Good Governance for Medicines Programme
Country Case Study

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GGM Country Case Study

A. SUMMARY

The Malaysian health system consists of various stakeholders, the Ministry of Health (MOH), local government, the academic community, professional organizations, the private sectors and others. MOH works very closely with all these stakeholders to strengthen its health priority areas and is committed to fighting corruption at all levels. As the health system develops, greater emphasis has been placed on enhancing service delivery, scope and quality of health care, and collaboration in health care services between public, private and NGOs.

A strong pharmaceutical system is already in place and the GGM programme was introduced to complement many other governmental initiatives to increase transparency in the health systems.

Enhancing transparency and improving perception on integrity will ensure a more transparent and accountable pharmaceutical program. Improvements in the administrative procedures to increase transparency in the Pharmaceutical Services Division are ongoing as a matter of policy. These achievements are further complemented by the other initiatives taken by the government which are really in line with the objectives of GGM.

GGM in Malaysia is currently in Phase III and is institutionalized in the ministry of health and adopted by the Malaysian Pharmaceutical Services Division through the formation of a GGM steering committee and a GGM implementation committee. The GGM framework was developed in line with the National Integrity Plan. Activities designed to increase awareness of the potential for corruption in the pharmaceutical sector have been conducted, including seminars, workshops, and awareness campaigns. A series of brochures on integrity have been issued for all public servants and an audit value management system has been put in place.

The next step is to have further collaboration and networking with the other agencies working towards transparency, integrity and anti-corruption initiatives and produce integrity plan for the Pharmacy Program.
Malaysia is a fast developing country in South East Asia with a total area of 329,750 sq km. Its estimated population is 28.31 million, with a young population below the age of 15 years constituting 32%, while those aged 15-64 years accounting for 63.6% and those 65 years and older are about 4.4%. Life expectancy at birth for both genders has increased over the years; rising from 56 years for males and 58 for females in 1957 to 71.7 years and 76.5 years respectively in 2007. Since Independence in 1957, the Malaysian government had introduced various programmes, aimed at enhancing good moral values and integrity in the public service. More focused efforts on the promotion and implementation of concepts of 'Clean, Efficient and Trustworthy', 'Integration of Islamic Values,' 'Excellent Work Culture,' 'Code of Work Ethics,' 'Client's Charter' started in the eighties. In addition, the government focused on various quality improvement initiatives such as quality assurance programme, quality management system and using key performance indicators (KPI).

Public officials are governed by the General Orders for Civil Servants (Conduct and Discipline) of 1993. For example, under section 8 of the General Orders, public officers and their spouse or family members are prohibited from receiving on his/her behalf whether directly or indirectly, all forms of gifts. Also, any person who joins the public service is asked to sign the Letter of Undertaking [Aku janji] and must declare any assets every 5 years or every time there is a new property/assets. In addition there are several codes of conduct for the professional bodies in the country including pharmacists.

Malaysia had taken serious efforts to compact corruption. The government established the Anti-Corruption Agency that was formed in 1967 and just in 2009 become a full Commission. The Malaysian Anti-Corruption Commission (MACC) (formerly Anti-Corruption Agency (ACA)) is a government agency that investigates and persecutes corruption in the public and private sectors. The agency is currently under the Prime Minister's Department. There are five independent bodies that monitor the MACC to ensure its integrity and to protect citizens’ rights.

Establishment of other agencies such as the Public Complaints Bureau (PCB) and the Auditor General Department are further steps to strengthen integrity, accountability and transparency. The PCB was established in 1971 as a channel for the public to lodge official complaints against government
departments, agencies and the civil servants. It is also under the Prime Minister’s Department and is
supervised by the chief Secretary to the government. The Malaysian Administrative, Modernisation and
Management Planning Unit (MAMPU) under the Prime Minister’s Department initiated change in the
government’s administrative system to ensure the implementation of a modern, competent and effective
public service while PEMUDAH is a public-private sector initiative aiming towards improving the public
delivery system.

Measurable benchmarks and key performance indicators had been identified by the Malaysian
government and various agencies and ministries including the Ministry of Health to grade the various
agencies in terms of performance, accountability, transparency and level of service delivery and these
include Star rating system introduced by MAMPU and the accountability Index.

The Integrity Institute of Malaysia, an autonomous body, was registered on the 4th March 2004 under the
company’s Act to to ensure that all the planning, implementation, coordination, monitoring and
evaluation related to implementation of National Integrity Plan (NIP) are carried out. The government had
formulated the National Integrity Plan (NIP) and launched it on the 23rd April 2004, to coordinate all
sectors in the country for the enhancement of integrity as a way of life among the people and to develop a
nation that is of high integrity, resilience and that embraces universal good values. In Malaysia, the 5th of
November is declared as the National integrity day. It is mandatory to set up Management Integrity
Committee (JKP), aimed to enhance the integrity of Government management at Federal, State and
District levels.

In Malaysia, health services are provided by both public and private sectors.
The total health expenditure was RM8.21 billion (US$2.6 billion) (2.9% of GDP) in 1997 and has been
growing steadily to reach RM35.15 billion (US$11.2 billion) (4.8% of GDP) in 2008.

The Ministry of Health is the largest contributor to the total health expenditure spending RM13.04 billion
(US$4.16 billion) (37.09%), followed by out-of pocket, RM10.80 billion (US$3.5 billion) (30.73%).
Other contributors spend as follows: all corporations (Other than health insurance) RM4.78
billion (US$1.5 billion) (13.60%), private insurance enterprises (other than social insurance) RM2.97
billion (US$0.9 billion) (8.44%), other federal agencies (including statutory bodies), RM1.58
billion (US$0.5 billion) (4.51%), Ministry of Higher Education (since there are 3 hospital Universities
under Ministry of Education, these hospitals are attached to the Universities), RM1.05 billion (US$0.33
billion) (3.00%) and others RM0.92 billion (US$0.29 billion) (2.63%).
The Malaysian healthcare system in general is faced with some challenges like the changing demographics with a growing middle-class and the escalation of health expenditures, as well as the rising expectations of the health care system.

Some of the challenges experienced by the pharmaceutical sector in particular include increasing cost of drugs and medical supplies, and the quality perception of generic products. Long-term financial sustainability of the public system is a constant concern as most drugs are currently supplied free of charge to patients in MOH facilities. Total public drug expenditure is RM1.8 billion (US$0.57) out of total Ministry of Health budget 12.9 billion (US$4.12) for 2008.

Nevertheless, the Government is very committed towards strengthening the healthcare system and continues to seek greater integration, enhancement in the quality of service provided and optimisation of resources. Recently, the Prime Minister launched the Government's Transformation Programme GTP for fighting corruption and focusing on the three areas most prone to corruption, namely the regulatory and enforcement agencies, government procurement and grand corruption (including political corruption). One of the core values of the (GTP) is integrity which is indeed an important concept in the GGM programme.

The case study will describe the process of initiating GGM in Malaysia and the implementation of phase I, II, & III, the main findings, the successes as well as the constraints that were faced.
C. GGM IMPLEMENTATION

The concept of GGM was first introduced in Malaysia when the Secretary General of Health received a letter dated 30th June 2004, from WHO. Later, the Pharmaceutical Services Division was requested to nominate 2 pharmacists from Universities to undertake the assessment in 16th July 2004 again by an official letter from WHO.

Malaysia is one of the first 4 Asian countries to adopt and participate in the GGM program.

Concurrently, the Malaysian Institute of Integrity was formally registered in March 2004, to look into the integrity and good governance both in public and the private sector. GGM program introduction was seen as a complementary on the ongoing initiatives and processes towards promoting transparency and integrity.

GGM program is considered to be a contributing factor to the on-going improvements in the administrative procedures and to the continuous efforts to increase transparency and integrity among staff in the Pharmaceutical Services.

The WHO GGM 3 – step model was adopted and followed. The assessment was carried out using the instrument provided by the WHO and the development of the GGM framework was based on the WHO Model framework and the National Integrity Plan (NIP) which was already in place. One of the goals of the NIP is to fulfil the fourth challenge of Vision 2020, namely, "to establish a fully moral and ethical society whose citizens have strong religious and spiritual values and imbued with the highest ethical standards".

The GGM program is confined within the Pharmaceutical Services Division and is considered as a sub-committee of the Management Integrity Committee at the Ministry of Health since the terms of reference of the 2 committees are very similar. The Management Integrity Committee is chaired by the Secretary General of Health and consists of all the program heads in the ministry of health, such as senior director of pharmacy, medical program head, public health programme head, finance programme head etc. This was the first step towards the institutionalization of GGM within the Ministry of Health current structure.

The Malaysian government initiatives started before the GGM came to Malaysia and had been accepted by all (private and public sectors) and when GGM came, it blended into the system easily.

2. Key milestones

See annex 1.

3. Report on main activities
a) **Transparency assessment results**

The English version of the assessment instrument was used, since English is considered as a second language and is very widely spoken in Malaysia. The assessment instrument included 3 sections at the time: Registration, Selection and Procurement.

The nominated assessors were both pharmacists, one a lecturer at a local University and the other one was a staff at the Pharmacy Programme at the Ministry of Health who was doing a PhD in 2004-2005.

The assessment was done within the Ministry of Health facilities, where 10 key informants were chosen for each section of the assessment. The key informants included 19 pharmacists from the Ministry of Health, five pharmacists from the private sector, three physicians from the Ministry of Health and one physician from the private sector, one representative from an NGO and another public service officer. They were all selected from 5 out of 14 states in Malaysia. The assessment was conducted between January and April 2005. The assessment provided qualitative and quantitative information on the level of transparency present in the three functions of the public pharmaceutical sector.

The assessors reported that they had difficulty in obtaining relevant supporting documents.

The major findings of the assessment can be summarized in the strengths and weaknesses listed below for each section of the assessment:

**For Registration:**

There is a list of all registered pharmaceutical products and an information system for the registration process of the pharmaceutical products. A publicly accessible written procedure on how to submit and assess applications for registration of medicines products along with a standard application form for submission of applications are publicly available at the website of the ministry: www.bpfk.gov.my. There is a formally established and an operational committee responsible for registration of pharmaceutical products which function according to a well defined mechanism regarding providing official written reports for all decisions of registration applications, explaining the reasons for rejection if it takes place. The principle weaknesses in the area of registration are the absence of a written document that describes clearly the registration committee’s terms of reference and a conflict of interest (COI) forms that members of the committee and public officials are obliged to sign. The registration function was found to be marginally vulnerable to corruption based on the assessment scores.

**For Selection:**
There is a National Essential Medicines List (EML) (MOH Drug Formulary) that is available on the following website: www.pharmacy.gov.my. This list was developed based on criteria for the selection process for including and deleting medicines from the MOH Drug Formulary that is clearly written and only available within the MOH Institution but not available publicly. The selection process follows transparent procedures that are in line with WHO recommendation, such as listing the medicines by their generic name. Same as in registration, there is no conflict of interest (COI) form that members of the committee and public officials are obliged to complete and the criteria of MOH Drug Formulary Selection Committee is not publicly available. In addition, at almost all levels of the procedure, information and decisions are not made available to the public.

The selection function was found to be moderately vulnerable to corruption.

For Procurement:

In Malaysia, the Procurement system is controlled by the Ministry of Finance’s directives and there are transparent procedures in place for competitive procurement of pharmaceutical products that are available on www.treasury.gov.my. The procurement is done based on an objective quantification method to determine the quantity of pharmaceutical products to be purchased by ministry of health. There is a well established clear procedure to ensure that payment is linked to drug delivery. In addition, post tender monitoring and reporting of suppliers’ performance is followed. There is no formal appeal process after the final decision for applicants who have their bids rejected, however early at the tender process, if the specifications of a particular product are found to be “leaning” towards a particular brand, at that stage competitors have the right to complain and request the MOH to call for a new tender with new specifications. The Audits of procurement offices are not conducted by independent auditors. There is no Lot quality testing, as part of procurement procedures that is carried out at the receiving level. The MOH has assigned specialists from various fields and pharmacists from public health facilities as members of the tender committee, but key informants found no indication of the length of service. But in fact, usually there is a time limit in the appointment letter but KIs did not know about it.

The reporting of product problems and account-keeping are left to the purchasing hospitals and health centers. The informants reported that there seem to be no product records, no proper monitoring of suppliers and facility performance, and no quality assurance record. Again, this was the perception of the KI, actually there are such reports as most hospitals are accredited or are ISO certified.

The assessment showed that the procurement function is marginally vulnerable to corruption.

After the conduction of the assessment, the assessors set several recommendations among which is to revisit the current practices of pharmaceutical registration, selection and procurement, and take concrete measures to improve and address the shortcomings found in the assessment. Also, it was recommended to
initiate a culture of declaring any ‘Conflict of Interest’ by signing a document addressing the possible ethical dilemmas, to make information available for public viewing, to allow appeal to ensure better transparency of the procurement process and to enforce accountability of people in charge of decision-making process. Concrete measures need to be taken to correct misperceptions on the responsibility and authority of committees. As a result of the assessment, it was found that there is a need to conduct programmes to enhance public awareness on the implementation of pharmaceutical services and understanding of the laws pertaining to the pharmaceutical registration in Malaysia. Need to create an independent body to vet information on drugs and relay this to the various committees involved in the registration, selection and procurement of pharmaceuticals. For procurement in specific, it was recommended to have a computerised management system that incorporates performance of suppliers and quality of products and services, to perform lot quality testing as part of the procurement routine process and to conduct an annual audit for the procurement unit to help improve work processes to minimize flaws.

The Pharmaceutical Services Division at the Ministry of Health did not agree with some of the recommendation made and elaborated on what was identified as a weakness in the assessment.

Some of the clarifications came as follow:

i) The composition of the selection committee is available on the website of the Pharmaceutical Services Division, Ministry of Health Malaysia but without the names of the members. The members are appointed for 2 years subject to renewable based on members’ contribution to the work of the committee. The names of the selection members are not made public and should not be made public to avoid trials of companies to lobby with the officers in charge.

ii) Only the final list and a summary of the essential medicine list is made public and is being uploaded on the website. While the decision making process need not be made public, since the decision of the selection of medicines is for the use of institutions inside the Ministry of Health

iii) There is a formal appeal mechanism including procedures and processes in place at the Procurement and privatisation Division inside the Ministry of Health and not within the Pharmaceutical Services Division.
iv) The Pharmaceutical Services Division strongly believe that there is no need to perform Lot Quality Testing as a routine process of procurement. There are many reasons for this; Malaysia is considered to have a well developed drug regulatory system. The Pharmaceutical Services Division is a WHO Collaborating Centre for Drug Registration and a member of Pharmaceutical Inspection Collaboration Scheme [PIC/s]. Products that are bought by the MOH are products that are registered by the regulatory authority, the Drug Control Authority (DCA). The DCA has a post market surveillance and pharmacovigilance system well structured in place. The receiving institutions check physically the items received for expiry dates and quantities as these are essential for payment processing.

The assessment has succeeded in highlighting the operating structures and processes of the current pharmaceutical system that are prone or vulnerable to corruption.

As a result of the assessment, the COI form had been enforced since 2008. Now most of the important committees members at the Pharmaceutical Division are asked to fill and sign such form. Transparency is enhanced since most of the relevant information can be found at www.pharmacy.gov.my, www.bpfk.gov.my, www.moh.gov.my and other websites. Updating procedures and processes is an ongoing process. Information are made available at the ministry website, such as the list of the essential medicines, medicine registrations forms and the results of the tenders that are posted. In addition, some services are offered online including the registration of medicines.

b. Development of the GGM framework or strategy

A workshop on ethical practices in medicine was held in December 2005 that was organized by the University of Technology Mara (UiTM), where one of the assessors lectured. It was an echo of the WHO regional workshop held in Penang earlier. Pharmacists from the Ministry of Health and academia attended this workshop. During the workshop version 1 of the framework was produced focusing on the 3 pharmaceutical functions of registration, selection and procurement.

A GGM steering committee including members from university, Procurement department in MOH, Audit department, and the major units in the pharmaceutical services, namely Pharmacy Practice and Development, Enforcement, Drug Regulatory Authority was formed at the Pharmaceutical Services Division in September 2006, and the first task of the steering committee was to discuss the results of the assessment. In April 2007, the Pharmaceutical Services Division organised a 4 1/2 days workshop to
further develop the framework for the GGM. Presentations were given at the beginning of the workshop by the two assessors, a representative from the Malaysian Institute of Integrity and the secretary of the steering committee.

35 participants attended the workshop; they were mainly pharmacists from the MOH hospitals from all over the country, and pharmacists involved in the registration, selection, procurement, inspections and advertisement regulations. At the end of the workshop the ethical framework version 2 was produced. The ethical framework was based on the country assessment results, WHO Ethical Framework for Good Governance in Pharmaceutical Sector and the National Integrity Plan of Malaysia.

The ethical framework was edited and reviewed several times before it was finally published in November 2009. The framework is yet to be presented to the MOH Management Integrity Committee at the Ministry level for final approval.

The key components included in the framework were the moral values, ethical principles and the “do’s and don’ts” for the 5 areas in the pharmaceutical sector namely registration, selection, procurement, inspection and promotion.

c. Implementation of the GGM programme

Malaysia is currently in Phase III of the Good Governance for Medicines project. A GGM implementation committee was created in January 2009 to socialize and promote the GGM framework developed.

The GGM implementation committee had decided that the implementation of GGM by the Pharmaceutical Services Division will be only within the pharmacy program, while the Ministry of Health (MOH) Management Integrity Committee works for strengthening the integrity and governance of the administration management in the Ministry of Health as a whole. The terms of reference for the GGM implementation committee and the steering committees were revised in order not to contradict or overlap with the MOH Management Integrity committee.

Since, there is a need to promote integrity and good governance among pharmacy staff and rectify the loopholes that make the regulation and supply systems vulnerable to corrupt practices/conflict of interest, various seminars, workshops and awareness campaigns on integrity and good governance had been carried out throughout the country by various hospitals and institutions alone or in collaboration with other agencies like Institute Integrity of Management, IKIM(Institute of Islamic understanding Malaysia),
MACC(Malaysian Anti-corruption Commission), INTAN(Malaysian public sector Institute. The Public Service Department/civil service had also been issuing brochures titled ‘My Integrity’ series to all public servants. (To see the brochures, please refer to: http://www.agc.gov.my/index.php?option=com_content&view=article&id=12&Itemid=689&lang=en).

An audit value management system had been implemented to evaluate the effectiveness of the various programmes introduced to infuse ideal values within the public personnel since the eighties. The evaluations consist of set of questionnaires based on organization, personal and ideal values that can be answered and done electronically (please refer to http://www.interactive.jpa.gov.my/auditnilai/).

The first task the GGM Implementation committee undertook was to hold a workshop in August 2009, to develop or summarise available guidelines on:

• Conduct pertaining to giving and receiving gifts/sponsorship etc
• Dealing with the representatives from industry/ promotional talk
• Academic Detailing

It is worth mentioning that the funding of the GGM from the beginning was internal, namely from the Pharmaceutical Services Division at the Ministry of Health

D. LESSONS LEARNT

• Key Barriers:
• The main barrier encountered was the presence of many stakeholders of the Pharmaceutical system that are not limited to the Pharmacy program alone but others from within as well as outside the Ministry of Health. The other programs within the ministry of health are independent and the Pharmaceutical Services/Pharmacy Program has no control or power over them. If GGM to be expanded horizontally to other programs within the ministry of health, then the management Integrity committee will be the most suitable body to achieve that. **Key Successes:**

In Malaysia the GGM program is considered a success story due to many contributing factors. A well established pharmaceutical system is already in place, thus, enhancing transparency will ensure a more transparent and accountable pharmaceutical program. The existence of an internal control system that is comprised of internal audit activities, compliance to work procedures, and enhancing accountability and integrity had helped in increasing the effectiveness and transparency of the administration.

All important documents are published on the website. The Malaysian National Medicines Policy was published since 2006. The policy is focusing on ensuring safety &quality, affordable prices and increasing access to medicines. MOH Drug Formulary is updated 3 times per year and the updated list is available on the website along with the updated Essential Drugs list. The price monitoring bulletin is also publicly available since the price monitoring process for medicines had started in 2006. The registration of medicines is all done online.

Other successes seen in the country; a one stop center was established to receive complains in addition to the national call centre at the Kuala Lumpur hospital and the pharmacy information center in every hospital. Declaration of conflict of interest had been enforced for Drug Control Authority members of drug registration, Medicines Advertising Board Members and the Drug Review Panel members responsible for the selection process for the national formulary. All public servants in Malaysia have to sign declaration /COI once join public service employment. This step was initiated due to GGM.

Other ministries and organizations in the country are joining efforts to fight corruption. Details of all government procurement contracts and tenders are disclosed on the websites of all ministries and agencies and on the e-government portal.

Another example, the Ministry of Finance tender portal, known as Myprocurement is also working on improving the public’s perception on its efforts to fight corruption. The treasury had also enforced the integrity pact in all government procurement. The Whistleblower Protection Bill 2010 had been recently passed in the Parliament. All this lead to the decrease in the number of public servants accused of
corruption in the past three years due to increasing awareness on integrity and increasing online services had also improved transparency.

This success was not due to GGM alone, but is an ongoing policy by the government of Malaysia.

Another contributing factor is the Government Transformation Programme (GTP) which has 2 major objectives. First Objective is to transform the government to be more effective in its delivery of services and accountable for outcomes that matter most to the people. Second objective is to move Malaysia forward to become an advanced, united and just society with high standards of living for all. This is in-line with the national mission of achieving vision 2020- for Malaysia to become a fully developed nation.

- Future Directions

Continuous, consistent and strong political will in combating corruption is very important to ensure future success. There is a need to strengthen collaboration and networking with the other agencies working towards transparency, integrity and anti-corruption initiatives to produce a unified integrity plan for the Pharmacy Program. Training modules on good governance in medicine should be developed targeting staff in the pharmacy programme so that integrity and ethical values are well promoted. Use of technology driven reporting should be encouraged while ensuring anonymity if necessary, and greater self auditing should be instituted. Research on integrity in the community should be encouraged for better understanding.

References:

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6. Health Fact 2008, Malaysia
7. Measuring Transparency in Medicines Registration, Selection and Procurement, four country Assessment Studies, WHO, 2006
8. Speech by the Director General of Malaysian Anti-Corruption Commission, during the campaign to fight against corruption, 26th April 2010
9. Talking points by the Director General of Malaysian Anti-Corruption Commission to Associated Chinese Chambers of Commerce and Industry of Malaysia, 5th May 2010
10. BG indicators, DUNAS 2009 report, Pharmaceutical Services Division, Ministry of Health Malaysia

Acknowledgments

1. The GGM Steering Committee Members
2. The GMM technical / implementation Committee Members.

Annex 1

<table>
<thead>
<tr>
<th>Key milestones</th>
<th>Dates</th>
<th>Comments</th>
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<tr>
<td>Phase I: National assessment of transparency and potential vulnerability to corruption.</td>
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<td>• Official letter MOH supporting transparency assessment</td>
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<td>• Official letter MOH nominating national assessors</td>
<td>17/8/04</td>
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<tr>
<td>• 1st interview</td>
<td>January 2005</td>
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<td>• last interview</td>
<td>April 2005</td>
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<tr>
<td>• 1st draft transparency assessment report submitted to WHO</td>
<td>April-June 2005</td>
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<td>Phase II: Development of a national GGM framework.</td>
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<td>Event</td>
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<td>1st national GGM workshop</td>
<td>December 2005</td>
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<tr>
<td>1st draft national GGM framework document</td>
<td>December 2005</td>
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<tr>
<td>Nomination of GGM team (s) for phase II</td>
<td>September 2006</td>
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<td>*Formation of GGM steering committee</td>
<td>January 2007</td>
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<td>*Formation of GGM working team to develop GGM framework</td>
<td>January 2007</td>
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<tr>
<td>Workshop to draft GGM framework</td>
<td>April 2007</td>
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<tr>
<td>National GGM framework officially adopted</td>
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<td>Framework published November 2009</td>
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**Phase III: Implementation of the national GGM programme.**

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<th>Event</th>
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<td>GGM team for phase III created/nominated to socialize and promote the national GGM framework</td>
<td>January 2009</td>
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<tr>
<td>Training of GGM team members</td>
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<tr>
<td>1st monitoring and evaluation report</td>
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