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AEC Blueprint Implementation Performance and Challenges: Standards and Conformance*

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Abstract: *ASEAN aims to reduce, if not eliminate, technical barriers to trade through standards and conformance (S&C) initiatives towards a highly integrated economy, or the so-called single market and production base. This paper aims to evaluate the progress and challenges of S&C initiatives implementation in three ASEAN priority integration sectors, namely, the automotive sector, the electrical and electronic equipment sector, and the health sector (cosmetics, medical devices, and pharmaceutical). The paper uses questionnaires and interviews with government officials and the private sector in 10 ASEAN members states (AMSs). The scoring method is similar to the one used in the ERIA Mid-Term Review study 2011, thus allowing for comparison across period. The result shows, in general, there have been many improvements in reducing technical barriers to trade through the S&C initiatives in ASEAN compared to the 2011 mid-term review; nonetheless, the progress varied across sectors and across member states. The main challenges include technical capacity, physical infrastructure, governance, and some country-specific and sector-specific challenges. The paper concludes with recommendations for ASEAN S&C initiatives post-2015.*

Keywords: ASEAN Economic Community, standards and conformance, standards harmonization, mutual recognition arrangement, technical regulations.
JEL Classification: F13, F14, F15

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1. Introduction

The virtual elimination of tariffs among the six original members of the Association of Southeast Asian Nations (ASEAN-6)[2] (and, in 2018, for the newer ASEAN member states [AMSs]) brings greater policy relief to the issues related to non-tariff measures (NTMs) and barriers. Technical measures form a large segment of NTMs in many AMSs (Cadot, Munadi and Ing, 2013; Pasadilla, 2013). Technical measures such as national standards, technical regulations, and conformity assessment procedures become the so-called technical barriers to trade (TBTs) when applied too stringently. Studies indicate that TBTs can have a large adverse impact on firms' exports, especially producers of perishable products and firms that rely on imported inputs (Wilson, 2005, p.81).

Under its standards and conformance (S&C) initiatives, ASEAN aims to reduce, if not eliminate, TBTs in its drive towards a highly integrated, unified economy, or the so-called 'single market and production base', under the ASEAN Economic Community (AEC). Led by the ASEAN Consultative Committee for Standards and Quality (ACCSQ) established in 1992, ASEAN's S&C initiatives involve primarily the harmonization of standards, technical regulations, and conformity assessment procedures with '…greater transparency, improved quality of conformity assessment and active participation of the private sector' (ASEAN 2009, p.25). The key actions under S&C in ASEAN are:

i. Harmonize standards, technical regulations, and conformity procedures through their alignment with international practices, where applicable.
ii. Develop and implement sectoral mutual recognition arrangements (MRAs) on conformity assessment for (identified) specific sectors.
iii. Enhance technical infrastructure and competency in laboratory testing, calibration, inspection, certification, and accreditation based on regionally/internationally accepted procedures and guides.

[2] ASEAN-6 refers to Brunei Darussalam, Indonesia, Malaysia, the Philippines, Singapore, and Thailand.

iv. Promote transparency in the development and application of standards, technical regulations, and conformity assessment procedures in line with the requirements of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade and the ASEAN Policy Guideline on Standards and Conformance.

v. Strengthen post market surveillance systems to ensure the successful implementation of the harmonized technical regulations.

vi. Develop capacity building programs to ensure smooth implementation of the work programme.

The ACCSQ also oversees the implementation of three initiatives related to the six key elements mentioned above: (i) information exchange on laws, rules, and regulatory regimes on S&C assessment procedures; (ii) cooperation with dialogue partners (especially important for expertise support and capacity building); and (iii) implementation of the TBT chapter in the ASEAN+1 free trade agreements (Erna, 2014).

The ACCSQ's approach to implementing the S&C initiatives is to focus on the priority integration sectors that have a bearing on intra-ASEAN trade; that is, agro-based products (prepared foodstuff); automotive products; health-care products (cosmetics, medical devices, pharmaceutical, traditional medicines, and health supplements); electrical and electronic equipment (EEE); and rubber-based products. Since its inception in 1992, the ACCSQ has added only one sector, the building and construction materials sector, to the original sectors. Its focus is on the mutual recognition of conformity assessment results for building and construction materials issued by listed testing laboratories or certification bodies.[3]

The ACCSQ's working structure revolves around the sectoral product working groups and three (horizontal) working groups on standards and MRAs, conformity assessment, and legal metrology. (A task force on an MRA on building and construction materials is under the working group on standards and MRA.) The ASEAN Policy Guideline (guiding principles for the development and implementation

[3] The products involved in the MRA are hot rolled steel bar for reinforcement of concrete, Portland cement and float sheet glass.

of S&C initiatives), the ASEAN Framework Agreement on MRAs (guiding principles for acceptance or recognition of conformity assessment results), and the ASEAN Good Regulatory Practice guidelines (guiding principles for the adoption of efficient regulatory arrangements to improve the consistency and transparency of technical regulations) guide the ACCSQ in its implementation of the S&C initiatives (Ramesh, 2012b, slide 4).

Table 1 presents the major activities for the priority integration sectors under standards harmonization, conformity assessment, and technical regulations. Some elements are not undertaken in a number of the sectors, reflecting the applicability, importance, and prioritization of the key elements and difficulty in implementing such elements per priority integration sector. It is noted that harmonizing standards to international standards, with standards being essentially voluntary, may be considered easier to undertake than harmonizing technical regulations which are mandatory in nature, unless the standards become part of the technical regulations. For both cases, MRAs on conformity assessment are the important means of '…eliminating TBTs and enhancing market access and that such mutual recognition could be of particular interest to small and medium-sized businesses in ASEAN' (ASEAN Framework Agreement on MRAs, p.1). Moreover, '…MRAs could contribute positively in encouraging greater international harmonization of standards and regulations… [nonetheless], such MRAs would require confidence in the other Member States' capacity and competence to test or assess conformity to a Member State's own requirements' (ASEAN Framework Agreement on MRAs, p.1, parenthesis provided). It is noted that the basic principle of the harmonization process in ASEAN is that national standards bodies would need to adopt regionally agreed international standards; if they do not adopt any of the identified international standards as their national standards, then they would accept the direct use of these international standards (*Harmonization of Standards in ASEAN*, ASEAN n.d.).

In a region such as ASEAN consisting of countries with widely varying levels of economic development and institutional capacity, ensuring a well-performing S&C system will be difficult to fulfil. For example, it means the harmonization of standards to international standards and convergence of product safety regulations allowing for some modifications to be consistent with the realities of each country, but which

should not become a barrier to trade and deeper economic integration of the region. It means balancing the interests of large firms and multinational corporations on the one hand and the concerns of small and medium-sized firms in each of the member states on the other hand.

It also means confidence on, and efficacy of, the conformance assessment results and procedures in AMSs. Thus, the Framework Agreement on MRAs explicitly states that the assessment bodies need to meet one of the following criteria to demonstrate technical competence: (i) accreditation by a body that is a signatory to a regional or international MRA which is conducted in conformance with the relevant International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) standards and/or guides (for example, Asia Pacific Laboratory Accreditation Cooperation, International Laboratory Accreditation Cooperation, Pacific Accreditation Cooperation, International Accreditation Forum); (ii) participation in regional/international MRAs for testing and certification bodies which are conducted in conformance with the relevant ISO/IEC standards and guides; or (iii) regular peer evaluations which are conducted in conformance with ISO/IEC guides. This is important because AMSs have different compliance mechanisms from regional regulatory requirements (Ramesh, 2012b, slide 12). There is, thus, the corollary imperative to enhance the technical infrastructure and competency in laboratory testing, calibration, certification, and accreditation based on internationally accepted procedures and guidelines in AMSs. Where a member state does not have the facilities, it can engage the services of other member states to undertake conformity assessment activities.

Table 1: Activities of the Priority Integration Sectors

Sector	Standards Harmonization	Conformity Assessment	Technical Regulations
Agro-based products	Harmonization of food safety standards and technical requirements for food activities and contaminants	Development of mutual recognition agreements (MRA) for inspection and certification of prepared foodstuff products issued by listed conformity assessment bodies	Harmonization of requirements for good manufacturing practices, safety management and hygiene requirements based on hazard analysis of critical control points, import–export inspection and certification system, food control systems, food hygiene, and food labelling
Automotive	Harmonization of national standards and technical requirements/regulations with United Nations Economic Commission for Europe (UNECE) Regulations of the 1958 Agreement	Development of ASEAN MRA for Type Approval of Automotive Products for mutual acceptance and recognition of conformity assessment results issued by listed technical services	–
Building and construction materials	–	Development of MRA on building and construction materials	–
Cosmetics	–	ASEAN Cosmetics Testing Laboratory Committee	ASEAN Cosmetics Directive (Schedule B of ASEAN Cosmetics Harmonized Regulatory Scheme) Harmonization of technical requirements for cosmetics ingredients
Electrical and electronic equipment	Harmonization of national standards with International Electrotechnical Commission (IEC) standards	ASEAN sectoral MRA for electrical and electronic equipment	ASEAN Harmonized Electrical and Electronic Equipment
Medical devices	Harmonization of national standards with International Organization for Standardization (ISO) standards for medical devices	–	ASEAN Medical Device Directive
Pharmaceutical	–	ASEAN Sectoral MRA for good manufacturing practices (GMPs), inspection of manufacturers of medicinal products for mutual acceptance and recognition of GMPs certificates issued by listed inspection services	Adoption of the ASEAN Common Technical Requirements and ASEAN Common Technical Dossier Development of guidelines for bioavailability (BA)/bioequivalence (BE) studies, variation guidelines, stability guidelines and validation guidelines
Rubber	Harmonization of national standards with ISO standards for rubber-based products	Directory of accredited laboratories for rubber-based products	–
Traditional medicines and health supplements (TMHS)	–	–	Harmonization of technical requirements for claims, negative list of substances, maximum levels of vitamins and minerals, limit of contaminants, additives and excipients, safety, GMPs and labelling. Development of ASEAN regulatory framework for TMHS

Note: The list above is not comprehensive. Other activities related to those in the table are not included.
Source: Adopted from Ramesh (2012a).

Perhaps, not surprisingly, getting agreements completed, signed, and implemented has been a long process, as the monitoring results below indicate. An example of how involved and structured the process is in ASEAN S&C is the development of ASEAN regulations on pharmaceuticals (Latzel, 2007; Javroongrit, 2012). The main scope of the Pharmaceutical Product Working Group (PPWG) is to harmonize pharmaceutical regulation primarily in pharmaceutical registration to reduce barriers to trade while at the same time ensuring that the products entering the ASEAN market meet the three main criteria of safety, quality and efficacy. The outputs of the PPWG are the 'ASEAN pharmaceutical product' (wherein the same regulatory requirements apply for the registration of a pharmaceutical product among member states) and MRAs. Towards defining the ASEAN pharmaceutical product, the PPWG developed the (i) ASEAN Glossary of Terms; (ii) ASEAN Common Technical Dossier (ACTD); and (iii) ASEAN Common Technical Requirements (ACTR) and its quality guidelines (that is, analytical validation, bioavailability/bioequivalence studies, process validation, and stability study).

The PPWG created ad hoc expert working groups and committees to set out the technical aspects of the ACTD and the ACTR and its technical guidelines, focusing on safety, quality, and efficacy, and determining from various internationally accepted standards and guidance documents (including the International Conference on Harmonization [ICH], World Health Organization [WHO], and international pharmacopoeia), which are applicable to ASEAN. Industry representatives at the national level earlier and at the regional level more recently (through the ASEAN Pharmaceutical Club) and experts from international organizations were engaged in formulating and finalizing the harmonization scheme on pharmaceutical regulations. The PPWG consultation process follows the ICH consultation procedure, but with a difference that adoption is by consensus and not partial votes for the ICH steering committee, and that the PPWG only recommends to the ACCSQ and Senior Economic Officials while the ICH Steering Committee has a legal right to make decisions. This makes the PPWG decision process lengthier than the ICH decision process (Latzel, 2007).

Nonetheless, as AMSs and the business sector increasingly share a heightened focus on addressing non-tariff measures and TBTs and as the business sector becomes more deeply engaged in the process at both the national and regional levels, and as lessons learned from the previous and ongoing initiatives cumulate, it is hoped that ASEAN will accelerate efforts and invest more towards a well-performing S&C system. Indeed, S&C initiatives in ASEAN are

gaining traction, with two new MRAs expected to be signed and two MRAs expected to be finalized by 2015.[4]

2. ASEAN Standards and Conformance Scorecard Performance

In evaluating the implementation performance of ASEAN S&C measures, the ERIA AEC Scorecard project developed a scoring system to compare AMSs (Appendix A). The scoring weights are necessarily arbitrary; nonetheless, the weights drew from the input and advice of a previous key ASEAN Secretariat official involved in supporting the activities and initiatives of ACCSQ and its horizontal and product working groups. The AEC Scorecard project prepared questionnaires for respondents in their respective countries. The scoring results notwithstanding, the monitoring report gives more emphasis on the accomplishments and bottlenecks of S&C implementation at both the regional and national levels. The report ends with recommendations.

For this project, the AEC Scorecard Phase 4 project, the review of the implementation of S&C measures focuses on three priority sectors: the automotive sector, the EEE sector, and the health sector (cosmetics, medical devices, and pharmaceutical).

Cosmetics sector

It is worthwhile to start with the cosmetics sector because it is the most developed and one of the earliest among the ASEAN sectoral S&C initiatives. In fact, the ASEAN Cosmetics Association was the driving force for the signing of the Framework Agreement on MRAs in 1998, which is one of the foundation agreements on ASEAN's S&C initiatives. ASEAN cosmetics regulators and the cosmetics industry worked together from mid-1997 to mid-2003 to remove barriers to cosmetics primarily through the harmonization of technical regulations and mutual recognition of product registration approval, the two key elements of the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS) signed on 2 September 2003.

The AHCRS was intended to enhance cooperation in ensuring the safety, quality, and claimed benefit of all cosmetic products marketed in ASEAN. It likewise intended to eliminate

[4] The MRAs expected to be signed in 2015 are on automotive products and prepared foodstuffs. The MRAs on building and construction materials and bioavailability/bioequivalence study reports should be finalized in 2015 (Interview with Isagani Erna, ASEAN Secretariat).

trade restriction of cosmetic products among member states by harmonizing technical requirements, mutually recognizing product registration approvals, and adopting the ASEAN Cosmetics Directive (ACD). For instance, under the agreement, a manufacturer from any member state can use registration certificates from its home country as a basis for regulatory action in other countries, such as approval or re-issuing of product registration approvals.

Under the AHCRS, AMSs are required to adopt and implement five harmonized aspects of cosmetic products: (i) definition and scope, (ii) ingredients listing, (iii) labelling, (iv) product claims, and (v) good manufacturing practice. The member states have agreed to enhance existing cooperation to establish or improve infrastructure facilities and encourage or promote cooperation in technological development. The benefits of the agreement would be felt by consumers (bigger selection of cosmetics products), regulators (simplified regulatory system), and industry (ASEAN as a single market and production base). To support the agreement's implementation, the ASEAN Cosmetics Committee was established. Its role also includes monitoring, reviewing, and updating the technical documents prescribed by the agreement.

The ASEAN MRA of Product Registration Approval for Cosmetics is under Schedule A of the AHCRS. Under this MRA, participating member states are required to recognize the product registration approval of any signatory in accordance with agreed rules and procedures (that is, the ASEAN Cosmetic Products Registration Requirements, the ASEAN Cosmetic Labelling Requirements, the ASEAN Cosmetic Claims Guidelines, and the Cosmetics Good Manufacturing Practices (GMPs) and annexes of prohibited and restricted ingredients). AMSs were expected to identify a test laboratory to be under the ASEAN Cosmetics Testing Laboratory Committee (ACTLC) and competent conformity assessment bodies to be listed under the ACC, which can support the implementation of the ACD. This will facilitate the application of a common test method for products in the region as well as an alert notification for unsafe products. In addition, there would be other cooperation mechanisms such as support to regulatory authorities for quality assurance of the products based on the requirements of the harmonized regional agreement.

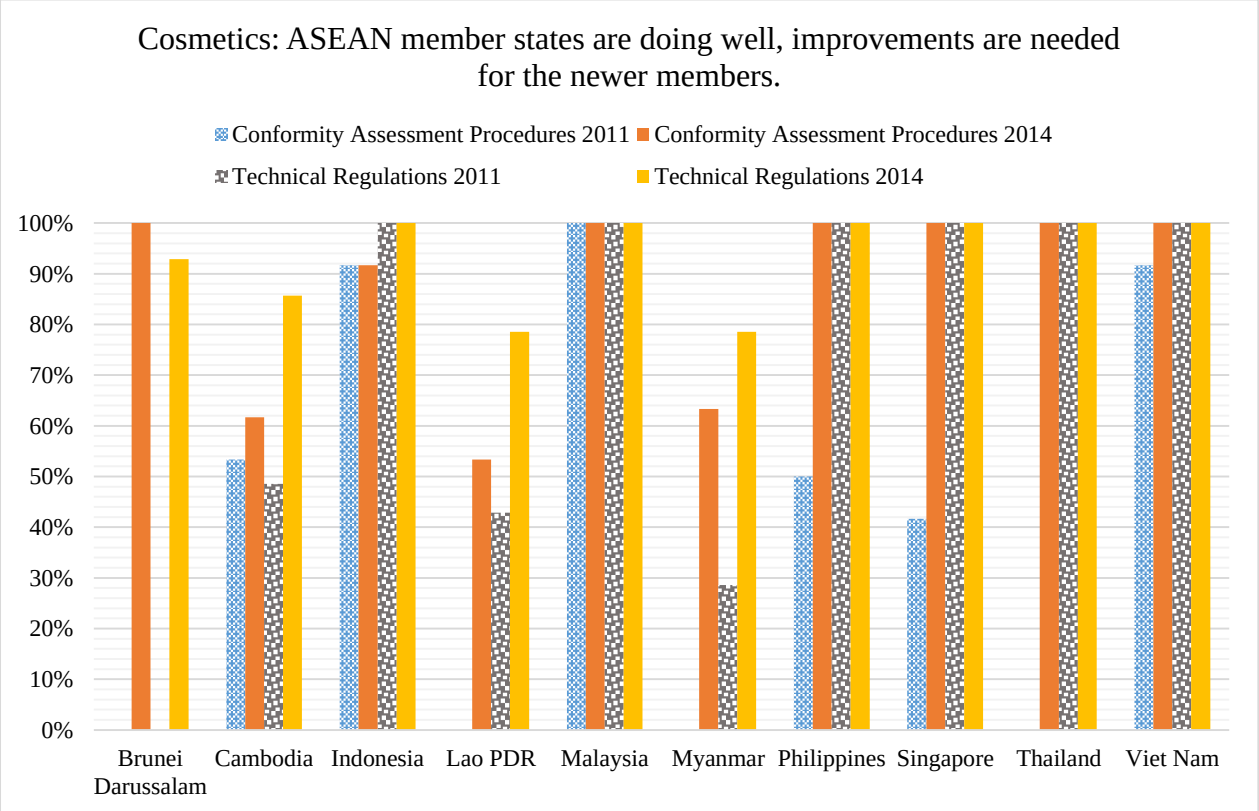
The ACD is under Schedule B of AHCRS. The member states were expected to put in place all the necessary harmonized technical requirements and infrastructure to support the effective implementation of the agreement on 1 January 2008. This agreement also entails a change from a pre-market approval (registration) system to post-market surveillance. The surveillance should be in place to enforce the law on cosmetic products not complying with the directive.

Overall, under the AHCRS, the business community will enjoy the benefit of complying with common standards through harmonizing national standards with international standards, a common methodology for determining conformity assessment procedures and strengthened post-market surveillance linked with safety alert notification.

ERIA questionnaire results. The questionnaire assessed the implementation of conformity assessment and technical regulation of the cosmetics sector. On conformity assessment, member states were asked whether the ACTLC terms of reference have been agreed and whether a laboratory has been identified to be part of the ACTLC. On technical regulation, member states were asked whether they have transposed the ACD into applicable national regulations and whether the post-market alert system has been established.

Based on ERIA's questionnaire, Brunei Darussalam, Indonesia, Malaysia, Philippines, Singapore, Thailand, and Viet Nam have fully implemented the institutional and regulatory requirements (for Brunei Darussalam, virtually fully implemented) in the cosmetics sector. Improvements are needed for Cambodia, Lao People's Democratic Republic (Lao PDR), and Myanmar (Figure 1).

Figure 1: Standards and Conformance Score: Cosmetics Sector, 2011 and 2014



Note: No national data for Brunei Darussalam in 2011 scorecard.
Source: ERIA questionnaire.

In the ***harmonization of technical regulations***, six member states have already fully transposed the ACD into applicable national laws, legislation, or regulations. In Brunei Darussalam, Cambodia, Lao PDR, and Myanmar, the ACD is partially transposed. Brunei Darussalam is in the process of ensuring all requirements are correctly aligned with the local context; nonetheless, there are no issues for full transposition. For Cambodia, the main reason is that the process takes time. Going forward, capacity building of technical staff, especially on legal matters, is needed (Chap, 2014). For Lao PDR, the current legal document in use came into force in 2003. It is consistent with the ACD but it does not specify all the provisions. Nonetheless, in practice, all required documents and procedures follow those of the AHCRS (Leebouapao and Sayasenh, 2014).

All member states have adopted the five guidelines of ACD. In Thailand, in addition to the ACD labelling requirement, an additional notification number is included for traceability reasons. This helps to trace back any post-market surveillance activity and to urge persons responsible to notify their product.

The ACD also shifts the pre-market approval system (that is, product registration) to a post-market surveillance system. This involves replacing the existing product registration system with a product notification system. All countries have adopted the system, although Myanmar states that the notification system is not yet operational; as such, it is still on a pre-market approval system. All countries have also adopted the mechanism for linking with the safety alert notification, although in Viet Nam, it is not yet linked. Myanmar has recorded the biggest increase in the technical regulations score (from 29 percent to 79 percent). In 2011, Myanmar had not amended its national legislation in alignment with the ACD; while based on the 2014 questionnaire, the country's law and regulations are similar to the ACD.

The ***conformity assessment procedure*** is done by establishing a regional laboratory network and the listing of conformity assessment bodies. All member states have agreed to the ACTLC's terms of reference, and all member states, except Cambodia and Lao PDR, have appointed a test laboratory to be part of the ACTLC (see Appendix B for a list of the bodies). Cambodia is appointing a test laboratory, while Lao PDR's challenge is the unavailability of a qualified laboratory. All member states except Myanmar have published their regulatory requirements, conformity assessment procedures, and applicable standards; however, Indonesia does not provide all information in English. Most countries have also conducted national projects, either initiated by a government body, industry player, or donor countries, to enhance the capability of regulators and for industry to meet the requirements. Some member states highlighted capacity building programmes initiated by the ASEAN Cosmetics

Association, the Japan International Cooperation Agency, and the ASEAN Regional Integration Support from the European Union programme.

Finally, the questionnaire results indicate that despite perceived actual or potential benefits from the cosmetics standard and conformance initiative, there are implementation problems. Among the benefits is the post-market alert system to keep member states informed of non-compliant products. The e-notification system facilitates faster flow of goods, free and fair competition, improved regulatory framework, increased number of products registered, greater consumer awareness on product safety, improved product competitiveness due to uniform labelling, and better consumer protection, among others. However, the Indonesian report highlights that the benefits of the ACD, especially the e-notification system, have not yet been felt although the system makes it cheaper and easier for new domestic firms to enter the market; in part, this is because of the dominance of non-ASEAN players in the Indonesian cosmetics market (Damuri *et al*., 2014).

There are also problems and challenges in implementing the ACD. The Philippines highlights the following problems: (i) not all AMSs use e-notification, (ii) risk classification is not yet harmonized, (iii) there are problems in implementing safety assessment, and, perhaps the most important in terms of the impact on industry, (iv) micro, small, and medium-sized enterprises (SMEs) cannot comply with the ACD in terms of GMP requirements. Singapore emphasizes the problem of inadequate knowledge and understanding of SMEs on the regulatory requirements of cosmetic products because they were subjected to minimum regulatory requirement before the ACD when most of the cosmetic products were low risk. Cambodia, Lao PDR, Myanmar, and even Viet Nam emphasized the human resource and financial constraints, the lack of infrastructure like testing equipment, inadequacy of staffing and weak controls on cosmetics quality, and for Myanmar, the lack of publicly available information on the ACD.

Thailand highlighted the ultimate challenge for the ACD in terms of impact. The country has more than 4,000 SMEs in the cosmetics sector but they need to improve their quality and standards to make their products comply with the regulations. To help the SMEs, Indonesia, the Philippines, and Singapore emphasize the need for more capacity building programmes to strengthen SMEs' capacity to penetrate the market and survive the competition. This calls for higher budgetary resources for the concerned national agencies and support from the regional institutions (for example, the ACCSQ), probably funded by ASEAN's dialogue partners. Other capacity building recommendations from the Philippine report, primarily for the regulators,

include post-market surveillance system resources and technical training, product information files, safety assessment, GMP training, and training on the classification of risks.

In summary, most AMSs have fully implemented the ACD; Cambodia, Lao PDR, and Myanmar have made significant strides since 2011. Nonetheless, challenges in most countries remain before there can be a well-performing ACD in the region that benefits most cosmetics producers, especially SMEs, and consumers. This calls for more training and information dissemination for firms, capacity building for regulators, facilities and human resource development especially in the newer member states, and ultimately more budgetary resources and technical support and assistance (especially for Cambodia, Lao PDR, and Myanmar).

Automotive sector

The main objectives of the ASEAN Automotive Product Working Group (APWG) are to (i) enhance cooperation among member states to ensure safety, quality and environmental protection of ASEAN automotive products; (ii) create a single market and reduce TBTs in automotive products by harmonizing technical requirements regarding safety, quality, and environmental protection for automotive products; (iii) develop sectoral MRAs for recognition of conformity assessment results; (iv) identify infrastructure needs; and (v) strengthen the capability of testing facilities. Through the standards harmonization and mutual recognition of conformity assessment results, the safety, quality, and environmental protection of automotive products in ASEAN could be ensured, in addition to improved trade facilitation. In the absence of harmonized standards, the manufacturer will need to comply with different standards, which could result in loss of economies of scale and higher information costs. In the absence of MRAs, manufacturers are required to comply with redundant certification which leads to higher costs and more time spent as well as hindering the establishment of ASEAN as a single market and production base (EU–ASEAN Business Council, 2014).

Within ASEAN, harmonizing standards in the automotive sector is carried out by aligning the national standards or technical requirements with the UNECE Regulations of the 1958 Agreement. For the first stage, AMSs have identified 19 priority UNECE regulations to be adopted (see Appendix C for the list of regulations). Member states are obliged to harmonize their national standards or technical requirements with these UNECE regulations to support the implementation of the ASEAN MRA for Type Approval of Automotive Products.

The MRA is currently under development (although initially expected to be completed in 2011), in its 13th draft and undergoing legal scrubbing and endorsement by the ACCSQ (one of the last stages before signing). ASEAN Economic Ministers are expected to sign it in 2015.

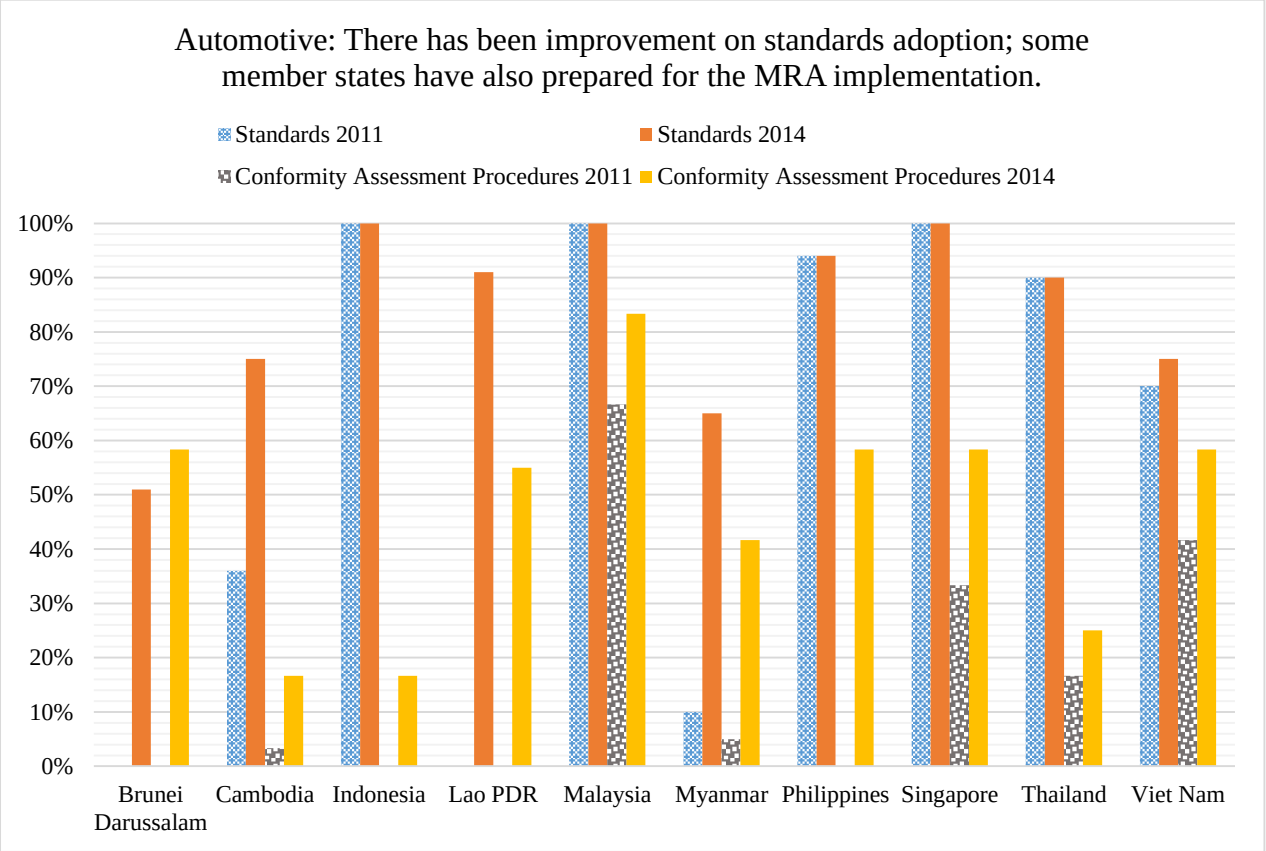
Under this MRA, covering new automotive products (parts, systems, and components),[5] member states are obliged to recognize the results (issued by a Listed Technical Service), which demonstrate conformity of automotive products with mandatory requirements (such as technical and safety requirements). The competence criteria for the Listed Technical Service include compliance with the 1958 agreement or the accreditation to ISO/IEC 17025, ISO/IEC 17021, and ISO/IEC 17020 requirements. When implemented, the MRA will eliminate duplication of product testing across member states. As a side benefit, the MRA will also push for improvements in member states' testing facilities and capability.

The establishment of a common regime in terms of regulations and procedures as a means of eliminating TBTs in automotive products in ASEAN is clearly designated for post-2015; ASEAN Senior Economic Officials consider the signing of the MRA for Type Approval for Automotive products in 2015 as the top priority under the automotive sector in the run up to the AEC 2015 (Munkwamdee, n.d.).

ERIA questionnaire results. The questionnaire assessed the availability of coordination and preparatory meetings among the stakeholders in supporting the ASEAN S&C strategies, progress of standards or technical requirements harmonization, and the readiness of member states to implement the MRA. Based on the questionnaire, within the automotive sector, there has been improvement in ASEAN across the relevant S&C strategies (Figure 2). The standards harmonization score is 90 percent or more in six member states. For conformity assessment procedures, even though the MRA is still being developed, some member states have improved their readiness for MRA implementation. In fact, Malaysia's score for MRA implementation reached 83 percent. Overall, the main improvement in this sector compared to the 2011 review is the transposition of regionally agreed standards into applicable national laws and regulations by most member states.

[5] The agreement does not cover used automotive products, either refurbished, reconditioned, or remanufactured. Note also that the agreement does not cover whole vehicle–type approval, which is not covered in the 1958 UNECE agreement that underpins the ASEAN MRA.

Figure 2: Standards and Conformance Score: Automotive Sector, 2011 and 2014



Note: No national data for Brunei Darussalam and Lao PDR in 2011 scorecard.
Source: ERIA questionnaire.

For ***standards harmonization***, Indonesia, Lao PDR, and Malaysia have fully adopted the regionally agreed international standards. For Singapore, the alignment rate is not 100 percent (18 out of 19 standards adopted) because the country has additional requirements for safety glass compared to the UNECE regulations. Thailand has adopted 15 standards, with its respondent reporting there are deviations of the national standards based on a series of amendments that member states refer to or adopt; thus, going forward, direct use or adoption of the latest series of the UN regulations could eliminate the deviations. The Philippines is adopting one more standard; previously it was not identified as an industry priority (Llanto *et al*., 2014).

Viet Nam's alignment rate is 50 percent to 75 percent (11 standards adopted). The challenge lies in the ability to meet the UNECE testing requirement. Furthermore, there are requirements in Viet Nam, such as infrastructure requirements, which lead to different regulations on weight and road, among others, thus hindering the harmonization process. In

fact, there has been little progress in adopting new standards since the 2011 review. Based on the 2011 questionnaire, eight standards were being adopted and, as of 2014, they are still in process. For Brunei Darussalam, all 19 standards are currently in the process of adoption, which is expected to be finished in 2015. For Cambodia, the adoption rate is between 50 percent and 75 percent. The main challenges lie in the time needed for adoption, the lack of technological expertise in the Institute of Standards of Cambodia, and the fact that Cambodia is not a car producer country. Nonetheless, compared to 2011, Cambodia has improved. The alignment rate in Myanmar is lower than 50 percent, with the main bottleneck being weak collaboration between the focal point, the private sector, and stakeholders (YUE, 2014).

Going forward, AMSs are considering adopting the remaining 32 standards in the 1958 UNECE regulations agreement. Indonesia reported that industry stakeholders (at the national and regional levels) reached consensus that the remaining standards will be adopted gradually because the standards are too detailed to be adopted all at once and small industry is not yet ready. For the remaining standards to be adopted, Indonesia's respondent suggested that there has to be capacity building in the industries, especially those that support the value chain. Currently, small industries have inadequate infrastructure. Some supporting industries, such as components and spare parts, cannot fulfil the needs of other industries; thus, the supply chain is hampered. Government commitment is critical to improve infrastructure quality, especially the testing facility and transport.

On ***conformity assessment procedures***, the ASEAN MRA for Type Approval of Automotive Product is still being developed. The detailed standard of the UNECE regulations and some revisions on the rules of origin are the main bottlenecks to the MRA completion. Nonetheless, many member states have prepared for its implementation. Malaysia is the most prepared, where some aspects of the MRA are already transposed into national regulations and the Listed Technical Service is already appointed. Brunei Darussalam, Lao PDR, Malaysia, Myanmar, Philippines, and Singapore have decided to adopt the terms and definitions prescribed in the MRA; while seven member states (Brunei Darussalam, Indonesia, Lao PDR Malaysia, Myanmar, Philippines, and Singapore) have decided to recognize the test reports and/or certificates issued by the Listed Technical Service under the MRA. So far, five countries already provide the necessary documents for conformity assessment procedures in English; this number can be expected to increase when the MRA is signed. On fostering MRA completion, Indonesia noted the major determinants are improvements in infrastructure quality and industry readiness.

The Philippines has recorded the biggest improvement in the preparedness for implementation of the MRA. Based on the 2011 questionnaire, the Philippines had not decided to adopt the terms and definitions prescribed in the MRA, nor recognized the test reports and/or certificates issued by the Listed Technical Service. As of 2014, the Philippines has now decided to adopt the terms and definition as well as to accept the test reports.

In ensuring transparency, six member states have listed the technical regulations applicable for the recognition of conformity assessment results available to other member states (through the APWG) and the ASEAN Secretariat. Many member states have reported the benefit from workshops and dialogue sessions conducted by the APWG and its dialogue partners such as the Japan Automobile Standards Internationalization Centre, the Republic of Korea, and the European Union.

Compared to 2011, member states reported that the standardization body and ministries are better informed. Cambodia, Malaysia, Philippines, and Viet Nam have also reported progress in adopting regionally agreed standards into national regulations. Technical service providers have also been appointed in Malaysia and Viet Nam. In Lao PDR, where a standards testing centre is not yet available, a new agency is being established to manage automotive product standards, quality, emissions and motor vehicles. In summary, there has been positive development within the ASEAN automotive sector to reduce technical barriers to trade through S&C initiatives.

Finally, the questionnaire results indicate that some member states do not hold national coordination and preparatory meetings, and some regulatory authorities do not inform the APWG and the private sector on the status of harmonization at the national level. Transparency is another aspect which could be improved in those countries. On the other hand, some member states, such as Indonesia, hold meetings every two months to discuss issues from standards development to the ASEAN MRA and technical regulations. They also include socialization of any agreements made at the regional level and public hearings to gain inputs from all agencies present at the meeting. The meetings serve as discussion platforms between regulator, coordinator, the private sector, and other relevant bodies to formulate a national stand on the APWG and to give feedback concerning AEC measures under S&C. This good practice could be emulated by other member states.

Electrical and electronic equipment sector

Being the sector with the highest share of intra-ASEAN commodity trade, the EEE sector has been the first, and arguably foremost, focus of ASEAN's S&C initiatives. ASEAN's first standards harmonization under the ASEAN Free Trade Area Agreement, the precursor of the AEC, involved virtually all products in the EEE sector (139 out of 142 harmonized standards) except for three rubber-based products, plus 10 electromagnetic compatibility standards. It is also among the first sectors that succeeded in having regional agreements not only on standards but also on mutual recognition of conformity results (ASEAN EE MRA in 2002) and harmonized regulatory regime (ASEAN Harmonized Electrical and Electronic Equipment Regulatory Regime [AHEEERR] in 2005).

Similar to the other priority sectors, in the absence of the above-mentioned strategies, an EEE manufacturer in ASEAN would need to comply with different standards and technical regulations and obtain test reports and certificates when exporting to other member states. This would create unnecessary barriers to trade and increase the prices that consumers would have to pay. Under the ASEAN EEE S&C initiatives, the standards and technical regulations will be harmonized across the member states, and the conformity assessment result issued by any member state can be used for obtaining product registration in the other member states. As a result, not only would '…manufacturers and traders of EEE made in ASEAN…find it easier and less costly to export their EEE to ASEAN Member Countries….(and)…save on cost of testing and certification…(but also).. can plan their new product launches with greater certainty and shorter time-to-market' (*FAQ on ASEAN EE MRA*, ASEAN n.d., p.1). In addition, under the AHEEERR, the business community will enjoy the benefit of complying with common methodology for determining conformity assessment procedures based on risk level and strengthened post-market surveillance linked with safety alert notifications.

The harmonization of standards for the EEE sector is carried out by aligning the national standards with the corresponding IEC standards. Member states are obliged to harmonize their national standards with these IEC standards to support the implementation of the ASEAN EE MRA and the AHEEERR. So far, there are 121 regionally agreed standards for the EEE sector.

The ASEAN EE MRA was signed on 5 April 2002 to support the trade facilitation of the EEE sector in ASEAN. Under this MRA, member states are obliged to accept test reports (issued by listed testing laboratories) and certificates of conformity (issued by listed certification bodies) that demonstrate the conformity of EEE with its mandatory requirements. The testing laboratories and/or certification bodies are identified and monitored by designating

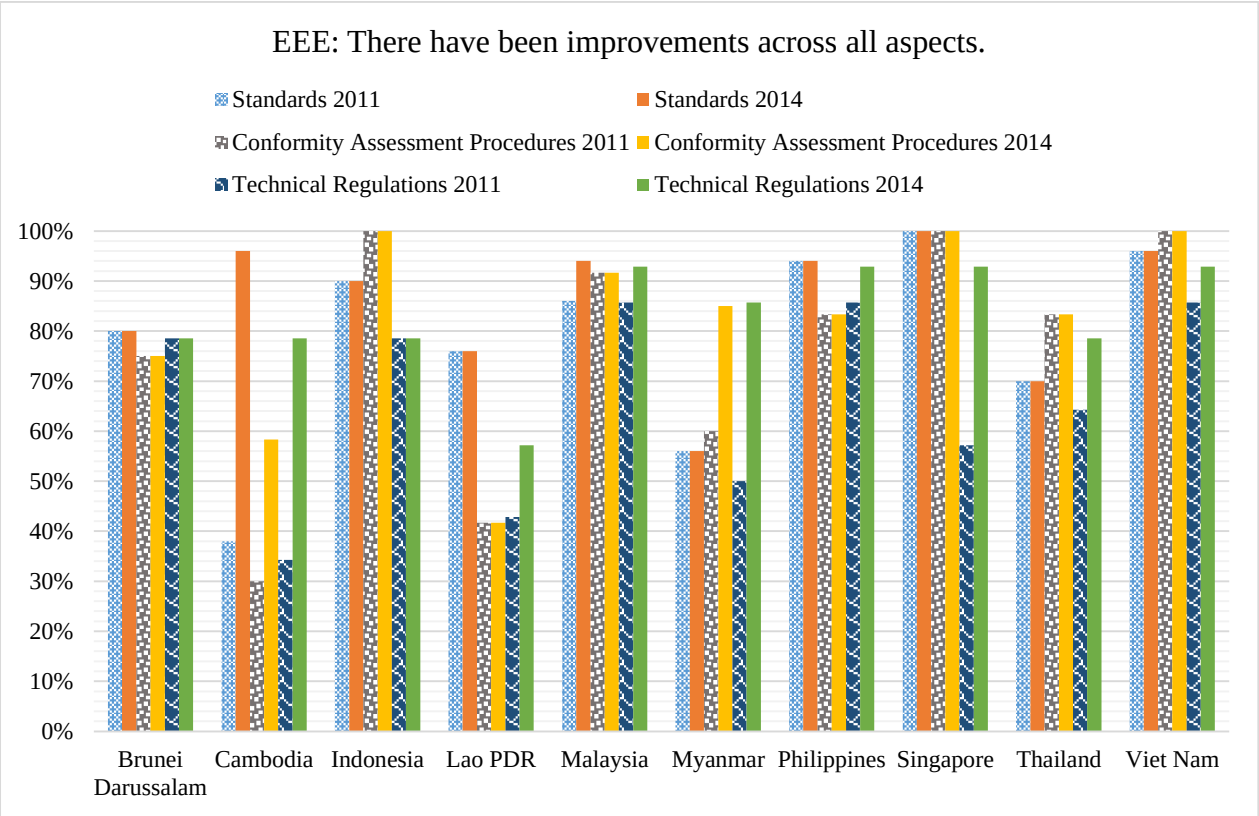
bodies and are accredited by an accreditation body (see Appendix B for list of conformity assessment bodies). As of September 2014, all member states have participated in the recognition of the test reports and certificates under the ASEAN EE MRA.

The AHEEERR was signed on 9 December 2005. In contrast to the ASEAN EE MRA where technical regulation and mandatory standards were not required to be harmonized, the AHEEERR demands harmonized technical regulation and mandatory standards and harmonized laws and administrative provisions in addition to harmonized conformity assessment procedures in line with the agreement (Kuan, 2008). Central to harmonized technical regulations are essential requirements for EEE (safety, prevention of environmental damage under reasonable conditions, and electromagnetic compatibility) and the list of relevant international standards to be used to demonstrate compliance with ASEAN essential requirements (ASEAN, 2005). The ASEAN Harmonized Conformity Assessment Procedures for EEE prescribe the procedures and the product certification system. The agreement also promotes conformity and/or registration marking as well as establishing the post-market alert system. Member states were expected to put in place all the necessary harmonized technical requirements and infrastructure to support the effective implementation of AHEEERR by 31 December 2010.

ERIA questionnaire results. The questionnaire assessed the progress in implementing the three S&C strategies mentioned above. On standards, the questionnaire asked about the progress of adopting the 121 IEC standards. On conformity assessment, the questionnaire asked whether the provision of MRA has been transposed into national laws or regulations, and whether the test laboratories and/or certification bodies have been listed under the Joint Sectoral Committee (JSC) EEE. On technical regulations, the questionnaire asked whether the harmonized standards and technical requirements have been transposed and whether the post-market alert system has been established.

Based on the questionnaire, within the EEE sector there have been many improvements in all aspects of S&C initiatives compared to the monitoring results in 2011 (Figure 3). The standards harmonization score is 80 percent or above in seven member states, although the scoring gives credit to the acceptance of the agreed-upon international standards for direct use. (Singapore gets top scoring as virtually all [except for three standards] have been accepted for direct use.) The conformity assessment procedures score is more than 80 percent in seven member states. For technical regulations, five countries score 80 percent or above and four countries score close to 80 percent. At the same time, however, the agreed effective implementation target date of 31 December 2010 was apparently optimistic.

Figure 3: Standards and Conformance Score: Electrical and Electronic Equipment Sector, 2011 and 2014



Note: EEE = electrical and electronic equipment.
Source: ERIA questionnaire.

For ***standards harmonization***, Singapore has accepted 118 out of the 121 standards for direct use and the remaining 3 standards were adopted with modification. Similarly, Viet Nam has the 121 standards accounted for, 80 under identical adoption and 41 under direct use; however, the 41 standards under direct use are still in the process of adoption as national standards. ('Direct use' means direct use without adoption of international standards and no national standards.) Malaysia has adopted 114 standards, 84 under identical adoption, 24 as direct use without national standards, and 5 with modification; the remaining 7 standards are still being adopted. Indonesia adopted 101 identically and 1 standard with modification; 19 standards are still being adopted. The Philippines has accepted or adopted 115 standards so far: 84 adopted identically, 11 with modification, and 22 accepted for direct use. The remaining 6 standards are not yet in the process of adoption; it is also not clear if the 22 standards under direct use would eventually be adopted as national standards with or without modification. Thailand has the lowest adoption rate among the major ASEAN producers and consumers of EEE products: 27 standards adopted under identical adoption and modified adoption, 11

standards are currently in process of adoption, and 83 standards remain unaccounted for. Lao PDR has adopted 78 standards and the remaining 43 standards will be adopted in the next batch. Cambodia has adopted 49 standards and the remaining standards are accepted for direct use. Brunei Darussalam has adopted 74 standards, 33 standards are in the process of adoption, and the remaining 14 standards are accepted for direct use. Myanmar is in the process of adopting 10 standards; the remaining standards are under discussion.

The ERIA questionnaire results provide reasons for the incomplete adoption of the agreed 121 EEE standards. The process of adoption in countries like Indonesia involves a long process of forming technical committees, reviewing and evaluating the feasibility and compatibility of the proposed standard, consultations with government agencies and public consultations with other stakeholders such as EEE producer associations (Damuri et. al., 2014). This process entails financial resources and technically competent personnel, the inadequacy of them being highlighted as a constraint to speedier adoption of the standards in Cambodia, Lao PDR, Philippines, and Indonesia. Thailand's key constraint is that all mandatory standards and test method standards must be in the Thai language by law. Viet Nam's key concern is the capacity of domestic enterprises to adjust to and adopt the new standards, thereby requiring more consultation with the business community. Lao PDR gives more emphasis on the standards for products that are widely used in the country and those that pose risks. The long process of adoption, given constraints stated above, suggests that full adoption would not occur by 2015 (although Indonesia's response indicates optimism for end 2015) and may drag towards 2020 as the Philippines and Viet Nam responses indicate.

On ***conformity assessment procedures***, all member states reported the MRA is already ratified. Brunei Darussalam, Indonesia, Myanmar, Singapore, Thailand, and Viet Nam have fully revised the national regulations, while Cambodia, Malaysia, and the Philippines have partially revised the national regulations. Lao PDR, on the other hand, has not yet revised the legislation, with lack of human and financial recourse cited as the cause. In Malaysia, further amendment on electricity regulation is needed. For the Philippines, one of the regulations—that is, the building wires regulation—cannot be harmonized with the IEC due to conflict with the Philippines Electrical Code. All member states have published their regulatory requirements, conformity assessment procedures, and applicable standards; however, not all of them provide the information in English.

All member states have adopted the terms and definitions prescribed in the MRA. However, not all member states recognize the test reports and product certification issued by the listed test laboratories and certification bodies of other countries. Indonesia reported that,

on average, there are two to three cases annually in which test reports or certifications from other countries' conformity assessment bodies (CABs) are not recognized. Indonesia always uses the latest version of the IEC, while other member states do not. This results in different standards used by the CABs.

Six member states have identified listed testing laboratories and listed conformity assessment bodies (see Appendix B for the list of bodies). Nonetheless, regular audit or assessment is not conducted regularly by all member states. In Brunei Darussalam, the existing laboratories are mainly for civil and structural engineering testing; while the electrical and mechanical engineering testing is not adequate. In Lao PDR, there are no certified testing laboratories; the relevant agencies are making an effort to establish qualified laboratories. Overall, for conformity assessment procedures, Cambodia recorded the biggest improvement, which in 2011 had not yet ratified the MRA, had not amended national legislation for alignment with the MRA, and did not recognize test reports and product certification from other listed testing laboratories and certification bodies. There is no progress with regards to listing of testing laboratories and certification bodies: the 2014 result indicates that the two bodies have still not been identified.

For ***harmonization of technical regulations***, Brunei Darussalam, Cambodia, Malaysia, Myanmar, the Philippines, Singapore and Viet Nam, have fully transposed the AHEEERR into applicable national legislation or regulations. For Indonesia, the challenge lies in the long process in the bureaucracy. The lack of coordination and a lack of a sense of urgency seem to be the problem. For Lao PDR, the lack of financial and human resources is a challenge. Thailand is currently in the process of drafting Notification on Criteria for EEE Certification under the AHEEERR.

Relatedly, the ASEAN Guidelines to Determine the Type of Conformity Assessment Regime Based on Risk Assessment for EEE as well as the ASEAN Conformity Mark (ACM) have not been adopted by the member states. The guidelines and the conformity mark are yet to be finalized by the EEE Joint Sectoral Committee. Singapore reported that under the guidelines, EEE products classified as high risk will require Type 5 Conformity Assessment Regime based on ISO/IEC Guide 67 under AHEEERR: however Singapore does not see a need for such a stringent regime and reported that the ACM is not feasible. Thailand reported that the JSC EEE agreed that the absence of the ACM will not affect the implementation of the AHEEERR, thus there is no need for an EEE ACM. With regards to the post-market alert system, only Indonesia, Lao PDR and Viet Nam have established the system and linked it with the safety alert notification system. Singapore reported the guidelines for the post-market

surveillance regime for the EEE sector are already adopted but they do not include safety alert notification because the JSC EEE is yet to agree on the mechanisms for such notification.

There are other improvements in 2014 compared to 2011. Some countries reported that industry and ministries are better informed about the harmonized technical regulations. The numbers of listed testing laboratories and certification bodies have also increased in the Philippines, from two in 2011 to four in 2014. Malaysia and Singapore have adopted measures for post-market surveillance. A safety alert system is currently being addressed in Singapore, and risk assessment scores are being addressed in Malaysia. Brunei Darussalam has established the Authority of Building and Construction Industry to oversee and coordinate the development of the initiatives. In Thailand, the Thai Industrial Standard Institute has accepted the reports of listed testing laboratories under the ASEAN EE MRA; the institute is ready to participate in acceptance of certification beginning 1 January 2015.

Going forward, improvements in human resources and testing facilities are needed. In addition, streamlining the bureaucracy or institutions is also of priority, especially in reducing the procedures which are impediments for regional agreement transposition. Promoting industries' awareness of standards and conformity through seminars and workshops is also needed.

Medical device sector

ASEAN S&C activities in the medical device sector consist of harmonizing standards or technical requirements as well as technical regulations. The initiative aims to improve trade efficiency and bring wider access of healthcare services to the society. The initiatives at the regional level are led by the ASEAN Medical Device Product Working Group. For the private sector, the benefits would include the reduction in the regulatory uncertainty for medical devices, a convergence of standards for product registration, distribution and post-market surveillance, and in a few countries (for example, Cambodia) the establishment of a registration system for medical devices. The improved regulatory environment is expected to support the growth of the medical device market in the region, which is projected to grow from about $4 billion in 2012 to about $8 billion in 2017 (Gross, 2014).

The harmonization of standards is carried out by aligning the national standards or technical requirements for medical devices with the corresponding ISO standards. AMSs are obliged to harmonize their national standards or technical requirements with these international standards or benchmarks to support the implementation of the ASEAN Medical Device

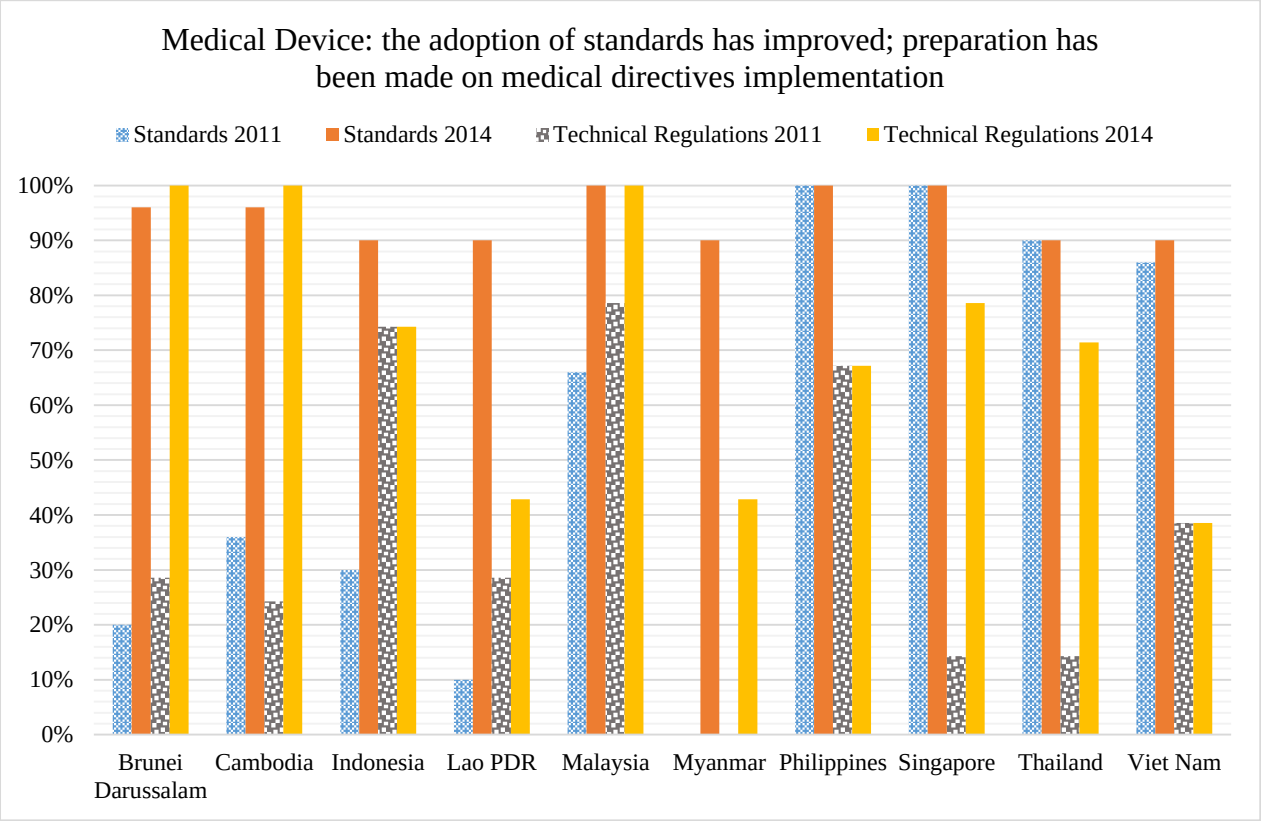
Directive (AMDD). As of June 2013, there were 14 first priority and 2 second priority regionally agreed upon standards (see Appendix C for the list).

The AMDD is the latest agreement signed by ASEAN economic officials on 21 November 2014. The directive lays out basic requirements for a harmonized classification system, medical device safety and performance, conformity assessment, a common submission dossier template and a harmonized set of elements for a product owner's or physical manufacturer's declaration of conformity. The directive uses a four-tier risk-based classification system of medical devices that can determine differentiated fees, processing times and clinical requirements. It also adopts the post-market alert system for information and action on complaints and adverse events such as death or serious deterioration of the health of patients.

AMSs agreed under the AMDD to put in place an appropriate system for the conformity assessment of medical devices primarily through conformity with the relevant technical standards recognized by the ASEAN Medical Device Committee (AMDC) established under the AMDD. They also agreed to put in place a system for the conduct of clinical investigation of medical devices and the post-market surveillance system. The AMDD entered into force on 1 January 2015 but only among the member states that have ratified it and/or accepted it. At the very least, the AMDD becomes a model framework for each member state even for those which do not ratify or accept it.

ERIA questionnaire results. The questionnaire assessed the progress of standards harmonization and technical regulation aspects of the medical device sector. On standards harmonization, the questionnaire asked whether the national standards have been aligned with the identified international standards. On technical regulation, the questionnaire asked whether preparations have been made for the AMDD implementation. Based on the questionnaire, within the medical device sector, technical barriers to trade are going down across all countries (Figure 4). The standards harmonization score has reached 90 percent or more in all countries. For technical regulations, even though the AMDD was only signed in November 2014, the score has improved. Brunei Darussalam, Cambodia, and Malaysia lead the region in this aspect.

Figure 4: Standards and Conformance Score: Medical Device Sector, 2011 and 2014



Note: No national data for Myanmar in 2011 scorecard.
Source: ERIA questionnaire.

On ***standards harmonization***, of 14 first priority standards, Brunei Darussalam, Cambodia, Lao PDR, Myanmar and Singapore have accepted the direct use of the standards. Malaysia has adopted all via modified adoption. Indonesia and the Philippines have adopted or accepted them by a mix of largely direct use (10 out of 14 for the Philippines) and identical adoption. As of mid-2013, Thailand has adopted 9 standards as identical adoption, 3 more are in the process of identical adoption while 2 standards have yet to be decided. Similarly, Viet Nam has adopted 12 out of 14 as of mid-2013 using identical adoption while the remaining 2 were in the process of adoption. The matrix on the harmonization status of medical devices as of mid-2013 in the ASEAN Secretariat website[6] indicates that Indonesia accepted 9 standards for direct use, 1 adopted identically, 2 under modified adoption and 2 more in process of adoption. Indonesia has already adopted 10 standards by identical adoption, 1 standard modified to become national guidance, while 19 more standards are in the process of adoption. (Note that

[6] ASEAN Medical Devices Product Standards (Harmonization Status), http://www.asean.org/images/archive/SnC/medical_devices_standards_for_harmonisation_ao%2017%20june%202013.pdf, accessed 5 December 2014.

one standard on biological evaluation of medical devices has 17 or 18 component standards [ISO 109993-1 to -18]) This means that Indonesia has moved from not merely accepting the direct use of the standards to adopting standards either as identical adoption or modified adoption or both.

The Indonesian report states that the process of adopting the remaining 19 standards will be finished on a staggered basis in 2015. Again, the report highlights that the main challenge lies in the long process required to adopt a national standard with numerous bureaucratic and documentation requirements in each and every process. Since there is a lot of interest involved in the discussion of the standards, it takes lengthy negotiation at the national level. In Thailand, the main bottleneck for adoption is the technology used is not advanced enough to comply with all the standards. Viet Nam has been much more aggressive in its adoption of international standards, not only of the 14 priority standards agreed upon among member states, it has also drafted a decree on Medical Device Management which was expected to be issued by end-2014 (Vo *et al*., 2014).

On ***harmonization of technical regulations***, even though the AMDD has just been signed, Brunei Darussalam, Cambodia, Malaysia, the Philippines and Thailand have aligned their applicable national regulations with the AMDD provisions. Indonesia is in the process of aligning its national regulations. The main bottleneck is in the difference of risk classification. The AMDD acknowledges four classes of risk classification while Indonesia only acknowledges three classes. To revise the risk classification, Indonesia needs to amend a law, which can be a lengthy process. For Lao PDR, the legislation is currently being developed and amended; however, Lao PDR is facing financial and human resource constraints. Singapore reported the requirements are largely in place, except a minor portion which requires legislative amendment.

The national guidelines for the AMDD technical requirements have also been finalized in Brunei Darussalam, Cambodia, Malaysia, the Philippines and Singapore. For Indonesia, the process could be started once the alignment mentioned above is finished. For Myanmar, the guidelines are not yet finalized due to lack of experience. For Thailand, the revision is underway and expected to be finalized by September 2015. For Viet Nam, the incomplete regulatory framework is the main bottleneck.

As mentioned earlier, the AMDD has several technical requirements. Indonesia, Thailand, and Viet Nam do not have the same risk-based classification system as the AMDD. Indonesia currently uses three classes of risk and Viet Nam uses two classes. Lao PDR, Singapore, Thailand, and Viet Nam do not have the same differentiation of fees, processing times, and

clinical requirements as the AMDD;[7] and the Lao PDR, the Philippines, Thailand and Viet Nam do not have an expedited registration channel. The Philippines currently does not have an expedited registration channel; however it plans to use the system for products strictly for export, for products with previous approval from the five countries (under study) and for the ASEAN member countries. For these countries, only the products' legal requirement will be reviewed.

The member states must have an AMDD compliant system for conformance assessment of medical devices. Currently, Brunei Darussalam, Cambodia, Indonesia, Malaysia, Singapore, Thailand, and Viet Nam, have the system in place. The Philippines will install the system after the AMDD is signed. For Lao PDR, the compliant system is being set up. For Myanmar, there is no effective conformance system and it faces a lack of competent regulators and fully equipped laboratory facilities.

Regarding the regional strategy or mechanism for post-market surveillance of the medical device sector, Malaysia, Myanmar, Singapore and Thailand reported the current system as operational and well performing. Meanwhile, Indonesia, Lao PDR, and Viet Nam reported the system as not well performing. Six member states have participated in the post-market alert system.

Compared to the 2011 review, many countries reported significant efforts towards transposing and implementing the regional agreement. In Brunei Darussalam, the Guide to Application for Registration of Medicinal Products has been published; the guide aligns with the requirements stipulated in ASEAN standards. In Indonesia, the common submission dossier template, which is part of the AMDD, has been applied in the registration of medical device products. In the Lao PDR, the related law (Drug and Medical Product law) has been updated and the regulations have been drafted for approval. Lao PDR also reported more collaboration and improved coordination among relevant agencies. In Malaysia, the Medical Device Act was enacted in 2012; the act takes into account the agreed regional standards or technical requirements. Singapore compared existing medical device legislation and stated that stakeholders are well informed on the AMDD requirements. In Thailand, the common submission dossier template is also in use. In Viet Nam, the Decree on Medical Device Management is being developed. Many member states have also implemented efforts in institutional capacity building.

[7] The respondent from Singapore reported the AMDD does not state details of application fees and processing times.

Going forward, improvements in human resources (capacity building), managing regulatory agencies' workloads, availability of testing laboratories and updating the database are among the priorities. In addition, Indonesia emphasizes that capacity building directed towards SMEs should be continued because many SMEs are not ready to face open competition.

Pharmaceutical Sector

As stated earlier, the main scope of the Pharmaceutical Product Working Group (PPWG) is to harmonize pharmaceutical regulation to reduce barriers to trade while at the same time ensuring that the products entering the ASEAN market meet the three main criteria of safety, quality and efficacy. The outputs of the PPWG are the so-called 'ASEAN pharmaceutical product' (wherein the same regulatory requirements apply for the registration of a pharmaceutical product among member states) and MRAs. Towards defining the ASEAN pharmaceutical product, the PPWG developed the ASEAN Glossary of Terms, the ACTD and the ACTR and its quality guidelines (analytical validation, bioavailability/bioequivalence studies, process validation and stability study). The ACTD is a guideline of the agreed upon format and structure of the common technical dossier applications for submission to ASEAN regulatory authorities for the registration of pharmaceuticals for human use. The ACTD is expected to reduce the time and resources needed to compile applications for registration as well as facilitate regulatory reviews and communication. The ACTR and its guidelines intend to guide applicants to ensure applications are consistent with the expectations of all ASEAN drug regulatory authorities (Latzel, 2007).

The ASEAN MRA for GMP Inspection of Manufacturers of Medicinal Products was signed on 10 April 2009. Under this MRA, member states are obliged to accept the GMP inspection reports (issued by a listed inspection service) for manufacturers of medicinal products and to accept the GMP certificate (issued by a listed conformity assessment body) which verify conformity of a manufacturer of medicinal products with the mandatory requirements. To support the implementation of the MRA, a JSC was established. The MRA was to be adopted no later than 1 January 2011.

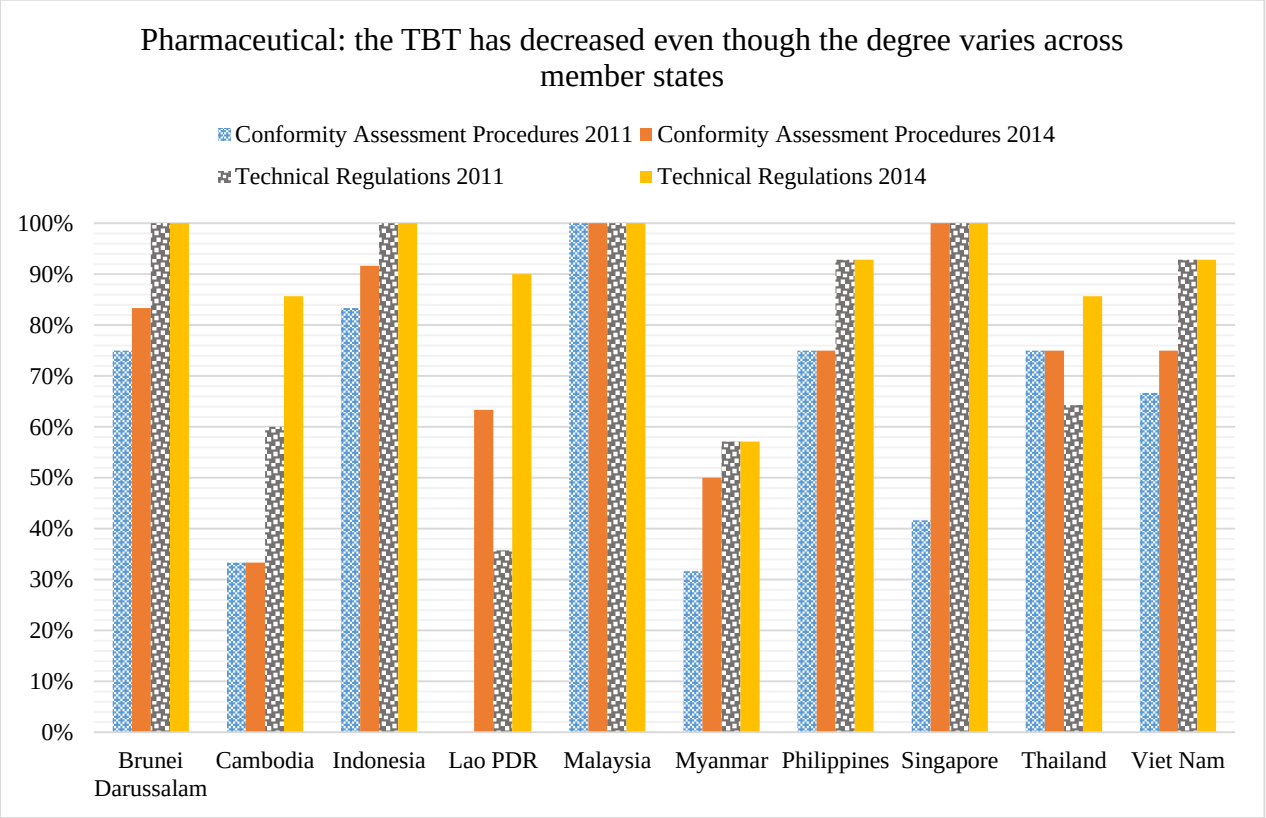
All member states endorsed the ACTD and the ACTR for application from 1 January 2009 onwards. The ACTD covers administrative data, quality, safety and efficacy, while the ACTR covers quality, safety and efficacy. The ACTD is part of a marketing authorization application dossier that is common to all member states; while the ACTR are the written materials intended

to guide applicants to prepare application dossiers in a way that is consistent with the expectation of all ASEAN drug regulatory authorities (*ASEAN Standards and Conformance*, ASEAN n.d.). Under this agreement, the business community will enjoy the benefit of complying with common standards through the harmonization of national standards with international standards, a common methodology for determining conformity assessment procedures based on risk level, and strengthened post-market surveillance linked with safety alert notification.

ERIA questionnaire results. The questionnaire assessed the implementation of the conformity assessment and technical regulation aspect of the pharmaceutical sector. On conformity assessment, the questionnaire asked whether the MRA has been ratified and whether a listed inspection service (LIS) and a listed conformity assessment body (CAB) have been appointed. On technical regulation, the questionnaire asked whether the provisions of the ACTR and the ACTD have been transposed into applicable regulations and whether the post-market alert system has been established.

Based on ERIA's questionnaire results, **Figure 5** shows that the condition has improved in conformity assessment procedures and technical regulation for all member states in the pharmaceutical sector. Technical regulation has also improved in all member states. The score is above 80 percent in most member states, led by Brunei Darussalam, Indonesia, Malaysia, and Singapore which all scored 100 percent. The conformity assessment procedures score is above 80 percent in four member states, led by Malaysia and Singapore.

Figure 5: Standards and Conformance Score: Pharmaceutical Sector, 2011 and 2014



Note: TBT = technical barriers to trade.
Source: ERIA questionnaire.

On ***conformity assessment procedures***, ERIA's questionnaire reported that Indonesia, Malaysia and Singapore have become members of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Scheme (PIC/S): the Health Science Authority of Singapore, the National Pharmaceutical Control Bureau of Malaysia and the National Agency for Drug and Food Control of Indonesia. The questionnaire also shows that Brunei Darussalam, Indonesia, Lao PDR, Malaysia, the Philippines, Singapore, and Viet Nam have identified a CAB to carry out conformity assessment of pharmaceutical products (see Appendix B for list of bodies). For Cambodia, the process is under preparation. For Lao PDR, the Department of Standard and Metrology was already identified as the CAB; however, human and financial resources and infrastructure are lacking to initiate conformity assessment. As part of the MRA, the listed inspection service (LIS) will issue a GMP inspection report. Brunei Darussalam, Indonesia, Malaysia, Singapore, and Viet Nam have identified the LIS; however, in Viet Nam, the LIS is not yet accepted by the JSC. The capacity building programme is currently under way in Viet Nam. The LIS is to be adopted in Cambodia. For the Philippines, the designating body has not identified the LIS. The Philippines is currently concentrating on getting the PIC/S

accreditation, which would then make it unnecessary to have for LIS. To improve MRA implementation, all countries, except Cambodia, have been conducting national programmes, projects, or initiatives to enhance the capacity of regulators and industry.

On ***harmonization of technical regulations***, AMSs have agreed to implement the ACTR and the ACTD. Based on the questionnaire results, all member states have also amended national legislation to ensure its alignment with the ACTD. In addition, all member states, except Myanmar, have transposed the quality, safety, and efficacy guidelines under the ACTR; Myanmar expects the transposition process to be completed in 2015.

To support the implementation of technical regulations, all member states established a post-market alert system and linked it with the safety alert notification. They reported the alert system is effective and efficient so far, except in the case of the Philippines. For the Philippines, additional staffing and a more robust IT infrastructure are needed. Thailand also reported the need for more staff to widen the coverage area down to the provincial level.

Compared to the 2011 review, member states have reported many improvements. In Cambodia, for instance, compared to 2011, the government has issued notifications informing drug store owners, drug importers, and drug producers to register pharmaceutical products in compliance with the ACTD. Meanwhile, Lao PDR, in transposing the regional agreement, revised the Law on Drugs and Medical Products in early 2012. Institutional capacity also improved; for instance, Lao PDR's Food and Drug Quality Control Center was awarded the ISO17025.

Three AMSs became members of PIC/S; thus, their national guidelines and regulations had been revised in accordance with PIC/S. Member states had reported some benefits. For example, Indonesia reported that the National Agency of Food and Drug Control (or BPOM), as Indonesia's assigned CAB, has been a member of PIC/S since 2012; Indonesia's bargaining position has improved in the international market. In addition, since 2012 the World Health Organization (WHO) has recognized Indonesia as a functional national regulatory authority in the pharmaceutical sector. This has eliminated disputes regarding the credibility of BPOM testing results in the international market. The Philippines has also improved institutional capacity and links through programmes such as the Qualified Person in the Industry Regulatory Affairs training.

Going forward, improvements in human resource capacity (in terms of quantity and quality), financial resources, and infrastructure remain top priorities to be addressed. Viet Nam noted more advocacy and promotion of GMP adoption among local manufacturers as well as promoting foreign partnership in research and development are necessary (Vo *et al*., 2014). In

addition, as noted by Malaysia, decentralizing (or outsourcing) some CAB functions could improve the efficiency and impartiality of certain processes, such as accreditation.

3. Summary, Challenges, and the Way Forward

There have been many improvements in reducing technical barriers to trade through the S&C initiatives in ASEAN compared to the 2011 mid-term review. At the regional level, almost all obligations have been met in all sectors where applicable. At the national level, progress has also been recorded across all sectors (see Appendix D for figures of S&C initiatives progress at the national level).

- In the cosmetics sector, most member states have transposed the ACD into applicable national regulations and have identified a test laboratory to be under the ACTLC.
- In the automotive sector, compared to 2011, most member states have transposed the regionally agreed-upon standards. The main challenge lies in improving technical capacity and providing quality infrastructure.
- In the EEE sector, despite some progress, conditions remain challenging, especially for the harmonization of technical regulations. Four member states have not fully revised their national legislation to align with MRA provisions and technical regulations. The ongoing discussions at the regional level regarding risk assessment and the ACM have hindered technical regulations progress at the national level.
- For the medical device sector, the majority of member states have transposed the regionally agreed-upon standards to the applicable national regulations. Furthermore, even though the ASEAN Medical Device Directive was signed only in November 2014, some member states have already prepared for its implementation.
- Finally, for the pharmaceutical sector, three AMSs have become members of PIC/S and seven member states have identified their conformity assessment body. On the ACTR and ACTD implementation, almost all countries have transposed the regional guidelines.

Table 2 presents the summary of S&C initiatives progress in ASEAN. Member states have reported various noticeable benefits from implementing the regional agreements. The benefits

include improved consumer protection and improvement in the country's regulatory framework.

Table 2: Summary of Standards and Conformance Initiatives Progress in ASEAN

Sector	Strategy	Status
Cosmetics	Technical regulations	Six member states have fully transposed the ACD. Four member states have partially transposed the ACD. All member states have adopted the 5 harmonized aspects of the ACD, product notification system, and post-market surveillance system (but the performance varies).
	Conformity assessment	Seven member states have appointed test laboratory and conformity assessment bodies.
Automotive	Standards harmonization	Three member states: 100% alignment rate Three member states: 75% to 100% Four member states: Less than 75%
	Conformity assessment	The MRA is under negotiation by 2015; but Malaysia and Viet Nam have appointed listed technical services and conformity assessment bodies. Six member states have decided to adopt the terms and definitions prescribed in the MRA; seven member states have decided to recognize the test reports and/or certificates issued by LIS.
EEE	Standards harmonization	Adoption of 121 standards: 6 member states: 101–121 standards 1 member state: 80–100 standards 3 member states: Less than 80 standards
	Conformity assessment	Six member states have fully revised the national regulations; three member states have partially revised; one member state has not revised any regulation. Six member states have appointed testing laboratories and conformity assessment bodies.
	Technical regulations	Seven member states have fully transposed the AHEEERR into applicable national regulations. Most member states have not adopted the ASEAN Guidelines to Determine the Type of Conformity Assessment Regime Based on Risk Assessment for EEE and the ACM due to ongoing discussions at the regional level.
Medical device	Standards harmonization	Of 14 priority standards: 7 member states have fully adopted; 3 member states are in the process of adoption.
	Technical regulations	The AMDD was signed only in November 2014, but five member states have fully aligned the applicable national regulations with the provision of the AMDD; three member states do not yet have the same risk classification with AMDD. Four member states reported the post-market surveillance system as well performing while three member states reported as not well performing.

Sector	Strategy	Status
Pharmaceutical	Conformity assessment	Three member states have become members of PIC/S. Five member states have identified listed inspection service and seven member states have identified conformity assessment body.
	Technical regulations	Nine member states have transposed the 'quality, safety, and efficacy' guidelines of the ACTR; and all member states have amended national legislation to ensure its alignment with the ACTD. All member states have established a post-market alert system.

Note :ACD = ASEAN Cosmetics Directive: ACM = ASEAN Conformity Mark; ACTD = ASEAN Common Technical Dossier; AHEEERR = ASEAN Harmonized Electrical and Electronic Equipment Regulatory Regime; EEE = electrical and electronic equipment; LIS = listed inspection service; MRA = mutual recognition arrangement; PIC/S = Pharmaceutical Inspection Convention and Pharmaceutical Inspection Scheme.
Source: ERIA questionnaire.

Challenges. In general, the challenges for the S&C efforts in ASEAN can be placed in four groups: (i) technical capacity, (ii) physical infrastructure, (iii) governance, and (iv) other challenges. Technical capacity is the main challenge for conformity assessment and harmonized technical regulations. For instance, some country reports emphasize the lack of qualified testing laboratories, the lack of competence in the accreditation body, and the lack of manpower to implement the post-market surveillance. On the industry side, some reports highlight the lack of SME capability to meet the identified standards, the lack of supporting industries, and/or the technology used in industry as not being advanced enough.

Inadequate physical infrastructure is another main challenge in conformity assessment and harmonization of technical regulations. For example, the unavailability of testing facilities, transport infrastructure, and IT infrastructure has hindered conformity assessment and implementation of the post-market alert system. Governance is mainly the problem of harmonization, be it standards or technical regulations harmonization. For example, many steps are required in revising or adopting a standard, related laws or regulations need amending, clear and direct regulatory framework in some sectors as well as communication or consultation with stakeholders is lacking.

Some other challenges include the ongoing discussions on the scope and coverage of the recognition arrangements at the regional level, the requirement that standards should be developed in the local language, and not all countries support certain initiatives. The technical capacity and physical infrastructure challenges are pressing mainly in the newer members of ASEAN.

Key Recommendations

Efforts on improving the technical capacity, physical infrastructure, and governance should be continued.

- On improving technical capacity, more capacity building programmes directed towards SMEs and government officials (especially in the newer members of ASEAN) are needed.
- On improving physical infrastructure, governments should allocate more financial resources to establish qualified testing centres. Governments should understand that the unavailability of qualified testing centres hampers the opportunity of domestic industries to expand to the regional market.
- On improving governance, for instance, in Malaysia, some sectors have technical working groups and safety expert committees to harmonize national standards with regional/international standards; this ensures that adoption of standards becomes more coherent. In Indonesia, bimonthly meetings serve as a discussion platform between regulator, coordinator, the private sector, and other relevant bodies to formulate a national stand and to give feedback that concern ASEAN Economic Community measures under S&C. This initiative helps reduce miscommunication and lack of consultation that have been reported previously.
- In addition, concerted national strategies to improve member states' competitiveness should also be taken. This could be done by establishing national task forces on productivity enhancement (for example, Malaysia's Malaysia Productivity Corporation programmes) or enacting regulations which promote quality improvement (for example, the Philippines' National Quality Infrastructure Law). To streamline regulations, other member states could also emulate a national task force, such as the PEMUDAH task force in Malaysia.

As stated earlier in the report, ASEAN is a region with varying levels of economic development and institutional capacity; thus, the challenges for S&C initiatives vary between member states. **Table 3** outlines several country specific recommendations for S&C initiatives.

Table 3: Country Specific Key Recommendations for ASEAN Standards and Conformance Initiatives

Country	Recommendation
Brunei Darussalam	More resources directed to improve the conformity assessment procedures in the EEE sector
Cambodia	(1) More resources directed to build technical capacity of staff, testing facilities, and accreditation system; (2) mapping of the regulations to expedite standards and technical regulations harmonization; this could be done through integrated Cambodia S&C infrastructure; (3) improving transparency through publication of Cambodia's regulatory requirements, conformity assessment, and applicable standards in English; and (4) engaging more the private sector in the S&C initiatives development
Indonesia	(1) More capacity building program directed to improve the competitiveness of SMEs, especially in the cosmetics, automotive, and medical device sectors; (2) directing more resources for quality infrastructure to improve the supply chain, especially for the automotive sector; (3) improving coordination, mapping of regulations, as well as more efficient review process in adopting standards and technical regulations; (4) enforcing the compliant system for domestic-oriented medical device products (i.e., not only enforced for export-oriented medical devices); and (5) concerted policy action to improve competitiveness of local medical device producers
Lao PDR*	More resources directed to build technical capacity of staff and conformity assessment bodies
Malaysia	(1) Seeking alternatives whereby the lengthy process of amending national law does not hinder the implementation of conformity assessment, such as in the EEE sector; and (2) outsourcing some tasks of NPCB, such as accreditation, to improve its efficiency and objectivity
Myanmar	(1) Streamlining the GMP inspection and final approval procedure for locally manufactured cosmetic products; (2) directing more resources on building capacity of conformity assessment bodies with clear roles and responsibilities; (3) more capacity building for regulators and industries to meet the requirements of ASEAN standardization, such as in cosmetics; (4) publication of regulatory requirements, conformity assessment procedures and applicable standards; and (5) improving coordination between the government, the private sector, and related stakeholders through a national coordination forum
Philippines	(1) More capacity building programmes directed at SMEs; (2) seeking alternative whereby the lengthy process of amending national laws does not hinder the conformity assessment implementation, such as in the EEE sector; (3) speeding up the enactment of National Quality Infrastructure Law; (4) greater engagement with stakeholders through public consultation; and (5) directing more resources on building capacity of conformity assessment bodies.
Singapore	More capacity building programmes directed to improve the competitiveness of SMEs, especially in the cosmetics sector
Thailand	(1) Greater private sector participation in the national standards committee; (2) more capacity building programmes to improve the competitiveness of SMEs, especially in the cosmetics sector; (3) consider revising the regulations so that national standards can be developed in English; and (4) more resources directed to the conformity assessment bodies, especially in the automotive sector

Country	Recommendation
Viet Nam	(1) Benchmarking on regional agreements in developing new regulatory frameworks, such as in the automotive and medical device sectors; (2) providing incentives to the private sector which can make adjustment to adopt the regional standards, especially in EEE sector; and (3) allocating more resources to improve the testing facilities and conformity assessment bodies.

Note: * Country report is not yet submitted or final.
EEE = electrical and electronic equipment; Lao PDR = Lao People's Democratic Republic; NPCB = National Pharmaceutical Control Bureau; SMEs = small and medium-sized enterprises.
Sources: ERIA questionnaire and Research Institute Network member country reports.

Role of and engagement with the private sector, international organizations, and dialogue partners. This paper discusses the role of the private sector, international organizations, and development partners sparingly; yet, their participation is critical for any success of the S&C initiatives.

Indeed, as indicated earlier, the ASEAN Cosmetics Association was a key driver towards the signing of the framework agreement on MRAs. Similarly, as another example, experts from international organizations like the World Health Organization (WHO) and the International Conference on Harmonization (ICH) were invited to participate in working sessions of the Pharmaceutical Product Working Group; their influence can be discerned by the fact that the ASEAN pharmaceutical regulatory harmonization processes and standards were similar to the ICH and the WHO, which is not surprising as ASEAN aims to emulate global best practices. The engagement of the private sector is either via the ASEAN regional industry associations where there exist[8] or the national industry associations working through their government representatives in the product working group concerned where there are no regional industry groups.[9] Direct participation of industry in the technical committees that develop the technical documents and guidelines, together with government experts, is useful in providing the necessary technical inputs for the formulation of regional policies and strategies in ASEAN (Ramesh, 2012a, p.21; Erna, personal communication).

Some country reports highlight the concern of domestic firms, especially SMEs, that the harmonization process would make them more vulnerable to tougher competition from abroad.

[8] ASEAN Food and Beverage Alliance for agro-based products (prepared foodstuff), ASEAN Automotive Federation for automotive, ASEAN Cosmetics Association for cosmetics, ASEAN Pharmaceutical Club and ASEAN Pharmaceutical Research Industry Association for pharmaceuticals, ASEAN Alliance on Traditional Medicines Industries and ASEAN Alliance on Health Supplements Association for traditional medicines and health supplements, and ASEAN Furniture Industry Council for wood-based products (Erna, 2014).
[9] This is the case for the medical device, rubber-based, electrical and electronic equipment, building and construction materials sectors and product working groups.

While this calls for firms to improve their productivity and competitiveness, it also brings out the importance of deeper engagement of the private sector in the harmonization and regulatory reform process. Ramesh (2012a, p.21) writes: 'Increasingly the stakeholders are demanding more information and transparency in the ASEAN regulatory and policy environment to better prepare them for the business opportunity ...(and challenges)…that ASEAN provides…(and presents)...through the integration of the ten markets' (words in parenthesis inserted by authors).

Towards developing deeper engagement with the private sector in the S&C arena, the following recommendations from country and other studies (for example, Pettman, 2014) could be considered:

- Continue and deepen private sector direct participation in the working group meetings and discussions.
- Conduct more dissemination activities to more firms, especially the SMEs.
- Press harder for the industry associations to engage especially with the SMEs.
- Private sector monitors and assesses the implementation and impacts of the initiatives especially on SMEs. The monitoring and assessment, using a common template agreed with the ACCSQ and senior economic officials, can be outsourced to credible institutions or groups, not necessarily undertaken by the private sector associations themselves.
- Annual meetings of small delegations from the private sector across industries with officials of the ACCSQ, senior economic officials and/or the High Level Task Force on Economic Integration to '…deliberate on the achievements and challenges and identify, where possible, solutions to issues which run across PWGs' (Pettman, 2014, p.4). In addition, improving SMEs' competitiveness in the face of the harmonization initiatives may call for better and pro-SME implementation at the national level of other related AEC measures such as on NTMs and trade and investment facilitation, thereby highlighting the importance of the annual meetings of the private sector not only with ACCSQ officials but also the senior economic officials, and where feasible, the High Level Task Force on Economic Integration officials.

Many of the country papers emphasize capacity building and infrastructure enhancement activities for the institutions and agencies involved in S&C, especially in Cambodia, Lao PDR, Myanmar, and Viet Nam. In this regard, ASEAN dialogue partners have been important

partners in providing technical assistance. ASEAN's major cooperation partners in S&C include (Erna, 2014):

- Australia and New Zealand: Australia and New Zealand Free Trade Agreement Economic Cooperation Work Programme
- China (PRC): ASEAN–China Technical Barriers to Trade Memorandum of Understanding on Standards, Technical Regulations and Conformity Assessment Procedures
- Germany–Physikalisch-Technische Bundesanstalt: Strengthening Quality Infrastructure Programme
- European Union: ASEAN Regional Integration Support from the EU Programme
- United States: ASEAN Connectivity Through Trade and Investment

An example of technical or facilitation assistance provided to ASEAN in the S&C field is the study visit in May 2014 of '…regulators from Cambodia, the Lao PDR, Myanmar, Viet Nam, and Brunei Darussalam …to the National Pharmaceutical Control Bureau (NPCB), Malaysia, and the Food and Drug Administration, Philippines. The focus of the study visit was to develop the online notification system for the ACD. The ASEAN Cosmetics Committee that oversees the implementation of the harmonized cosmetics regulations in ASEAN has set a target for all member states to establish systems that permit online notification of new cosmetic products placed in their markets. Participants studied the systems that have been implemented in Malaysia and the Philippines. The visit also provided participants an opportunity to study the respective post-market surveillance systems that are being implemented by two member states' (arise.asean.org[10]). It may be noted that the lack of an online notification system in some member states is one of the challenges to implementing the Agreement on the ASEAN Harmonised Cosmetics Regulatory Scheme that was raised in the Philippine report.

There are limits to the financial resources for S&C from the technical cooperation programmes of ASEAN dialogue partners. In the end, given the significant challenges facing the institutions and agencies of many AMSs involved in implementing the S&C initiatives, it is the responsibility of governments to invest more in building the appropriate infrastructure and personnel to have a smoother implementation of S&C initiatives for the benefit of their

[10] Study Visit of Cosmetics regulators from CLMV to Malaysia and Philippines, http://arise.asean.org/study-visit-of-cosmetics-regulators-from-clmv-to-malaysia-an-philippines-4-to-8-may-2014/, accessed 5 December 2014.

industries and peoples. In addition, Pettman (2014) highlights the need for AMSs to invest in strengthening the institutional capability of the ASEAN Secretariat to manage the expanding and complicated regional initiatives in S&C.

To sum up and conclude, there is growing traction of S&C initiatives' implementation in ASEAN. Going forward, member states need to invest more in improving the S&C ecosystem through more facilitative conformity assessment procedures, improved technical and infrastructure capability, as well as improved governance. Indeed, the AEC Blueprint measures are more than just liberalization. Improvements in trade and investment in the AEC involve the design and implementation of good regulatory practices and development of capable and effective institutions as well as improved institutional coordination and consultation among government agencies and other instruments as well as with nongovernment stakeholders, including the concerned industries.

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Appendix A
ERIA Standards and Conformance Scorecard Scoring System

Technical Barriers to Trade	Specific Activities	Weight	Remarks
1. Standards (includes technical requirements which are not published as national standards but define the safety and quality requirements to be met)			
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 harmonize the national standards with agreed international standards or international benchmarks.	Review of equivalence of corresponding national standards or technical requirements with international standards or international benchmarks identified for harmonization at the regional level.	5%	Upon agreeing at the regional level to harmonize the national standards with the identified international standards or international benchmarks, the ASEAN member states must carry out a review of the equivalence of the national standards with the identified international standards or international benchmarks. In the case that these standards are non-equivalent, the national standards must be revised.
	Consensus reached at the national level among stakeholders on revision of national standards or technical requirements to ensure alignment with international standards or international benchmarks identified for harmonization at the regional level.	30%	Reaching consensus on the technical contents of the draft standards is an essential step in the development of standards.
	Public comments on the revised national standards sought among stakeholders prior to publication of the standard.	10%	Transparency is another essential step in the development of standards and this is achieved through circulation of the draft standards to the public for comments.
	Publication of the revised national standards or technical requirements which is aligned with the international standards or international benchmarks identified for harmonization at the regional level.	5%	ASEAN member states to provide lists of the national standards harmonized with the identified international standards or international benchmark and declare that degree of equivalence.
	Total	**50%**	
2. Conformity Assessment Procedures			
The process flow covers the activities to be carried out to address conformity	Ratification of the MRA by ASEAN member states	10%	Upon signing the MRA, the member states will deposit the instrument of ratification with the ASEAN Secretariat as a formal acceptance of the agreement.

Technical Barriers to Trade	Specific Activities	Weight	Remarks
assessment procedures as non-tariff barriers to trade. Within ASEAN the approach taken is to establish mutual recognition arrangements (MRAs) as a means to facilitate the acceptance or recognition of results of conformity assessment procedures, produced by the conformity assessment bodies among the member states. This will avoid multiple testing of products and reduce the time taken for products to reach the market, having direct implications on cost of products. The success of the MRA is on its effective implementation which is dependent on the availability of the related institutional and technical infrastructure.	Transposition of MRA provisions into applicable national laws, legislations, or regulations	20%	Transposition of the requirements of the MRA is critical to ensure that the MRA is operational.
	Publication of a country's regulatory requirements, conformity assessment procedures, and applicable standards for the sector	5%	The publication of country's regulatory requirements, conformity assessment procedures, and applicable standards for the sector are critical for the implementation of the conformity assessment.
	All documents issued are provided in English.	5%	Publication in international language will facilitate the conformity assessment.
	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	10%	Proposals for listing of conformity assessment bodies are evaluated by the Joint Sectoral Committee based on the agreed criteria in the MRA.
	Regular audit or assessment of listed conformity assessment bodies by the respective ASEAN member states	5%	Regular audits or assessment of conformity assessment bodies are necessary to ensure that these bodies are capable and remain capable of properly assessing conformity of products or processes, as applicable, and as covered in the MRA.
	Identification and implementation of capacity building programs to enhance the capability of ASEAN conformity assessment bodies to meet the requirements under the MRA	5%	Enhancing the capability of conformity assessment bodies will encourage more of them to be listed under the MRA as well as boost their confidence.

Technical Barriers to Trade	Specific Activities	Weight	Remarks
	Total	**60%**	
3. Technical Regulations			
The harmonization of standards and mutual recognition of results of conformity assessment procedures will enhance intra-ASEAN trade facilitation. However, for ASEAN to operate as a single market and production base, the harmonization of technical regulations among the member states is necessary.	Ratification of the regional agreement (harmonized technical regulation) by ASEAN member states	10%	Upon signing the regional agreement (harmonized technical regulation), the member states will deposit the instrument of ratification with the ASEAN Secretariat as a formal acceptance of the agreement.
	Transposition of regional agreement (harmonized technical regulation) provisions into applicable national laws, legislations, or regulations.	20%	Transposition of the requirements of the regional agreement (harmonized technical regulation) is critical to ensure that the regional agreement (harmonized technical regulation) is operational. This includes the review of existing applicable national laws, legislations, or regulations; the verification of the alignment of these national provisions with the regional agreement (harmonized technical regulation); and if necessary the amendment of the relevant national provisions.
	Actions taken for the interpretation of the regional agreement (harmonized technical regulation), including adoption of the regional guidelines for national implementation	10%	The implementation of the regional agreement (harmonized technical regulation) is monitored through reports from the member states on the status of implementation at the national level.
	Availability of harmonized standards and technical requirements to support the implementation of the regional agreement (harmonized technical regulation)	10%	Adoption of the harmonized standards and technical requirements at the national level is necessary to ensure the effective implementation of the regional agreement (harmonized technical regulation) to realize the ASEAN single market.
	Availability of technical infrastructure such as competent conformity assessment bodies to support the implementation of the regional agreement (harmonized technical regulation)	10%	Technical infrastructure such as competent conformity assessment bodies with capabilities to carry out testing in line with the provisions of the regional agreement (harmonized technical regulation) are necessary to support the implementation of the regional agreement (harmonized technical regulation).

Technical Barriers to Trade	Specific Activities	Weight	Remarks
	Post-market alert systems established for linking with the member states to strengthen regional post-market surveillance efforts	10%	As ASEAN operates as a single market with the implementation of the regional agreement (harmonized technical regulation), regional efforts for post-market surveillance, which is one of the main pillars of the safety of the consumers and an essential tool for enforcing the regional agreement (harmonized technical regulations\), must be strengthened.
	Total	**70%**	

Notes: The weight is based on the 'national obligations' weight in the mid-term review 2011 report. The score is scaled to 100 percent for comparative graphical presentation in this report.
Source: Authors.

Appendix B

ASEAN Member States' Conformity Assessment Bodies

1. Cosmetics Sector

Country	Designating Body	Listed Testing Laboratory and Conformity Assessment Body	Accreditation Body
Brunei Darussalam	Department of Pharmaceutical Services, Ministry of Health	Drugs Quality Control Unit, Ministry of Health	Consultant from Singapore
Cambodia	Department of Drug, Food, Medical Device and Cosmetics (DDFMC)	DDFMC (conformity assessment body)	Not yet identified
Indonesia	National Agency of Food and Drug Control (BPOM)	Balai BPOM	National Accreditation Body/KAN
Lao PDR	Not yet identified	Not yet identified	Not yet identified
Malaysia	National Pharmaceutical Control Bureau (NPCB)	NPCB	Not yet identified
Myanmar	*	*	*
Philippines	Food and Drug Administration	Food and Drug Administration	Philippine Accreditation Bureau
Singapore	Health Sciences Authority and SPRING Singapore	Cosmetics Laboratory under the Health Sciences Authority	Singapore Accreditation Council (SAC)
Thailand	Bureau of cosmetic and hazardous substance, Dept. of medical science, Min. of Public health	Bureau of Cosmetic and Hazardous Substance, Department of Medical Science, Ministry of Public Health	Not yet identified
Viet Nam	Not yet identified	Drug Administration of Viet Nam – Ministry of Health coordinates with National Institute of Drug Quality Control, Ho Chi Minh Institute of Drug Quality Control (in Ho Chi Minh City), and Department of Health at the provincial level	Not yet identified.

* No information.
Source: ERIA questionnaire.

2. Electrical and Electronic Equipment Sector

Country	Designating Body	Listed Testing Laboratories and Conformity Assessment Body	Accreditation Body
Brunei Darussalam	Not yet identified	Not yet identified	Authority of Building and Construction Industry (ABCI)
Cambodia	Institute of Standards of Cambodia (ISC)	Not yet identified	Not yet identified
Indonesia	National Standardization Body/BSN	PT PLN Research Development Indonesia – Testing Lab, PT Sucofindo Laboratory – Testing Lab, Laboratory for Quality Testing of Export and Import Goods (BPMBEI) Indonesia – Testing Lab, PT HIT Indonesia – Testing Lab, Laboratory for Quality Testing of Export and Import Goods (BPMBEI) Indonesia – Testing Lab, LSPro – PUSTAN DEPPERIN – Certification Body	National Accreditation Committee/KAN
Lao PDR	Not yet identified	Not yet identified	Not yet identified
Malaysia	Suruhanjaya Tenaga (ST)	SIRIM QAS	The Department of Standards Malaysia (DSM)
Myanmar	Not yet identified (currently assumed by Ministry of S&T)	Not yet identified	Not yet identified (currently assumed by Ministry of S&T)
Philippines	Bureau of Philippine Standards (BPS)	BPS Testing Center, OMNI Solid Testing Laboratory (Solid Laguna Corp. Test Labs), Scientific Environmental and Analytical Laboratory Services, TUV Rheinland Philippines	Philippine Accreditation Bureau (PAB)
Singapore	SPRING Singapore	Listed Test Laboratories: TUV SUD PSB Pte Ltd., Intertek Testing Services (S) Pte Ltd., Singapore Electrical Testing Services, Certification Bodies: TUV SUD PSB Pte Ltd.	Singapore Accreditation Council (SAC)
Thailand	Thai Industrial Standard Institute (TISI)	Intertek Testing Services (Thailand) Ltd., TUV SUD PSB (Thailand) Limited	Not yet identified but it will be accredited by the National Standardization Council of Thailand – Office of the National Accreditation Council (NSC – ONAC)
Viet Nam	Bureau of Accreditation (BOA)	Test Laboratories: QUATEST 1 (Hanoi), QUATEST 3 (Ho Chi Minh City) Certification Body: QUACERT	Not yet identified

Source: ERIA questionnaire.

3. Pharmaceutical Sector

Country	Designating Body	Listed Inspection Service and Conformity Assessment Body	Accreditation Body
Brunei Darussalam	Pharmacy Enforcement Section, Ministry of Health	Pharmacy Enforcement Section, Ministry of Health	BV
Cambodia	Department of Drug, Food, Medical Device and Cosmetics (DDFMC)	Not yet identified	Not yet identified
Indonesia	National Agency of Drug and Food Control (BPOM)	Balai BPOMs	National Accreditation Committee (KAN)
Lao PDR	Not yet identified	Department of Standard and Metrology is the CAB. The LIS is not yet identified.	Not yet identified
Malaysia	National Pharmaceutical Control Bureau (NPCB)	National Pharmaceutical Control Bureau (NPCB)	Not yet identified
Myanmar	Not yet identified	Not yet identified	Not yet identified
Philippines	Not yet identified	Food and Drug Administration is the conformity assessment body. The listed inspection service is not yet identified.	Not yet identified
Singapore	Health Sciences Authority, Singapore	Health Sciences Authority, Singapore National Pharmaceutical Control Bureau (NPCB), Malaysia National Agency for Drug and Food Control (NADFC), Indonesia	Not yet identified
Thailand	*	*	*
Viet Nam	General Department of Measurements and Quality, Ministry of Sciences and Technology	Drug Quality Management Division, Drug Administration of Viet Nam	Not yet identified

* No information.
Source: ERIA questionnaire.

Appendix C

ASEAN Regionally Agreed International Standards for Adoption

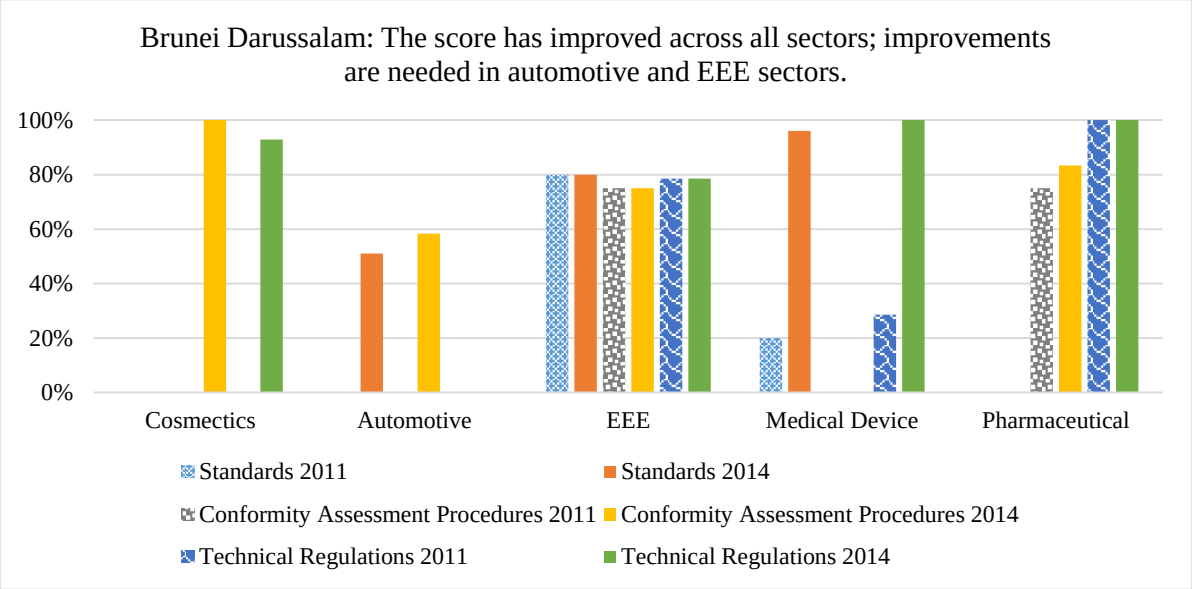
No.	Sector	Reference	Title of Standards
1	Automotive	ECE R13	Heavy vehicle braking
		ECE R13H	Braking of passenger cars
		ECE R14	Safety-belt anchorages
		ECE R16	Safety-belts
		ECE R17	Strength of seats, their anchorages, and head restraints
		ECE R25	Head restraints (headrests)
		ECE R28	Audible warning device
		ECE R30	Tyres for passenger cars and theirs trailers
		ECE R39	Speedometer
		ECE R40	Exhaust emission
		ECE R41	Noise emission (L category)
		ECE R43	Safety glass
		ECE R46	Devices for indirect vision (rear view mirror)
		ECE R49	Diesel emission
		ECE R51	Noise emission of M and N categories of vehicle
		ECE R54	Tyres for commercial vehicles and their trailers
		ECE R75	Tyres for motorcycles/mopeds
		ECE R79	Steering equipment
		ECE R83	Exhaust emission of M1 and N1 vehicle
2	Electrical and electronic equipment	IEC	121 standards
3	Medical device	IEC 60601-1:2005 Third edition	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
		ISO/IEC 17011	Conformity assessment General requirements for accreditation bodies accrediting conformity assessment bodies
		ISO 13485:2003	Medical devices – Quality management systems – Requirements for regulatory purposes
		ISO/TR 14969:2004	Medical devices – Quality management systems – Guidance on the application of ISO 13485: 2003
		ISO 14971:2007	Medical devices – Application of risk management to medical devices
		ISO 15223-1:2007	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
		ISO 11135-1:2007	Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
		ISO 11137-1:2006	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
		ISO 15190:2003	Medical laboratories – Requirements for safety

No.	Sector	Reference	Title of Standards
		ISO 11607-2:2006	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing, and assembly processes
		ISO 14155-1:2003 ISO 14155-2:2003	Clinical Investigation of Medical devices for human subjects
		ISO 10993-1 to -18	Biological evaluation of medical devices
		ISO 14729-2001	Contact lens
		ISO 14730-2000	Contact lens substances
		ISO 81060-1:2007	Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type
		IEC60601-2-19:2009 Second edition	Medical electrical equipment – Part 2–19: Particular requirements for the basic safety and essential performance of infant incubators

Appendix D

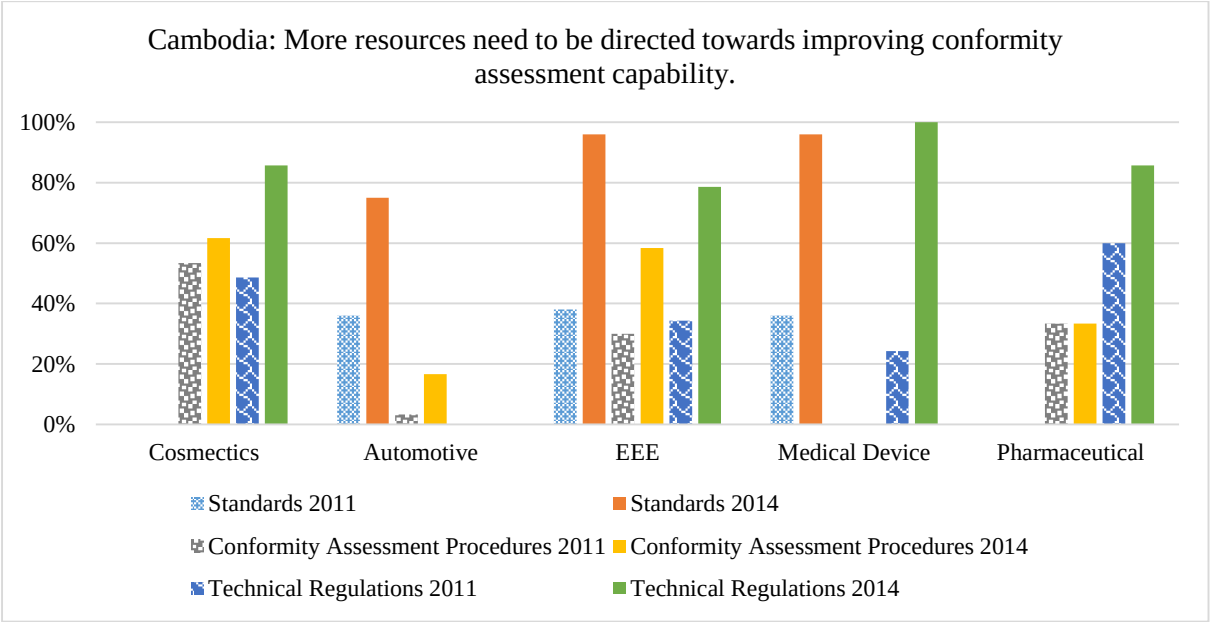
Progress of Standards and Conformance Initiatives by Country

Figure D.1: Standards and Conformance Initiatives Score, Brunei Darussalam



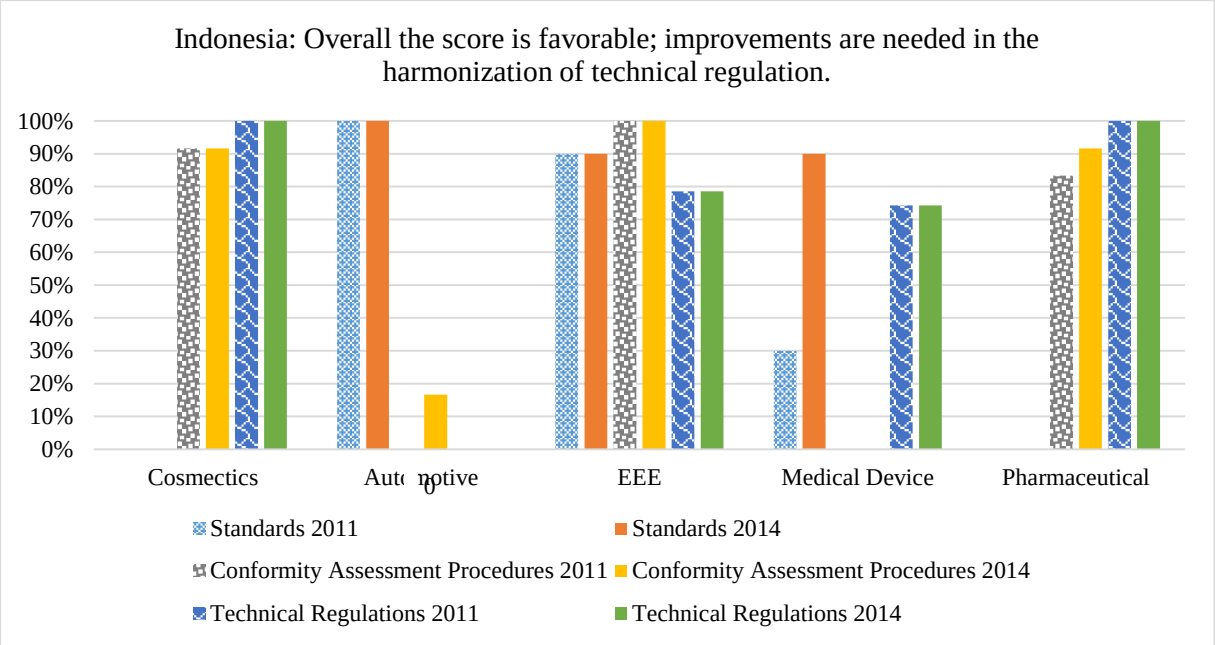
Note: No national data for Brunei Darussalam in 2011 cosmetics and automotive scorecard.
EEE = electrical and electronic equipment.
Source: ERIA questionnaire.

Figure D.2: Standards and Conformance Initiatives Score, Cambodia



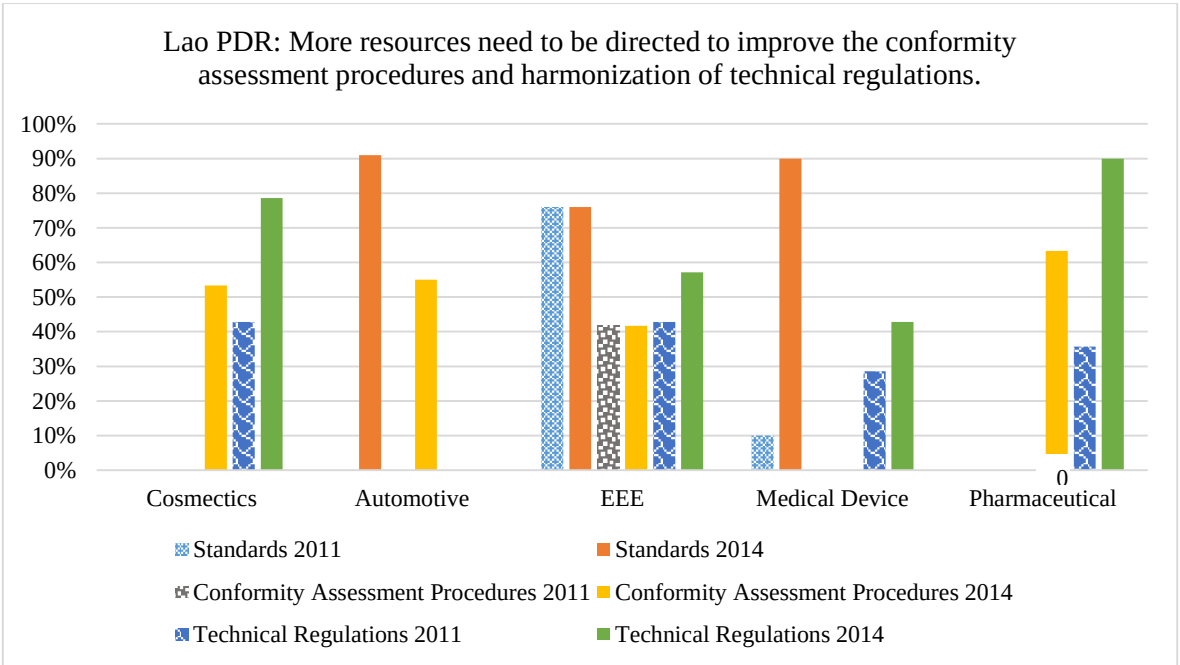
EEE = electrical and electronic equipment.
Source: ERIA questionnaire.

Figure D.3: Standards and Conformance Initiatives Score, Indonesia



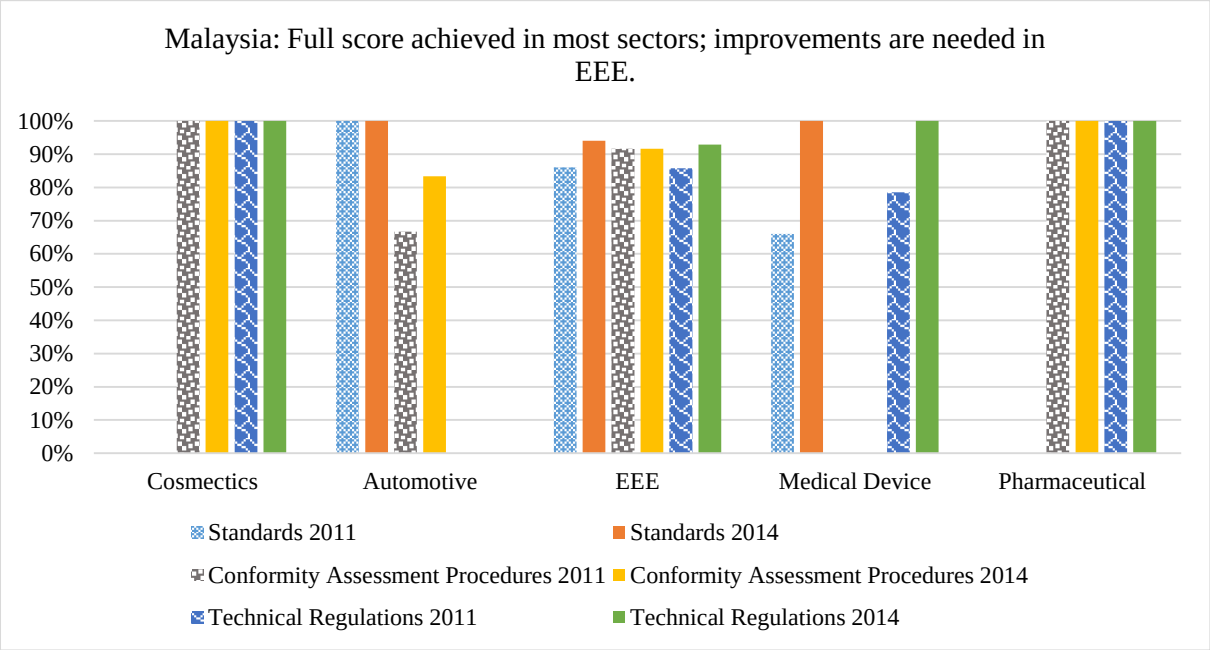
EEE = electrical and electronic equipment.
Source: ERIA questionnaire.

Figure D.4: Standards and Conformance Initiatives Score, Lao PDR



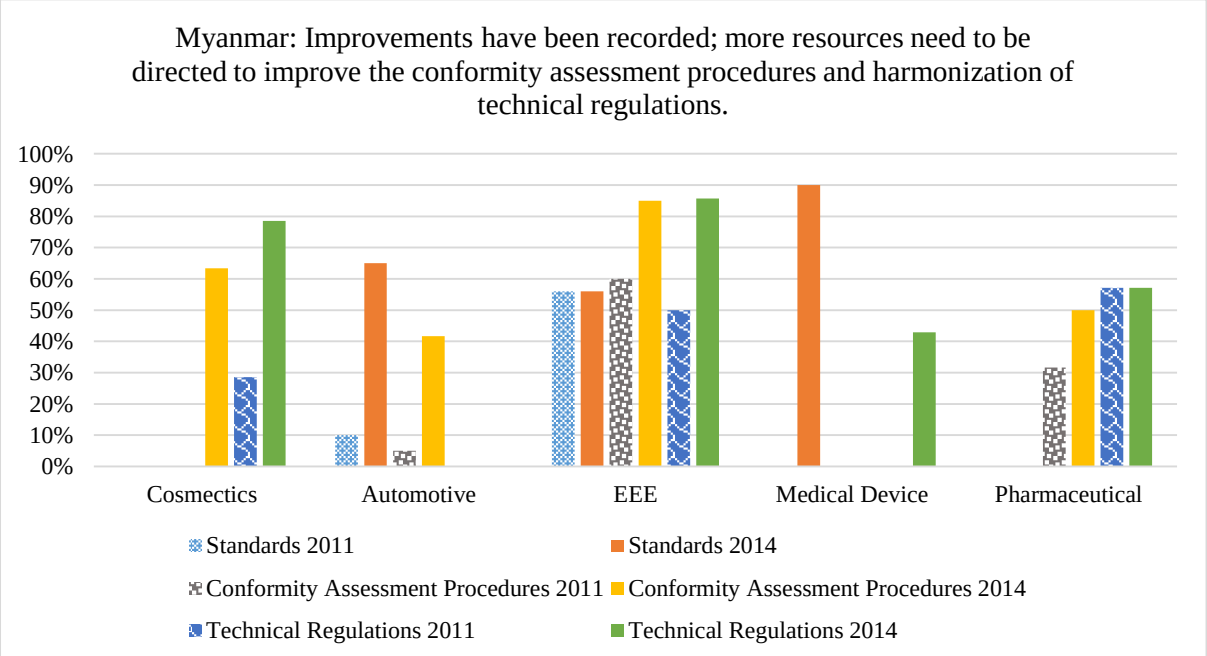
Note: No national data for Lao PDR in 2011 automotive scorecard.
EEE = electrical and electronic equipment.
Source: ERIA questionnaire.

Figure D.5: Standards and Conformance Initiatives Score, Malaysia



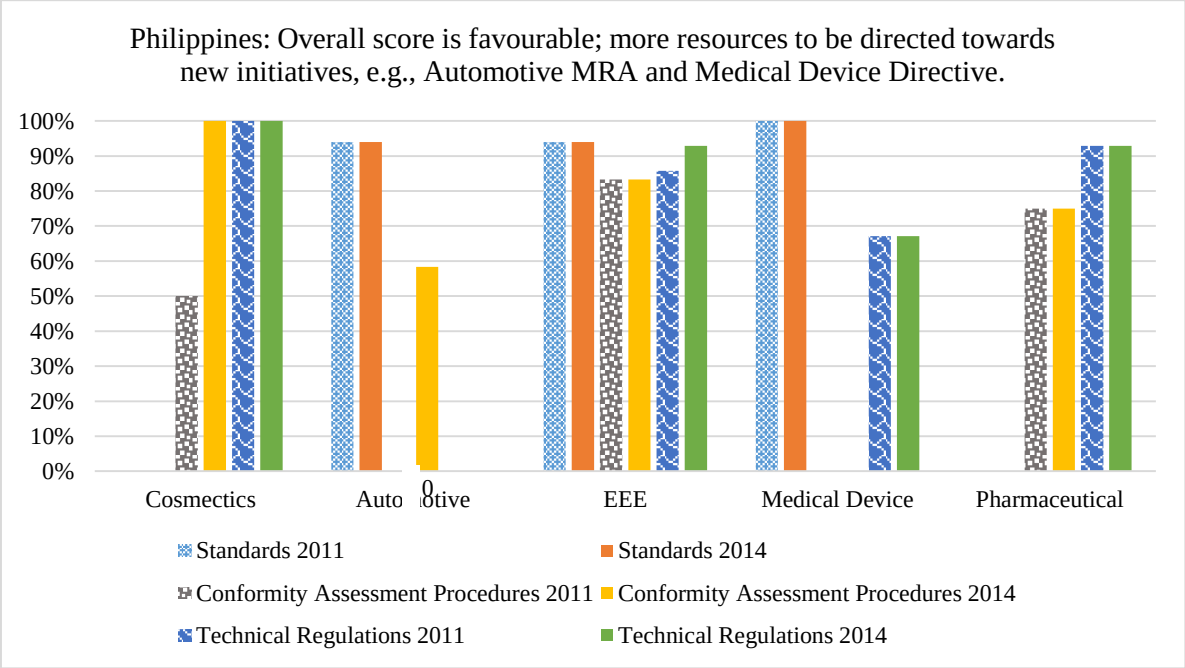
EEE = electrical and electronic equipment.
Source: ERIA questionnaire.

Figure D.6: Standards and Conformance Initiatives Score, Myanmar



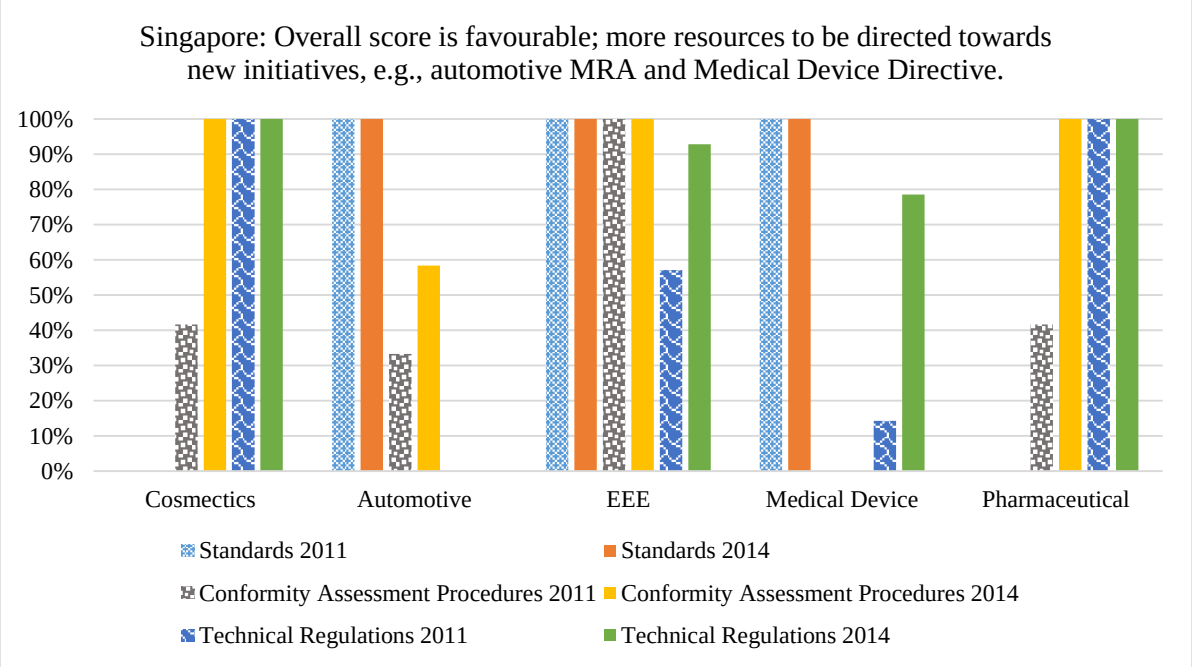
EEE = electrical and electronic equipment.
Note: No national data for Myanmar in 2011 medical device scorecard.
Source: ERIA questionnaire.

Figure D.7: Standards and Conformance Initiatives Score, the Philippines



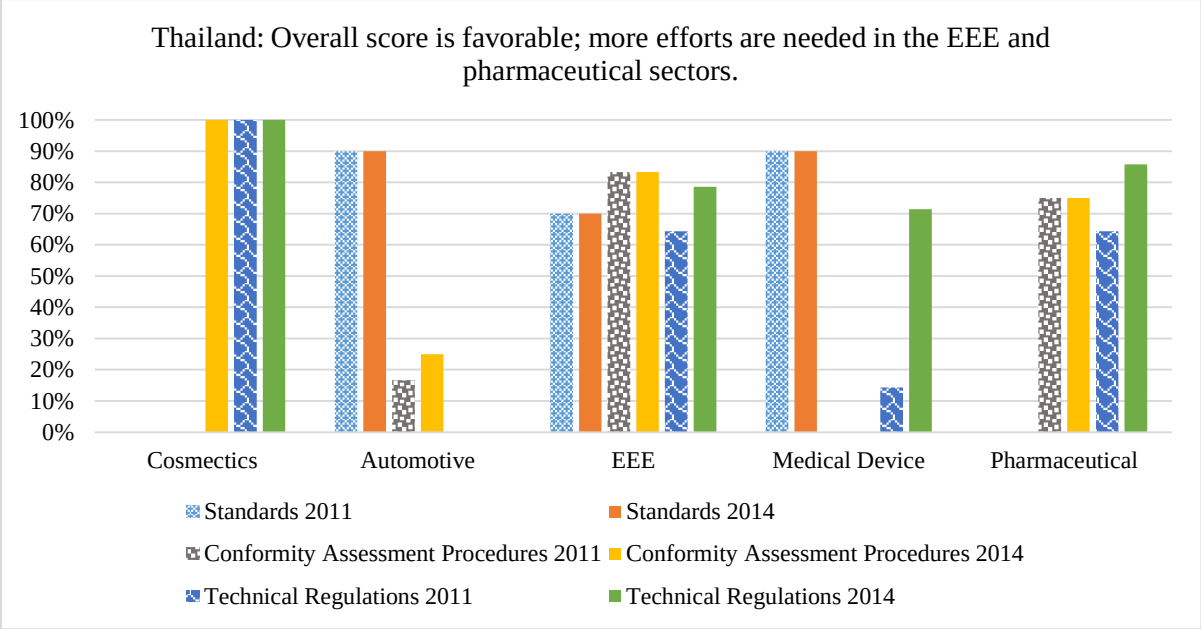
EEE = electrical and electronic equipment; MRA = mutual recognition arrangement.
Source: ERIA questionnaire.

Figure D.8: Standards and Conformance Initiatives Score, Singapore



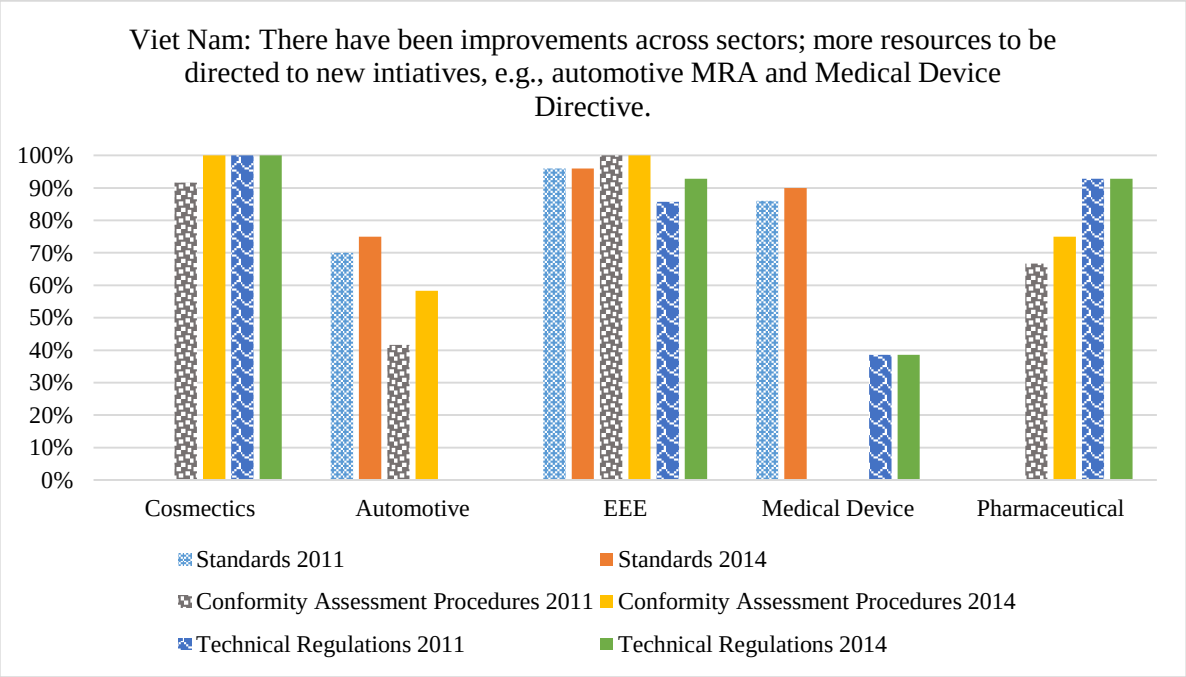
EEE = electrical and electronic equipment; MRA = mutual recognition arrangement.
Source: ERIA questionnaire.

Figure D.9: Standards and Conformance Initiatives Score, Thailand



EEE = electrical and electronic equipment; MRA = mutual recognition arrangement.
Source: ERIA questionnaire.

Figure D.10: Standards and Conformance Initiatives Score, Viet Nam



EEE = electrical and electronic equipment; MRA = mutual recognition arrangement.
Source: ERIA questionnaire.

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