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AEC 2015: Issues and Challenges in Standards and Conformance

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ABSTRACT

The ASEAN Economic Community (AEC) Blueprint envisions the transformation of the ASEAN region into a single market and production base through the facilitation of the free flow of goods and services. With tariffs declining to near-zero levels, nontariff barriers are increasingly the focus of coordination efforts by ASEAN member-countries. The ASEAN standards and conformance measures aim to harmonize national standards, technical regulations, and conformity assessment procedures to achieve connectivity among similar regulatory institutions in the region and to facilitate trade. The Mid-Term Review of the AEC Blueprint set out surveys and a scorecard mechanism to assess each country's progress in the implementation of standards and conformance in eight key areas, including automotive and rubber-based products, electrical and electronic equipment, cosmetics, medical devices, pharmaceutical products, prepared foodstuff, and traditional medicine and health supplement sectors. This paper presents the survey results and includes a background on key national institutions in-charge of standards and conformance. Overall, the survey results show that the Philippines is committed to aligning national standards with international benchmarks and has achieved significant progress in most sectors through measures that include the amendment of the relevant laws and regulations. While the Philippines remains committed to the AEC and the AEC Blueprint, challenges to

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implementation remain, including adequate funding and support. The way forward for standards and conformance in the Philippines lies in capacity building and strengthening regulatory institutions.

INTRODUCTION

Trade facilitation is a key component of the economic integration agenda of the Association of Southeast Asian Nations (ASEAN). The realization of the vision of an ASEAN Economic Community (AEC) as a single market and production base involves member-states working together to remove both tariff and nontariff barriers to trade.

Countries impose national standards and technical regulations on domestically produced and imported products to ensure quality products in the market and safeguard the public's safety. However, excessive national product standards or a very strict application of these standards can impede the flow of trade in goods. The ASEAN established the ASEAN Consultative Committee for Standards and Quality (ACCSQ) in 1992 to reduce and, if possible, eliminate these technical barriers to trade (TBT).

The standards and conformance initiatives of the ACCSQ are focused on four main activities:

(i) Harmonization of national standards with international standards, practices, and guides to eliminate conflict among national standards that are a restriction to trade.
(ii) Harmonization of mandatory technical requirements that include registration and premarket approval requirements to ensure free movement of goods.
(iii) Harmonization of conformity assessment procedures, which include accreditation, certification, testing and inspection, and mutual recognition of test reports and certification to save transaction time and to avoid high cost arising from multiple testing requirements.
(iv) Harmonization of technical regulations for national adoption.

Dismantling of the national borders represented by standards, technical regulations, and conformity assessment procedures is necessary for achieving connectivity among similar regulatory institutions in the region and facilitating trade (Ramesh and WG3 Chair 2014).

The Philippines supports the standards and conformance agenda of the ASEAN and is an active member and leader in the various regional working groups. In 2012, the country was the chair of the working groups in the cosmetics and electrical and electronic equipment (EE) sectors. In the context of the country's full cooperation and willingness to fulfill its obligations, this paper will give an overview of standards and conformance in the Philippines and discuss the

results of the scorecard exercise set out in the Mid-Term Review (MTR) of the AEC Blueprint.

The next section introduces the main government agencies in-charge of the standards relevant to the regional standards and conformance initiatives. A summary of the Philippine scorecard for standards and conformance based on surveys conducted in the ERIA Phase Two Study is featured in the third section, while the fourth section discusses the results of the AEC Blueprint MTR surveys for the cosmetics and EE sectors. The concluding discussion summarizes the results and recommendations for the way forward for standards and conformance in the Philippines, specifically for these two sectors.

The methodology used for the Standards and Conformance scorecard was a structured questionnaire specific to each of the eight sectors but similarly divided into three main sections consisting of standards, conformity assessment procedures, and technical regulations. Interviews with key government officials involved in each sector under study were conducted to obtain detailed responses and the requisite background information. Analysis of secondary data was also employed. The results were obtained through a scoring method for the three main sections corresponding to the three major technical (nontariff) barriers to trade covered in the questionnaire, namely, national obligations for standards, national obligations for conformity assessment procedures, and national obligations for technical regulations. Each section had three to five specific activities with predetermined weights for each sector determined through corresponding questions in the survey.

Results for the AEC Blueprint MTR were determined through questionnaires specific for the cosmetics and EE sectors. Face-to-face interviews with key government officials as well as industry experts and representatives of private sector companies were conducted, including focus group discussion.

PHILIPPINE GOVERNMENT AGENCIES IN-CHARGE OF STANDARDS

The Bureau of Product Standards (BPS) is the agency of the Department of Trade and Industry (DTI) designated as the National Standards Body of the Philippines. The BPS was established by Republic Act (RA) No. 4109, also known as the Philippine Standardization Law, and Executive Order (EO) No. 133.

As the National Standards Body, BPS is mandated to develop, implement, and coordinate standardization activities in the Philippines. It is primarily involved in standards development, product certification, and standards implementation/promotion to raise the quality and global competitiveness of Philippine products. It also aims to protect the interests of consumers and businesses. The BPS is

the World Trade Organization's Technical Barriers to Trade (WTO-TBT) Enquiry Point for the country.

The BPS approves and implements the Philippine National Standards (PNS) that are established by consensus through technical committees composed of representatives from the industry, trade associations, government, academe, and consumer groups. The BPS maintains a Standards and Conformance (S&C) portal that features standards, regulations, and conformity assessment activities in the Philippines, and provides a complete listing of published PNS classified both by International Classification for Standards (ICS) and Harmonized System (HS).

The Food and Drug Administration (FDA) is the agency of the Department of Health (DOH) that formulates rules, regulations, and standards for licensing and accreditation of processed foods, drugs, and other related products, conducts licensing and accreditation, and monitors, evaluates, and ensures compliance of manufacturers, distributors, advertisers, and retailers to these standards. The FDA was created in 1963 by RA No. 3720, also known as the Food, Drug, and Cosmetic Act. In 1982, it was renamed as the Bureau of Food and Drugs and on its 46th year, its name was reverted back to Food and Drug Administration with the enactment of RA 9711 (Peralta and Matienzo 2011).

The FDA is currently organized into five process-focused divisions. Two regulation divisions conduct inspection and the issuance of licenses for establishments that manufacture, import, export, and distribute processed foods, drugs, medical devices, in vitro reagents, cosmetics, and household hazardous substances. The Product Services Division formulates standards and guidelines as well as evaluates the applications for the registration of these health-related products while the Laboratory Services conducts laboratory tests on both packaging materials and finished products. The Policy, Planning, and Advocacy Division develops regulatory policies and performs customer-facing functions such as the provision of technical information and assistance. The current transitioning of the FDA into its new organizational setup will be discussed in the fourth section of this paper.

With reference to the eight ASEAN Priority Investment Sectors (PIS) covered in the ERIA Phase Two Study, the BPS directly oversees the automotive, rubber-based products, and EE sectors. The FDA is responsible for the cosmetics, medical devices, pharmaceutical products, prepared foodstuff, and traditional medicine and health supplements sectors.

STANDARDS AND CONFORMANCE SCORECARD OF THE PHILIPPINES

Results of the scorecard exercise show the Philippines is making good progress in the ASEAN standards and conformance roadmap defined for the eight priority

Table 1. Summary of Philippine scorecard for the implementation of standards and conformance measures: national obligations for standards

TECHNICAL BARRIERS TO TRADE	SPECIFIC ACTIVITIES	WEIGHT	AUTOMOTIVE	COSMETIC	ELECTRICAL & ELECTRONIC EQUIPMENT	MEDICAL DEVICES	PHARMACEUTICAL PRODUCTS	PREPARED FOODSTUFF	RUBBER-BASED PRODUCTS	TRADITIONAL MEDICINE & HEALTH SUPPPLEMENTS
1. STANDARDS										
The process flow covers the activities to be carried out to address national standards as non-tariff barriers to trade. Within ASEAN this is based on the approach to harmonise national standards with agreed international standards or international benchmarks.	**NATIONAL OBLIGATIONS**									
	Review of equivalence of corresponding national standards or technical requirements with agreed international standards or international benchmarks identified for harmonization at the regional level.	5%	5%	5%	5%	5%	5%	5%	5%	5%
	Revision of national standards or technical requirements to ensure alignment with agreed international standards or international benchmarks identified for harmonization at the regional level.	30%	30%	30%	30%	30%	30%	30%	30%	30%
	Public comments on the revised national standard sought among stakeholders prior to publication of the standard.	10%	10%	10%	10%	10%	10%	10%	10%	10%

Source : Ledda (2011)

investment sectors. The results of the Standards and Conformance scorecard generally show a high degree of conformance of national standards with international benchmarks across the surveyed sectors and openness to conformity assessment procedures and harmonized technical regulations. The scores were obtained through a scoring method for the three main sections corresponding to the three major technical (nontariff) barriers to trade covered in the questionnaire, namely, national obligations for standards, national obligations for conformity assessment procedures, and national obligations for technical regulations. Each section had three to five specific activities with predetermined weights and the weight for each sector was determined through corresponding questions in the survey.

All eight sectors obtained high scores for National Obligations for Standards (Table 1). The processes of review and revision of national standards or technical requirements to ensure alignment with agreed international standards and benchmarks identified for harmonization at the regional level are either ongoing or have been completed for all sectors. The cosmetics and EE led all sectors in obtaining high scores for the equivalence of national with international standards. The Philippines has fully adopted the ASEAN Cosmetic Directive (ACD) implemented in 2008. The national standards for EE are 98-percent compliant with the identified international benchmarks, covering 51 out of 52 mandatory electrical products. In addition, the respective regulators of all eight PIS are diligent in soliciting comments from stakeholders on the revised national standards prior to their publication (Ledda 2011).

The Philippines has a mixed scorecard for National Obligations for Conformity Assessment Procedures (Table 2). The pharmaceutical and EE sectors led all others in the ratification of the relevant mutual recognition arrangements (MRAs), the transposition of MRA provisions into applicable national laws and regulations, the identification and implementation of capacity-building programs to enhance the capability of ASEAN Conformity Assessment Bodies (CABs) to meet the requirements under the MRA. The automotive, medical devices, prepared foodstuff, and traditional medicine and health supplements sectors need to have key processes in place to cover national obligations for conformity assessment procedures.

Scores again varied widely among sectors in the Philippine scorecard measuring National Obligations for Technical Regulations (Table 3). Cosmetics and pharmaceutical products led all sectors in obtaining high scores, with the processes of ratification of the regional agreement and the transposition of regional agreement provisions into applicable national laws already in place, among others. Implementation scores remain very low for the prepared foodstuff and traditional medicine and health supplements sectors.

Following is a summary of the overall position of the Philippines for each sector.

Automotive sector. The Philippines is a net importer of products in the automotive sector. There is competence for testing but the country's regulatory agency needs to build up the necessary capability to test and confirm that a particular imported product is compliant with the international standards. Identification and implementation of capacity-building programs and market surveillance and market monitoring activities will also raise the implementation scores in this sector.

Cosmetics sector. The current published national standards of the cosmetics sector are aligned with international standards. The Philippines has fully adopted the ACD that was implemented in 2008. With the signing of the administrative orders to implement the ACD, the standards of the Philippines' cosmetics sector are now 100-percent compliant with international benchmarks. Capacity building especially in postmarket surveillance will further strengthen regulatory powers to ensure quality products in the market.

Electrical and electronic equipment sector. In 2008, the Philippines issued Department Administrative Order (AO) 3 on Rules and Regulations Concerning the Safety of Low Voltage Equipment (LVE) to comply with the ASEAN MRA. However, because of the additional concerns and agreements discussed at

Table 2. Summary of Philippine scorecard for the implementation of standards and conformance measures: national obligations for conformity assessment procedures

TECHNICAL BARRIERS TO TRADE	SPECIFIC ACTIVITIES	WEIGHT	AUTOMOTIVE	COSMETIC	ELECTRICAL & ELECTRONIC EQUIPMENT	MEDICAL DEVICES	PHARMACEUTICAL PRODUCTS	PREPARED FOODSTUFF	RUBBER-BASED PRODUCTS	TRADITIONAL MEDICINE & HEALTH SUPPPLEMENTS
2. CONFORMITY ASSESSMENT PROCEDURES										
The process flow covers the activities to be carried out to address conformity assessment procedures as non-tariff barriers to trade. Within ASEAN the approach taken is to establish Mutual Recognition Arrangements as a means to facilitate the acceptance or recognition of results of conformity assessment procedures, produced by the Conformity Assessment Bodies among AMS.	**NATIONAL OBLIGATIONS**									
	Ratification of the MRA by AMS.	10%	0	0	10	0	10	0	x	0
	Transposition of MRA provisions into applicable national laws, legislations or regulations.	20%	0	0	20	0	20	0	x	0
	Availability of equivalent standards and technical requirements to support the implementation of the MRA or conformity assessment of products.	10%	0	10	10	0	10	0	x	0
	Evaluation and assessment of proposals for listing of the Conformity Assessment Bodies submitted through the AMS to the Joint Sectoral Committee for these bodies to be approved for listing under the MRA or under regional harmonized technical regulation.	10%	0	10	10	0	10	0	x	0
	Regular audit or assessment of Listed Conformity Assessment Bodies by the respective AMS.	5%	0	5	5	0	5	0	x	0
	Identification and implementation of capacity building programmes to enhance the capability of ASEAN Conformity Assessment Bodies to meet the requirements under the MRA.	5%	0	5	5	0	5	0	x	0

Source: Ledda (2011)

Table 3. Summary of Philippine scorecard for the implementation of standards and conformance measures: national obligations for technical regulations

TECHNICAL BARRIERS TO TRADE	SPECIFIC ACTIVITIES	WEIGHT	AUTOMOTIVE	COSMETIC	ELECTRICAL & ELECTRONIC EQUIPMENT	MEDICAL DEVICES	PHARMACEUTICAL PRODUCTS	PREPARED FOODSTUFF	RUBBER-BASED PRODUCTS	TRADITIONAL MEDICINE & HEALTH SUPPPLEMENTS
3. TECHNICAL REGULATIONS										
The process flow covers the activities to be carried out to address national standards as non-tariff barriers to trade. Within ASEAN this is based on the approach to harmonise national standards with agreed international standards or international benchmarks.	**NATIONAL OBLIGATIONS**									
	Ratification of the regional agreement (harmonized technical regulation) by AMS.	10%	x	10	0	0	10	0	x	0
	Transposition of regional agreement (harmonized technical regulation) provisions into applicable national laws, legislations or regulations.	20%	x	20	20	20	20	0	x	0
	Actions taken for the interpretation of the regional agreement (harmonized technical regulation), including adoption of the regional guidelines for national implementation.	10%	x	10	10	10	10	0	x	0
	Availability of harmonized standards and technical requirements to support the implementation of the regional agreement (harmonizes technical regulation).	10%	x	10	10	10	10	0	x	10
	Availability of technical infrastructure such as competent Conformity Assessment Bodies to support the implementation of the regional agreement (harmonized technical regulation).	10%	x	10	10	10	10	0	x	0
	Post Market Alert Systems established for linking with the AMS to strengthen regional post market surveillance efforts.	10%	x	10	10	10	10	10	x	10

Source: Ledda (2011)

subsequent Working Group meetings, the regulator has seen the need to revise the document to accommodate expanded provisions. The transposition of MRA provisions into applicable legislation revisions was expected to be completed last November 2011. The testing of domestically produced EE for export to other

ASEAN member-states is more efficient at present with the inclusion of three Listed Test Laboratories and Certification Bodies. It is important to note that the Philippines is a net importer of these products, similar to the automotive sector, and has the view that compliance with MRAs may bring limited benefit at present in terms of enhancing the exporting capabilities of local manufacturing firms.

Medical devices sector. The Philippines does not have its own national standard for medical devices. FDA through the Center for Device Regulation, Radiation Health, and Research (CDRRHR) continually reviews and directly adopts available international standards. There are currently 85 international standards for medical devices that have been adopted as the national standards.

The implementation score for the Philippines is expected to rise with the approval of the FDA RA 9711 that will harmonize technical requirements for use in the registration of medical device products in the Philippines. At present, the FDA is formulating new regulatory guidelines in line with the passage of this law.

Another factor that may impact the pace of implementation is the ongoing reorganization at the FDA that will be discussed later in the report. The enhanced mandate of the regulator will make possible the creation of new positions for additional personnel for CDRRHR through a timeline of five years. This transition to a new regulatory system will also make possible the implementation in phases of increasing coverage of the medical devices for mandatory registration until 2016.

Rubber-based products sector. Similar to the automotive sector, the rubber-based products sector is still unprepared in terms of technical infrastructure or capability compared to other ASEAN member-states that may have a larger manufacturing industry. Market monitoring and market surveillance activities for rubber-based products need to be strengthened. The country's regulatory agencies also need to increase their capability to test and confirm compliance of imported products with international standards.

Pharmaceutical products sector. The implementation scores for the pharmaceutical products sector are expected to increase with the recently issued DOH AO No. 2012-0008 dated June 25, 2012 - Adoption of PIC/S GMP Guide for Medicinal Products. The FDA will now implement this new Good Manufacturing Processes (GMP) guide superseding AO 43 s. 1999 - GMP for Drugs that is in line with the FDA's accession to be a member of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). This will also be the legal basis for the issuance of GMP certificate and License to Operate classified as Drug Manufacturer/Drug Trader.

FDA is preparing for the PIC/S inspection and the MRA circle in 2012. The FDA is also working on the harmonization of the GMP and preparedness programs for its regional Listed Inspection Services. Accreditation in these entities, especially in the PIC/S, is perceived to be beneficial both for the national regulator and the industry players. Currently, the Philippines has 25-percent share of the ASEAN market for pharmaceuticals, and membership with PIC/S is expected to facilitate the entry of these products into the ASEAN and global markets.

Prepared foodstuff sector. The national standards for the prepared foodstuff sector are aligned in principle with the international benchmark CODEX, although the FDA does not use exactly the same terminology. The discussions on harmonization of standards are still ongoing at the regional level, and the Philippines continues to seek clarification on a number of important issues, including CABs and the ratification of the ASEAN Common Food Control Requirements (ACFCR) before implementation. The Philippines has adopted the provisions of the ACFCR in principle.

Traditional medicine and health supplements sector. At present, 80 percent of the national standards for both traditional medicine and health supplement are compliant with international standards. Of the 20 percent that are still non-equivalent, some national standards are more stringent than the proposed regional benchmarks (e.g., the arsenic limit in traditional medicine). The Philippines is being requested to review these.

To raise implementation rates for traditional medicine, the Philippines needs to formulate and implement specific guidelines for products from other countries that do not conform to the categories of herbal medicine that constitute traditional medicine in the Philippines. For example, Chinese medicine and Ayurvedic medicine need to be accommodated in new regulation.

A further concern for the Philippines regarding GMP compliance which it shares with other ASEAN countries is the capability of small and medium enterprises (SMEs) to meet the standard. FDA needs to build a nationwide database of SMEs as a first step to enforce registration and implement capacity-building activities.

AEC BLUEPRINT MID-TERM REVIEW: SURVEY RESULTS

Cosmetics sector

Profile of survey respondents

The MTR Questionnaire on the Status of Implementation of the ACD was administered to seven respondents—five multinational companies and one

SME—and the regulator, the FDA. Of the six firms, half are distributors while the other three, all multinationals, engage in manufacturing activities. Manufacturing activity is diverse for these firms: two firms export 10–20 percent of their output while the other does 100 percent local toll manufacturing, meaning it focuses on processing raw materials for local companies.

Survey responses

Awareness on the entry into force of the ACD. The cosmetics sector in the Philippines is highly aware of the implementation of the ACD. Survey respondents unanimously affirmed that the industry was given sufficient notice of its implementation and correctly identified the FDA as the regulatory authority overseeing its implementation. Awareness seminars and industry dialogues are the mechanisms employed by the FDA to inform firms about the ACD's implementation, with all respondents rating these measures as effective. This may be due to the frequency of the employment of these measures. The regulator launched its regular awareness programs even before the implementation of the ACD and has continued to accommodate requests for related programs from stakeholders. The FDA hosts awareness seminars around five times a year in different parts of the country with 80–100 industry representatives in attendance at every gathering. Industry dialogues are held on a similar frequency in coordination with industry associations, especially on the topic of compliance. In addition, there are multinational firms that regularly attend the regional meetings together with the regulator. Some Philippine cosmetic industry associations are members of the ASEAN Cosmetic Association, which means they can participate in the discussions at the regional level.

Notification of cosmetic products. The surveyed representatives of the cosmetics industry appear to have a high awareness and understanding of the requirements and system for the notification of cosmetic products. All respondents affirmed that the process, beginning with the acknowledgement of notification of cosmetic products by the FDA until the products are available in the market, takes about two to three weeks on average. The regulatory authority conducts trainings on the notification process and requirements, and the respondents acknowledged that in cases where the notification is rejected, the FDA issues a notification of deficiency explaining the reasons for the denial and provides guidance. In addition, none of the exporter firms reported having had its cosmetics products rejected, prohibited, or restricted in any of the ASEAN member-states. All respondents cited the reduced time for the placement of cosmetic products and the increase in the volume of these products in the market as the most important benefits gained from

the implementation of the notification of cosmetic products. The simplification of requirements means faster releasing time and a shorter wait for products to reach the market.

Harmonized technical requirements. Updated information on the harmonized technical requirements for product safety and quality are readily available to the cosmetic industry in the Philippines. All respondent firms confirmed the availability of the following documents from the FDA: ASEAN Definition of Cosmetics and Illustrative List by Category of Cosmetic Products, ASEAN Cosmetic Ingredient Listings, ASEAN Cosmetic Labelling Requirements, ASEAN Cosmetic Claims Guidelines, ASEAN Cosmetic Product Registration Requirements, ASEAN Cosmetic Import/Export Requirements, and ASEAN Guidelines for Cosmetic Good Manufacturing Practice. The regulator pointed out that while available, the document ASEAN Cosmetic Product Registration Requirements has actually been phased out already with the implementation of the notification system. Revised and updated versions of these documents are also available with the regulator as well as the harmonized cosmetic test methods implemented at the regional level. High awareness of the harmonized technical requirements translates to high compliance: All surveyed firms reported that 100 percent of the cosmetics products they manufacture or distribute meet these technical requirements.

Technical infrastructure. The Philippine cosmetic industry registered high awareness of the accredited CABs for the testing of cosmetic products. All survey respondents reported that the regulator accepts conformity assessment results issued by accredited CABs and that their companies obtain reports for the notified cosmetic products from local CABs as well as those located outside the country. An importer and distributor of European-sourced cosmetic products said a smooth process is ensured when one trades with quality products since reputable manufacturers in developed countries pass compliance with accredited CABs.

Postmarket surveillance. Survey respondents coming from private firms reported that all parts of the Product Information File (PIF) are readily available to the regulatory authorities. The regulator clarified that some companies find it difficult to comply with Part IV so they are referred to industry associations that guide them on the topic of safety assessment. The FDA requests for the PIF during GMP audit, and during the renewal of the License to Operate that is valid for two years. The regulator also conducts surprise PIF reviews of high-risk companies and those with high-risk products and with significant volume or number of products.

Technical assistance. The regulatory authority in the Philippines gives adequate support to the industry to ensure the effective implementation of the ACD. The FDA makes available on its website the guidelines for the understanding and interpretation of the technical documents and carries out training sessions for the industry's guidance. All the respondent firms reported having a thorough understanding of the ACD's provisions.

Facilitating factors and deterring factors or barriers. The respondents unanimously rated the following as facilitating factors toward the implementation of the ACD: awareness on the entry into force of the ACD, notification of cosmetic products, harmonized technical requirements, technical infrastructure, postmarket surveillance, and technical assistance. Rated very important were the first four factors, namely, awareness of ACD, product notification, technical requirements and infrastructure. Respondents were clearly aware that noncompliance with the regulation meant no market access and that faster notification and release of the product in the market were considerable advantages.

Rated as important facilitating factors were postmarket surveillance and technical assistance. The respondents, however, clarified that these were less important than the previously cited factors only because there was not enough government budget at present to improve capability in these areas. Some respondents from multinational companies pointed out that it is mainly SMEs that are actually helped by the regulator, given its current resources—an issue that will be discussed further in the last section. The respondents said they were highly aware of the importance of product safety and how postmarket surveillance improves the overall quality of the products on the market, and stressed the responsibility for self-regulation.

Analysis of survey results

The Philippines is progressing well in the implementation of the ACD. Participating firms showed high awareness and understanding of the entry into force of the ACD and the process of notification of cosmetic products. The harmonized technical requirements are readily available to the industry and both manufacturers and distributors appear to register high compliance with the essential requirements for product safety and quality. The technical infrastructure, consisting of accredited CABs, is acknowledged by the surveyed firms that source test reports for notified cosmetic products from both local and foreign CABs recognized by the regulatory authority. In addition, postmarket surveillance is being executed through the availability of the Product Information File to the FDA. There is a system in place that includes routine audits, technical courses held in cooperation with industry associations, and a feedback mechanism on corrective actions in case of

noncompliance. Lastly, technical assistance from the regulator appears adequate as surveyed firms reported a thorough understanding of the ACD's provisions and the availability of support mechanisms including training sessions and guidelines for understanding technical documents available on the FDA website.

Nonetheless, there is room for improvement. Addressing the unavailability of online notification of cosmetic products and augmenting the technical expertise of the regulator are the main suggestions offered by the surveyed firms to facilitate the faster and smoother implementation of the ACD. Some survey respondents would welcome greater technical expertise from the regulator in the area of postmarket surveillance to make Philippine cosmetic products more competitive. From the point of view of the regulator, information dissemination regarding technical requirements can still be enhanced. For example, some products are recalled in the local market mainly because they do not comply with the notification and labeling requirements of the FDA as mandated by the ACD. Awareness of the required procedures, especially the online process of application and approval of the Certificate of Notification which was instituted by the FDA, could be targeted via information campaigns.

The reorganization of the FDA will be the key to addressing many of the concerns expressed by respondents. This important milestone for the regulator will be discussed in the last section of this report.

Electrical and electronic equipment sector

Profile of survey respondents

The ERIA MTR Questionnaire on the Status of Implementation of the ASEAN Sectoral Mutual Recognition Arrangement for Electrical and Electronic Equipment (ASEAN EE MRA) was administered to three respondents—a representative of an industry association actively involved in standards setting, an official of the BPS, and an executive from a testing laboratory. All the respondents have been working in the field for several years and have attended regional technical working committee meetings.

Survey responses

Awareness on the entry into force of the ASEAN EE MRA. In general, firms engaged in the EE industry in the Philippines are highly aware of the implementation of the ASEAN EE MRA. Survey respondents correctly identified the BPS as the regulatory authority in charge of its implementation. The regulator updates them about the implementation of the ASEAN EE MRA through government circulars, awareness seminars, and industry dialogues with respondents rating these

measures as effective. Advertisement is not an option given the limited funds of the regulator. The awareness mechanisms are frequently employed, starting in the period before actual implementation and sustained through regular information seminars convened by the regulator and other dialogues organized by industry associations.

A number of industry associations and organizations cooperate with the BPS in disseminating information on the ASEAN EE MRA including the Philippine National Committee of the International Electrotechnical Commission (IEC), the Philippine Appliance Industry Association (PAIA), the Philippine Lighting Industry Association (PLIA), the Philippine Electric Wires Manufacturing Association (PEWMA), and the Federation of Electrical and Electronics Suppliers and Manufacturers Association of the Philippines (PESA).

The BPS is currently focused on the preparations for the next phase of the implementation of the ASEAN EE MRA in the Philippines, which is the implementation of the acceptance of certification starting in 2013. The regulator has given notice to the industry that anticipates and welcomes this phase. The formal launch of the awareness campaign is scheduled for mid-2012 leading to the full implementation.

Harmonized technical requirements. The national standards for the scope of the EE within the MRA are aligned to the ISO/IEC standards. Standards that have been aligned to the identified benchmarks are made available by the regulator on its website. The BPS regularly updates this list. Survey respondents said ASEAN member-states accept national standards or technical requirements that are identical to the ISO/IEC standards in the case of a local company exporting to an ASEAN member-state. The respondents also agreed that the application of common standards for the EE sector has contributed to the trade facilitation objectives of ASEAN through the use of the same or equivalent standards. However, since the Philippines is a net importer of these products, the implementation of the ASEAN EE MRA is particularly important for the protection of Filipino consumers who are assured that the products available in the domestic market comply with international standards.

Technical infrastructure. There are three accredited, private testing laboratories in the Philippines listed under the ASEAN EE MRA, namely, the Scientific, Environmental Analytical Laboratory and Services Incorporated (SEALS), Solid Laguna Corporation Testing Laboratory, and TUV Rheinland, Inc. (TUVRI). The accreditation of the fourth testing laboratory, the BPS Testing Center operated by the regulator, has been listed as a testing laboratory under ASEAN EE MRA effective March 6, 2102 until July 14, 2013. The regulatory authorities do not

accept test reports and certifications issued by laboratories and certification bodies not listed under the ASEAN EE MRA. The respondents also agreed that although the BPS accepts test reports issued by a CAB that is a signatory to the APLAC/ILAC MRA, there are national regulations and additional requirements that EE products seeking to enter the Philippine market need to comply with. In the Philippines, the updated information on Listed Laboratories and Certification Bodies is made available by the regulator to firms in the EE industry.

Respondents stated the benefits gained from the implementation of the ASEAN EE MRA with the acceptance of test reports and/or certification from listed CABS as shorter time for placement of EE products in the market and increase in the volume of these products placed in the market. Other reasons will be discussed further in the section on analysis of survey results.

Technical assistance. Respondents responded affirmatively to all the questions in the section on technical assistance. The Frequently Asked Questions (FAQ) of the ASEAN EE MRA is made available by the BPS through a link on its website to the ASEAN website. The regulator conducted training sessions on the provisions of the ASEAN EE MRA and the respondents are confident that their organizations have a thorough understanding of the document.

Facilitating factors and deterring factors or barriers. The respondents unanimously rated the following as facilitating factors toward the implementation of the ASEAN EE MRA: awareness on the entry into force of the ASEAN EE MRA; harmonized technical requirements; technical infrastructure; and technical assistance. These factors were rated as very important. Respondents said knowledge of the ASEAN EE MRA was crucial to compliance and they perceive the regional agreement as facilitating trade and increasing the time to market EE in the country. Both the regulator and respondents from the private sector agree that given the limited funding from the national government, technical assistance from dialogue partners, donors of official development assistance, and even mechanism within ASEAN would yield benefits in terms of increased technical competence and the purchase of adequate and up-to-date testing equipment.

Analysis of survey results

The implementation of the ASEAN EE MRA in the Philippines is on track. There are three private laboratories listed under the ASEAN EE MRA with the regulator's own testing laboratory expecting accreditation within 2013. Preparations are also in place for the implementation of the acceptance of certification in 2013. Industry associations appear to work closely with the regulator in the dissemination of relevant information (Maglalang 2012). Survey respondents have a favorable

view of the ASEAN EE MRA citing the advantages of faster time to market. They particularly refer to the cost advantages enjoyed by EE importers in possession of a testing report and certification compliant with the standards and regulatory requirements. Doing away with retesting and recertifying in the Philippines, importers can cut storage costs as goods do not need to stay in warehouses while products wait in line to be tested. This also means quicker response time to market conditions, for example, restocking is faster as shipment of goods is facilitated.

Room for improvement for the EE industry in the Philippines lies in taking advantage of the ASEAN EE MRA to export to ASEAN member-states through the globally accepted testing and certification process. However, at present, locally produced EE products are not competitive in terms of price. These products fulfill the technical standards given the adequate information on standards provided by the regulator and the availability of local testing laboratories listed under the ASEAN EE MRA. However, high manufacturing costs associated with electricity and labor continue to prevent domestic firms from embarking on a sustained, outbound initiative.

The regulator will also benefit greatly from increased resources to adequately fulfill its role in implementing the ASEAN EE MRA. Currently, the BPS implements and monitors compliance for 50 of the 133 standards harmonized under the ASEAN EE MRA. To increase coverage and implementation of the remaining standards would require fiscal support. A full complement of personnel would ensure documents of EE firms are processed faster, translating to lower costs for firms and faster entry into the market. Adequate equipment to test new kinds of products would also be attainable given a bigger budget allotment and a mechanism for the BPS to retain its income.

CONCLUSIONS AND RECOMMENDATIONS ON THE WAY FORWARD

The standards and conformance initiatives of the ASEAN have influenced and continue to drive change in the policies on standards in the Philippines. The Philippines has been developing national standards for the majority of the priority integration sectors covered in the ERIA Phase Two Study and Mid-Term Review. A number of national standards across sectors were already equivalent to international standards, but the commitment of the Philippines to the ASEAN standards and conformance initiatives has served to further focus the efforts of the competent regulatory bodies to work at harmonizing standards with international benchmarks. The initiatives for alignment by the Philippines have extended to the amendment of the relevant laws and regulations. An administrative order was signed by the DOH secretary to implement the ACD. This move has enabled the standards of the cosmetics sector of the Philippines to be 100-percent compliant

with international benchmarks. For the pharmaceutical products sector, the approval of AO 43 also by the DOH secretary completed the legal basis for the implementation of the ASEAN Common Technical Dossier (ACTD) in the Philippines.

The ASEAN initiatives in standards and conformance are also instrumental in creating new regulation. This is the case for the traditional medicine and health supplements sector. The Philippines needs to formulate and implement specific guidelines for products from other countries that do not conform to the categories of herbal medicine that constitute traditional medicine in the Philippines. Chinese medicine and Ayurvedic medicine are examples of foreign types of traditional medicine that need to be accommodated in the new regulation.

The way forward for standards and conformance in the Philippines lies in capacity building and institutional development. The signing into law of the Food and Drugs Administration Act in 2009 and the ensuing ongoing reorganization at the DOH is a positive step for regulatory bodies in obtaining adequate support and recognition. It is significant that apart from protecting and promoting the right to health of the Filipino people, the other stated objective of the reorganization is to establish and maintain an effective health products regulatory system.

Three years ago, RA 3720 was amended with the passage of a new law, RA 9711, also known as The Food and Drug Administration Act of 2009. RA 9711 confers two important powers on the FDA: (1) expanded quasi-juridical power with regulatory functions over food, drugs, medical devices, cosmetics, household hazardous substances, and radiation devices and facilities; and (2) the power to retain and use its income to support operations, expand personnel complement, and upgrade and augment laboratory facilities and equipment. The quasi-juridical power means the FDA has the power to immediately recall, ban, or withdraw health-related products within its mandate when these do not pass safety standards or are found to be hazardous. The agency is also authorized to conduct inspection of facilities for compliance and seize health-related products deemed unsafe. The power to retain its income will enable the FDA to spend on much-needed resources to support its functions.

The FDA Act of 2009 mandates the creation of four separate centers within the FDA focused on major product categories: Center for Food Regulation and Research, Center for Drug Regulation and Research, Center for Cosmetics Regulation and Research, and the Center for Device Regulation, Radiation Health and Research. The focus on product will mean greater efficiency in processes and areas of specialization that should translate to faster transaction time and cost benefits for firms. It can be noted that the product categories are closely aligned to key Priority Investment Sectors of the ASEAN.

The BPS would do well to have a similar arrangement. Income retention appears to be the key to addressing concerns regarding the lack of personnel and testing facilities for electrical and electronic equipment. This would require a change in legislation similar to the creation of the new FDA. The BPS is currently preparing the draft amendment of RA 4109, a step in this direction.

Finding solutions for strengthening the technical infrastructure and increasing the technical expertise of the country's regulatory agencies will facilitate the compliance of the Philippines with its standards and conformance obligations on the regional level. Domestic firms engaged in manufacturing, trade, and distribution, as well as foreign companies seeking to enter the local market will benefit from administrative and procedural efficiencies in terms of lower costs and faster speed to market. Last but not least, fully equipped and well-functioning regulatory agencies will raise public awareness of the importance of product safety and quality, and generate greater appreciation and understanding of the importance of standards in daily living and the practical utility of the standards and conformance initiatives of the ASEAN.

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