



german
cooperation

DEUTSCHE ZUSAMMENARBEIT



Financial Sustainability and Coverage Effectiveness of the Indonesian Health Insurance System

The role of benefit package design and pharmaceutical policy

Published by

giz Deutsche Gesellschaft
für Internationale
Zusammenarbeit (GIZ) GmbH

Acknowledgements

This report was commissioned by Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH on behalf of the Federal Ministry for Economic Cooperation and Development (BMZ). It is part of the German contribution to the EU Social Protection Systems (EU-SPS) initiative.

The assessment was performed under the bilateral Social Protection Program Indonesia, implemented by GIZ under the leadership of Cut Sri Rozanna (GIZ Social Protection Program, Indonesia).

The report was prepared by Ioana Ursu (Mapping Health Ltd.) and Viktoria Rabovskaja (GIZ Social Protection Program, Indonesia).

Sebastian Kuhn provided coordination and editing of the publication under the overall lead of Alicia Spengler (both GIZ Sector Initiative Social Protection). The report benefited from comments provided by Tobias Bündler (GIZ Global Project Access to affordable and high quality medicines).

The assessment builds on inputs from representatives of Indonesian institutions. The completion would not have been possible without their vast expertise and cooperation.

Table of Contents

A. Introduction	>	6 - 7
B. Analytical Framework	>	8 - 14
I. The mandatory functions of a pharmaceutical system		8 - 9
II. The information flow – ideal pathways of interaction and communication of information between the functions		10 - 12
III. The working practices, tools and outputs of each function		12 - 14
C. Research Methodology	>	15
D. Main Findings	>	16 - 21
E. Discussion	>	22 - 28
I. Are the mandatory functions of a pharmaceutical system in place?		22
II. What is the information flow between the existing functions?		23 - 25
III. What are the working practices of each unit, and are there any international best practices that could be adapted to the local needs?		26 - 28
F. Conclusion	>	29

List of Abbreviations

AIFA	<i>Agenzia Italiana del Farmaco</i> (Italian Medicines Agency)
BMZ	<i>Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung</i>
BPJS Kesehatan	<i>Badan Penyelenggara Jaminan Sosial Kesehatan</i> (Social Health Insurance Carrier)
BPOM	<i>Badan Pengawas Obat dan Makanan</i> (Indonesia Food and Drug Administration)
CEA	Cost Effectiveness Analysis
CUA	Cost Utility Analysis
DRG	Diagnosis Related Groups
EMA	European Medicines Agency
FDA US	Food Drug Administration
FORNAS	List of Reimbursed Medicines in Indonesia
GBA	<i>Gemeinsamer Bundesausschuss</i> (German Federal Joint Committee for Health)
GIZ	<i>Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH</i>
HITAP	Health Intervention and Technology Assessment Program, Thailand
HAS	<i>Haute Autorite de Sante, France</i>
HTA	Health Technology Assessment
INA-CBG	Indonesian Case Based Groups (equivalent of DRGs in Indonesia)
IDR	Indonesian Rupiah
IQWiG	<i>Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen</i> (German Institute for Quality and Efficiency in Health Care)
JKN	<i>Jaminan Kesehatan Nasional</i> (National Health Insurance)
LKPP	<i>Lembaga Kebijakan Pengadaan Barang Jasa Pemerintah</i> (Indonesia national procurement agency)
MoH	Ministry of Health
NICE	National Institute for Clinical Excellence, UK
OOP	Out of Pocket
SJSN	<i>Sistem Jaminan Sosial Nasional</i> (National Social Security System)
GIZ SPP	GIZ Social Protection Programme, Indonesia

List of Figures

Figure 1: The functions of a pharmaceutical system	9
Figure 2: The ideal flow of information between the system functions	11
Figure 3: Mandatory outputs for each function	13
Figure 4: The pharmaceutical decision-making as continuous process	14
Figure 5: Identification and mapping of Indonesian stakeholders based on their function	16
Figure 6: Overview of the decision flow in Indonesia	23

A. Introduction

Indonesia introduced a national health insurance programme (known as JKN) in 2014, based on the National Social Security (SJSN) Law No. 40 which was passed in 2004. This required the integration of the various public health insurance schemes existing at that time into a single insurance system. Accordingly, a single health insurance carrier, namely BPJS Kesehatan, has been established to operate the JKN scheme from 2014 onwards.

The JKN programme currently covers 170 million people, 91 million of which are classified as poor and receiving contribution subsidies from the government. The scheme aims to achieve Universal Health Coverage (UHC) for the entire population of 250 million by 2019. In contrast to the various health insurance schemes that existed before the reform, JKN promotes equity as it provides the same services for all population groups, irrespective of income or employment status. Per law, JKN has a comprehensive benefit package that covers services from infectious diseases to open-heart surgery, dialysis and cancer therapies, including medicines.

JKN policy design and implementation have made remarkable progress since it came into being. However, challenges in the implementation of such largescale reform occur. A major challenge is the financial sustainability of the scheme. After the first year of operations, the balance resulted in a deficit of about 15% of the fund. Moreover, there has been anecdotal evidence, highlighted in the media, that suggests health care service providers still charge JKN members and that patients continue to incur out of pocket (OOP) expenses. A study conducted by the GIZ Social Protection Programme (SPP) examined both of these claims. It could show that given the current conditions, such as the

contribution and expenditure levels, the deficit is most likely to rise significantly in the coming years. A survey of JKN insured patients demonstrated that in 18% of hospital cases, patients were charged by the providers. The main reason for OOP were medicines, accounting for 70% of all payments.

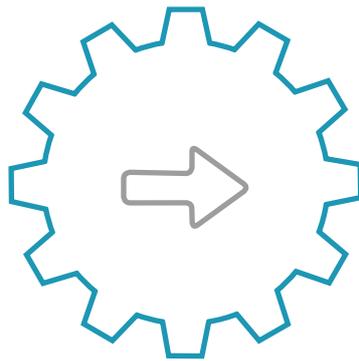
Based on the results of this study, GIZ SPP aimed to examine the spending on medicines as the main driver for OOP under the JKN scheme. In view of the equity promoted by JKN, as well as financial sustainability of any universal healthcare system, it seems crucial to address the current pharmaceutical policy and medicine management strategy. The final recommendations of such exercise would aim to: a.) ensure financial sustainability and cost containment within JKN and b.) to effectively protect patients from OOP.

Looking across health systems, the issues JKN is currently confronted with are not unique to Indonesia. We know that spending for medicines account for the second largest cost block of a health care system, after the expenses for human resources. In OECD countries, on average, pharmaceutical spending was 20% of the total health care spending in 2013. From a macro-economic perspective, this spending accounted on average for 1.4% of the countries national GDP. In developing and emerging countries the share of total health care spending is typically larger, due to lower wage levels for the medical staff. In Indonesia, the estimate ranges from 35-45% respectively. In addition, global trends like an ageing population, rise of non-communicable diseases but also more expensive new medicines have been leading to higher medicine related expenses and cost pressure for the national payer(s), i.e. national health insurance(s) or other bodies funding health care.

¹ For details see: GIZ SPP (2015) "Out-of-Pocket Payments in the National Health Insurance of Indonesia: A First Year Review", available at: http://health.bmz.de/what_we_do/Universal-Health-Coverage/Indonesia_on_the_way_to_universal_health_coverage/index.html

To respond to the steadily growing pharmaceutical expenditure within publically funded health care, various countries have introduced policies and developed multiple mechanisms with one common aim: ensuring access to drugs for a broad population, while containing cost. To achieve this, decision makers have evaluated the policy set up and introduced reforms aligning to international best practices or created new innovative approaches.

The aim of this assessment has been to fulfil the first step – evaluate the set-up of medicines reimbursement under the JKN, as well as make initial recommendations on how to improve decision making practices, based on international experience.



B. Analytical Framework

When discussing the financial impact of medicines in a publically financed health care system, the temptation is to simplify things by assuming it is merely a question of pricing (e.g. reorganising tendering processes) or controlling for new and rather expensive products entering the reimbursement package (e.g. by creating a Health Technology Assessment (HTA) unit). While that may help in some cases, in our experience, frequently the situation is more complex, and an in depth, systematic analysis of the pharmaceutical system is required.

For analytical purposes, we define three layers of a pharmaceutical system – issues or gaps in any of these layers generally translate into inefficiencies like incorrect prices (either too high to cover them, or too low to foster competition), over- or under prescribing, increased OOP expenditure, and ultimately poor health outcomes.

The proposed analytical framework considers the following three steps to assess the layers of a national pharmaceutical system:

- I. Are the mandatory functions of a pharmaceutical system in place?
- II. What is the current information flow between the existing functions?
- III. What are the working practices and outputs from each function?

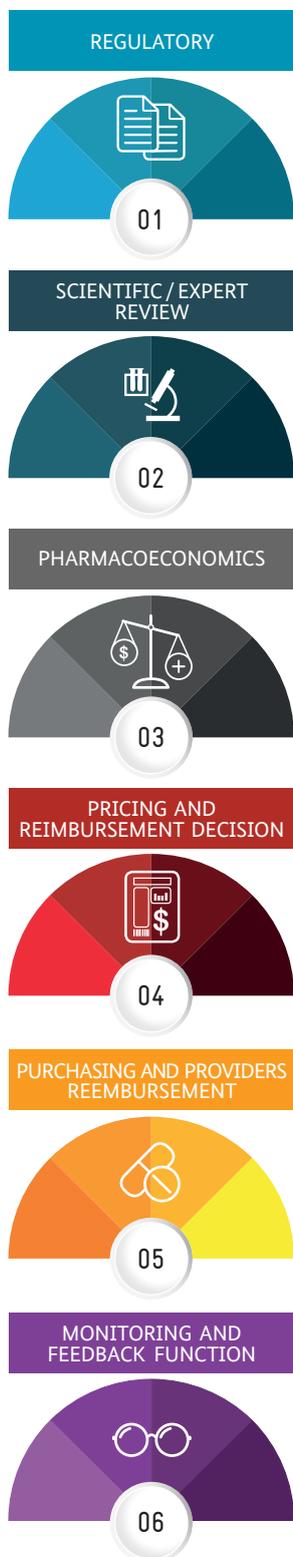
In the following pages, we firstly provide a description of a template pharmaceutical system and template answers to the above three questions. In a second stage, we compare our findings from the Indonesian setting

with this framework. Finally, we discuss the identified gaps and potential for adjustments in accordance with international best practices.

I. The mandatory functions of a pharmaceutical system

Worldwide, countries have developed and strengthened various functions, from regulatory capacity, to health technology assessments, price negotiation groups, and units to monitor usage. However, over the past

two decades, there has been a convergence of best-practices, leading to the following basic functions that all working pharmaceutical systems tend to cover (see Figure 1):



The regulatory function – has the role to assess the safety of a new drug, in order to then grant a market authorization. Implementation of international manufacturing and clinical standards within production sites also falls under the remit of regulatory agencies.

The scientific/expert review – groups of experts in charge of reviewing clinical data of newly authorized products, in order to decide if the drug is effective and how it compares to the current drugs used in the same disease and population of patients.

The pharmacoeconomics /Health Technology Assessment – units in charge of establishing a correlation between the clinical performance of the drug, and the potential price that a patient or the healthcare system can pay, within their purchasing power capacity. This function can use various tools and economic models.

The pricing and reimbursement decision – generally the most publicly visible function of a pharmaceutical system as main decisions on the benefit package composition are made here. The pricing and reimbursement unit(s) leads price negotiations with manufacturers, while also being politically aware of national political priorities. Once a decision on whether to include a product on the reimbursement list is reached by this function, the health provision system must provide the product as part of the benefit package.

Purchasing and payment – administrative function ensuring the drugs are procured as efficiently as possible (e.g. tenders), and providers (hospitals/ pharmacies) are reimbursed according to their services and drug expenditure.

Monitoring, control and feedback – unit(s) in charge of monitoring expenditure, drug usage and drug prescribing. Moreover, the function provides:

- a. policy solutions for adjusting the budget/prescribing;
- b. statistical, real world data on usage and disease burden.

The data represents essential evidence for further decision making and is then fed back to all previous functions.

↑ Figure 1: The functions of a pharmaceutical system

II. The information flow – ideal pathways of interaction and communication between the functions

The number of units and agencies required to perform the functions of a pharmaceutical system varies in each country, reflecting national characteristics.

Germany – there are four main institutions involved: The German Regulatory Agency, the IQWiG Institute which covers both scientific and economic reviews, while in the following the Gemeinsamer Bundesausschuss (GBA, Federal Joint Committee) makes the reimbursement decision and negotiate price; the Association of Health Insurers will ensure physicians compliance, as well as monitor usage which they will also share back with the other institutions.

Russia – there are 3 units within Federal MoH and 81 regional MoH: once the drug is approved by the Registration Division, a Clinical Committee will review the data and recommend to the Essential Drugs Committee to negotiate a price and on which grounds; once the federal MoH decides to reimburse the drug, regional MoH will ensure procurement, reimbursement, control physician prescribing and feed-back statistical data to the Federal MoH.

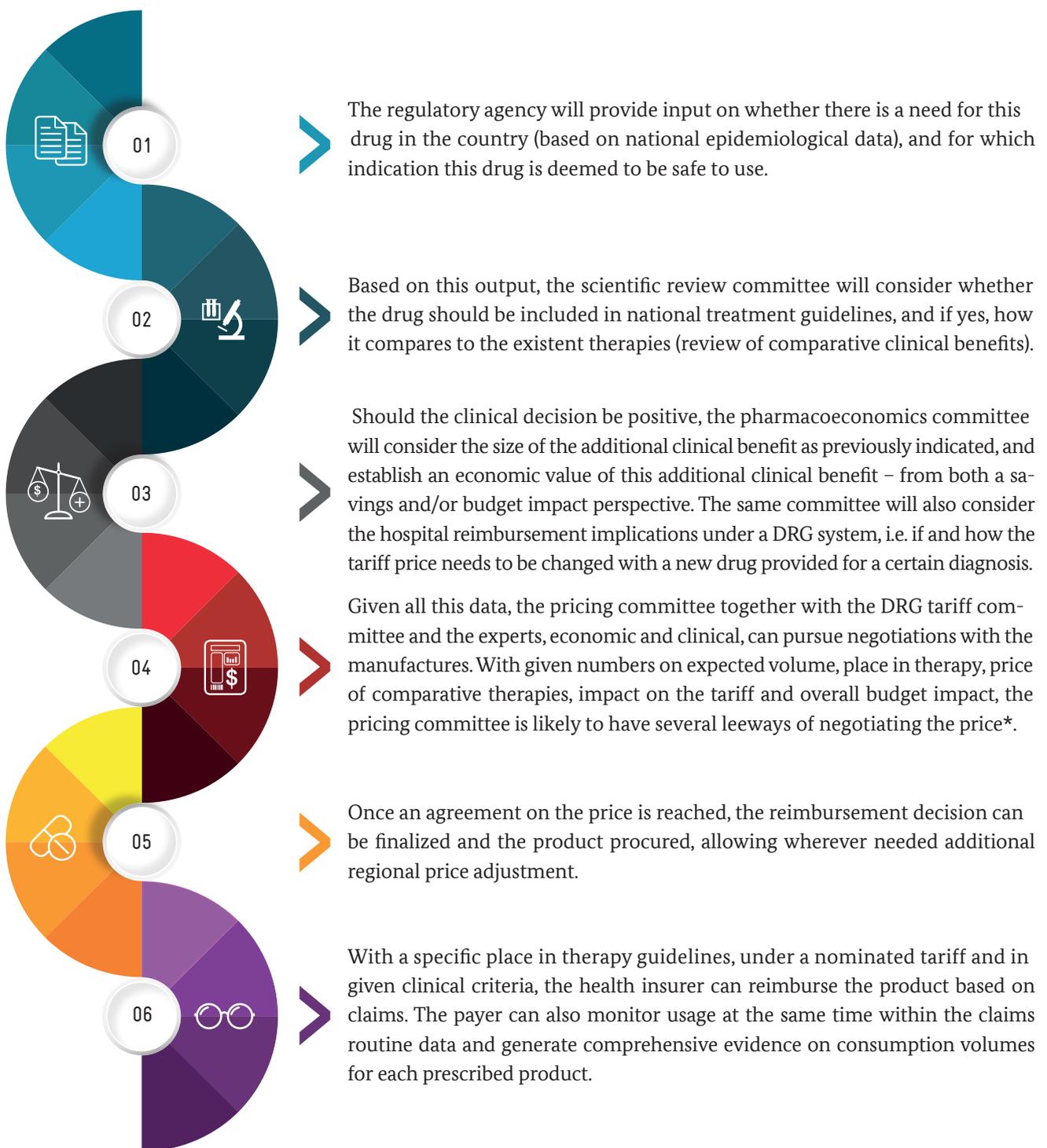
US – there is only one federal institution involved (the FDA who will grant market access approval), and over 400 health insurers. In each of the health insurance units, there is a Medical and Pharmaceutical Director, in charge of evaluating the clinical and economic data, and then together with the Procurement Director negotiate a price with manufacturers. The Medical and Pharmaceutical Director will then monitor and control usage of each drug.

The functions described earlier are executed by different public agencies, according to each country's organigram. Sometimes multiple stakeholders cover different aspects of one function, other times there is one major organization covering several functions.

Whichever way organised, the **key is to have all functions in place, and also to ensure there is a clear alignment between all the organizational units, with the flow of information between them passing clearly, predictably and comprehensively.**

As in any system with multiple stakeholders, decisions taken by one actor (for example, the decision by the scientific committee to replace an older, cheaper, drug with a new, more expensive one) have implications for the following units (the pricing committee and the providers). In this example, assuming the decision to replace the older drug has only been communicated to the prescribers, and not to the pricing committee, the pricing unit will likely not consider the new drug as a replacement, but rather as an additional treatment, and therefore assume smaller volumes, with incorrect budget impact. Alternatively, they may decide to reimburse the drug only partially, as the old one has been the gold standard and fully reimbursed. As a result, coverage for the product is not provided and ultimately OOP expenditures appear.

In an ideal world, the flow of information from one function to the next would have the form of a 'snowball effect' – each function adds its own layer of information to the initial data, thus ensuring that each following unit makes its decision being fully aware of all previous decisions (Figure 2).



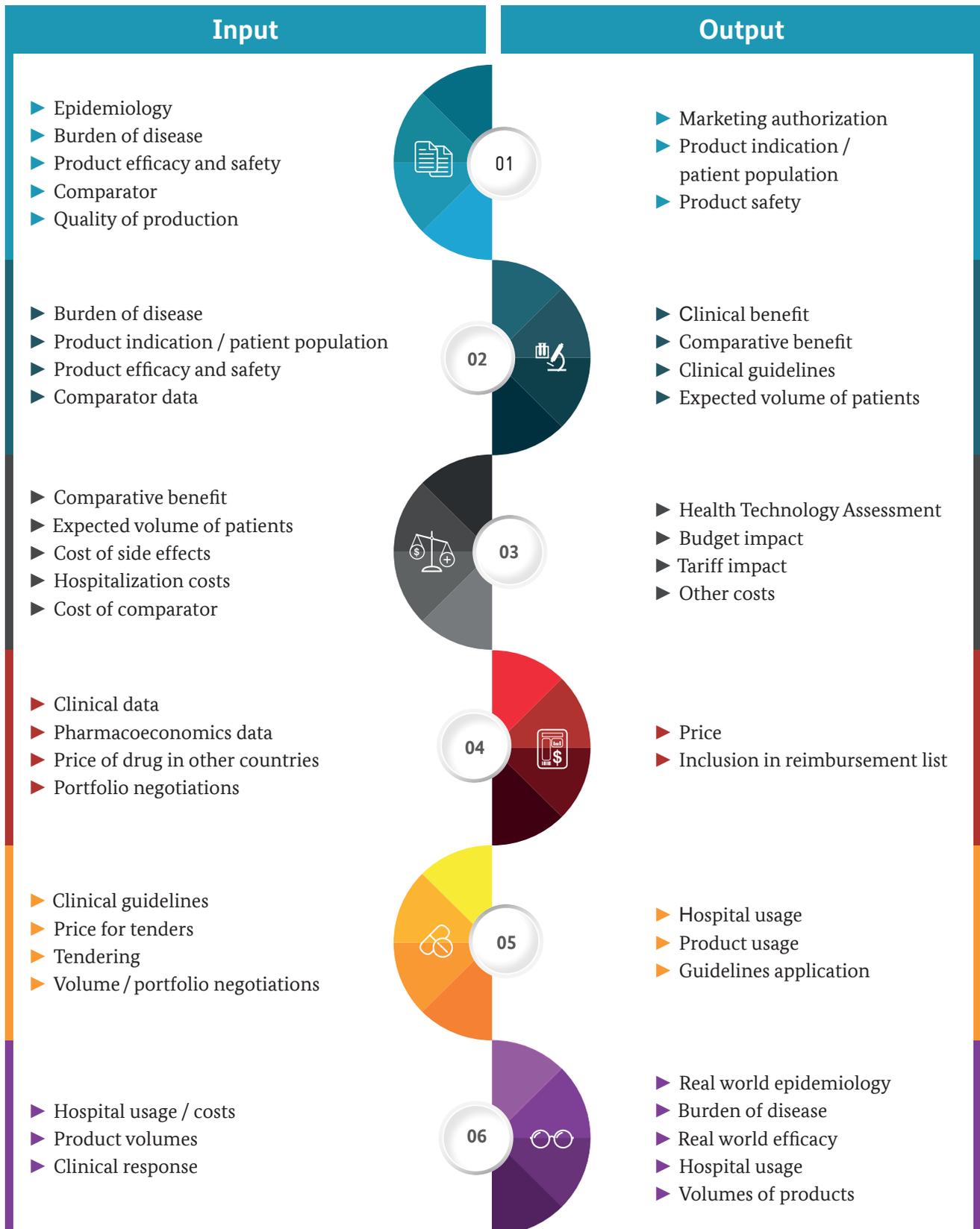
↑ Figure 2: The ideal flow of information between the system functions

*For the past decade, Italy has been the lab for testing innovative pricing methodologies in Europe, under the so called ‘managed entry agreements’ (MEA). MEAs can take the form of financial or outcome agreements. In a financial agreement, the MoH negotiates a maximum volume for a given price, which once reached can lead to a lower price for the exceeding consumption or a claw-back (any extra volumes used and paid are reimbursed by the manufacturer). Recently, Italy has made a similar two-step agreement with Gilead for Sovaldi, the hepatitis C drug: once the first agreed on volume was surpassed, there was an additional decrease of 25% in price; once the 2nd limit on volume has been reached, for any additional patient, the MoH receives credit from Gilead (and procure whichever other Gilead drugs for free).

III. The working practices, tools and outputs of each functions

As mentioned earlier, each country is likely to have its own organisational system, with various stakeholders performing the functions and roles. There is no silver bullet for working practices of each unit, and any solution provided needs to be adapted to local contexts. Plus, adherence to any change will take place only if there is local ownership and support of the process.

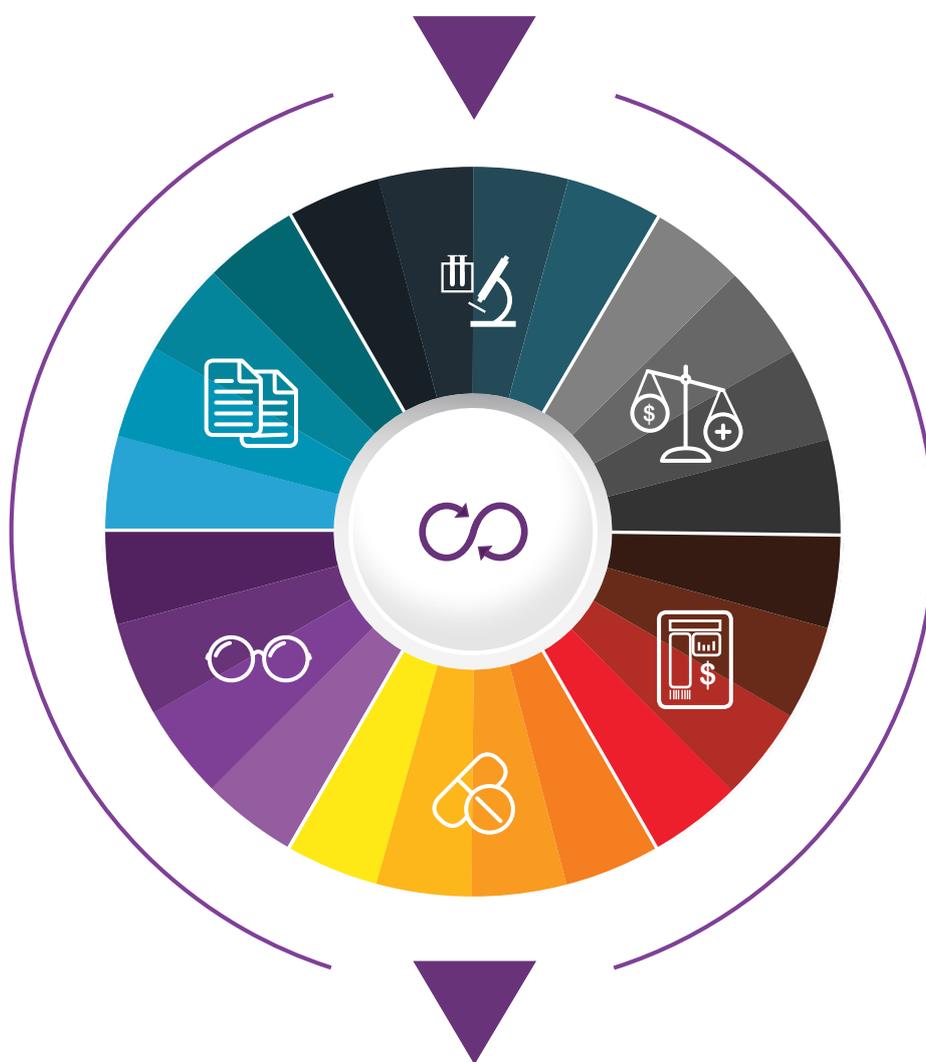
Following the idea of mandatory functions and flow of information between those, we now consider the basic mandatory outputs of each function (Figure 3). In order to ensure an efficient flow of information, each unit should be able to generate these outputs, so they can be further used by the following functions of the system.



↑ Figure 3: Mandatory outputs for each function

When reviewing the figure below, it is also helpful to remember that each output will be added on top of the ones already existent (“the snow-ball effect”). This ensures that the purchasing function (generally the health insurer) will have a full image of all aspects related to the reimbursed medicine. Furthermore, once collected,

the output of the monitoring and feedback function becomes input for the regulatory function, as well as providing support in the decision making of all other functions. As such the pharmaceutical decision making should be seen as an ongoing process (Figure 4).



↑ Figure 4: The pharmaceutical decision-making as a continuous process

C. Research Methodology

Based on the analytical framework described above, we identified the main profiles of decision makers who were contacted for an in-depth face to face qualitative discussion. The discussion guide was built around the three perspectives mentioned in the analytical framework, including the interaction between existing institutions, as well as their formal and informal output of data. Decision makers from all institutions involved in the sector participated in the qualitative evaluation.

Following, a joint stakeholder workshop was conducted together with TNP2K to verify and cross-check the results, as well as to identify challenges and gaps of the process occurring between the different functions.

This stage was important to increase awareness of gaps across all stakeholders, but also to ensure that moving forward, during the development of solutions and implementation, there will be ownership from all institutions involved in the (reform) process.

During the workshop, several solutions responding to the specific needs were jointly identified based on international best practices and experiences across multiple healthcare systems. The assessment results and proposed solutions are summarized in this paper, though the final format of any new policy will be up to the decision of Indonesian stakeholders involved in the process.



D. Main Findings

The field assessment with face-to-face interviews took place in June of 2016. There were eight main institutions identified as having a role in the Indonesian phar-

maceutical decision making system. An aggregated, quick overview of the institutions fulfilling mandatory system function is presented in Figure 5.

System Functions	Indonesian institutions fulfilling the system functions
Regulatory	BPOM
Scientific/Expert Review	MoH Pharmacy – FORNAS groups
Pharmacoeconomics	MoH Pharmacy – Pharmacoeconomics Committee
	MoH Health Financing – HTA Committee
Pricing and Reimbursement Decision	MoH Pharmacy – FORNAS groups
	MoH Pharmacy – Pricing Committee
Purchasing and Providers Reimbursement	LKPP
	BPJS
Monitor, Control, Feedback	LKPP
	BPJS

↑ Figure 5: Identification and mapping of Indonesian stakeholders based on their function

As depicted above, the main functions of the pharmaceutical system in Indonesia are fulfilled by:

1. The regulatory function (market authorization and quality control) is fulfilled by the agency Badan Pengawas Obat dan Makanan (BPOM).
2. Once the product has been deemed safe, the scientific review is done by the Clinical Committees under the Pharmacy Directorate (BINFAR), MoH. The committees decide if the product should be listed on FORNAS, the national formulary. Listed products are automatically subject to reimbursement under JKN; not listed products are left available to purchase on the free market.

3. The pharmacoeconomics function is split between two newly established units the Pharmacoeconomics unit within the Pharmacy Directorate and the HTA unit within the Health Financing Directorate, both departments being part of MoH, however without any coordination yet.

4. The pricing function is fulfilled by the Pricing Committee unit within Pharmacy Directorate of MoH.

5. The purchasing and reimbursement function is split between two independent institutions: Lembaga Kebijakan Pengadaan Barang Jasa Pemerintah (LKPP), the national procurement agency, and Ba-

dan Penyelenggara Jaminan Sosial (BPJS), the health insurance agency. LKPP purchases drug in volumes declared by hospitals, independent of the services offered. BPJS reimburses services, independent of the volume of drugs used by those hospitals.

6. The monitoring and feedback function is very limited. BPJS reports the claims received for each tariff to the Health Financing Directorate, while LKPP can provide on request the volumes ordered by hospitals (but not necessarily consumed under the public health insurance). Furthermore, there is no overall feedback on burden of disease, epidemiological profile, overall volumes or changes in consumption volumes.

As such, the identified stakeholders fulfil five out of the six system functions. The last function, *Monitoring and Feedback*, is the one not yet fully developed and integrated in the system.

In the following part, we provide a more detailed overview and summarize the challenges voiced by the stakeholders. The summary structure follows the outlined system functions and respective executing units.

a

BPOM acts as gate entry in the system, as well as quality assurance agent, reviewing manufacturers' products, production standards and production sites. When a new drug wants to enter the Indonesian market, it has first to be evaluated by BPOM in terms of efficacy and safety. A marketing authorization is issued on average one year after submission of initial documents by the manufacturer. During this time, internal experts evaluate the studies, including whether they are representative for the population of Indonesia, and whether they respect the treatment pathways already used. Both internal and external, independent evaluators from public Indonesian universities perform the evaluation.

Furthermore, a clinical panel formed of major Key Opinion Leaders (KOLs) is likely to look at all the data and opinions, before a final authorization is granted. Time- and process-wise, BPOM functions similarly to most regulatory agencies, like the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), and is currently in the process of adhering to international regulatory standards.

However, a few issues have risen during the interviews conducted with BPOM decision makers:

- ▶ While a thorough clinical evaluation is done in order to decide whether access to the market should be granted or not, these evaluations are generally kept internally. They do not accompany the documents sent to the MoH Clinical Panel Committee. Sometimes, the same KOLs will be involved in the BPOM clinical evaluation and the following MoH clinical evaluation for the same product, so the opinions will be passed on. But this is not common practice.
- ▶ When deciding whether the drug is effective, evaluators tend to look for data comparing the new drug to the local standard of care (what is currently used in Indonesia) for the same situation/disease. However, there are no standard clinical guidelines for most diseases, so the comparator chosen may not be representative for the local practice (i.e. BPOM may decide a new drug is more effective than the old through indirect comparison, but in practice the two have the same efficacy).
- ▶ Due to the lack of clear vision at the level of BPOM of what are the most urgent health needs in Indonesia there is no prioritisation of approvals. Lack of national clinical guidelines, as well as lack of feedback in terms of epidemiology and consumption, means BPOM may not give priority to assessment of those drugs that are really needed because there are not enough treatment alternatives in the market (e.g. prioritisation of orphan diseases; prioritisation

of diseases with high prevalence in the Indonesian population). As such, patients may end up waiting too long for life saving therapies, while other therapy areas may be packed with products, making it difficult for physicians to keep up to date, and prescribe the right drug, rather than the latest drug.

b

The Clinical Panel Committees (the so-called “FORNAS groups”), within the MoH, Pharmacy Directorate, decide on the inclusion of medicines into FORNAS, the national formulary which is automatically binding for BPJS. Once a drug is listed, the reimbursement by the national health insurance is mandatory.

The decision to include a drug is mainly driven by clinical arguments, with direct and indirect comparisons done for comparative analysis purposes. Similar to the process within BPOM, the experts will be looking at studies, or subsets of patients within clinical studies, that appear similar to the genetic make-up of the Indonesian population. Additional data may be requested from the manufacturer of the drug, based on whether the data submitted by the manufacturer and literature meta-analysis are considered enough. There is limited capacity to do indirect cross-comparison within MoH Pharmacy Directorate, for both clinical and economic groups.

During the interviews, several challenges were highlighted:

- ▶ The decision to include the drug on the national reimbursement list does not formally take into consideration the national need for the drug (the burden of disease – is it a national priority or not?) or the volume of potential patients.
- ▶ Similar to BPOM, the interviewees within MoH Pharmacy Directorate raised the issues of lack of

national standards of treatment (guidelines). As such, when the Clinical Committee decides to put the new drug on the reimbursement list, it is not automatically correlated to a place in a specific disease therapy, or specific sub-sets of patients.

- ▶ The results of the evaluation done by KOLs, with crucial details such as whether the drug is more beneficial than the existing one, and in which patients (all, or a sub-set) is not published in any format. In the absence of clear recommendations which patients should receive the new treatment, physicians are likely to prescribe based on experience, or influence of sales representatives.

- ▶ A final issue raised in the interviews is the absence of a high-level committee that oversees and coordinates all FORNAS committees: decisions are made in separate groups, based on disease, and with limited or no information on the overall disease burden across the entire population.

As result of the issues above, the reimbursement list is forever growing, with considerable impact on the overall budget which is not taken into consideration at any point in the reimbursement decision.

c

Once a drug is included in FORNAS, a reimbursement price needs to be decided on. A new Pharmacoeconomics committee has been set up in the Pharmacy Directorate of the MoH with the role to assess economic impact of new therapies, including budget impact, days of hospitalization, etc.

- ▶ Based on the discussions with the Pharmacy Directorate and the two representatives of this committee, our understanding is that it is still early days for this unit. In terms of data used to assess the pharmacoeconomics aspects, models used by other countries are being requested from the manufactu-

rer, and then the committee inputs their own data to establish what the budget impact would be. However, it is not clear how the results of this analysis are used in the pricing negotiations, if used at all.

- ▶ There was also no indication whether the estimated impact on the days of hospitalization would be communicated to the Tariff Committee for updating the hospital tariffs.

d

The pricing decision is taken by the Pricing Committee, a unit in the MoH, Pharmacy Directorate. Direct, product specific, price negotiations are only used for those drugs that are still on patent and imported in the country. For the generic drugs (majority of reimbursed drugs), the pricing committee sets ceiling prices, based on anticipated volumes and overall production costs which are reported by manufacturers.

e

Issues raised during discussions have been mainly around the pricing methodology and lack of reliable data:

- ▶ Currently the maximum price is equal to the production costs for the given volume, multiplied by four. The choice of multiplication factor seems to have no argument or analysis behind it, either prospective or retrospective. There is no analysis showing if the formula used to establish the maximum price leads to prices too high, too low, fair or if they allow enough room for competition and revenue to justify investment in production lines. Discussions with manufacturers suggest the resulting price is generally too low, but in the absence of a detailed statistical analysis of the market,

a definitive conclusion about the chosen pricing methodology cannot be reached.

- ▶ The issue of data used to calculate the maximum reimbursed price has been raised by both public and private sector interviewees. Currently the pricing committee seems to rely mostly on the sales volumes and production costs declared by the manufacturers. There is no cross-referencing with the consumption data from the health insurer BPJS. This in turn is likely to create various distortions in the market, as drugs with declared high volumes may eventually not be used in reality, and potentially the production costs remain uncovered. Conversely, not enough volume of a drug may be produced, thus encouraging a higher price due to higher demand.

f

In parallel, and independent of the drug price setting process, there is a process of setting and updating the diagnosis related groups (DRG) or tariffs, i.e. the amount reimbursed to hospitals for each service provided. The Indonesian system uses a nationally adjusted set of DRGs, the Indonesian case based groups (INA-CBGs). A tariff unit in MoH, Health Financing Directorate, is in charge of setting up, monitoring and updating the INA-CBGs. In Indonesia, as in many countries, the tariff incorporates the cost of hospitalisation, the cost of procedures and diagnostics, as well as the cost of the drugs given to the patients during their in-stay.

According to interviewees, the initial tariff was established based on Malaysian system as well as data from the former health insurance systems in Indonesia. However, since the introduction of JKN in 2014, there has been no comprehensive update of tariffs, only some selected case groups were adjusted due to severe deviations.

► Lack of reliable consumption data from BPJS and hospitals has been identified as the main barrier for updating the tariffs. Furthermore, as new, expensive products have been added to FORNAS, the stakeholders have also been considering approaches to evaluate these new technologies, and ensure their reimbursement is reflected correctly in the corresponding tariffs.

g

The newly created HTA Committee, under the Health Financing Directorate, MoH, is now in charge of developing a methodology to evaluate highly expensive drugs for their reimbursement as part of hospital tariffs. The current method used, with the support of NICE UK and Thai HITAP, is the usage of cost-effectiveness analysis (CEA) to compare between drugs.

► At the time of this research, the Indonesian cost-effectiveness threshold required in order to use the CEA was still to be developed. At the time of the research there was limited capacity within MoH to perform the analysis. The first HTAs were produced jointly with external support based on CEA models developed by NICE UK and adapted to Indonesian data.

► Discussions about the choice of the HTA type applied (particularly the choice of cost-effectiveness as opposed to other ones, like simpler cost-volume-innovation scales, or cost-benefit analysis) yielded limited answers. The overall agreement during the workshop with all stakeholders was that potentially the decision to use CEA should be re-evaluated, considering also the need for specialists and time required to create a functioning unit.

h

Once the maximum price is set, LKPP, the public procurement agency, calls for annual national tenders announced via the E-Catalogue, a web-based procurement tool. The hospital purchasing price is then established as result of electronic bidding by manufacturers (for generics) or individual negotiations (for branded products). Multiple winners can be announced, if they cover different regional areas. Once the bidding ends, the products to be reimbursed and their final price are listed in the E-Catalogue from where they are ordered by hospitals on a rolling basis.

There were several issues raised by stakeholders in relation to LKPP:

► When establishing the volumes for the tender call, LKPP relies mainly on forecasted needs given by the hospitals. These volumes are not however necessarily reflecting the actual need, as they are not correlated to BPJS claims for reimbursement or any epidemiological data. As such, it seems that the hospitals base their requests on some historic usage data. The overall capacity of hospitals to correctly forecast their annual needs has been raised as an important gap by the majority of stakeholders involved in the research.

► The hospital based volume figures are not correlated in any way to the volume data used by the Pricing Committee when establishing the maximum price. The committee uses sales volumes given by manufacturers.

► The final price reached as result of electronic bidding only takes into consideration the maximum price set by the Pricing Committee. This set price ceiling does not take into consideration the cost of the drug within the tariff. As such, the winning drug price may or may not fit within the respective hospital tariff.

The hospitals order drugs via the E-Catalogue and pay the manufacturer directly, at the established price, from their global budgets. In turn, hospitals submit their request for reimbursement of services (tariffs) to BPJS. BPJS Kesehatan, the national health insurer, holds the social health protection budget and reimburses the treatment cost based on claims from providers.

The issues raised by BPJS were mainly around the mandate they were (not) given by the MoH in relation to data they can ask from hospitals in order to reimburse their services.

► The current claim forms only require the diagnostic code, patient identification data, and the actual diagnostic. They do not record separately the drugs used or the amount used for the given patient/claim. As result, there is little or no infor-

mation on whether the tariffs decided in 2014 are under- or over-reimbursing the specific disease.

This is problematic as it undermines one of the reasons case-based payments such as DRGs are used (as opposed to overall hospital budgets): They supposed to better reflect the treatment cost by disease. In absence of respective details in the claim forms it is impossible to perform cost monitoring and adjustment.

► Furthermore, currently BPJS is only in charge of disbursement, it has no role in the process of setting the hospital tariffs or tools to measure the drug consumption under each tariff. It has therefore limited ability to provide feedback on utilization volumes and burden of disease among the insured. An exception would be the several “disbunded” diagnostic groups, where the medication is extremely expensive (e.g. cancers) and paid separately from a distinct budget.

E. Discussion

In the following section, we compare the findings from Indonesia to the analysis framework presented earlier.

Through this comparison, we are able to identify structural gaps or mismatches and the root causes (e.g. system set up, information flow between the sta-

keholders, working practices within the functions, etc.) of resulting challenges in the system.

Finally, we recommend a course of action to potentially tackle each of the core challenges. As mentioned earlier, the final decisions on how to move forward should be taken by Indonesian stakeholders.

I. Are the mandatory functions of a pharmaceutical system in place?

In the methodology chapter, we have introduced the concept of mandatory functions of a pharmaceutical system. It is also important to highlight that, globally, each country has developed differently, and the systems can fulfil the same functions with a variety of institutional set ups, be it by just one big or 10 smaller institutions taking on the tasks. Furthermore, in most countries, the institutions and their working practices are continuously evolving, with the aim of ensuring faster, more efficient, transparent, and accountable decisions.

As such, when mapping the Indonesian stakeholders, the discussion is not about the number of institutions fulfilling each function, but rather about identifying which institutions fulfil which function, what output each of them produces, and how the information flows from one institution to another.

In the findings chapter, we demonstrated that most of the key functions are present in the Indonesian set up. It is the last (but by far not least important) function, the monitoring and feedback, that is currently not yet established.

BPJS does not have the tools and capacity to monitor the prescribing of drugs, control physician prescribing behaviours, or collect and quantify usage of drugs reimbursed under the national insurance. However, this function is key to maintaining a sustainable insurance

system, even more so as new, expensive therapies become available and patients expect access.

As the closest institution to providers (hospitals, pharmacies), BPJS is best placed to collect usage data and provide real world evidence in terms of volumes of drugs used as well as days of hospitalization. This data should then be correlated to the epidemiological data, and also to the volumes used to price the drugs. An up to date, local, epidemiological profile is likely to help the decision makers correctly quantify the main diseases of the population; it would also help decide on national disease priorities. Exact volumes of drugs used are key to establishing a fair price level, and routine data collected automatically through hospital claims by BPJS could be used as main leverage in pricing negotiations with manufacturers, with less reliance on their sales data.

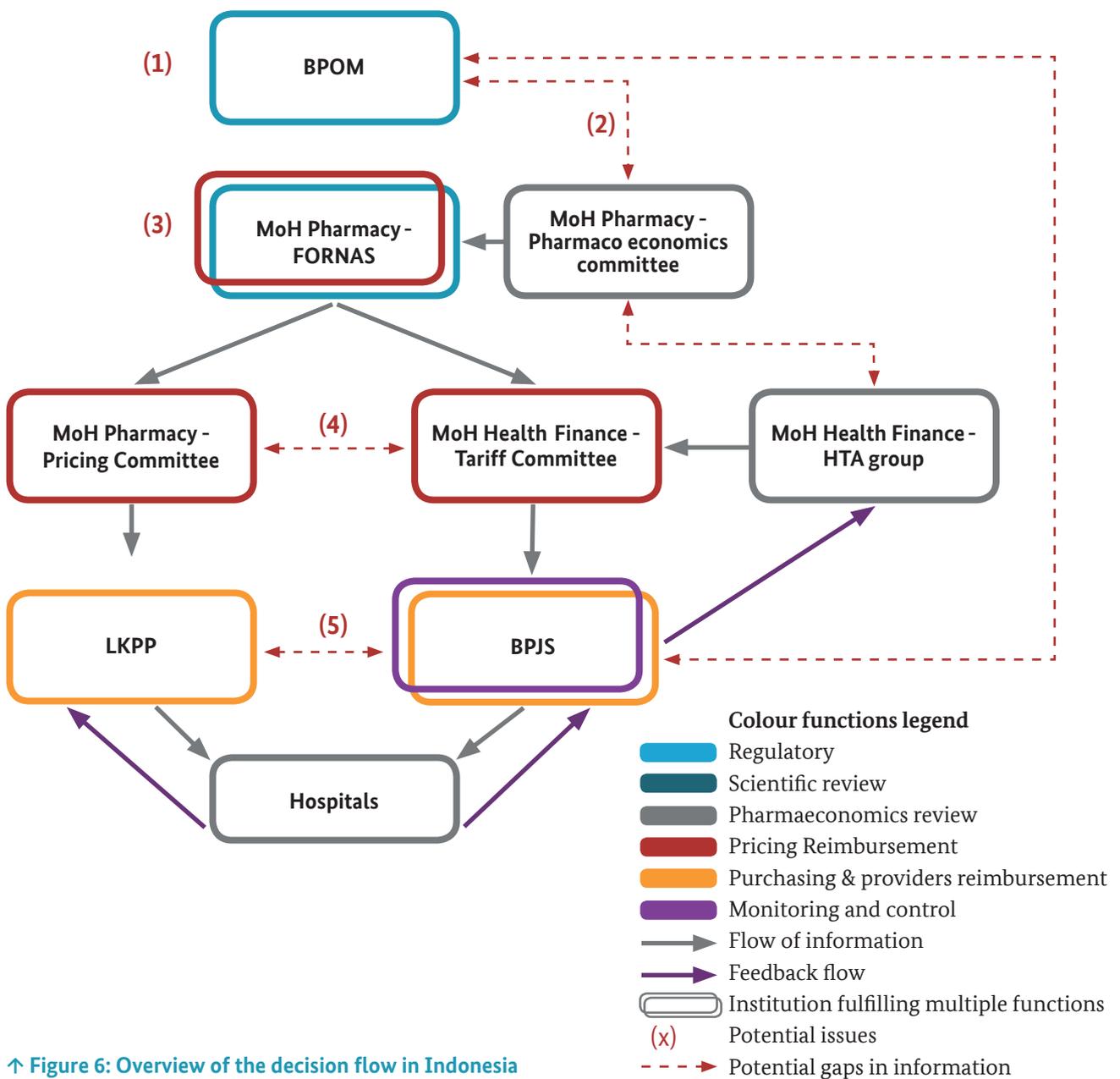
Recommended course of action:

- ▶ Enhance the monitoring, control and feedback function by measuring patient and physicians' behaviour, as well as drugs usage data in hospitals and pharmacies in correlation to the diagnostic and disease code used. To obtain accurate data we recommend this function to be fulfilled by the institution closest to the point of access (in this case, BPJS).

II. What is the information flow between the existing functions?

We have established that most functions of the pharmaceutical system are currently in place in Indonesia. In the next stage, we evaluated the interaction between the functions, and the flow of information between them. For this stage, we conducted a workshop together with TnP2K to confirm the findings with all

stakeholders. The resulting flow and the areas of potential limited communication have been represented in Figure 6. Where such limitations have been identified, and confirmed, we have highlighted them in red. We discuss them in more detail below and propose potential solutions for each of them.



↑ Figure 6: Overview of the decision flow in Indonesia

(1) In an ideal situation, the regulatory agency establishes the safety of the drug, and also, based in national epidemiological data, establishes the size of the potential population that would benefit from this new therapy. The Clinical Committee (“FORNAS groups”) would then consider this information, and together with additional comparative clinical data, would recommend a place in therapy and establish national protocols. However, this does not happen currently in Indonesia. BPOM grants access, while the Clinical Committee starts the review all over again, potentially collecting and using partially the same data already analysed by BPOM experts.

(2) As the new pharmacoeconomics committee comes in place, there is an expectation that BPOM data would be fed into the Scientific Committee. There has been no discussion though on how the evaluation of burden of disease, efficacy or volume done by BPOM will be transferred to the pharmacoeconomics committee and to the Clinical Committee.

(3) To complicate matters, the Clinical Committee then takes the reimbursement decision almost solely based on clinical efficacy, without taking into consideration the potential volume of patients, or cost of therapy (as no price is set yet). In some instances, the experts decided to place the drug in later lines of therapy, and thus tried to limit the overall budget impact, but this information was not necessarily shared with further stakeholders.

Taking the decision to reimburse before a potential volume and price are set, likely has a negative impact on the sustainability of the health insurance scheme. As result of an early reimbursement decision, there is mounting pressure on the pricing negotiation team to reach consensus with the manufacturer, giving less leverage to decrease the price in a face to face negotiation.

Recommended course of action:

► We strongly recommend delaying the final decision on reimbursement until the actors involved

(FORNAS groups, pricing committee, tariff committee) have reached a price agreement with the manufacturer. A final decision to reimburse a drug should be taken only after an agreement on price and potential volume is reached.

► A full report of the clinical decisions in FORNAS should be published and shared with the tariff groups, BPJS and providers (hospitals).

► Developing and publishing treatment standards should be a priority for the current system of Indonesia. The added benefit is likely to be also an increase in the quality of services offered in both public and private hospitals.

► Should the medical associations oppose the publication of standards, consider using the volume data used for each tariff to establish the current common treatment practice, and use that as benchmark for all hospitals.

(4) By law the reimbursement tariff is supposed to cover the cost of a drug used for treatment. As such, the price of the drug has to be reflected in the reimbursement tariff. Consequently, when establishing the drug price, a decision factor should be the current level of the tariff paid to the hospital for treating the associated diagnostic. Currently in Indonesia the Pricing Committee and the Tariff Committee, while both part of the MoH, sit in two different departments, and have limited interaction between them. The result has been the miscorrelation between the amount reimbursed to the hospital and the amount the hospital pays to the distributors. This may be an explanation for the persisting OOP expenditure identified by the GIZ SPP (2015) study.

As new (oral) therapies come into the market, shifting the cost from hospitalized patients to ambulatory care, getting a good understanding of how the hospitalization length and complexity is impacted by the usage of the new drug is key to establishing a fair price, and the level of the tariff given to the hospital. Lack of correlation

of data between these aspects in the long term is likely to create the issue of budget silos, a problem currently confronted by most insurance systems in the world. The result of these budget silos is either the limited access to new therapies, or inefficient care, with patients hospitalized longer than required. In either case, this has a negative impact on the capacity of the system to ensure a fair and equitable financial protection.

Recommended course of action:

- ▶ Consider creating a (bi)monthly working group, where representatives from all units, including clinical, economics, tariff, HTA and pricing are being announced of the products likely to enter, with projections on economic impact and tariff impact.
- ▶ Consider the price of the new drug in terms of CBG tariff impact as criteria for price setting.

(5) Once a reimbursed drug has a maximum price, there is little to no coordination between the purchasing unit (LKPP) and the reimbursement unit (BPJS). When holding the tenders and/ or negotiating on behalf of the MoH, LKPP considers the maximum price given by the Pricing Committee and the forecasted volumes given by the hospitals. However, LKPP has no indication of either the overall budget for drugs of BPJS, nor the actual drug consumption under the health insurance. The volumes data provided by the hospitals is not an optimal source of information. There are evident reported distortions between volumes ordered versus consumed. More-

over, it is probable that some of the drugs ordered by hospitals may be sold directly to the patients, as OOP services. BPJS in turn, has no power to regulate the drug price on the one hand and must blindly reimburse whatever is claimed by the hospitals on the other. As the payer, BPJS could and should control prescribing behaviour to be able to manage the cost to the system. However, as the product inclusion in the reimbursement list is not followed or preceded by mandatory national guidelines, BPJS has no grounds to enforce prescribing behaviour either.

This is further aggravated by the reporting of hospitals: the actual drug volumes consumed are used by hospitals to forecast future needs, data which is then sent to LKPP. BPJS does not receive any information on volumes of drugs, just on volumes of services. Due to this missing link BPJS cannot adjust its budget to the actual drug consumption, control cost or find solutions to overspending in certain disease areas.

In fact, the current mismatch of functions endangers the effective coverage of drugs under JLN leading to OOP by the insured.

Recommended course of action:

- ▶ For the procurement of drugs reimbursed under JKN, a joint working committee with LKPP and BPJS members could be considered. Such a committee could then ensure alignment between tender prices, volumes forecasted and volumes reimbursed.

III. What are the working practices of each unit, and are there any international best practices that could be adapted to the local needs?

Precise written working procedures from each of the units mentioned above are not available yet. As such, we based our evaluation of practices and potential gaps solely on qualitative interviews. The issues raised in the following part of the paper, as well as any recommendations, are not meant to be an exclusive list. Other internal management inefficiencies are likely to be present, like in any organisation, and it is not the scope of this paper to point all of them out. We will focus mainly on the topics that are likely negatively impacting the sustainability of the health insurance in Indonesia. Individual support, based on the exact needs of these institutions could be provided in the next stage of implementation of these recommendations.

A. Within BPOM, the issue of limited, reliable, national epidemiological data likely makes it difficult to have an accurate view of what should be the main disease priorities, as well as adapting these priorities to how the overall population health evolves (e.g. prioritize the entry of drugs for high burden diseases, or diseases with high volumes but limited therapeutic options). While some statistical data are available in BPOM, there is no real-world treatment data from BPJS being incorporated so far.

Recommended course of action:

► As the monitoring and feedback function develops, ensure claims based routine data is filtered back to BPOM on a regular basis.

As result of new monitoring tools in early 2000s, Italy adjusted its epidemiological profile: the new data showed that specific types of cancer were more spread than initially assumed for their population, with some particular sub-groups being at very high risk. As result, Italy's AIFA has prioritized the authorization of new targeted

therapies that were relevant for their high risk patients, but also decided to recommend new mandatory testing – Italy is now among the countries with decreasing prevalence of breast and ovarian cancers.

B. The Scientific review is actually a number of Clinical Committees, each specialised on one main therapeutic area. As result, there is little clinical overview of the whole population, as well as understanding of which diseases determine the highest budget impact. That also means one specialist group has no (or limited) information which drugs are being considered for reimbursement at the same time in other groups.

Recommended course of action:

► Consider creating an overall expert group, to review the drugs across all diseases. As one of the main decision criteria, consider the impact of each disease area on the BPJS budget and how the new drug would alter it. Based on national priorities, and clinical and economic data, the expert group could vote (see China model*) which drugs should be added or even potentially removed from the reimbursement list.

* China has two sets of reimbursement lists: a national one, binding for all provinces, at national level, and provincial lists. The addition of new drugs to both type of lists uses the same pattern of clinical and economic reviews as discussed in this paper. However, there is an additional step for the inclusion of a drug in the national list: the vote. In an annual meeting, experts from all provinces of China across all diseases meet to discuss which drugs should

be added to the national list, in addition to the provincial ones. The drugs with multiple/broad indications, high volume, and ideally generics are prioritized. Breakthrough drugs responding to a high demand, or highly political items are also considered as criteria, together with the expected budget impact for each province. In the end, only the drugs obtaining the majority of votes will be added to the national list. For the drugs that are not selected, each province still has the choice to include or maintain it in their provincial lists, and pay it from their own provincial budget.

C. The working practices of the Pharmacoeconomics and HTA committees are not yet fully defined. Apart from establishing the mandates, tasks and building up the technical capacities of the units, the biggest hurdle seems to be how the HTA will be able to make assessments in the absence of pharmacoeconomics data. We can only assume that as the capacity the pharmacoeconomics team to gather and evaluate health outcomes, impact on healthcare services (including hospitalization days, sub-groups of patients etc.) grows, this information will then be used by the HTA team.

Recommended course of action:

- ▶ We strongly recommend considering an increased communication/integrated approach for the two units.
- ▶ Furthermore, we also recommend initially using simple models (budget impact, cost savings from hospitalization etc.) until more data are collected within the country and capacity for more complex models is built to apply cost-effectiveness analysis (CEA) and/or cost-utility analysis (CUA).

The integration of data into HTA decisions is an on-going process in most countries in the

world. France has created the pharmacoeconomics committee in 2010 with the specific aim to assess the budget impact of some of the major diseases in the country. The first evaluation of treatments used in depression, and their efficacy vs budget impact appeared in 2010, and was seen as the pilot study. Only since Jan 2017, the Transparency Committee (the French HTA agency) has formally and officially included the request for pharmacoeconomics studies for all new drugs demanding reimbursement.

D. A new pricing methodology to be used by the Pricing Committee could also be considered. There is currently a clear disconnect between the innovation aspect of a drug and its price. Interlinkage of the actual burden of disease, national priorities, and the price are also crucial to consider when estimating the value of a drug. The current procedure, while very simple and easy to calculate, no longer seems to reflect the needs of a more sophisticated health system and patient expectations. In our understanding, after discussing with several private sector representatives, the tender prices set (for some disease areas at least) make it highly unattractive for manufacturers to participate. The issue of too low prices is also reflected by the need for state subsidies. As expected, unsustainable prices lead potential competitors out of the market, decreasing competition and ultimately decreasing the access to treatment under the JKN.

Recommended course of action:

- ▶ As more detailed data on volumes, and burden of disease is gathered through BPJS, a move from the blanket pricing system (the cost of raw materials multiplied by 4) should be considered.
- ▶ Potential negotiations with manufacturers across their portfolio, not only product specific, can be considered.

In 2014, Russia has introduced a new pricing methodology for the drugs to be included in the essential drugs' list (the national reimbursement list). The main criteria used: 1. burden of disease, health priority and sales volumes in Russia (forecasted or already achieved); 2. Price in Russia if product already available on the market or proposed price for new products. 3. Comparative budget impact versus drug(s) to be replaced or similar products; 4. Production and marketing costs if the manufacturer is in Russia; 5. Foreign production costs and price in all countries where the drug is registered.

► A comparison between HTA models used by Germany, France, UK, Italy or Russia, may be considered to develop an Indonesian specific pricing methodology. We recommend a combination of international referencing, innovation scales, budget impact, measurement of cost savings and managed entry agreements.

E. The collection tools, as well as the forecasting tools used by hospitals, either for the claims submitted to BPJS or LKPP have been raised as potential issues by the workshop participants. For example, in an effort to get a better understanding of the drugs market in Indonesia, LKPP led an exercise whereby they correlated the actual orders placed by hospitals through E-Catalogue, and their own forecasted needs sent at the request of LKPP. The result suggested there is wide variability on how hospitals established their future needs, with differences up to 1.5-2 times higher or lower than their current consumption.

Recommended course of action:

► Develop one standardized (electronic) tool to be used by all hospitals to establish their annual needs

based on recent consumption and link them to the volume estimation for tenders.

The easier the collection tool, the more likelihood of correct input can be expected for the forecasting tool. In recent years many development agencies have provided supply chain programs, many times based on excel. In our experience, online programs and interfaces, with possibility to transmit the data at intermittent times, worked better than local excel databases (see Burkina Faso new monitoring for vaccination program; see Romania electronic records etc.).

F. BPJS currently only receives claims based on diagnostic code. There is no specific information requested about the drug types and quantities used during the patient in-stay.

Recommended course of action:

► Consider adding a field in the claim form in which the hospitals nominate which drugs have been used for the specific DRG. This way there will be a constant monitoring of actual volumes used, and also a more detailed view of the disease burden in Indonesia. This information can then be fed back to all other stakeholders as they make their decisions.

► As the monitoring capacity increases, claim forms that include type and quantity of drugs prescribed can also be used as a provider control tool, to ensure physicians stick to national standards of treatment and the correct drug is given to the right patient. Should the claim only be partially filled in, or the drugs used to not correspond to the national guidelines for that diagnosis, BPJS should be allowed to (partially) refuse reimbursement.

² In order to maintain the state-owned manufacturers, who are also the main providers of drugs, the Indonesian state intervenes and provides subsidies.

F. Conclusion

Multiple essential functions of the pharmaceutical system in Indonesia are well established, including a regulatory agency currently in the process of obtaining international recognition, as well as electronic tenders, a nation-wide electronic system to order drugs, and a tariff unit looking at how to optimise hospital expenses. The main goal of this research has been to identify the gaps, and as such more attention was given to them, but recognition is due to the already done efforts to develop and sustain the pharmaceutical expenditure within JKN.

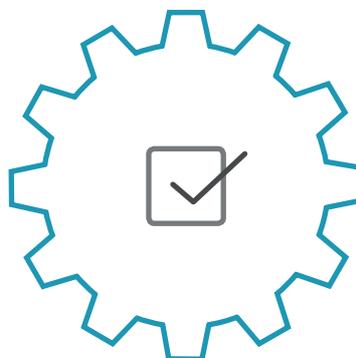
The persistent OOP expenditure for drugs, as well as some of the 15% deficit of JKN is likely the result of the pharmaceutical system set-up. And while the main focus aiming at fixing the challenge currently is on building up the limited HTA capacity in Indonesia, that is just one element of the bigger picture.

Based on the presented analysis framework, the identified gaps in the system are broader than strictly a lack of technical knowledge on how to price new, expensive drugs, for which there is no competition due to patent

protection. A thorough and wider assessment of the system, pointed out several limitations, from lack of a monitoring function, to a limited pricing methodology and reimbursement decisions taken in the absence of volume data. We have also confirmed the initial hypothesis whereby some HTA capacity should be built in the system in the next few years. However which HTA methodology should be used to fit best the Indonesian context is still an area that we recommend giving some thought to.

The efforts done by the Indonesian Government, including supporting this research are commendable – it shows there is initiative, and willingness to improve and adapt the newly created health insurance system to the realities of the country.

It will be up to the Government of Indonesia and also of their international partners to take forward the findings of this paper, and to address the pharmaceutical system as a whole, with a multitude of layers and stakeholders.



Impressum

Published by

Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)
GmbH

Registered offices

Bonn and Eschborn / Germany

GIZ Bonn	GIZ Eschborn
Friedrich-Ebert-Allee 36 + 40	Dag-Hammarskjöld-Weg 1 - 5
53113 Bonn	65760 Eschborn
Germany	Germany
T +49 228 4460 - 0	T +49 6196 79 - 0
F +49 228 4460 - 1766	F +49 6196 79 - 11 15

Sector Initiative Social Protection
E Social-protection@giz.de
I www.giz.de

As at

November 2017

Authors

Ioana Ursu, Mapping Health Ltd
Viktoria Rabovskaja, Social Protection Program, GIZ Indonesia

Cover Design and Layout

Bettina Riedel / briedel64@gmx.de

On behalf of

Federal Ministry for Economic Cooperation and Development (BMZ)
Division 304 - Health, Population Policy and Social Protection

Address of the BMZ offices

Bonn and Berlin / Germany

BMZ Bonn	BMZ Berlin
Dahlmannstraße 4	Stresemannstraße 92
53113 Bonn	10963 Berlin
Germany	Germany
T +49 228 99 535 - 0	T +49 030 1 85 35 - 0
F +49 228 99 535 - 3500	F +49 030 1 85 35 - 2501

Poststelle@bmz.bund.de
www.bmz.de

GIZ is responsible for the content of this publication.

