

ASEAN Roadmap for Integration of the Healthcare Sector

Executive Summary



This assessment presents a review of measures taken to implement the ASEAN Roadmap for Integration of the Healthcare Sector. Healthcare is one of the 12 priority sectors identified by ASEAN leaders to help drive ASEAN integration and the creation of the ASEAN Economic Community. While the Roadmap and this assessment focus primarily on economic issues, the healthcare sector also is an integral part of the ASEAN Socio-Cultural Community and therefore should be considered in a broader context. The disparity in health profiles among ASEAN Member Countries and the emergence of highly infectious diseases that respect no geopolitical boundaries place an additional premium on regional cooperation beyond economic integration.



In broad economic terms, an integrated ASEAN market in healthcare – consisting of harmonized standards, registration and evaluation, an operable post-marketing surveillance mechanism, effective mutual recognition agreements and cross border provision of healthcare services – would benefit consumers and economic growth. Domestic firms that successfully adjust to the Roadmap requirements would gain access to a greater ASEAN market, move up the technology curve and be more competitive with imports. Consumers would benefit from wider choices and from potentially lower prices through increased competition.



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Care, however, should be exercised in the movement to a more efficient market to avoid or minimize adverse side-effects such as temporary price increases, shortages in medical personnel (particularly in rural areas), and the proliferation of counterfeit, substandard products. Policy measures by Member Countries and concerted action through ASEAN cooperation could help mitigate such difficulties, as envisaged in the creation of an ASEAN Socio-Cultural Community.

This assessment concludes that there has indeed been progress in the implementation of the Healthcare Roadmap. However, from a methodological perspective, the lack of measurable indicators to assess progress renders any assessment necessarily qualitative. Despite this challenge, this study extracted cross-cutting and sector-specific recommendations that should increase the chances of ASEAN success in integrating the healthcare sector by 2010.

GENERAL OBSERVATION AND RECOMMENDATIONS

Provide adjustment assistance to SMEs

A notable characteristic of the ASEAN healthcare industries covered in the Roadmap is the presence of a large number of small and medium enterprises (SMEs). This poses a challenge to relevant authorities. In some ASEAN Member Countries, certain SMEs, concerned about increased competition from an integrated ASEAN healthcare sector, are vehemently opposed to the implementation of the Roadmap. In particular they cite the imposition of Good Manufacturing Practice (GMP) guidelines or rules that, in their assessment could drive them out of business.

SME concerns should not be ignored but also should not impede ASEAN implementation of the Roadmap. Dual sets of standards -- one for large, exporting companies and another for SMEs -- as suggested by some SMEs is not tenable. Instead, Member Country governments should seriously consider programs that would ease SME adjustment to a more competitive environment, such as toll manufacturing under which SMEs contract large companies to manufacture their products. In this way, SME production would be able to meet GMP standards and the firm would retain the rights over product formulas. Such a program may be more successful if it were coupled with assistance to help SMEs market products beyond their traditional local markets.

Thus, ASEAN Member Countries should make GMP an obligatory requirement for all companies, but allow a transition period for SME implementation. Special ASEAN capacity building and training programs should be undertaken and targeted to SMEs to assist in their transition to the new regimes.

Adopt international standards

Whenever possible, ASEAN should aim to adopt international standards that are widely accepted. This would enable ASEAN companies to compete in the world market as well as within ASEAN itself. A piece-meal approach to the adoption of standards is costly and should, as much as possible, be avoided. However, care should be taken to ensure that higher standards do not constitute de facto barriers to entry and hence a reduction in consumer choice.

Increase public awareness

Many healthcare companies contacted for this assessment claimed that they have either never heard of the Roadmap or have heard of it but do not know much about

it. An outreach program is, therefore, necessary and important to explain to the industry, the media and the public of the benefits of the Roadmap to facilitate compliance and generate support for implementation. While some awareness efforts exist, they should be expanded.

Build capacity in regulatory authorities

Regulatory authorities in some member countries need assistance to enable them to implement and enforce the Roadmap in full. Training and capacity building should be held or coordinated at the ASEAN level and could include exchange programs between ASEAN Member Country regulatory authorities. Such cross visits would not only build trust and capacity among the region's competent authorities, but would also create peer pressure for Member Countries to improve their regulatory

PHARMACEUTICALS

Intra-regional trade would benefit from non-restrictive rules of origin

Most of the basic inputs for pharmaceutical manufacturing are imported from outside of ASEAN; the majority of intra-ASEAN trade in the pharmaceutical sub-sector is in finished products. Hence, to foster trade within the region ASEAN authorities should ensure that the rules of origin are not too restrictive, thereby allowing traders to access ASEAN Free Trade Agreement (AFTA) tariff preferences.

Consider incentives to encourage implementation of harmonized GMP

Some ASEAN Member Countries, such as Singapore, Malaysia, and Thailand, have opted for PIC/S¹. The objective of PIC/S is to develop, implement and maintain harmonized GMP standards and quality systems of inspectorates. This provides ASEAN a good foundation upon which to build.

In some ASEAN Member Countries, such as Indonesia, the pharmaceutical industry has resisted implementation of ASEAN GMP. In the case of Thailand, most manufacturers are GMP compliant because drugs purchased with government funds must be from GMP certified companies. Moreover, the Thai Government provides incentives to companies if they adopt PIC/S before 2008. Thailand's success could be considered by in other countries.

¹ Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP

Establish ASEAN regional laboratories and registration

ASEAN should consider establishing regional quality control laboratories for pre-market testing, evaluation and licensing of manufacturers. Regional laboratories would ease cost, build confidence, foster professional relationships, and facilitate regional trade.

Pharmaceutical registration too would benefit from a regional versus national approach. Regional models based on the European Medicines Agency (EMA)² should be explored. Additional clinical studies in specific settings may be required for new drugs, but could be carried out regionally. This approach would alleviate the need for costly national laboratories which add little or no value to work already conducted by regional centers. In addition, regional labs could build relationships with other well-known regulatory authorities, possibly using their lab results as a basis for regional testing and evaluation, thereby reducing duplication and cost.

TRADITIONAL MEDICINES

Encourage ASEAN collaborative efforts and protection of intellectual property

ASEAN cooperation in the field of traditional medicines needs to be intensified, particularly in research and development. Each country produces unique traditional medicines that should be allowed to be traded freely within ASEAN if they meet ASEAN standards. Countries should focus on specialized areas where they might have comparative advantage, e.g. herbal plants in Indonesia and Thailand. Producers of traditional medicines should be urged to apply for protection of the intellectual property rights (IPR) for their traditional medicines as soon as possible to prevent imitation.

Step up post-market surveillance

There is an urgent need to improve post-market surveillance. The products/service liability requirements, such as traceability measures, are an issues that need to be taken into account in post-market surveillance.

² EMA is a decentralized body of the European Union that EMA coordinates the evaluation and supervision of medicinal products throughout the European Union.

COSMETICS

Urgent attention to implementation

The ASEAN Harmonized Cosmetic Regulatory Scheme should be the flagship for regional cooperation in the field of standards and conformity assessment, an important building block for the ASEAN Economic Community. The ASEAN cosmetics industry has developed rapidly with trade among the ASEAN-6 soaring from US\$140 million in 1993 to US\$354 million in 2000. Implementation of this ASEAN Harmonized Cosmetics Regulatory Scheme would set a precedent for ASEAN to implement more ambitious schemes, such as in pharmaceuticals. Assessments of Member Country readiness to implement the cosmetics regime have been conducted or are underway. The case studies of this report suggest that the important implementation deadline might be missed. ASEAN should redouble efforts so that the effective implementation of the ASEAN cosmetics regime provides a positive demonstration effect in other standards and conformity assessment activities under the Healthcare

MEDICAL DEVICES

Need for uniform standards

As in other areas, there appears to be a division in ASEAN between large companies that want to adopt international standards, and smaller companies that prefer standards just for the domestic market. In some countries, such as Indonesia, the competent authority is sympathetic to those concerns. As in the case for pharmaceutical products, there should be one standard in ASEAN. If necessary, special ASEAN adjustment assistance measures, including capacity building, should be extended to SMEs that are likely to adjust to a more competitive environment.

Raise stakeholder awareness

The few firms and associations in ASEAN contacted in the course of case studies did not seem to be aware either of the work of the ASEAN Consultative Committee on Standards and Quality Medical Devices Working Group, including details of the ASEAN Common Submission Dossier Format or the post-market surveillance system. Minimal information is available on the ASEAN Secretariat website. A review of the working group's website (accsq-mdwg.org) showed general information about the group's objectives but no details on the work or documents for public review and comment. Increased transparency could help uninformed stakeholders become champions of Roadmap integration efforts.

HEALTH SERVICES

Increase commitments in services

A truly integrated ASEAN Healthcare sector would also permit the free flow of services within ASEAN. Although ASEAN Member Countries recognize the need to further liberalize healthcare services, commitments in schedules of the ASEAN Framework Agreement on Services (AFAS) have been limited.

Increase ability of skilled labor to provide services across border

Government regulations in restricting movement of healthcare professionals³ within ASEAN present substantial barriers to trade in healthcare services. Several studies⁴ recommend that ASEAN undertake standardize arrangements for visa and work permits. Efforts to improve educational and professional standards should be encouraged to minimize the social costs of brain drain. In the case of countries that “export” medical personnel to the region, the cost of educational expansion to increase the supply of medical personnel should be shared with the private sector as it is also the beneficiary of medical graduates.

The mutual recognition arrangement (MRA) for nursing services signed in December 2006 is the first attempt to develop a common set of professional standards or competencies in medical services. Work is underway for a similar MRA on medical practitioners. The MRA on nursing services can be regarded as a first step toward more robust MRAs in the region. Host countries still retain the right to recognize foreign nursing qualifications; foreign-trained nurses are required to work with local nurses and will still need to apply for a license to practice from the competent authority of the host-country. Over time, the ASEAN Joint Coordinating Committee on Nursing that was established under the MRA could explore further acceptance of home market credential and experience as members become more familiar with each others’ regimes and practices and skills converge at a high level.

In sum, there is significant movement in the integration of the ASEAN Healthcare sector. Key issues remain with respect to implementation and potential consequences for SMEs and the availability of health care services for low income individuals, both of which could be addressed by public policy measures.

³ Including visa arrangements, language tests, citizenship requirement etc.

⁴ ASEAN-ANU Migration Research Team (2005), Arunanondchai and Fink (2005), Hiong and Djandam