

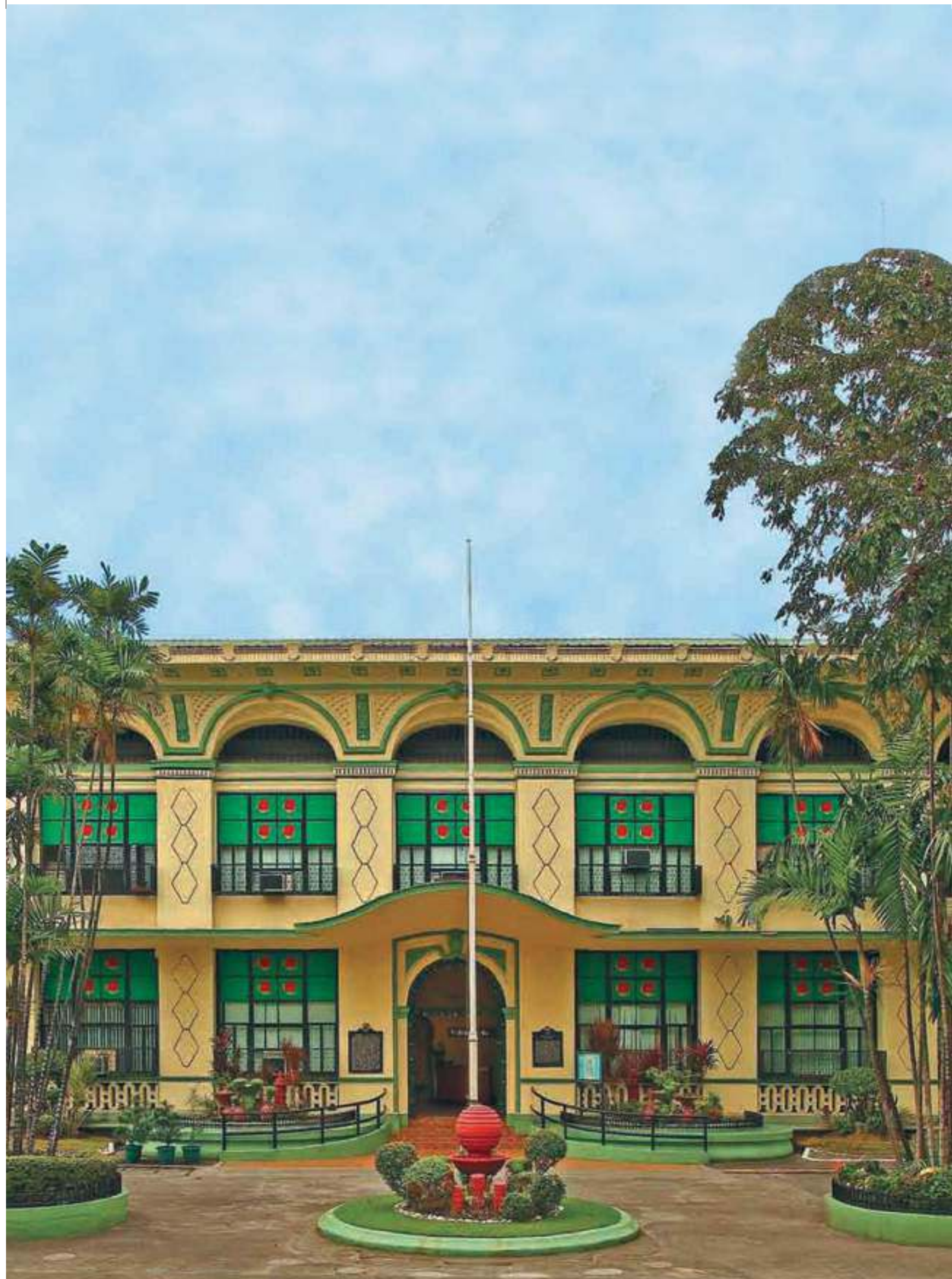


GENERIC @ 25

(1988-2013)

CHAMPIONS
CONQUESTS
CHALLENGES





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MESSAGE

1988 saw the enactment of a landmark legislation that promised to provide greater access to quality drugs and medicines at the lowest possible price to the Filipino people. 25 years later, we bear witness to the transformation engendered by the Generics Act of 1988: a vibrant local pharmaceutical industry and improved quality of life for families previously unable to shoulder the financial burden of prescription medications.

I extend my congratulations to the Department of Health for chronicling this critical moment in our journey towards Universal Healthcare. *Champions, Conquests, Challenges: Generics @ 25* tells the tale of our solidarity in building an inclusive, revitalized Philippines: Where no Filipino is impoverished by healthcare costs and denied a dignified, productive life.

We in government remain committed to implement the Generics Act through our continuing partnership with the DOH-Pharmaceutical Division, Food and Drug Administration, PhilHealth, and local government units, along with our industry partners, civil society, and all other stakeholders. We ask for your continued cooperation; with our synergy, I am confident that we can reach out to the broader public, raise consumer



BENIGNO S. AQUINO III
President

Republic of the Philippines





MESSAGE

Twenty-five years ago, a policy was enacted that has proven to be the landmark legislation for reforms seeking equitable, affordable, and quality health care for all Filipinos. It was with foresight and perseverance, often courage that we pursued the passage of the Generics Act of 1988 or RA 6675, an act that rolled back the cost of drugs for Filipinos.

Two and a half decades journey of standing on our call to promote generic drugs use and ensure the adequate supply and distribution of drugs at the lowest possible cost where full of challenges. Yet, the fight has been very vital. As we review the progress of the implementation of the health sector reforms through Kalusugan Pangkalahatan, let us carry on and improve further in providing universal medicine access and coverage, promoting rational use of medicines, and promoting the use of generics.

I would like to extend our heartfelt gratitude to the local government units led by our dedicated local chief executives (LCEs), the development partners, the support in realizing the vision of making medicines accessible to our citizens through the implementation of the provisions of the Generics Act.

To all the leaders and members of the Pharmaceutical Division (PD), I urge you to continue to pursue excellence in every aspect of your work. Together, let us contribute to the betterment of the health sector, and the nation — in our pursuit of Universal Health Coverage by 2016.

It has been a fruitful twenty-five years of implementation. Much has been achieved but we still have a long way to go. Our efforts and accomplishments may not lead to immediate results and success, but for as long as the call for a committed and responsive DOH remains, we will endure and persevere until we finally witness the fulfillment of our goals.

To God be the glory! Thank you and Mabuhay!



MADELEINE ROSAS-VALERA, MD, MScIH (Heidelberg)

Undersecretary of Health

Health Policy Finance and Research Development Cluster

FOREWORD

I would like to extend my felicitations to my colleagues at the Department of Health as we mark 25 years of steadfast commitment to provide quality and affordable medicines for all Filipinos, with the enactment of the Generics Acts of 1988.

Pharmaceutical expenditures, as reflected in the analyses of various Family Income and Expenditure Surveys (2000 - 2009) comprise that almost 66% of the total out-of-pocket health expenditure of an average Filipino family, where a big chunk goes to expenses on drugs.

Cognizant of the impoverishing effects of the exorbitant costs of medicines, specifically in the Philippines where it is more expensive than in other Asian countries, the national government pursued the enactment of laws specifically the Cheaper Medicines Act and an Executive Order requiring maximum retail prices for a number of drugs all aimed toward improving accessibility to affordable quality medicines.


The Department, performing its regulatory function, has facilitated the enactment of the Generics Law of 1988, a milestone for the country in providing the Filipino people with universal access to medicines and quality health care, in line with the health agenda of Kalusugang Pangkalahatan.

As we strive to further improve the safety and quality, access and availability, and rational use of medicines, we continuously strengthen education and advocacy campaigns to increase local acceptability of generic medicines.

We hope that this Coffee Table Book entitled, **“CHAMPIONS, CONQUESTS, CHALLENGES: Generics Act @ 25”**, will capture the essence of Generics in the Philippine drug industry. Also, may this inspire the administrators and staff of the Pharmaceutical Division (PD) to stay committed to its mandate to improve access to medicines.

Together, let us work to overcome this challenge and have our efforts continuously directed towards serving the Filipino people.

Congratulations and Mabuhay tayong lahat!



ENRIQUE T. ONA, MD
Secretary of Health





Miting de Avance

ATIONALIZATION OF THE GENERICS ACT OF 1988



THE REVOLUTIONARY YEARS





HON. ALFREDO R.A. BENGZON
Health Secretary
March 1986 - January 1992

THE FATHER OF GENERICS

When he was designated by the late President Corazon as the Health Secretary after the People Power Revolution, it was the first time Dr. Alfredo Bengzon assumed a position in the government. From then on, he was no longer just a neurologist confined to curing individual patients. He had become a health leader and a nation-builder. He described the seven years he served as the Secretary of Health as the most fulfilling period of his life.

Dr. Bengzon believed that it was a part of the Health Secretary's job to look for true heroes. "We are so busy trying to copy the Americans instead of looking inwards to discover the giftedness of the Filipino," he said. A turning point in his career was when he met Bing Magala, a midwife stationed in a remote barangay health center in Abra. She lost a kidney, parts of her intestines and a four-month pregnancy in a crossfire between rebels and the military.

When Dr. Bengzon asked why she continued to do her work despite her harrowing ordeal, she said she had to take care of the people and the health center. When she died in 1994, it was no longer a surprise to Dr. Bengzon to find out that she drowned while crossing the Abra River, carrying a backpack of vaccines.

Until today, he recalls this story with misty eyes because through the story of Bing Magala, he said, "I discovered a country and people I thought I knew."

In the first three months of his term, he spent most of his time talking to the people in the DOH to learn about their work and responsibilities. He would regularly meet with former President Corazon Aquino to give progress reports and plans in changing the healthcare system.

Looking back, he said there were two things he learned from his 88-year-old father who had worked in three branches of the government: patience and service. From his experience, he said it was possible to bring different interests and perspectives into coherence, provided there was a common understanding of what bound people together and there was discipline to do the job. It was also essential to have the audacity to formulate reforms and enforce them.

Dr. Bengzon graduated from the Ateneo de Manila University in 1956 with the Bachelor of Arts degree. He finished his Doctor of Medicine degree from the University of the Philippines and completed his Masters in Business and Accountancy from the Ateneo Graduate School of Business in 1972.

His long and distinguished career as a neurologist was also complemented by his stints as a peace commissioner when he was vice-chair of the Philippine Negotiating Panel for the US Military Facilities during the presidency of Corazon Aquino. In 1991, he was conferred the Ramon Magsaysay Award for Government Service.

Dr. Bengzon is currently vice-president of the Ateneo de Manila University Professional Schools, dean of the Ateneo School of Medicine and Public Health, dean emeritus of the Ateneo Graduate School of Business, and president and CEO of The Medical City.

THE FIGHT FOR CHANGE

Dr. Alfredo Bengzon described the courage of the Filipino people who took pains in setting up a new-found democratic government after the People Power Revolution as the power transformation that made the Philippines the first country in the world to stand up to the realities of their circumstances and to have understanding of themselves as individuals and as a country.

Indeed the immense job of revolutionizing the healthcare system and structure took him to task upon his assumption into office, first noticing the unethical and corrupt process of policy and procurement marked by anomalous purchases and substandard medicines.

“The crisis loomed large, and it was the huge reason why medicines were not accessible. Medicines are very central to health and yet for many Filipinos at that time, they were not available,” he lamented.

Eventually, there was a creation of a command structure, a nucleus group to attend principally to the drug industry. He said that “Process” and “People” were the two essential concepts in formulating the *National Drug Policy (NDP)*. These concepts were used to develop the four pillars of the *NDP*: *QRST* - *Q* for *Quality Assurance*, *R* for *Rational Drug Use*, *S* for *Self-reliance*, and *T* for *Targeted Procurement*. The letter *P* was eventually added to stand for *People Power*, Dr. Bengzon said that the *NDP* was a result of the restoration of democracy that focused on people’s rights and their quest for quality of life. The *NDP*’s pillars were independent but mutually reinforcing, and they articulated the Filipinos’ right and responsibility to health. These pillars became the bases of the creation of the *Generics Act of 1988*.

“We made generics labelling become a reality. We took the challenge to the pharmaceutical industry which is a global power and it worked,” he said. The law also empowered patients to embrace their right to ask questions from the medical professionals.

In those years when the law was beginning to be implemented, Dr. Bengzon said he stood strong amid the scars that he got going against the lobby of big industry and even a resistant medical association who disapproved of the Generics Law.

“My scars are like medals,” he declared proudly, stressing that, “When you work in the government, acting as regulator is one of your critical responsibilities, and if you are not willing to be scarred, you have no business being there.”



Members of the first National Formulary Committee chaired with Dr. Estrella Paje-Villar (center right) as the first Chair in 1998.



Secretary Bengzon with the National Formulary Committee.



HON. ORLANDO S. MERCADO
The Author of the Generics Law
1987 - 1998

THE PRIMARY AUTHOR OF THE GENERICS ACT

As the primary author of the Generics Act of 1988, Senator Orlando Mercado credited the success of the passage of the law to the urgent need to provide Filipinos with affordable medicines and health care. This was topmost in his mind amid the relentless opposition from the multi-national drug companies and physicians.

Before serving the government, Mercado was a broadcaster of the Republic Broadcasting System while taking his Political Science course at the University of the Philippines where he also earned his Masters degree in communications and PhD. He later on became the anchor of the popular radio program, Radio Patrol of ABS-CBN, from 1969 to 1972. He also produced and hosted Kapwa Ko, Mahal Ko, the country's first and longest running public service program that helps the indigents from the different parts of the country.

Mercado's venture into politics started in 1984 when he ran in the First Regular Batasang Pambansa as an opposition member of the Parliament in Quezon City. He topped the May 14, 1984 elections and bested more seasoned politicians associated with former president Ferdinand Marcos.

He served as a senator for three terms, from 1987-1998. During his terms, he headed various Senate Committees on health and environment as well as science, trade and national defense.

Mercado was also known as the author of other groundbreaking health measures such as the Salt Iodization Law or RA 8172 which mandates the nationwide iodization of salt products to combat iodine deficiency. Another is the Blood Donation Act or RA 8180 which promotes voluntary blood donation and regulation of blood banks. He also authored the Barangay Health Workers Benefits and Incentives Act of 1995 or RA 7883.



President Corazon Aquino (center) signing the historical Generics Act into law on September 13, 1988.







POPULARIZING GENERICS





HON. JUAN M. FLAVIER
Health Secretary
July 1992 - January 1995

MR. LET'S DOH IT!

The energetic and cheerful Dr. Juan M. Flavier was perhaps the most popular Secretary of Health because of his engaging style of communicating with people. He was one of the writers of the Generics Act during his stint as Secretary of Health. He became a strong proponent of the Act from which millions of Filipinos benefit today. He even had a mascot, *Eric Generic*, as part of an effective media campaign to promote generics.

As Dr. Flavier continued the implementation of the Generics Act, he also introduced innovative approaches to healthcare such as Oplan Alis Disease, a massive immunization campaign and the Sangkap Pinoy, a nationwide campaign against micronutrient malnutrition.

During his term, the National Drug Committee underwent restructuring. The Philippine National Drug Formulary (PNDF) was also officially adopted as the basis of procurement of drug products in relation to the Philippine Health Insurance Act of 1995.

Always savvy in his health campaigns, he popularized upbeat slogans such as “Let’s DOH it” and the anti-smoking catchphrase “Yosi Kadiri”. He was known for transforming unpopular health programs into exciting promotional campaigns.

A former barrio doctor who believed in the healing powers of natural and traditional remedies for ailments, Dr. Flavier drummed up information on the country’s vast flora that have been effectively used as traditional medicines. He said that natural remedies were timely interventions to the majority of Filipinos who could not afford expensive drug treatments. He came up with *Botika Binhi and Botika sa Paso* which promoted planting and caring for medicinal plants.

During his term, local government units were still reeling from the birth pangs of the devolution of health services, but Dr. Flavier persevered in encouraging the private and non-government sector to participate in health care. He put in order the organization and fielding of barangay health workers for delivery of health care in the grassroots. His other health projects include the Healthy Places Initiative, STOP D.E.A.T.H. program, Oplan Sagip Mata, Hataw Fitness Program, Pusong Pinoy and Hospitals as Center for Wellness Program.

Because of his successful term as Secretary of Health, Dr. Flavier was popularly asked to run for Senate. He won and served for two terms. There he continued to be the champion of Health Agenda by pushing for reforms in health care delivery, health care regulation and health care financing. He authored and sponsored numerous landmark legislations such as the *Traditional Medicine Law*, the Poverty Alleviation Law, Clean Air Act and the Indigenous People’s Rights Act.



Secretary Flavio popularized the DOH slogan,
"Let's DOH it!"

Secretary Flavio speaking during a mission of Oplan Sagip Mata,
a program which provided free operations and services to address
the increasing rate of blindness in the country.





Government employees participate in the Hataw Fitness, a program launched to promote healthy lifestyle by participating in regular exercise, physical fitness, sports and recreation activities.

A patient being carried into an ambulance by STOP D.E.A.T.H. health care workers. STOP D.E.A.T.H. is an acronym for Strategic Tactical Option for the Prevention of Disasters, Epidemics, Accidents and Trauma for Health which was a strategy to consolidate resources and capacities of the DOH towards coherent and effective response during disasters and emergencies.



A MAN OF SERVICE BEFORE SELF

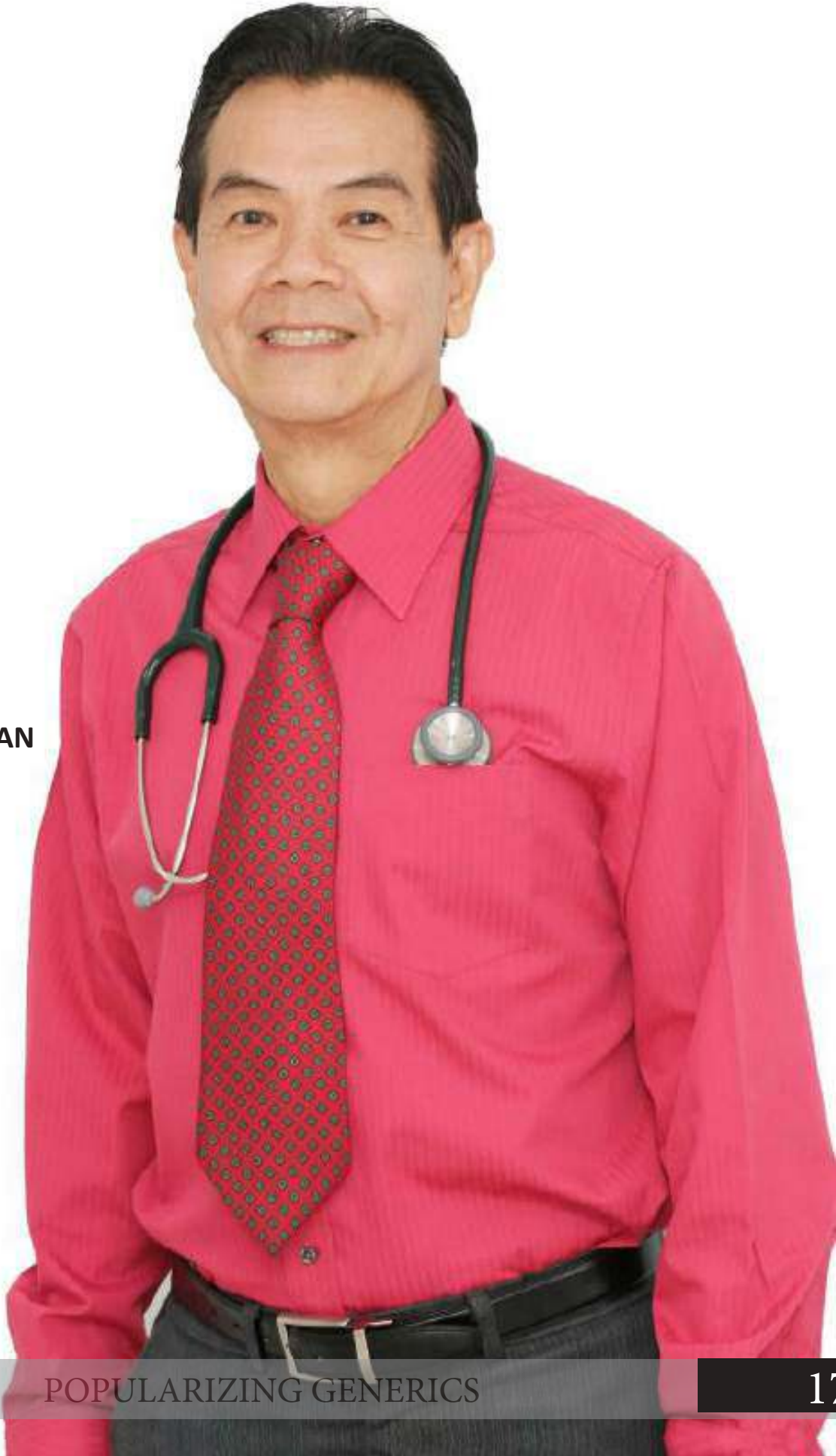
Dr. Jaime Galvez-Tan was an ardent advocate of traditional healthcare such as hilot, acupuncture, acupressure and herbal medicines because of his long working experience in grassroots communities in far-flung rural areas with no doctors, no electricity and rarely any transportation. He never gave in to the tempting lifestyle of other physicians and always believed that service should come first.

He continued the efforts to encourage the local drug industry to manufacture ingredients of medicinal plants into drugs that could be distributed and sold alongside medicines already available in the market. It was under his brief administration that a center for traditional healthcare was established.

His background in community work made it easier for him to campaign for generic labeling on medicines and for more affordable prices of drugs to poor Filipinos.

Doc Jimmy, as he was commonly called, also had expertise in various fields such as in national and international health planning and programming, national health policy development, academe and integrative medicine.

He founded Alay sa Ginawa at Kalusugan, which aims to strengthen the Philippine healthcare system through renovation of Barangay Health Stations, along with continuing professional education of health workers, in the poorest communities nationwide in partnership with the local government units and the private sector.

A portrait of a middle-aged man with dark hair, smiling. He is wearing a bright pink long-sleeved shirt, a red tie with a small dark pattern, and a black stethoscope around his neck. He is also wearing a black belt and dark trousers. The background is plain white.

HON. JAIME GALVEZ-TAN
Health Secretary
January 1995 - June 1995



Dr. Galvez-Tan during an operation of free tetanus toxoid vaccination, a part of the mass immunization program initiated by Sec. Flavio and continued by Dr. Galvez-Tan.



INNOVATION **AND REFORMS**





HON. CARMENCITA NORIEGA-REODICA
Health Secretary
March 1996 - June 1998

BEACON OF HOPE AFTER THE STORM

As the first woman health secretary, Dr. Carmencita Reodica provided a glimmer of hope amid the disarray left by her predecessor. Appointed by President Fidel V. Ramos who believed in a woman's power to effect change, Dr. Reodica's dedication to public service, transparency, personal integrity and moral courage became her guiding principles for the task. She endured a turbulent period of more investigations over questionable transactions and more resignations and suspensions of key health officials.

While she succeeded in regaining stability and morale within the DOH during her administration, the landscape of medicines offered another difficulty as the Generics Law continued to face resistance from multinational companies and the private sector.

Dr. Reodica made certain that the DOH's duty to provide informed choices on Filipinos about affordable and accessible generic medicines was among the priorities in the programs she initiated. She used the "people-based" approach to public health and created programs focused on specific target age and sectoral groups such as children, adolescents and women. Among these programs were Early Childhood Development, the Adolescent Health program, the Measles Elimination Campaign, the Integrated Management of Childhood Illness (IMCI) .

**Dr. Carmencita Reodica
administering an oral polio
vaccine to an infant.
She initiated various
key programs focused
on improving the health
of infants, children,
adolescents and women.**



A CHAMPION OF HEALTH REFORMS

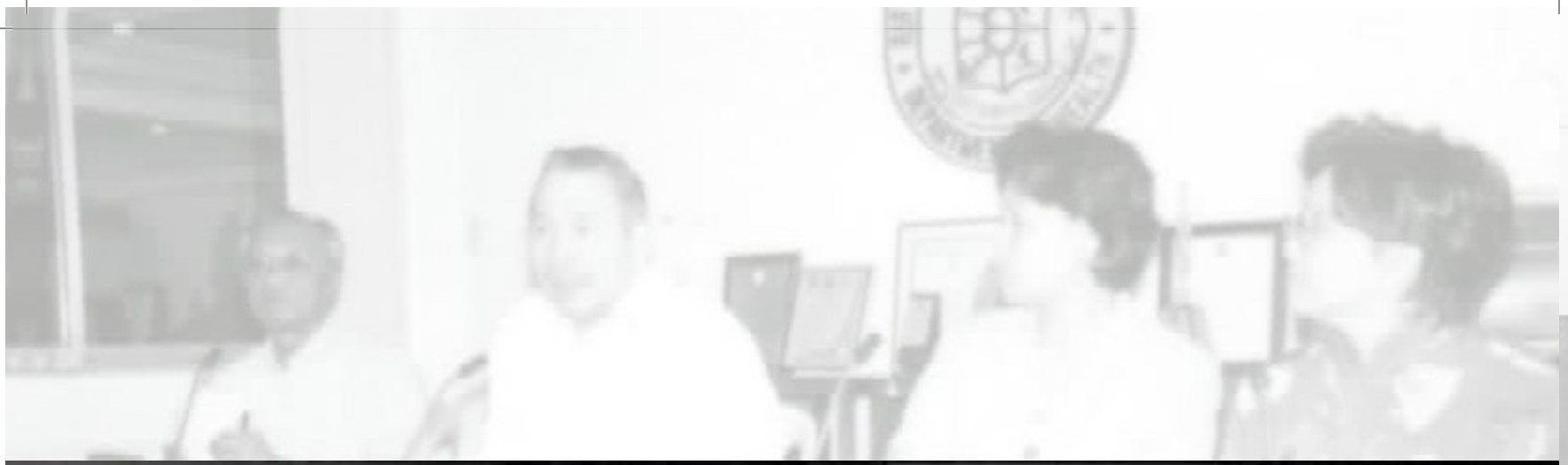
Dr. Alberto “Quasi” Romualdez, Jr. was among the leaders of health whose advocacy was reforms for the poor. He always fought for public health reforms particularly delivering universal healthcare to all Filipinos. One of his historic legislations was the Sin Tax Law of 2012. Amidst the aggressive opposition from the tobacco industry, he stood firm in making health the central framework of pushing for the law. Fueled by his unparalleled dedication to public health, he also played a crucial and instrumental role in the passage of other laws such as the Reproductive Health Law, PhilHealth Law and of course, the Cheaper Medicines Act.

When he took over as Director of the DOH, Dr. Romualdez lamented about the low compliance rate of hospitals and pharmacies nationwide to the Generics Law because its reinforcement was not given much attention by his predecessors. It was below 50% when he took over but he managed to raise it to more or less 80% by the time he left his post in 2001. Moreover, he strengthened the reinforcement of policies against substandard generic medicines which contribute to a weaker competition against prescription of branded medicines.

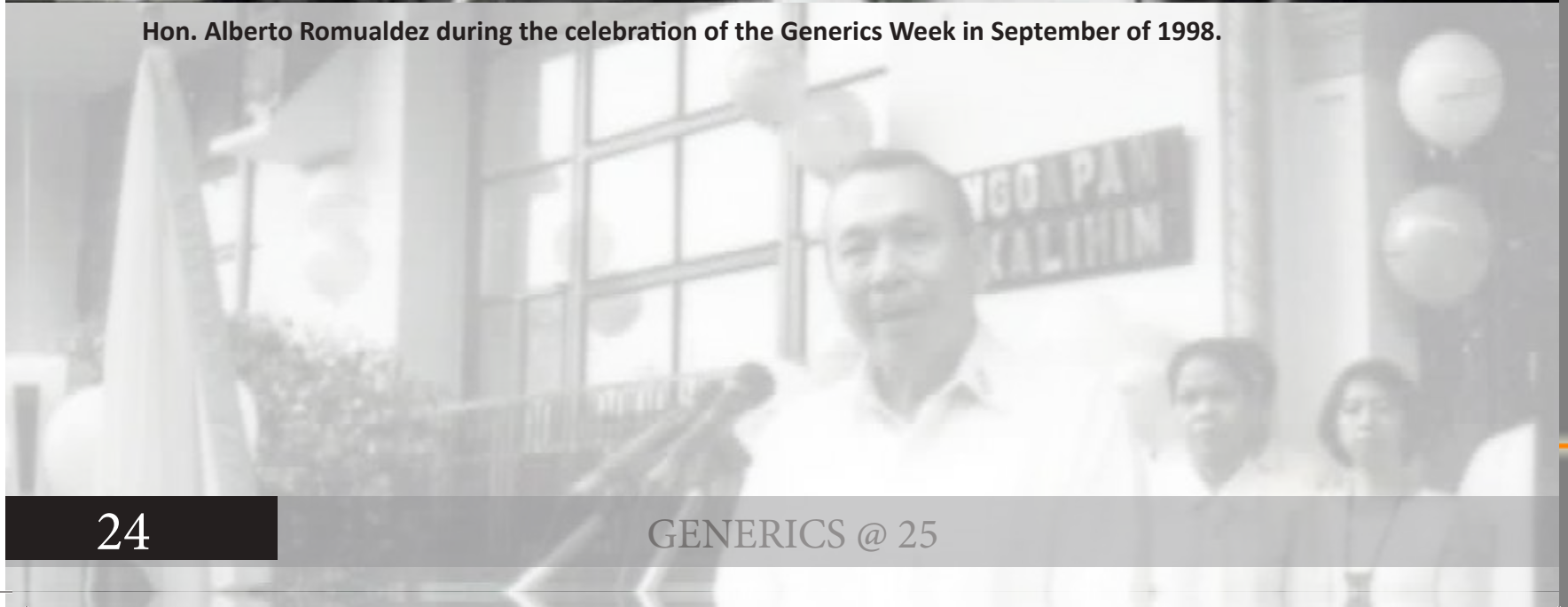
Not new to health policy making, Dr. Romualdez served as Medical Adviser to the Minister of Health before assuming a position in the WHO Western Pacific Regional Office as the regional adviser in Development of Human Resources of Health and director of Health Services, Development and Planning. He said that when he was appointed by President Estrada as health secretary, his instruction was simple and that was to serve the people, especially the poor.



HON. ALBERTO G. ROMUALDEZ, JR.
Health Secretary
September 1998 - January 2001



Hon. Alberto Romualdez during the celebration of the Generics Week in September of 1998.



BOTIKANG BARANGAY
NCRPO Multi Purpose Cooperative

CUTTING the COST OF MEDICINES





HON. MANUEL M. DAYRIT
Health Secretary
February 2001 - May 2005

STRENGTHENING THE GENERICS ACT

Dr. Manuel Dayrit was actively involved in the campaign for the Generics Act as head of the DOH Public Information Office even before he was appointed as the DOH Secretary. “We were fighting on three fronts in the advocacy – for labeling, monitoring compliance by doctors, and dispensing by pharmaceutical outlets,” he recalled the DOH mantra at the time.

The DOH found a low compliance rate, compounded by marketing of drug companies that provide perks to doctors in order to prescribe their medicines, including drug outlets who sign up for ex-deals with these drug companies. “The choice of what drug product to buy was in the hands of the patient but it was influenced by what the pharmacist would say,” he said. This was further complicated by the public’s lack of understanding on the concept of Generics.

Because influencing private distribution was difficult, Dr. Dayrit strengthened the Botika ng Barangay program. The program became an early success story that within a few months, over 1,000 botikas manned by volunteer pharmacists were established nationwide – proof that somehow, generic pharmacies could work.

The National Drug Committee, renamed as the National Drug Formulary Committee, was further reorganized as the DOH guidelines on the establishment and operations of BnB were consolidated. Guidelines on the exclusive use of generic names in all prescriptions in DOH facilities were issued, including revised policies for institutionalizing and decentralizing the DOH consignment system.



DEPARTMENT OF HEALTH
Lungsod ng Marikina
Tungkong-Gubat
Barangay Health Center
Reliability . Affordability . Quality

BOTIKA NG BARANGAY
Gamot na Mabilis at Abot-kaya
Reliability . Affordability . Quality

ICE FOR SALE

BOTIKA NG BARANGAY
WHITE BEACH

Presya ng Lutas sa Kaligtasan
Mangulong Gloria Macapagal Arroyo
50th Anniversary
Medicine Program
BARANGAY
BOTIKA NG BARANGAY
BPAD LTD NO
MARIKINA CITY
Reliability . Affordability . Quality

Barangay Health Center
Mangulong Gloria Macapagal Arroyo
50th Anniversary
Medicine Program
BARANGAY



BOTIKA NG BARANGAY

NCRPO Multi Purpose Cooperative

Botika ng Barangay outlets. The BnB promotes equity in health by ensuring the availability and accessibility of affordable, safe and effective, quality essential drugs to all, with priority for underserved and hard to reach areas. The BnB serves over-the-counter medicines and some prescription medicines as recommended by the National Drug Formulary Committee.

CHEAPER QUALITY MEDICINES

In 2005, amid an emerging scare of a bird flu outbreak, then Health Secretary Francisco T. Duque III invoked a public health emergency and called on the international health community to look at the issue of patent on medicines after global experts recommended the stockpiling of anti-flu drugs as a first-line strategy to avert a pandemic.

“It’s almost bordering on the immoral to have just one drug company produce a drug that going to be a big part of the solution to avoiding the influenza pandemic,” he was quoted as saying during a high level health ministers meeting in Bangkok.

This would initiate the remarkable saga of challenging existing patent laws on medicines and the artificially high prices of drugs that block access to treatment and lead to the impoverishment of millions of Filipino patients because of the catastrophic costs of drugs in the country which are known to be among the highest in the world.

Halving the prices of medicines became the slogan of his administration marked by the passing of the *Universally Accessible Cheaper and Quality Medicines Act of 2008* and its twin legislation, the *Food and Drug Administration Strengthening Act of 2009*, that would complement the gains of the Generics Act by (1) upgrading the capacity of the Philippine FDA to allow the entry of more generic drug products, (2) strengthening flexibilities on the patent property rights on medicines, (3) allowing compulsory licensing and parallel importation, and (4) giving the Philippine President the power to set maximum retail prices of drugs when there is evident failure of market competition.

While his efforts to reduce drug prices were met with fierce resistance and numerous attempts to lobby against the pricing reforms by the pharmaceutical industry, Secretary Duque proceeded with what was needed to be done by engaging different sectors including the civil society in an open and multi-stakeholder dialogue to bring more affordable medicines and protect the more important public health interests of the Filipino people.

His term also saw the expansion of Botika ng Barangay (BnB) outlets nationwide with a record growth of up to 17,000 in a span of five years across the Philippines. The BnBs would later on become the blueprint for the private sector to create generic drugstore chains and outlets such as the Botika ng Bayan, The Generics Pharmacy, Generika, Botika ng Pinoy and other independent generic drugstores. Over the years, his reforms have led to the transformation of the pharmaceutical industry with better access for consumers through more generic choices and affordable prices and tools to create drug price transparency. After 25 years, the generics campaign have turned full circle because he dared to confront an industry long known to generate the highest profits than any other to defend the sovereign right of our nation in protecting the health of our people through affordable medicines.



HON. FRANCISCO T. DUQUE III
Health Secretary
June 2005 - January 2010

(Right)
In a ribbon cutting ceremony for the opening of a new BnB outlet. Sec. Duque initiated the expansion of the BnB outlets nationwide.

(Below)
During the launch of the P100 Treatment Pack, a package of essential medicines for common diseases such as diabetes, hypertension, asthma and arthritis available at much lower costs than in commercial drugstores.



(Above) Posters of the "Oplan Murang Gamot" as a part of his nationwide campaign to promote the consumption of cheaper generic medicines.



GOING UNIVERSAL





HON. ENRIQUE T. ONA
Health Secretary
July 2010 - December 2014

MEDICINES FOR THE POOR

The Cheaper Medicines Act of 2008 or RA 9502, completes the sphere of measures and policies that enhance affordable and quality health care for Filipinos.

On the 25th year of the Generics Act, Health Secretary Enrique T. Ona happily reported that 5 to 6 out of 10 Filipinos take generic medicines, signifying the law's wider acceptance and its effects on greatly improved access to quality and affordable medicines 25 years after the enactment of the law in 1988.

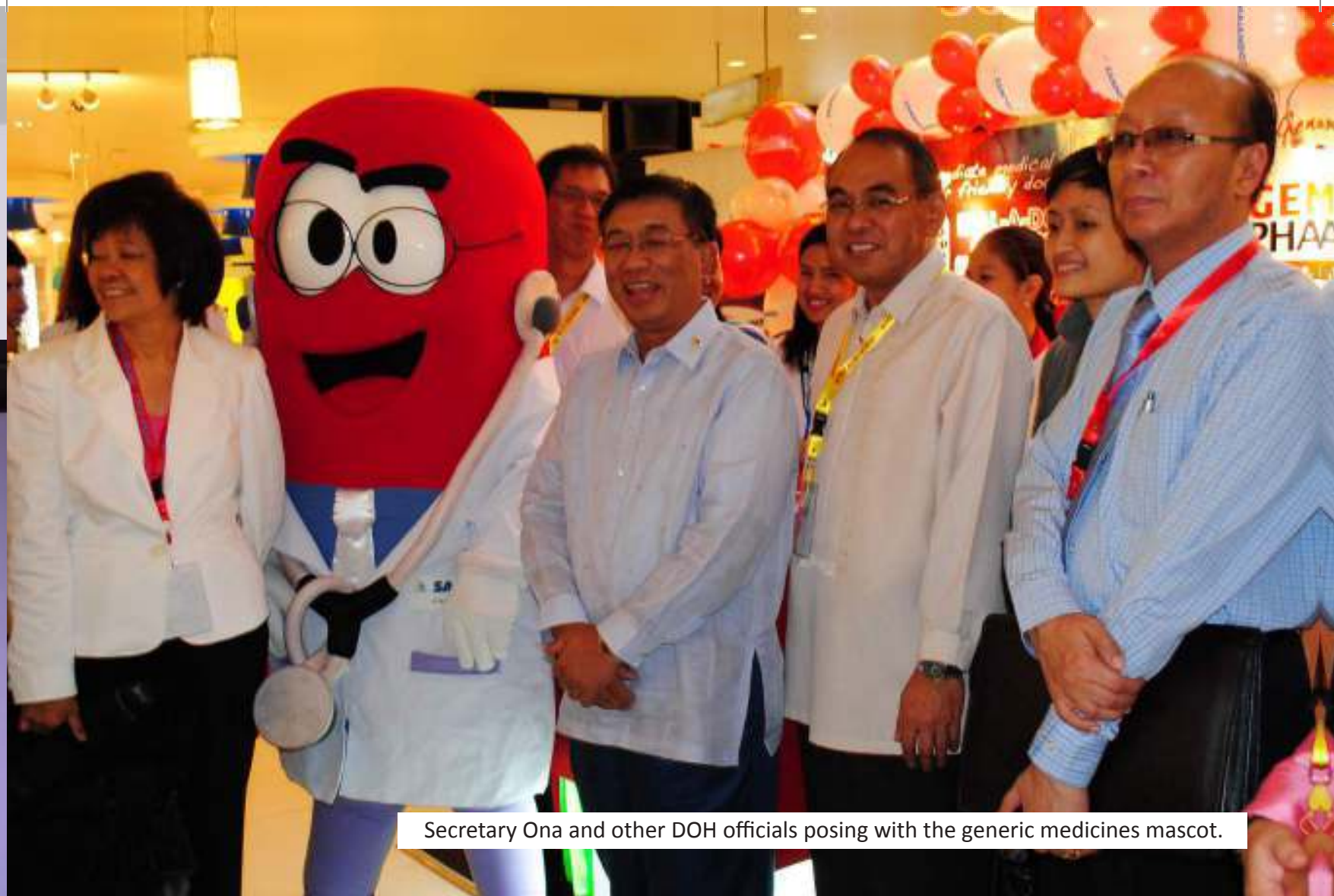
Speaking before the September 2014 Generics Summit, he emphasized the importance of access to medicines in the attainment of universal health care. He also highlighted the 2011 assessment of the Cheaper Medicines' Act of 2008 that placed the awareness level on generic medicines at 65% for Metro Manila, 48% for Luzon, and 53% for Visayas and Mindanao.

"Generic medicines are now significantly cheaper by more than 50% compared to its branded counterparts." Furthermore, Ona said that the market share of generic medicines has increased to 60%, widely enhanced by generic drugstores such as Generics Pharmacy, Generika and Botika Pinoy. With Dr. Ona, the DOH partnered with the Department of Social Welfare and Development (DSWD) in providing the free drug access program for indigent families covered by DSWD's Pantawid Pamilyang Pinoy Program (4Ps). Dr. Ona also launched the DOH Complete Treatment Pack (ComPack) that contains essential medicines for poor families to access basic medicines for common ailments. The medicines are for hypertension, diabetes, diarrhea, pneumonia and other common infections.



(Above) The DOH staff during the launching of the Complete Treatment Packs (ComPacks) at the Generic Medicines Summit 2011.





Secretary Ona and other DOH officials posing with the generic medicines mascot.



Secretary Ona delivering his message during the Generic Medicines Summit 2011.



The Gawad
Generics Trophy



GAWAD GENERICS

The Generics Act is hailed to be one of the landmark legislations of the Corazon Aquino administration. On the 25th year of its enactment, the Gawad Generics Award was given to the men and women who made significant contributions to the passing of the law. The Gawad Generics Awardees are as follows:

- | | |
|-------------------------------------|---|
| 1. Hon. Orlando S. Mercado | 26. Hon. Manuel A. Roxas II |
| 2. Hon. Joseph E. Estrada | 27. Hon. Pia S. Cayetano |
| 3. Hon. Joker Arroyo | 28. Hon. Arthur Y. Pinggoy, Jr. |
| 4. Hon. Edgardo J. Angara | 29. Hon. Fergenal G. Biron |
| 5. Dr. Alfredo R.A. Bengzon | 30. Hon. Janette L. Garin |
| 6. Dr. Carmencita N. Reodica | 31. Dr. Francisco T. Duque III |
| 7. Dr. Alberto G. Romualdez | 32. Atty. Alexander A. Padilla |
| 8. Dr. Manuel M. Dayrit | 33. Dr. Robert Louie P. So |
| 9. Dr. Quintin L. Kintanar | 34. Dr. Estrella B. Paje-Villar |
| 10. Mr. Rhais M. Gamboa | 35. Dr. Nelia C. Maramba |
| 11. Dr. Antonio C. Acosta | 36. Dr. Ernesto O. Domingo |
| 12. Dr. Madeleine De Rosas - Valera | 37. Prof. Leticia Barbarra B. Gutierrez |
| 13. Dr. Linda L. Milan | 38. Dr. Adriano G. Dela Paz |
| 14. Dr. Carmencita A. Banatin | 39. Dr. Isidro C. Sia |
| 15. Dr. Eduardo C. Janairo | 40. Engr. Rainier M. Galang |
| 16. Dr. Leonita P. Gorgolon | 41. Dr. Romeo Quijano |
| 17. Dr. Edgardo M. Gonzaga | 42. Ms. Malou C. Mangahas |
| 18. Dr. Kenneth Hartigan – Go | 43. Mr. Horacio G. Severino |
| 19. Ms. Amorcita M. Pallera | 44. Mr. Jose Miguel R. Gomez |
| 20. Ms. Catalina C. Sanchez | 45. Ms. Shiela S. Coronel |
| 21. Dr. Lilian V. Lee | 46. PHAREX HealthCorp |
| 22. Mr. Jose Dennis A. Dela Cruz | 47. The Generics Pharmacy |
| 23. Dr. Susan Pineda-Mercado | 48. Generika Drugstore |
| 24. Dr. Tomas Maramba | |
| 25. Dr. Edolina Dela Paz | |

Milestones



1988

GENERIC ACT
1ST NATIONAL DRUG POLICY

OLD PRICE	MAXIMUM DRUG RETAIL PRICE
100	10
200	20
500	50
1000	100
2000	200
5000	500
10000	1000

2009

MAXIMUM DRUG
RETAIL PRICE



1995

PHILHEALTH
ADOPTS THE
NATIONAL DRUG
FORMULARY AS
BASIS FOR DRUG
REIMBURSEMENTS



2013

DRUG
PRICE
REFERENCE
INDEX



1991

NATIONAL
DRUG
FORMULARY



2008

CHEAPER
MEDICINES
ACT



2011

MEDICINES
ACCESS
PROGRAMS



2001

BOTIKA NG
BARANGAY



THE DRIVERS OF THE GENERICS ACT





THE DOH PHARMACEUTICAL DIVISION

The DOH Pharmaceutical Division was created by virtue of Republic Act No. 9502, otherwise known as the Universally Accessible Cheaper and Quality Medicines Act of 2008. This institutional policy and operational office was formed under the authority of the Secretary of Health, and now currently performing its responsibilities to promote and ensure access to affordable quality medicines for all Filipinos.

The powers and functions of the DOH-PD include the management and implementation of the National Drug Policy, undertaking policy studies and recommendations that contribute to improved access to medicines, building coalitions and agreements with relevant stakeholders, providing support in the effective implementation of the law, and performing medicines price monitoring along with other agencies of the government. Moreover, its functions were intensified by the crafting of the DOH Administrative Order 2010-0005 focusing on increased access to medicines in line with the Millennium Development Goal (MDG) No. 8. (Target 8.E: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries).

In 2011, the National Drug Policy was revised to become the Philippine Medicines Policy (PMP) 2011-2016 in response to the various challenges posed by the Cheaper Medicines Act and in the adoption of the current pharmaceutical landscape. The PMP outlines the five key pillars for targeted and sustained action by relevant health and other sectors, namely: 1) Safety, Efficacy and Quality (SEQ) of medicines, 2) Affordability and availability, 3) Rational Drug Use, 4) Accountability, transparency and Good Governance and 5) Health Systems Support. It is a comprehensive strategy to ensure sustainable access to essential medicines by serving as a framework for the entire health sector and all other vital partners involved in the management of medicines. It sets a five-year strategy for the government to sufficiently meet its obligation to protect public health through continuous access to medicines while creating a commercial climate conducive to the industry to significantly manufacture pharmaceutical products attuned to the country's public health needs. The DOH-PD partners with relevant stakeholders to achieve the set goals in the attainment of universal health care.

The DOH-PD envisions being the leading Office that ensures the universal access to quality essential medicines. Its mission is to guarantee better health outcomes by using policy instruments and setting strategic directions aimed at improving access to quality essential medicines by means of (1) improving the supply side access to quality essential medicines, (2) ensuring rational use of medicines by prescribers, dispensers, and patients, and (3) institutionalizing transparency and good governance in the pricing and procurement of medicines.

Since its establishment, the DOH-PD has performed numerous undertakings that included the following: (1) strengthening the execution of the Generics Act of 1988 (RA 6675) as amended by the Cheaper Medicines Act (RA 9502); (2) promotion of the Rational Use of Medicines that include the Philippine National Formulary which serves as the basis for government procurement and PhilHealth reimbursement of essential medicines, and the development of Antimicrobial Resistance (AMR) program; (3) efficient drug price monitoring that include the setting of maximum retail prices (MRP) and price adjustments through the Government Mediated Access Prices (GMAP); (4) utilization of TRIPS flexibilities that address high cost innovator products needed for public health emergencies and other situations in the country; (5) development and implementation of national drug pricing strategies that include the Electronic Drug Price Monitoring System (EDPMS), the newly developed Drug Price Watch, and the Drug Price Reference Index (DPRI); (6) development of policies and systems for managing the drug supply chain in the public sector; (7) Medicines Access Programs (MAPs); and (8) conduct of researches for the strengthening of RA 9502.

PHILIPPINE HEALTH INSURANCE CORPORATION

The Philippine Health Insurance Corporation is considered as the single largest purchaser of services in the health system in the Philippines. After 19 years, PhilHealth has managed to come up with responsive programs that have provided financial protection to all Filipinos in times of ill-health.

Despite continuous efforts to cover for the health expenditure of PhilHealth members, still a lot has to be done to accomplish fully the mandate of providing financial protection against illnesses. The out-of-pocket payment has remained to be high, thus making the support value of PhilHealth lower than expected.

In the 2010 statistics of PhilHealth on benefit payments utilizing the fee-for-service scheme, PhilHealth paid a total amount of 30.5 billion pesos to its members. The largest share went to medicines with a total of 8.8 billion pesos comprising about 29% of the total amount paid by PhilHealth. This trend of distribution of benefit payment per benefit item has not changed much over the years.

This is the reason that PhilHealth has given significant attention in reimbursement of claims for medicines. In the accreditation of hospitals, applicants are required to ensure that procurement of safe and cost-effective drugs are consistent with scientific evidence and government policies.

PhilHealth established the Health Technology Assessment (HTA) Committee in 1999 to develop reimbursement policies on medical claims based on the cost-effectiveness of tests and treatments. Assessments of medicines done by the HTA Committee were published in The HTA Forum which is the official publication of the HTA. Specifically, it contains the recommendations and evidence reports of the medicines that were reviewed, prepared and translated into policies by the HTA Committee and the Quality Assurance Group.

The HTA Forum also featured work resulting from other programs of HTA including the appraisal and dissemination of clinical practice guidelines developed by local medical societies used for reviewing reimbursement claims; and the evaluation of the effectiveness and safety of medical and surgical procedures.

In the same year, PhilHealth issued Memorandum Circular No. 9 which strictly enforced the use of generics, rational drug use and principles of good prescribing in reimbursement rules. This issuance required the use of the Philippine National Formulary, then known as the Philippine National Drug Formulary (PNDF) as the basis for the reimbursement of medicines both in public and private facilities and the use of generic terminology when reimbursing these medicines.

When Republic Act 9502 or The Universally Accessible Cheaper and Quality Medicines Act of 2008 was enacted and Executive Order No. 821 prescribing the maximum drug retail prices (MDRP) was signed in 2009, PhilHealth applied it in the computation of benefits – the MDRP represents the “ceiling price” that may be reimbursed by PhilHealth per unit of drug to make medicines affordable and accessible.

In 2011, PhilHealth has implemented case based payment scheme which offers a more predictable and equitable benefit payment based on patients’ medical condition. With this novel payment scheme is the introduction of the No Balance Billing (NBB) Policy which provides that no other fees or expenses shall be charged or be paid for by the indigent patients above and beyond the packaged rates. However, resource constraints have proved to challenge the effective implementation of the NBB policy.

Many healthcare facilities operate on limited resource settings and still require the technical capacity to manage its resources resulting in persistent stock-out of medicines. PhilHealth members are compelled to purchase drugs and medicines in private pharmacies that mushroomed around hospitals thus incurring high out-of-pocket expenses. In a monitoring done in 315 hospitals in 2013, results showed only 7% compliance to the NBB policy for indigents members. Sixty five percent of the respondents in national hospitals reported outside purchases of medicines. This problem on accessibility of medicines necessitates, among others, the strong political will of both national and local government to do their share in resource management and policy enforcement to assure that every poor Filipino is truly protected against financial risk.

PhilHealth will always continue improving its services and performing its mandate in order to achieve financial protection to achieve Universal Health Care.

FOOD AND DRUG ADMINISTRATION



The Food and Drug Administration has always stressed the important role of regulators in achieving Kalusugan Pangkalahatan (universal health care) and access to medicines guaranteeing the quality, efficacy and safety of medicines which entails monitoring the whole life cycle of drugs starting from manufacturing up to consumption.

Kalusugan Pangkalahatan cannot be dissociated with strengthening health systems – human resource health, logistics, good governance, information and communication technology, health products, and healthcare financing – and challenges can be best addressed with a holistic community approach which encourages the engagement of every stakeholder from other government agencies to the industry as well as health professionals and consumers.

First, compliance to good manufacturing practice (GMP) needs to be strictly enforced in order to ensure the quality, efficacy, and safety of drugs. The FDA is now more than ever vigilant in meeting this obligation to safeguard public health. However, the FDA would want to be more proactive by conducting on-site GMP inspections of drug manufacturers abroad in order to guarantee the quality, safety, and efficacy of imported medicines.

On changing irrational and improper prescribing behavior of medical practitioners, the FDA is fully aware of the need to address the unethical marketing promotions. Accurate information on drugs is very essential as these pieces of information influence the choice of medicines. Likewise, prescriptions also have a great influence in the choice of medicines. The FDA takes full responsibility of monitoring the unethical marketing practices. In the coming months, the FDA will implement the Asia-Pacific Economic Cooperation (APEC) Declaration of Ethical Marketing Practices in the country to address this issue.

However, a more pressing issue is the question on the quality of generic drugs. The FDA is now working on requiring bioavailability and bioequivalence (BA/BE) analyses for generic drugs. To continuously monitor the quality of drugs available in the market, the FDA is strengthening its post-marketing surveillance. The FDA has established its Regulatory Enforcement Unit which now requires companies to provide risk management plans, including the voluntary recall of products if proven unsafe, substandard and ineffective. The FDA has already established an e-reporting system for adverse drug reactions (ADR) providing an avenue for consumers to lodge their complaints on the safety, quality, and efficacy of medicines. It is also complemented with the continuous advocacy on pharmacovigilance and the ongoing education and promotion efforts to increase awareness on ADR.

In addition, the FDA is challenging the Pharmacy Law with regard the deregulation of the requirement for pharmacists in drugstores. The significant mismatch between the number of drugstores and licensed pharmacists poses a challenge to access to medicines with drugstores facing closure with this stringent requirement and potentially reducing the accessibility of medicines especially in remote areas.

Acting Director General Kenneth Hartigan-Go believes that the agency still has a lot to do to fully become an effective regulator. The regulator needs to be equipped, but there is no school for regulators to equip them with the science of regulation. Also, the regulator needs to be protected from any political and economic agenda that can compromise its regulatory obligation to the public. Finally, the FDA must be strengthened with improved science, equipment, and facilities in order to register better products, in turn, gaining credibility as a regulator.



THE PARTNERS OF THE GENERICS ACT





DRUGSTORE ASSOCIATION OF THE PHILIPPINES

DSAP, as an association of small and medium drugstores, supports and understands the importance of the Generics Law for the betterment of health of our fellowmen. In the year 2006, under the leadership of the late Ms. Erlinda Pascual, projects were conceptualized to increase awareness of this law. Ms. Pascual was very passionate in her advocacy that each DSAP member was tasked to share information on the Generics Law within their community.

It had been difficult as Filipinos had the concept that Generics were inferior compared to the innovator and branded medicines. People thought that Generics were less effective. With the help of Pharex Health Corporation and RiteMed, both local pharmaceutical companies manufacturing uni-branded generic medicines, DSAP educational programs were conducted to give better information to the community and refute the misinformation.

The first project that DSAP performed was the Generics Menu Book for the use of its member. It provided patients given alternative medicines to choose from. Patients learned that they can stretch their peso and at the same time, comply with the regimen of their medication. The problem on patient compliance with their medication was one of the issues resolved with this initial project.

There were various educational programs that were conducted since the year 2006. The seminars were in full blast in the year 2008 under the leadership of Ms. Josephine Inocencio, the DSAP President 2008-2009. The barangay health workers and the drugstore owners were the focus of the project. On the other hand, the barangay health workers were sought to be an important channel for spreading information. They visited communities within their respective barangays and taught people on health. The educational seminars embraced the concept of appreciation for the value of savings and medication compliance through cheaper quality generic medicines.



PHILIPPINE PHARMACISTS ASSOCIATION

The Philippine Pharmacists Association celebrates its 95th year of existence this year since its establishment on August 29, 1920. Established as an organization of pharmacists in the country, PPhA had evolved to become an umbrella organization for 10 affiliate organizations of pharmacists from different practice settings – community, hospital, academe, pharmaceutical industry, private and government institutions, wellness and cosmetics industry, veterinary industry – as well as the young pharmacists group and pharmacy students. It is also the PRC-accredited professional organization for pharmacists with 85 chapters all over the country and a membership of more than 15,000 registered pharmacists.

In the year 1990, PPhA supported the Generics Law through its participation in the Trainors' Training for the cascade of the provisions of the law. It included a module on Generics Law in its nationwide annual continuing education (CPE) program for its local chapters. The organization also encouraged the academe to include the law in the curriculum, particularly the provisions on generic dispensing. PPhA also provided resource speakers on the Generics Law requested by other groups and sectors of the society. In recent runs of the annual CPE, PPhA also enlightened its member pharmacists on the issue of generic equivalents, bioavailability, bioequivalence and other relevant topics to guide them in their professional practice.

Representatives of the organization had actively participated in many Congress and Senate hearings and fora concerning generic medicines, including R.A. 9502, the Cheaper Quality Medicines Act of 2008. Recently, it had participated and supported the Department of Health – National Center for Pharmaceutical Access and Management (NCPAM) in the crafting of policy on Rational Use of Medicines and also in the development of the concept of Quality Circle in the provision of medicines. The same concept is being taught to pharmacists in their continuing education and is expected to raise awareness on the value and contribution of the pharmacist in providing quality medicines through Good Pharmacy Practice.

QUALITY CIRCLE FOR GENERICS

What is the Quality Circle for Generics?

The Quality Circle for Generics is a campaign to provide patients and consumers with the best value in healthcare by ensuring the safety, efficacy and quality of given medicinal products. It is a practice and principle that should be embodied by different stakeholders involved in the regulation, manufacture, production, prescription, dispensing, sale and use of medicines.

Quality does not depend solely on strong regulations by the FDA but also adherence of all players to the standards of quality which include:

- * **Good Manufacturing Practices (GMP)**
- * **Good Laboratory Practices (GLP)**
- * **Good Clinical Practices (GCP)**
- * **Good Distribution Practices (GDP)**
- * **Good Storage Practices (GSP)**
- * **Good Pharmacy Practices (GPP)**

Everyone has a stake in ensuring that generic medicines fulfill their intended effects to provide cure to patients as clinically tested and expected.

Why is Quality important?

Quality is important as this will ensure that the product or the medicine will deliver the clinically-tested effects of medicines when used by the patients or consumer.

Who are part of the Quality Circle for Generics?

1. Legislators

Provide the legal and policy framework to assure the quality of generic medicine and allocate adequate budget/ resources to ensure that health regulators enforce the provisions of health laws

2. Regulators (DOH and FDA)

Enforce the provisions of the Generics Law (RA 6675) and other pertinent laws and issue and update a sound national medicines policy anchored on the quality, safety, efficacy and costeffectiveness of medicinal products

3. Pharmaceutical Industry

Produce and manufacture quality generic drugs for the Filipino public and adhere to the regulatory standards on safety, efficacy and quality as well as ethical codes on the promotion, marketing and sale of medicinal products

4. Prescribers

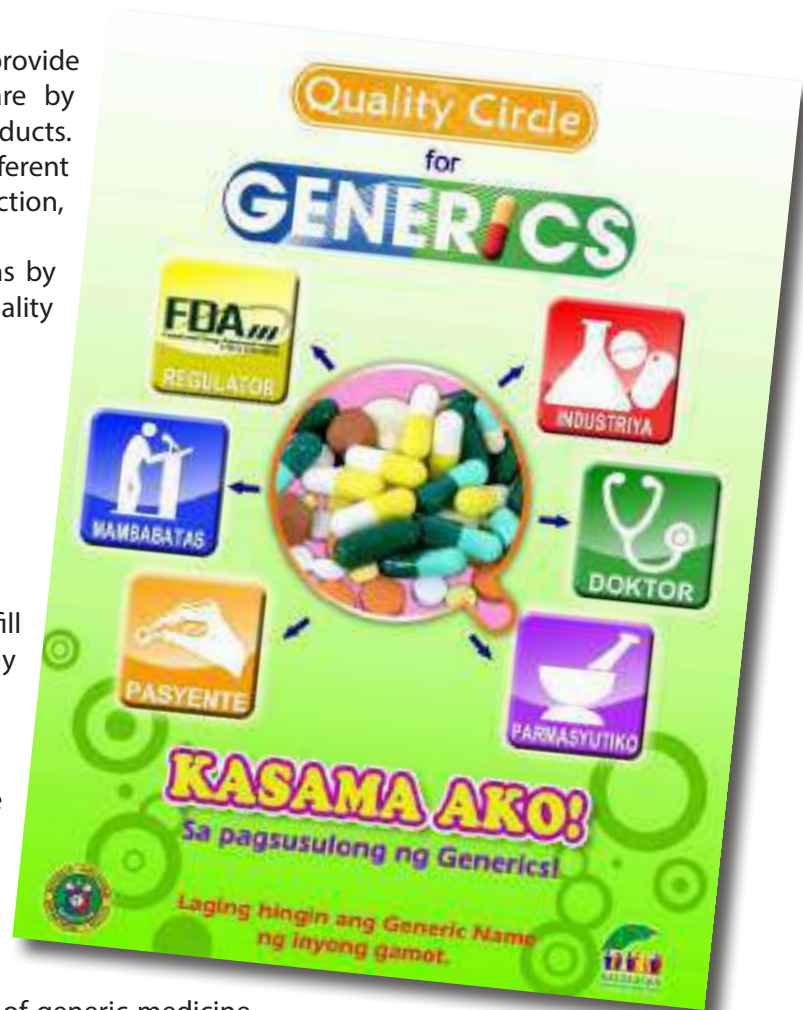
Adhere to professional and ethical standards on the prescription and use of medicines and educate patients on the benefits and rational use of generic medicines

5. Dispensers

Source quality generic medicines from reputable manufacturers, traders and distributors; ensure a safe, clean, and secure dispensing environment for generic drugs and counsel individual patients on generic drugs and give informed choice to consumers

6. Consumers/Patients

Buy medicines only from FDA licensed outlets properly authorized to dispense medicines; examine physically and visually the medicines they purchase to make sure that the right product strength was dispensed to them and that the product has a current expiry date and read product labels and follow the advice of their physicians and pharmacists to guarantee that generic products work



The **P**harmaceutical **D**ivision

