving or disapproving drug registration and reimbursements, and the average duration of the registry and reimbursement processes, are therefore unknown. This can be viewed as evidence of lack of transparency in the process, which could easily be resolved if information from the SCoHI and the FDO were published. In addition, the repetition of some activities during the evaluation process likely means redundancy, inefficiency, and delays in decision making. A good example of this is the requirement by the applicant to supply various economic documents to both the CCCD and the DBPRC.

The drug reimbursement process uses the same approach in dealing with different applications regarding required documents, evaluation, and the decision-making process, regardless of the budget impact and whether or not the drug is essential. However, modern health technology assessment methods are not evident in this process. One consequence of these issues is reduction in process dynamicity and accumulation of different applications with different degrees of importance in patient safety. Although standardization of the required documents and assessment protocol of the applications is a strength of the reimbursement system in Iran, it does have its limitations. That is, process dynamicity could be improved by developing different approaches to assess drugs in different categories on the basis of their medical and economic characteristics. Policymakers could then apply a set of criteria to prioritize drug reimbursement reviews. For example, a drug with great budget-saving potential might receive a higher priority. In contrast, a drug could be given a lower priority if another drug (with a similar safety and effectiveness profile) is already available on the market.

Improvements in the drug reimbursement system cannot sufficiently compensate for the problems that arise when total drug expenditures are lower than the desired expenditures; sometimes a greater budget may be the best way to address the problem. Moreover, it will be difficult to develop a system that can satisfy all stakeholders. Nevertheless, it is clear that improvements need to be made. If the number of new and expensive drugs continues to be high, this can lead to delays in decision making and various problems such as distrust between the public and policymakers and an increased number and expenditure of nonreimbursed drugs, which can, in turn, lead to insurance fraud by patients and physicians.

The sharing of expertise and experience in middle-income countries would be beneficial for HTA developers and policy makers in these countries [16]. Iran, because of its geopolitical position, market size and relative good performance in terms of health indicators [14,15,17], is an important country for HTA researchers in the region and the western part of Asia.

**Conclusions**

The Iranian drug reimbursement system is a shared process between two different ministries and has an important role in the efficient allocation of resources. Some issues that have been discussed reduce the functionality of this system. Therefore, Iranian policymakers need to make changes and reevaluate the admission process of new drugs to the reimbursement lists under a new set of guidelines and possibly a more efficient regulatory body. In this new set of guidelines, one important step to improving decision making is greater transparency (e.g., by publishing reimbursement and registry decisions) on details. More transparency will help to improve other key performance indicators of new decision-making processes such as independency, timeliness, and dynamicity. Benchmarking studies on the Iranian drug reimbursement decision-making processes versus other countries’ processes are needed to highlight Iran’s procedural difficulties. Other studies, especially case studies, should evaluate the exact drug reimbursement decision making in Iran. These studies and the experiences of other countries can serve as a framework to find the best solutions to improve the drug reimbursement decision-making process.

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