



**Project on Strengthening Technical Competency for
Consumer Protection in ASEAN**

Health Care services

Version 22 January 2016



The overall objective of the project is to enhance the capacities of AMS to adopt and implement consumer protection laws at the national level. The project aims to build/strengthen capacity of government agency personnel through the design, development and delivery of training programs focusing on technical requirements provisionally involving consumer concerns and demands in 6 core areas, namely: 1) Product safety and labelling; 2) Phone and internet services, and e-commerce; 3) Consumer credit and banking; 4) Environment; 5) Healthcare services; and 6) Professional services. For further information about the project, please contact the ASEAN Secretariat, Ms Yap Lai Peng (yap@asean.org) or Ms Sarah Firdaus (sarah.firdaus@asean.org), and Mr. Pierre Horna (pierre.horna@unctad.org), Manager of the Project on Strengthening Technical Competency for Consumer Protection in ASEAN.

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Overview and summary of the module

1. According to a UN General Assembly resolution; “health is a precondition for, an outcome and indicator of all three dimensions of sustainable development; economic, social and environmental.” The resolution goes on to state that the goals of sustainable development can only be achieved in the absence of a high prevalence of debilitating communicable and non-communicable diseases, and where populations can reach a state of physical, mental and social well-being. Consumers of Health Services in ASEAN Member States experience differing levels of protection depending not only on which country they live in, but where in the country they live. This project seeks to provide training for Officials responsible for the establishment of policy and the regulation of providers of health care services, with a view to improve standards of practice and enhance the welfare of consumers generally.
2. ASEAN policymakers have been convinced that action on the social and environmental determinants of health, both for the poor and vulnerable and for the entire population, is important to create inclusive, equitable, economically productive and healthy societies. ASEAN Health Ministers have developed a new health agenda which involves identification of health priorities and goals for the coming five years. This training module on healthcare services has been developed to assist in the realisation of the vision of ASEAN as “A healthy, caring and sustainable community”
3. This training module, drawing from many sources, describes the many and varied challenges facing ASEAN member states as they work to improving the operation of healthcare systems for their citizens and consumers. The module summarises the painstaking work undertaken in the road mapping study in which stakeholders in every AMS described problems and prospects in health services. Key content in the report is drawn from the many reports prepared by the Asian Development Bank (ADB), the World Health organisation (WHO) other UN agencies as well as from previous ASEAN consumer protection projects. The centrepiece of the Training Module is a tabulation of healthcare issues classified in relation to their impact on Availability (quality and product), Accessibility and Affordability of healthcare services here seen as the three benchmark criteria to be applied to an analysis of consumer welfare issues in healthcare with the following structure.
4. Relationships between healthcare service providers and patients (business-related activities related to the rendering of health care services); The area of health-care products, pharmaceuticals and medicaments (generic or branded) medical devices, traditional medicines; Management of hospitals, clinics and other facilities that related to the platform (facilities – premises) where the services are taking place ‘Government agencies involved in consumer protection require specific expertise and knowledge in the workings of consumer protection mechanisms. This Module aims to strengthen



capacity of government agency personnel through the design, development and delivery of training programs in relation to health services, as well as soft skills required to facilitate customer redress

5. The module includes a summary of current rules and practices for regulation of health care services around ASEAN. Gaps in compliance, consumer information, and best practices were noted and areas for strengthening implementation mechanisms were identified. Material is presented which will enable better enforcement of laws through investigation of breaches. Challenges in effective implementation of enforcement and redress mechanisms delivering justice to aggrieved consumers is the objective of the module. Developing competent and well trained officials to administer current laws and design and implement new ones is a necessary pre-requisite to enhancing the welfare of ASEAN consumers in relation to health services.
6. A case study of best practice regulation and complaint resolution in the Thai hospital sector is provided as are guidelines for selection of internal complaint handling and external redress schemes.



I. Introduction

Learning objectives and outcomes of Section I

This section of the Train-the-Trainer Manual introduces the broad policy context for consumer protection in healthcare services. International and ASEAN policy measures for delivery of healthcare services are described as is the important role of consumer affairs agencies and policy instruments. The chapter identifies capacity building needs and lists key principles which form part of the manual

Background information from the road mapping study is presented in an outline of healthcare services regulation in ASEAN

Following completion of the Train the Trainer sessions, participants should be able to:

- contextualise consumer protection in healthcare services situated in ASEAN
- articulate measures taken by the UN and ASEAN Health Ministers to create a “Healthy, caring and sustainable ASEAN Community”
- identify those elements of the ASEAN Health Development Agenda which intersect with consumer policy
- nominate key health priorities and goals in ASEAN for the coming five years
- categorise the limitations of free-market delivery of healthcare services
- articulate key principles in healthcare services in consumer protection

I.1. Key principles in the development of the Training Module

7. The ASEAN Economic Community Blueprint calls for action with regional training courses for consumer protection officials and consumer leaders in preparation for an integrated ASEAN market. According to the Blueprint: “In order to work well, markets need effective mechanisms to promote and protect consumer rights. Developing the skills of consumers to improve their understanding of goods and services contributes to increased confidence and promotes healthy competition. This needs to be undertaken through consumer education and empowerment programs which are forward-looking whilst addressing the concerns of sustainable development³”. *Road Mapping Capacity Building in Consumer Protection in ASEAN 2010*
8. As a result of detailed research and extensive in-country engagement it is clear that AMSs are at different stages of political, social and economic development. This means that the policies, capacities and competencies of consumer agencies are quite different and a



careful and sophisticated approach will need to be taken to identification of training opportunities and needs to ensure success and sustainability. This module on health care services recognizes the need to validate the core areas for training, provide options for impactful training delivery, to test and evaluate training models and to leave behind a powerful, accessible toolkit for future implementation.

I.2. The ASEAN context

9. A recent paper published in the magazine “Global Health Action”⁴ reports on the integration of healthcare strategies throughout ASEAN. The findings were that, in general, ASEAN countries have made good progress towards universal health care, partly due to relatively sustained political commitments to endorse universal healthcare in these countries. However, continues the report, all the countries in ASEAN are facing several common barriers to achieving universal health care, namely;
 - Financial constraints, including low levels of overall and government spending on health
 - Supply side constraints, including inadequate numbers and densities of health workers and
 - The ongoing epidemiological transition at different stages characterised by increasing burdens of non-communicable diseases, persisting infectious diseases, and re-emergence of potentially pandemic infectious diseases.

⁴ *Global Health Action Volume 7, Progress Towards Universal Health Coverage in ASEAN*

Cluster	Goal 2020	Health priorities
1. Promoting healthy lifestyle	a) To achieve maximal health potential of ASEAN Community through promoting healthy lifestyle b) To ensure healthy lives and promote wellbeing for all at all ages	i. Prevention and control of NCDs
		ii. Reduction of tobacco consumption and harmful use of alcohol
		iii. Prevention of injuries
		iv. Promotion of occupational health
		v. Promotion of mental health
		vi. Promotion of healthy and active ageing
		vii. Promotion of good nutrition and healthy diet
2. Responding to all hazards and emerging threats	a) To promote resilient health system in response to communicable diseases, emerging infectious diseases, and neglected tropical diseases b) To respond to environmental health threats, hazards and disaster, and to ensure effective preparedness for disaster health management in the region	viii. Prevention and control of communicable diseases, emerging infectious diseases and neglected tropical diseases
		ix. Strengthening laboratory capacity
		x. Combating antimicrobial resistance (AMR)
		xi. Environmental health and health impact assessment (HIA)
		xii. Disaster Health Management
3. Strengthening health system and access to care	a) ASEAN Community has universal access to [essential] health care, safe and good quality medical products including traditional and complementary medicines b) To achieve the unfinished health related MDGs, in light of the SDG	xiii. Traditional Medicine
		xiv. Health related MDGs (4, 5, 6)
		xv. Universal health coverage (UHC)
		xvi. Migrants' health
		xvii. Pharmaceutical development
		xviii. Human Resources Development
		xix. Health Financing
4. Ensuring food safety	a) To promote access to safe food, safe drinking water and sanitation	xx. Food safety

10. Implementation by ASEAN of the new health agenda involves identification of health priorities and goals for the coming five years. These are clustered into four sets of interrelated measures as set out in the table below. Of particular importance for consumer policy are the measures which are linked to achieving healthy lifestyles, establishment of a resilient health system and the provision of universal access to healthcare, safe and good quality medical products including traditional and complementary medicines and access to services.

11. In order to achieve population well-being, both the UN, and ASEAN Health Ministers (Joint Statement, 12th ASEAN Health Ministers Meeting 18 September 2014, Ha Noi, Vietnam) are convinced that action on the social and environmental determinants of health, both for the poor and the vulnerable and for the entire population, is important to create inclusive, equitable, economically productive and healthy societies. The UN resolution calls for the full realisation of the right to the enjoyment of the highest attainable standard of physical



and mental health. In endorsing the UN resolution, ASEAN member states have adopted the ASEAN post – 2015 Health Program Agenda⁶ with the vision of “A healthy, caring and sustainable ASEAN Community”

12. A particular feature of the services sector within ASEAN is that constituent services have been largely closed to providers from outside the AMS. Unlike trade in goods, both the regulation and practice of services has been and remains highly restricted. Nonetheless, health services and professional services will be significantly liberalised providing both new opportunities for consumer welfare but also increased need for measures to protect the interests of consumers. To enable the movement of skilled workers and professionals, eight Mutual Recognition Agreements (including one on Medical Practitioners) are being made operational in stages.
13. According to the roadmap report, health care services are regulated by a wide diversity of legislation across the AMS. They include the following:
 - Statutes establishing and regulating public and private hospitals
 - Law, rules, codes and practices in relation to clinics, marketers of health care goods and services
 - Regulations (where they exist) covering traditional medicine
 - Medical Registration Acts
 - Registration of medical practitioners
 - Establishment of a Medical Council which governs the activities of medical professionals, with powers to suspend or revoke registration and impose financial penalties
 - Powers to suspend or revoke registration and impose financial penalties Traditional Medicine Practitioners Registration Act
 - Registration of traditional medical practitioners
 - Establishment of Traditional Medicine Practitioners Board with powers to suspend or revoke registration and impose financial penalties
 - Regulation of health-care service limited
14. Unlike most other areas of consumer complaint, regulation of health care service providers and the range of remedies available to consumers is quite limited. In a number of AMS, the outstanding problem is access to health care services. However, issues of the right to redress also exist. The right to redress means the right to a fair settlement of just consumer complaints. Consumer redress mechanisms are an essential element of consumer sovereignty and an integral part of an effective marketplace. For example, Small Claims Courts, Consumer Claims Tribunals, Mediation Bureaus, and Complaints Centres are redress mechanisms that are designed to be easily available to consumers in the legal system.



15. Challenges in effective implementation of redress mechanisms delivering justice to aggrieved consumers is the objective of a redress system. However, the existence of redress mechanisms by themselves does not ensure that consumers will have access to redress. During the course of the Road Mapping study a number of obstacles to redress mechanisms by consumers, were identified. Among the main challenges in the effective implementation of redress mechanisms in the AMSs are the following:
- Lack of awareness among consumers on laws that provide for consumer redress
 - Difficulty to access avenues for redress e.g. relevant government agencies, consumer groups, business associations or professional organisations as most of these agencies or organisations involved in consumer redress are urban based.
 - Procedures for filing complaints are technical and time consuming.
 - Assistance from voluntary organisations is not easily accessible.
16. To help in overcoming these challenges, this module focuses on training needs in relation to consumer protection in health care services in the following areas for the ASEAN region
- Developing consumer policies, framework and laws
 - Implementing consumer protection policies, framework and laws
 - Enforcing and monitoring of consumer laws and codes of conduct
 - Establishing and managing effective redress mechanisms
 - Implementing and evaluating consumer protection programs and mechanisms
 - Developing and implementing awareness and educational programs for consumer protection
 - Undertaking research and development
 - Implementing training programs
17. The ASEAN Region contains a great number of active NGO's many of whom have knowledge and skills in health care issues, however, there is little recognition of the role of NGOs in AMS programs. Generally speaking, NGOs adopt a role of transforming healthcare delivery through consumer advocacy, education and awareness programs and in particular work among urban and rural disadvantaged consumers. The most common method of work for NGOs is through building partnerships, developing opportunities and creating community consensus around solutions to often intractable healthcare problems.
18. A common set of values shared by healthcare NGOs is a concern for clean water, proper medical treatment, and minimum standards of education and responsive government policies towards the health and welfare of their population as consumers. Although there are many active NGOs, a good example is the international organisation "East meets West" with offices in Vietnam, Laos, Cambodia and other South Asian countries it has built up an enviable record of incorporation governments and regional agencies to improve the delivery of healthcare services to all and disadvantaged consumers. A key



value in involving NGOs in healthcare delivery is that they often have close links to urban and rural populations living in poverty, have close trust bonds with community leaders and often have access to international resources in the form of research and advocacy skills.

Assessment questions for Section I Introduction:

1. Explain the way in which key principles in the development of the training module found in this section match the commitment made by ASEAN health ministers to realise a vision of a healthy caring and sustainable ASEAN community?
2. Outline and summarise the key clusters, goals and health priorities as set out in the ASEAN Post – 2015 health program agenda
3. Articulate measures taken by the UN and ASEAN health ministers to create a healthy caring and sustainable ASEAN community
4. Identify those elements of the ASEAN health development agenda which intersect with consumer policy
5. Nominate key health priorities and goals in ASEAN for the coming five years

Further Reading for Section I Introduction

1. The Future We Want, Resolution Adopted by the UN Gen Assembly 27 July 2012 66/288
2. Blueprint for the ASEAN Economic Community ASEAN 2015
3. Global Health Action, volume 7, Progress Towards Universal Health Coverage in ASEAN 2015
4. ASEAN Post – 2015 Health Program Agenda, ASEAN 2015
5. A Healthy Caring and Sustainable ASEAN Community joint statement, 12 ASEAN health ministers meeting, 18 September 2014, Hanoi Vietnam



II. Substantive Consumer Protection Issues

Learning objectives and outcomes of Section II

This section of the Train-the-Trainer Manual identifies substantive consumer protection issues in the delivery of healthcare services in ASEAN member states. It provides a framework for analysis of consumer issues, provides recommendations for future action and identifies the importance of empowering consumers to a development of effective markets.

This chapter defines consumer safety in healthcare services and outlines challenges to consumer affairs policymakers and enforcement officers in improving outcomes for consumers.

Following completion of the train the Trainer sessions, participants should be able to:

- enumerate barriers to achieving universal healthcare in ASEAN
- describe the role of consumer agencies in healthcare service issues
- articulate a framework for analysis of consumer issues in healthcare service delivery
- identify and express priority areas for action in relation to healthcare services including:
 - developing and implementing consumer policies, laws and action plans
 - monitoring and enforcing of policies, laws and codes of conduct
 - developing effective redress mechanisms
 - developing and implementing awareness and education programs
 - undertaking research and development
- classify and categorise general areas of concern with healthcare services
- outline and discuss the limitations in available data and different stages of development throughout the AMS
- contrast and restate elements of consumer centred approach to healthcare policy
- nominate strategies for empowering consumers in improving healthcare service delivery
- analyse barriers to implementation of universal healthcare
- tabulate healthcare issues by reference to root causes of consumer detriment



II.1. Summary and tabulation of healthcare issues in ASEAN.

19. During the preliminary validation workshop for this training module, experts called for a tabulation of healthcare issues from the perspective of consumer policy. Table presented below lists key issues raised in the road mapping fieldwork and classifies them as to their source and impact on consumers using the key presented below the table. The table has been compiled from a review of fieldwork undertaken in the road mapping study together with the fieldwork undertaken by UNCTAD in connection with this project. In addition, the consultant has examined recent literature from The World Health Organisation office responsible for South Asia, the Asian Development Bank health policy documents for Asia as well as numerous ASEAN publications relating to implementation of Universal Health Coverage. The chart also includes a tabulation of issues raised at a meeting between UNCTAD consultants and health officials in Hanoi, Vietnam.

TABULAR CHARACTERISATION OF HEALTHCARE ISSUES FOR ASEAN CONSUMERS

Healthcare Issue	1	2	3
Providers			
Healthcare scams perpetrated by fraudsters	X	X	X
Inadequate registration for healthcare providers	X		X
Inadequate number of healthcare providers	X	X	X
Adverse clinical events			
Poor hand hygiene in clinics			
Inadequate training of healthcare professionals	X		X
Lack of safety culture			
Healthcare professionals failure to register adverse events			
Under reporting of adverse events			
Understaffing in clinics and lack of school workforce	X	X	
Excessive use of antibiotics			
Interaction of pharmaceuticals and traditional medicines			
Underqualified providers of healthcare and traditional medicine	X		
Proliferation of fraudulent healthcare providers	X		
Need for comprehensive complaint and redress mechanisms			



Products			
Poor quality or incompetently marketed traditional medicine			X
Unsafe or ineffective medical devices	X		
Lack of adequate drugs		X	X
Faulty medical equipment			X
Prevalence diagnostic and treatment errors	X	X	X
Adverse clinical events			
Disease caused by medical waste			
Resale of faulty equipment on the black market			X
Counterfeit and substandard drugs			X
Lack of safety culture			X
Healthcare professionals failure to register adverse events			
Under reporting of adverse events			
Excessive use of antibiotics			
Interaction of pharmaceuticals and traditional medicines			
Poor manufacturing practices			X
Need for comprehensive complaint and redress mechanisms		X	
High proportion of faulty medical devices			X
Lack of standards and compliance inspection for medical devices			
Better implementation of ASEAN Medical Device Directive			
Training needed in regulatory risk assessment			
Platforms			
Lack of standards for premises used for healthcare provision			X
Lack of available hospitals and clinics in rural areas	X	X	X
Lack of available hospitals and clinics in poor urban areas	X	X	X
Excessive waiting periods for hospital beds	X	X	X
Overcrowding in hospitals and clinics		X	
Faulty medical equipment			
Prevalence diagnostic and treatment errors	X	X	X
Adverse clinical events			
Poor hand hygiene in clinics			



Inadequate training of healthcare professionals	X		
Inadequate monitoring systems and procedures		X	
Lack of organisational knowledge in institutions			
Disease caused by medical waste			
Poor distribution of health care facilities		X	X
Lack of safety culture			
Healthcare professionals failure to register adverse events			
Under reporting of adverse events			
Understaffing in clinics and lack of school workforce	X	X	X
Inadequate infection control			
Excessive use of antibiotics			
Interaction of pharmaceuticals and traditional medicines			
Unsuitable packaging storage or distribution of goods for healthcare provision			
Proliferation of fraudulent healthcare providers	X		X
Need for comprehensive complaint and redress mechanisms		X	
Comprehensive data required on causes of adverse events			
Model laws required for regulation and consumer protection			
Crosscutting issues			
Inadequate sanctions and remedies			
Unaffordable healthcare goods and services		X	X
Lack of enforcement of laws and standards			
Poor coordination between different agencies	X	X	X
Usurious money lending practices to fund healthcare			X
Prevalence diagnostic and treatment errors	X	X	X
Inadequate training of healthcare professionals	X		
Lack of safety culture	X		
Financial constraints in health care funding			X



Burden of non-communicable diseases			
Re-emergence of TB as a serious problem			
Absence of universal healthcare rollout	X	X	X
Persisting infectious diseases			
Excessive waiting times for access to treatment	X	X	X
Risks from potentially pandemic diseases			
Widespread healthcare inequality		X	
Mechanisms required for consumer empowerment	X	X	X
Comprehensive consumer protection laws required		X	
Consumer awareness campaigns essential		X	
Inadequate data on consumer -related healthcare issues		X	
Need for engagement of NGOs with policymakers and providers			
Inadequate monitoring systems and procedures			
Lack of organisational knowledge in institutions			
Lack of national surveillance and data gathering			
Disease caused by medical waste			
Regional collaboration for accreditation institutions required			
Comprehensive monitoring schemes need			
Shortcomings in waste management, clean water and sanitation			
More action required for implementation of universal health coverage	X	X	X
Lack of safety culture			
Patients failure to question doctors due to lack of empowerment	X	X	X
Under reporting of adverse events			
Understaffing in clinics and lack of school workforce	X	X	X
Poor development and implementation of regulation			
Inadequate infection control			
Interaction of pharmaceuticals and traditional medicines			



Unsuitable packaging storage or distribution of goods for healthcare provision			
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KEY TO TABLE:

Providers: Healthcare issues mentioned in this part of the table refers to problems which arise in the relationships between healthcare service providers and consumers (patients). This category includes marketing and provision of healthcare services in clinical and other settings. It also includes provision of services by people who are under qualified not qualified to provide the service

Product: Healthcare issues mentioned in this part of the table refers to the category of problems including all healthcare products and services which may lead to consumer detriment. Included are pharmaceuticals and medicine is either generic or branded, medical devices, traditional medicine, counselling services and the whole range of products or services that constitute healthcare delivery

Platforms: Healthcare issues mentioned in this part of the table refers to problems which arise in the context of healthcare platforms. This includes hospital and clinical premises as well as all other facilities used for the delivery of healthcare services in ASEAN.

Availability: Refers to problems in relation to both the quality and quantity of healthcare goods and services

Accessibility: relates to the often inadequate distribution of health care professionals and facilities throughout the AMS. Typically, there is a lack of availability of provider’s products and platforms in rural and remote areas and also in high density impoverished urban settings

Affordability: self-explanatory description which, throughout the ASEAN countries remains one of the greatest challenges to provision of more effective healthcare services

II.2. Overall issues.

20. During July 2015, a preliminary validation workshop was held to consider the best way of presenting material in this training module. Expert delegates to the validation workshop expressed the view that in such a complex area as healthcare services, there was a need to devise a framework for analysis and description of the range of issues problems and remedies. As a result of the validation workshop, the following approach has been adopted in the development of this training manual:



21. Availability (quality and product), Accessibility and Affordability of healthcare services are seen as the three benchmark criteria to be applied to an analysis of consumer welfare issues in healthcare with the following structure.

- Relationships between healthcare service providers and patients (business-related activities related to the rendering of health care services);
- The area of health-care products, pharmaceuticals and medicaments (generic or branded) medical devices, traditional medicines;
- Management of hospitals, clinics and other facilities that related to the platform (facilities – premises) where the services are taking place

22. Efficient and effective redress mechanisms:

The framework described in the paragraph above will be applied against the overall structure of the training module. Issues will be divided into those which can be dealt with through premarket measures and in relation to those that can't certain post-market measures are proposed.

23. Empowered consumers and effective markets:

Empowered consumers and effectively competitive markets are a necessary but not sufficient condition for the attainment by Member States of the ASEAN Economic Community (AEC). Achieving an equitable level of protection to consumers in the region will require a range of strategic capacity building measures. These include policy development, legislation, enforcement mechanisms, financial and human resource development, acquisition of expertise and skills at national and regional level. The Road mapping capacity building needs in consumer protection in ASEAN report identifies priority areas of action in relation to health care services. These include:

- Developing and implementing consumer policies, laws and master plans
- Monitoring and enforcing of policies, laws and codes of conduct
- Developing effective redress mechanisms
- Developing and implementing awareness and educational programs that consumer protection
- Research and development

24. The Road mapping report identified a wide range of specific issues in relation to health care services in relation to each particular AMS. A range of generic issues and actions required and concomitant crosscutting issues applicable to all AMS.



II.2.1 Health services: summary of country reports

25. There is inadequate data on consumer complaints relating to health care services in the AMS. Where evidence does exist, it is limited to complaints by those already accessing mainstream hospitals or professional regulatory systems
26. A further limitation in the data relating to health care is that there is little or no data on traditional and complementary health care, with the exception of Malaysia. While there are a number of research projects now under way, for the purposes of this training module, there are no practical means of obtaining additional market intelligence.
27. It is a further feature of the health care market that laws and policies have been slow in the recognition of health related scams. While normal goods and services are subject to a degree of public enforcement activities, this is not the case for health care matters such as marketing of medical or therapeutic goods and traditional medicine.
28. It follows from the previous point that data on enforcement actions and available sanctions and remedies is also very sparse and patchy in coverage.
 - It was a strong conclusion of the road mapping study that better co-ordinate between different agencies is needed to protect consumers
 - As expected, there is a wide difference in the existence of, and effectiveness of health services regimes across the region:
 - By way of illustration, the region comprises countries with WHO global health care rankings from No. 6 to No. 190
 - In common with other regions, there is a mix between public and private delivery of health care services
 - One consequence of public sector provision is that regulation is difficult and involves complicated inter-governmental issues.
 - The ASEAN region is one in which there are great differences in both access to and quality of health care services. There is an urban/rural divide and a division based on the general state of development of the AMS.
29. ASEAN is active in regional and international efforts to improve health care services for the 600 million consumers residing in the AMS. As is clear from the country reports which form part of this training module, the ASEAN region faces great challenges in almost all aspects of healthcare policy, delivery and cooperation.
30. This section of the training module describes the substantive consumer protection issues in health care services which arise in the region and identifies areas for action and market mechanisms which may reduce the scale and scope of problems. The World Health Organisation has developed guidelines, checklists and programs to ensure quality and safety of health-care. ASEAN member states are increasingly turning to the



WHO for assistance in establishing policies for providing access to basic healthcare services and for research into key areas for concern and action.

II.2.2 Defining consumer safety in health care services

31. For the purposes of this training manual safety in health care services can be defined as freedom from unnecessary harm or potential harm associated with healthcare.
32. Medical errors can occur during various elements of prevention, diagnosis, treatment and follow-up and as health care delivery is increasingly complex it is an unfortunate corollary that there is an increased probability of error.
33. In a 2015 research report published by WHO it was noted that adverse events are occurring to around 10% of hospital patients and this means that adverse events occur in from 4% – 17% of hospital admissions. In a troubling finding, the report says 5% – 21% of these result in death. According to the report, half of these events could be prevented through better patient (consumer) protection policies.
34. Key factors contributing to clinical errors include failures due to unsafe clinical practices such as surgery, poor hand hygiene, practices unsafe use of injections, blood products, medications, medical devices and unsafe processes such as communication failures and ineffective teamwork constitute key areas of failure.
35. In addition, poor patient handovers, misdiagnosis, poor test follow-up, poor systems processes within an organisation add to the problem. In attempting to address issues problems are further compounded with a culture of blame and inadequate selection training and monitoring of healthcare providers. The lack of organisational knowledge or transfer and learning from adverse events to compound issue. It is a well-documented observation that the magnitude of poor healthcare service issues in developing countries is a major economic, social and political issue and the risk of acquiring a healthcare associated infection is up to 20 times higher in developing countries.
36. Attempts by policymakers to address failures in healthcare delivery are somewhat frustrated by very poor national surveillance and data gathering in ASEAN. Southeast Asian countries produce over 1000 metric tons of healthcare waste every day including injection related waste which is not properly disposed of and unsafe disposal leads to resale of used equipment on the black market. At least 50% of medical equipment is unusable or only partly usable resulting in substandard diagnosis and treatment while many healthcare devices sold in domestic markets are outside regulatory framework and do not meet international standards. It is estimated that developing countries account for 77% of all reported case of counterfeit and substandard drugs and that 50% of all medicines prescribed, dispensed or sold are not justified.



37. There are some challenges to healthcare consumers' safety in Southeast Asia that arise from limited resources, poor healthcare infrastructure and equipment, particularly for infection control, unreliable supply and quality drugs. Further areas for concern by policymakers which adversely affect consumers and justify a major focus on this policy area, include:

- Shortcomings in waste management, clean water and sanitation
- Poor distribution of healthcare facilities
- Lack of safety culture and attitudes that overlook basic safety rules
- Patients failure to question doctors owing to lack of patient empowerment
- Healthcare professionals reluctant to register or talk about adverse events and medical errors
- Considerable underreporting of adverse events
- Understaffing and lack of skilled workforce
- Poor development and implementation of regulation
- Limited resources, poor healthcare infrastructure and equipment, particularly for infection control, unreliable supply and quality drugs
- Shortcomings in waste management, clean water and sanitation
- Poor distribution of healthcare facilities
- Lack of safety culture and attitudes that overlook basic safety rules
- Patients failure to question doctors owing to lack of patient empowerment
- Healthcare professionals reluctant to register or talk about adverse events and medical errors
- Considerable underreporting of adverse events
- Understaffing and lack of skilled workforce
- Poor development and implementation of regulation.

38. As for the availability of health-care services Healthcare services have become more available but health and healthcare inequalities will likely worsen as better off citizens of member states might receive more benefits from the liberalisation of trade policy and health, either through regional migration of health workers or in country health worker movement towards private hospitals, which tend to be located in urban areas.

39. The results of the magazine study include that for ASEAN countries, universal healthcare should be explicitly considered to mitigate deleterious effects of economic integration. Political commitments are required to safeguard increased health spending which will be necessary given liberalisation risks to health equity as well as migration and population ageing which will increase demand on health systems.

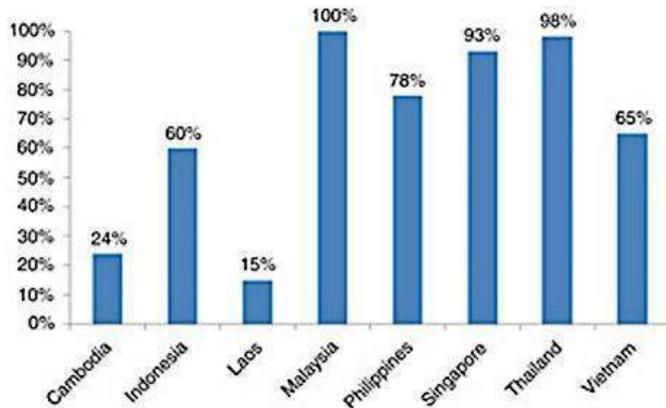


II.2.3 Government difficulties in coping with demand

40. Many governments face difficulties in coping with the increased demand for health services and are relying on the private sector to play a complementary, or even a primary role in providing for the health care needs consumers. It is a goal of international healthcare policy that countries moved to the adoption of schemes providing universal healthcare. The following section describes the state of progress towards universal health in ASEAN countries.
41. In describing progress towards universal health coverage (UHC) in ASEAN, the magazine Global Health Action provides a summary of progress to date and prospects for the future. These are highly relevant to the issue of protecting consumers of healthcare services in ASEAN. In general, the ASEAN countries have made good progress toward UHC. Healthcare services, both preventive and curative care services, have been more and more available in many ASEAN countries. In some countries such as Cambodia, Lao PDR, and Vietnam, most preventive care services are separately provided under vertical national programs.
42. In the ASEAN countries, social health insurance (SHI) has been considered as an instrument for achieving the breadth of UHC. Significant progress has been made in expanding the coverage of health insurance, despite the existing gaps of insurance coverage across these countries. As of 2012, Thailand's entire population is covered by SHI. In Malaysia, technically the entire population can use public health services funded via general taxation and low user charges whilst in Singapore, 93% of the population is covered by MediShield, the compulsory government organized health insurance scheme. In Indonesia, about 60% of the population is covered by health insurance.
43. The Indonesian government rolled out the Badan Penyelenggara Jaminan Sosial (BPJS) Kesehatan on January 1, 2014, with an ambition to achieve national coverage of UHC by January 2019. This initiative is coordinated by the BPJS – the Social Security Administration, a national body under the auspices of the President of the Republic of Indonesia.
44. The coverage of health insurance is however, still low in Lao PDR (15%) and Cambodia (24%). In Lao PDR, the government is now considering the creation of a national health insurance authority through the integration of the four different social health protection schemes.
45. The expectation is that a unified institutional arrangement will lead to universal coverage by 2020. In Cambodia, good progress has been made in using health equity funds to cover the poor. However, civil servants and private sector employees are not covered at



all by insurance, while certain vulnerable groups such as the elderly and disabled are excluded from the user fee exemption scheme. The chart reproduced below is taken from the magazine “Global Health Action” February 2015.



46. The political commitments to endorse UHC have at face value been strong in the ASEAN countries. In these countries, some to a greater extent than others, many policies and strategies have been established and implemented to facilitate progress toward UHC. For example, in Thailand, since 2002, the political commitment to universal access to healthcare was emphasized in the National Health Security Act that states that ‘Thai population shall be entitled to a health service with such standards and efficiency’.
47. In Indonesia, in 2004, the Presidential Bill No. 40/2004 on National Social Security System to protect Indonesian citizens from catastrophic household expenditure due to illness and death was enacted. In Cambodia, in 2005, a Master Plan for SHI was adopted, signifying an essential first step toward establishing a unified health protection system. In Vietnam, in 2012, the Prime Minister approved the Master Plan on UHC with a roadmap to achieve universal health insurance (UHI) coverage levels of 70% by 2015 and 80% by 2020, and to reduce OOP payment to 40% by 2020. In Myanmar, in 2012, the Government has endorsed the goal of achieving UHC by 2030 with aims to improve the health status of the poor and vulnerable, especially women and children.
48. In the Philippines, in 2013, the president amended the National Health Insurance Act of 1995 by signing Republic Act 10606 which mandates the government to shoulder the premiums for the insurance of the indigent and informal sectors thus benefiting many Filipinos.
49. Singapore recently announced the expansion of MediShield, a health insurance scheme designed to avert catastrophic OOP expenditure, which currently covers 93% of the population. The expanded program would be named MediShield Life. It will be



mandatory with 100% population coverage and a stated aim of reducing co-insurance levels from the current 10–20% to 3–10%. In Malaysia, the shape of UHC continues to be debated, with discussions currently centered on whether the country should transition to a SHI model, 1Care, which would allow the insured to access private facilities. Civil society and trade unions have expressed concerns that 1Care will subsidize private providers at the expense of the public, and discussions have since stalled. Furthermore, during the 11th ASEAN Health Ministers Meeting hosted by the Thailand Ministry of Public Health in 2012, a joint statement emphasizing five main health topics, including Building UHC, was signed.

50. Whilst there does appear to be a political commitment expressed for UHC, in reality it is difficult for policymakers to balance competing interests of the growing for-profit private sector (in most countries) and the moral imperative to ensure equal access to healthcare.
51. Major barriers to achieving UHC in ASEAN countries All the countries in ASEAN are facing several common barriers to achieving UHC, namely 1) financial constraints; 2) supply side constraints; and 3) the ongoing epidemiological transition at different stages, characterized by increasing burdens of NCDs, persisting infectious diseases, and re-emerging potentially pandemic infectious diseases. The key financial constraints are low levels of government spending and overall spending on health.
52. Most countries in the ASEAN region allocated less than 5% of the gross domestic product (GDP) as expenditure on health in 2012, with the exception of Cambodia (5.4%) and Vietnam (6.6%). Government expenditure on health as a percentage of total expenditure of health ranged from 23.9% in Myanmar to 91.8.1% in Brunei. The World Health Organization argues that it is very difficult to achieve UHC if OOP as a percentage of total health spending is equal or greater than 30%, and that the target for UHC could be set at 100% protection from both impoverishing and catastrophic health payments for the population as a whole.
53. Government spending on health as a percentage of total government spending varies, from a low of 1.5% in Myanmar to 14.2% in Thailand. Overall, there are higher levels of private spending than public spending on health, with the exception of Brunei and Thailand.
54. Government spending on health as a percentage of total health spending appears to be increasing moderately over time for most countries, except Malaysia, the Philippines, Indonesia and, to some extent, Cambodia. To ensure UHC, particularly given economic liberalization on the path to AEC, governments should safeguard health budgets and prioritize not only achievement but also maintenance of UHC. This is especially important among ASEAN's middle-income countries, which have arguably been underperforming



in terms of social progress relative to countries at similar income levels in other regions.

55. Issues found in the road mapping study and in the ASEAN healthcare report which form the appendix to this manual dealing with the relationships between healthcare service providers and patients (business-related activities related to the rendering of health care services)
56. Health care scams are a growing problem throughout the world but in particular in developing countries which lack adequate framework for detecting and persecuting fraud or anti-consumer conduct. Scams may take the form of unqualified or improperly individuals holding themselves out as healthcare providers or the promotion of services or therapies which are not objectively capable of enhancing health or welfare.
57. Related to the issue of healthcare scams is the widespread problem of inadequate procedures for assessing the qualifications of healthcare practitioners and monitoring of their competence. There is a notorious example reported in Cambodia in November 2014 in which an unqualified and unregistered person holding himself out as a medical practitioner has caused the transmission of HIV AIDS to more than 100 consumers through incompetent procedures performed on them. Although the individual has been arrested and charged with serious crimes, but does not in any way provide comfort to be injured consumers. Rigorous systems to ensure adequate training for doctors, nurses, therapists and all those engaged in the professional delivery of healthcare services should be a priority for AMS.
58. As noted above it is of great importance to AMS to ensure adequate levels of training and monitoring for professionals providing healthcare services. A slightly contradictory problem, however, exists throughout some AMS. Countries with a large number of urban and rural poor and those with high levels of immigrant and refugee populations suffer from an acute shortage of healthcare professionals and also a maldistribution. Healthcare professionals, tend to gather in urban middle class communities where standards of living and safety and economic rewards are highest. This means that throughout many AMS there are large numbers of people who are unserved by qualified doctors, nurses, therapists, clinicians and other healthcare workers.
59. Training and practice of healthcare professionals in basic issues of hygiene are often lacking in AMS. This relates in particular to poorly qualified or unqualified practitioners who are often to be found at village or urban street level who can cause great harm through transmitting serious infections to consumers.
60. Over prescription and poor supervision in the use of antibiotics pharmaceuticals is a worldwide problem. However, throughout ASEAN where issues of poverty and lack of education enable the often uncontrolled and unsupervised sale of antibiotics to the



public this is a particularly serious issue. At stake is the increasing emergence of antibiotic resistant pathogens as well as the immediate economic harm to consumers through paying for products which often don't work.

61. From the perspective of protecting consumers' economic interests, a further identified problem in AMS is the absence of or poor implementation of complaint and redress mechanisms. A fundamental feature of consumer protection is that consumers receive safe and competent care but they should also receive assurance that where things do go wrong there will be accessible, available and affordable mechanisms for complaint handling and redress. This matter receives considerable further treatment in the appendix on redress.

Progress in regional healthcare services delivery

62. For the past decade or so, and growing focus on improving healthcare services for consumers in the Southeast Asian region has borne considerable fruit. A Regional workshop "clean care is safer care" led to improved health care outcomes. Another initiative "patients for patient safety" workshop in Jakarta in 2007 led to a declaration for patient centred care.
63. More recently, Thailand has piloted a set of research tools for estimating adverse events and the Jakarta declaration has been included in the Indonesian National Hospital guidelines.
64. WHO has committed to development of a strategic framework and package intervention for strengthening consumer safety in healthcare and recognises and urgent need to consolidate and build on the current efforts consumer safety. To be effective it will need to analyse and learn from efforts and adapt and apply best practices.

II.2.4 Efforts by International organization: the role of WHO

65. In an ambitious move WHO has adopted a goal of "bringing consumer safety to the centre of all levels of healthcare – primary, secondary and tertiary", WHO committed to development of the strategic framework and package of intervention for strengthening consumer safety in healthcare to develop strategic framework for patient safety as a basis for development that national plans and policies. It will also provide guidance the implementation of consumer safety programs at national and subnational levels, recognising the need to integrate with vertical programs in the crosscutting areas to offer safe quality service delivery.
66. It is guiding principles for the prevention of consumer harm from adverse health care by focusing on health systems improvement which assumes adverse events are primarily



due to systems failure rather than individuals. Future success will be ensured by strengthening capacity through education and training including building competencies and skills and making consumer safety a necessary component of education. It remains an important principle that learning from mistakes and minimising risks in future by building an enabling environment to support non-punitive reporting will assist.

67. Elements of a patient centered approach

Adopting a patient centered approach which empowers patients and involves them as partners in targeting all levels of healthcare is a prerequisite to success. As is:

- Introducing evidence-based interventions
- Establishing priorities
- Reforming implementation agencies
- Establishing patient safety is a priority in the national health policies, plans and in all health programs affixing accountability and responsibility
- Establishing national multi-disciplinary patient safety committees involving professional and non-government organisations and consumer groups
- Informing policy by operational research and evidence-based interventions
- Identifying key government departments and other bodies who will be responsible for execution of policies
- Developing legal and regulatory framework as well a system of enforcement for quality and consumer safety
- Establish dedicated quality and patient safety department in the ministries of health
- Encourage third-party players to support and provide incentives for patient safety
- Educating in engaging the media and civil society partners

68. Key steps in securing better outcomes for consumers of healthcare services. In addition to initiatives taken to date, there are a number of premarket and post-market initiatives which AMS could take to achieve better results for consumers. They include:

- Establishing independent and autonomous government linked institutions for accreditation of health facilities involving health professional organisations
- Developing guidelines, National Safety Standards and indicators for healthcare quality
- Liaising and collaborating with regional healthcare accreditation institutions
- Establishing mechanisms for implementation of quality standards
- Developing systems for monitoring and evaluation of quality and feedback including complaints handling systems



II.3 Consumer protection issues in the area of health-care products, pharmaceuticals and medicaments (generic or branded) medical devices, traditional medicines

II.3.1 Counterfeit medicines.

69. The range of counterfeit products reaching markets has also broadened with the increased commercial use of the Internet to provide a dizzying array of both branded and generic drugs. In more than 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit, according to WHO.
70. Developing countries are an obvious target for counterfeiters, because the cost of legitimate drugs may be beyond the reach of much of the population and legal controls are often weak.
71. Lifesaving drugs are not exempt from the trade in counterfeit medicines. WHO is working with Interpol to dislodge the criminal networks raking in billions of dollars from this cynical trade. In 2006, the International Medical Products Anti-Counterfeiting Task Force (IMPACT) was launched by WHO.
72. In 2009, 20 million pills, bottles and sachets of counterfeit and illegal medicines were seized in a five-month operation coordinated by the International Criminal Police Organization (Interpol) across China and seven of its south-east Asian neighbours.
73. Even though higher-income countries have stringent regulations and better law enforcement, they also offer great rewards. In Singapore, 150 people were admitted to hospital in the first five months of 2008 having severe hypoglycaemia – a sharp drop in blood-sugar levels. Four of them died and seven suffered severe brain damage. They had reportedly taken counterfeit copies of drugs purporting to treat erectile dysfunction but which contained a hefty dose of glyburide, used for treating diabetes. The erectile dysfunction is a key market for counterfeit in Asia nourished by the growth in online pharmacies that offer access to prescription-only medicines without the embarrassment of consulting a doctor. However, the counterfeits ranged from antibiotics to birth-control medicines, anti-tetanus serums and antimalarials...all type of products.
74. The overall death toll attributable to counterfeit medicines, like the scale of the business, is unknown but the costs to public health are huge. Quite apart from the direct impact on individuals, counterfeits can cause resistance to medicines for tackling diseases that are leading causes of mortality. Malaria, which kills around a million people a year, is a prime example. An unprecedented international collaboration and investigation of counterfeit antimalarials found that half of the 391 samples collected contained no active ingredient (artesunate) or too little to have any benefit. Manufacturers' holograms provided no



guarantee of protection as investigators found the counterfeiters had developed their own sophisticated fake holograms. The results of the investigation, published in *PLoS Medicine* in 2008, concluded that the “epidemic” of counterfeits in south-east Asia had led to “deaths from untreated malaria, reduced confidence in this vital drug, large economic losses for the legitimate manufacturers and concerns that artemisinin resistance might be engendered.”

75. The scale and ingenuity of the trade in counterfeits poses a formidable challenge to enforcement. Moreover, international trade presents easy opportunities for counterfeiters to insert their products into the supply chain of legitimate pharmaceuticals and to disguise the source. Even in hospitals, there are deliveries where counterfeit medicines have been added to genuine batches of medicines. The counterfeiters simply falsify the delivery papers by adding an extra zero to the quantity supplied, and then they make up the difference by adding their own boxes to the order.
76. Health experts and IMPACT say enforcement remains severely handicapped by weak laws and regulations for tackling counterfeiters. Obstacles to effective action include the lack of a clear worldwide consensus on what constitutes a counterfeit drug and the fact that activities that are illegal in one country may be legal in another.
77. With the expansion of the burden of diseases, the increasing need for access to treatment and the significant number of suppliers in the global medicines market, countries continue to face challenges to regulate the pharmaceutical sector. Most countries in the Region have established medicines regulatory authorities and quality assurance systems. Also, a mechanism was established at the regional level to exchange information among countries and to alert them of detected cases of counterfeit medicines. Even though most countries in the Region have medicines regulatory authorities, their functionality vary at different levels. Weak regulatory systems coupled with weak and nontransparent enforcement of standards may result in the production, distribution and sale of medicines of doubtful efficacy, safety and substandard quality that can endanger the public. Products contaminated with diethylene-glycol, melamine and contaminated heparin are examples of substandard and spurious products that have penetrated the global market. Countries need to strengthen their capacity to safeguard public health by enforcing regulations in the pharmaceutical sector. An outstanding area of concern noted in the road mapping study is in relation to problem of fake drugs including dangerous traditional medicine. Such concerns were mentioned by most countries. This is a suitable candidate issue for interagency or inter country co-operation

II.3.2 Traditional Medicines, Complimentary/Alternative Medicine (TM/CAM):

78. Attractive features of TM practices include greater accessibility in many parts of the world, cultural acceptance in low-and middle- income countries, comparatively low cost and,



often, a lesser need for modern technology.

79. Many consumers use herbal products to treat themselves-often without a health practitioner's knowledge or advice because of the availability and relatively inexpensive cost of such products. Consumers and practitioners may not be adequately informed about potential adverse effects, drug interactions, and how to use herbal medicines safely. The label on a bottle of Chinese wintergreen oil indicated that it was primarily for external use but could be taken orally for enhanced efficacy, even though ingesting as little as 4ml can be fatal. An elderly consumer seeking relief from arthritis drank the entire contents of the 60ml bottle that she purchased in a grocery store, resulting in her death. Another problem is that most people do not communicate with their health care providers about other medications they are taking. Studies show that up to 70% of people use TM/CAM therapies simultaneously with conventional medicine without telling their health care providers.
80. Lack of regulations on quality of these products may cause problems resulting in the marketing of unsafe or ineffective TM/CAM products. In the countries that do recognize TM/CAM, the scope of regulations varies considerably because of differences in history, culture, and product use. Some countries classify herbal products as medicines and some as food, and regulate accordingly. Generally, countries do not register herbal or other TM products the same way as conventional medicines, and evidence of quality, efficacy, and safety may not be required before marketing.
81. The growing attention focused on TM has introduced a number of public health issues in developing and developed countries alike, including policy, safety and quality, efficacy, access, and appropriate use. Regulations that ensure the quality and safety of TM/CAM products and procedures are often lacking, and because herbal medicines are now marketed across regions and internationally, these issues have evolved from being local in scale and are now of global concern.
82. Typically, both traditional and conventional practitioners are unaware or even suspicious of what the other can offer in terms of health care and services. In addition, patients can be reluctant to admit to health care providers that they are using both types of treatment, creating what could be a potentially alarming risk.
83. Traditional medicine therapies are commonly used in developing countries because they are often more widely available and more affordable than conventional therapies. In addition, because TM/CAM practices are, often, woven into everyday life and belief systems, and because traditional healers are trusted members of the community, TM/CAM is often the first source of health care may be a last resort, especially if the nearest primary health care facility is some distance from the community. In resource-limited countries, especially in rural areas, there are usually fewer conventional health



care practitioners. In India, TM/CAM is the only available source of health care for a large part of the rural population. This situation has been aggravated as large numbers of trained and licensed conventional health care workers leave their native countries for better opportunities elsewhere.

84. Most poor people in developing countries buy their medicines out of pocket; even if the public health sector offers medicines at no charge, essential medicines may not be reliably stocked, or health facilities may be too far away. The rural poor often cannot afford the transportation costs to get to a public health facility. Herbal medicines in developing countries are often cheap, and the TM/CAM practitioner may accept a trade in-kind or offer a sliding payment scale. In addition, many herbal medications are available for purchase in store, so patients may buy and take without ever incurring the cost of seeing a practitioner.
85. TM/CAM therapies are also popular because of the lower rate of adverse effects compared with some pharmaceutical-based therapy, for example, St. John's wort taken to treat mild depression generally causes fewer side effects than antidepressive pharmaceuticals; capsaicin cream, derived from hot *Capsicum* peppers and used to treat osteoarthritis, does not cause gastrointestinal effects that non-steroidal anti-inflammatory medications do. Although consumers may perceive herbal products as natural and therefore less likely to cause problems, these products are not without risk and are not necessarily safer than conventional pharmaceuticals.
86. People also use TM/CAM because of its perceived efficacy, both in general and in particular for treatment of chronic, debilitating diseases that defy conventional pharmaceuticals. As long treatments for the most severe form of malaria have become ineffective because of antimicrobial resistance, artemisinin compounds from *Artemisia Annua*, a herb native to Asia, are now the first-line treatment for malaria in most countries.
87. The causes of adverse reactions are diverse: the use of inherently toxic herbal medicines or an overdose of herbs, conventional drug-herbal medicine interactions, and idiosyncratic reactions such as allergies.
88. A lack of strict standards for the production and manufacture of herbal medications can cause quality problems, such as adulteration, misidentification of ingredients, substitution of one herb with another, inclusion of pharmaceuticals without identification on the labels, contamination, and variability in the amount of active ingredient. An analysis of different red yeast rice products on the market showed levels varying by 100-fold across ten products, and four were contaminated with mycotoxin. Heavy metals, fumigation agents, microbial toxins, and pharmaceutical substances have all been found in toxic concentrations in TM/CAM medications. In 2009, a manufacturer recalled its herbal



weight-loss product, which was found to actually contain the unlabeled prescription drug sibutramine, which can substantially increase blood pressure, and phenolphthalein, a suspected cancer-causing chemical.

89. The incorrect usage of herbal medication therapies can have fatal outcomes. The inappropriate long-term use of kava kava (*Piper methysticum*), for example, has been associated with serious cases of liver damage and *Gingko biloba*, which stimulates circulation, may cause excessive bleeding during surgery. Problems also occur, when TM/CAM therapies are marketed and used in different cultures, with potentially hazardous changes in indicated uses and doses. *Ma huang* (*Ephedra sinica*), which contains ephedrine, has long been used in traditional Chinese medicine for respiratory symptoms, but its marketing at higher doses in as a weight-loss product led to a number of severe effects and death.

90. Examples of Herbs and their Interactions with Cardiovascular Drugs

- a. **Garlic** Garlic has been mentioned in medicinal texts since the Ebers papyrus (circa 1550 BC). It has been used for treatment of infectious conditions because of its presumed antimicrobial and immune-enhancing properties. Garlic is thought to have cholesterol-lowering and other antiatherosclerotic and antihypertensive effects and is used for prevention of cardiovascular disease. Despite such claims, a recent study concluded that raw, powdered, or aged garlic extract versus placebo for 6 months had no significant effect on low-density lipoprotein cholesterol or other plasma lipids in adults with moderate hypercholesterolemia. The active component ajoene in garlic inhibits collagen-induced platelet aggregation, and garlic is used for its antiplatelet and fibrinolytic effects in patients with cardiovascular disease. However, the risk of bleeding in people using anticoagulant or antiplatelet agents increases, so its concomitant use should be avoided. Garlic supplements should be discontinued about 10 days before elective surgical procedures, especially by patients taking aspirin or warfarin
- b. **Yohimbine** is marketed for treatment of sexual disorders and exhaustion. Many of its effects are attributed to its α_2 -adrenergic receptor antagonist activity. Yohimbine increases the release of norepinephrine, resulting in inadequate blood pressure control in people also using antihypertensive and diuretic agents. Use of Yohimbine is contraindicated in patients with hypertension, angina, and renal impairment.
- c. **Black cohosh** contains triterpene glycosides and has been used in remedies for relief of symptoms of menopause, pre-menstrual tension, and other gynecologic



problems. The mechanism of action is unclear. It may bind to estrogen and serotonin receptors. After estrogen replacement therapy was shown to increase the risk of thromboembolic and cardiovascular events and breast cancer, sales of black cohosh supplements soared (\$US79 million in 2003). In 2006, a clinical trial supported by the National Center for Complementary and Alternative Medicine failed to show that treatments containing black cohosh relieved menopause-associated symptoms. Commercially available dietary supplements made from black cohosh inhibit CYP3A4 and potentially increase the risk of adverse effects from some drugs. Hepatotoxicity has been reported, and black cohosh should not be used during pregnancy or lactation.

91. All countries in the ASEAN region have a heritage of traditional systems of medicine. There are large numbers of traditional medicine practitioners throughout the region and while some practitioners are qualified doctors, some learned by doing and some are frauds and charlatans.
92. The use of traditional medicine is by no means restricted to developing countries however a survey showed that 69% of Australians, 90% of Chinese, 86% of South Koreans and 53% of Singaporeans use some form of traditional medicine annually.
93. WHO studies note traditional medicine can be beneficial but remains largely untested. A key problem which arises from attempts to deal with the problems of traditional medicine is the fact that few jurisdictions record negative effects of traditional medicine.
 - a) Case study of underreporting
94. WHO claims adverse effects of traditional medicine is a significant health care problem for Korea as there is no comprehensive mechanism to identify and monitor adverse effects. Traditional Korean medicine includes acupuncture, herbal medicine and various forms of massage and manipulation. It is hard to plan effective action when few jurisdictions record negative effects of traditional medicine.
95. In Korea, of 95,000 adverse drug reactions reported between 1999 and 2010, only eight were attributed to herbal medicine. WHO concludes that there are deficiencies in reporting consumer injuries from traditional medicine.
96. The Korean consumer regulator receives more than 800 complaints a year in relation to traditional medicine but 27,000 relating to pharmaceuticals. Even with this limited number of complaints, the Korean Consumer Agency established a statistical database to categorise specific areas of deficiency in traditional medicine. The results were that 52% of complaints relate to the use of herbal medicine and 31% to acupuncture. The most common complaint is worsening of symptoms after treatment, adverse effects of



herbal treatment and infection. Established a scheme to measure adverse drug incidents known as the Pharmaco – vigilance scheme. Each WHO member state is required to monitor use of herbal medicines and investigate cases of adverse effects and in 2010 China identified 95,620 cases including 13,420 severe adverse effects of herbal medicines. At the same time Korea reported only eight cases under the WHO Pharmaco – vigilance scheme.

97. Reasons for underreporting. In a review of the suspected underreporting of adverse reactions from traditional medicine in Korea, it was found that Korean regulator relies on pharmaceutical companies to report while Hospital reporting agencies rarely provide herbal treatment and thus numbers would be low. Marketers and industry associations for the traditional medicine sector may well collect data but this is not usually disclosed to the regulator. Nor does the consumer body pass data to the regulator.

II.3.3 Medical devices.

98. Consumer protection issues as a result of mismanagement of hospitals, clinics and other facilities that related to the platform (facilities – premises) where the services are taking place are common throughout AMS. A selection of specific issues taken from the Country Reports Appendix of this paper follows.

99. Lack of available hospitals and clinics in rural areas is perhaps one of the most serious healthcare issues confronting AMS. Solutions to this huge problem are not to be found in simple application of existing consumer laws and policy but the implementation of those policies may lead to better healthcare outcomes and a greater focus on dark data gathering which will enable AMS and development partners to target areas for strategic investment in healthcare.

100. Adverse clinical events occur with unacceptably high frequencies throughout the AMS. Elsewhere in this paper there is a description of the high incidence of clinical errors in Cambodia and the resultant loss consumer welfare and even loss of life which results. Solutions are not straightforward and are not expensive. However, the application of consumer safety principles and the institution of rigorous complaint handling systems and redress schemes will enable the development of accurate contemporary databases to begin the long and expensive process of overcoming high incidence of clinical events which negatively impact consumers.

101. Excessive waiting periods for hospital beds is a further chronic problem in healthcare systems which are limited in budget and facing huge and growing populations in urban slums and rural poverty. As with other systemic problems, it is naive to imagine that consumer policy alone can have a significant impact on this. Needed are entire suites of national regional and even global development programs. However, in common with other problems the application of the principles of consumer protection lead to a clearer



identification of the worst areas for such problems and the accumulation of accurate data on the incidence of problems such as shortage of hospital and clinical places throughout AMS.

102. Inadequate infection control leads to be wasteful expenditure of tens of billions in healthcare costs and inflicts untold misery and suffering on consumers who in consequence of attending clinics or hospitals and up acquiring often life-threatening infections.
103. Need for comprehensive complaint and redress mechanisms has been mentioned in a number of issues above however it is worth stating as a standalone proposition that in every field of trade and commerce or provision of public service to consumers, it is essential that efforts be taken to provide an opportunity for consumers who receive horn adequate service to express their views in a way that might. There are a whole suite of measures which are described in a later appendix to this module which can be employed to bring about improvements in complaint and redress handling in AMS.
104. Model laws are required for regulation and consumer protection guidance to those AMS who currently lay in this important area. An important role for those AMS with highly developed systems is to enter twinning arrangements of partnerships with those who are lacking to provide personnel and technical assistance for the improvement of legislative and regulatory instruments for improving healthcare service delivery.
 - Lack of organisational knowledge in institutions particularly in countries facing huge growth in demand for clinics and treatment centres as well as hospitals is a growing and serious concern throughout AMS.
 - Lack of standards for premises used for healthcare provision is a contributing factor to the reported very high levels of failure of hospital and clinic systems and equipment. In one study around 50% of medical devices in clinical situations were found to be faulty.
 - Shortage of manpower and resources. The main consumer problems related to health care services in the ASEAN region spring from a shortage of manpower and resources. Common complaints such as lack of beds long waiting time for treatment, insufficient drugs, overcrowding, faulty equipment
105. As previously observed under the categorisation of health-care products, medical devices have a major impact on the quality of care and consumer safety. Dealing with the issue however, requires more than simply the development of products standards for the design and sale of devices. Also needed are rigorous policies within clinics and WHO estimates that at least 50% of medical equipment in developing countries is unusable or



only partly usable and in some situations up to 75% is unusable. Often equipment cannot be utilised due to inappropriate selection and lack of supporting skills or commodities and many countries procure medical devices that may be substandard. Some managers of healthcare facilities and manufacturers of medical devices may be unaware of minimum standards as most developing countries import them.

106. Interventions to improve management of medical devices within hospitals and clinics where harm to consumers may result from faulty or dangerous medical devices include:
- Developing a policy on health technology in collaboration with all stakeholders.
 - Dedicating a department for health technology at national authority.
 - Developing capacity for health technology assessment.
 - Establishing and strengthening health technology assessment.
 - Sound national medical device regulatory structure.

a) Regulation of medical devices.

107. To better equip AMS in the task of ensuring safe and effective medical devices the Medical Devices Regulatory Harmonization Training Program was held in April 2013 in Petaling Jaya, Selangor, Malaysia.

108. As ASEAN moves towards the ASEAN Economic Community (AEC) in 2015, healthcare remains a high priority sector to be integrated across the region and vital to successful integration of the sector is the harmonization and efficiency of its regulations.

109. To boost the capability of ASEAN medical device regulators and the medical device industry, over 40 ASEAN medical device regulators met in Malaysia for the Medical Devices Regulatory Harmonization Training Program.

110. The workshop is the first of a multi-year medical devices training program for ASEAN that will ensure ongoing improvement in the understanding and interpretation of the ASEAN Medical Device Directive (AMDD). The AMDD requires ASEAN countries to implement standardized medical device classification criteria and device placement systems, and to establish post-marketing surveillance alert systems. The Medical Device Product Working Group (MDPWG), which is one of 11 bodies of the ASEAN Consultative Committee for Standards and Quality (ACCSQ), developed the draft AMDD.

111. Topics covered in the workshop included a big-picture overview, product life cycles, roles and responsibilities of regulatory authorities, the definition of a medical device, risk management, conformity assessment, listing and registration of devices, and



post-market surveillance to provide regulators rapid identification of defective or unsafe devices.

112. Following the implementation of the AMDD, uniform systems and regulations that come with the directive are expected to help improve patient safety standards across the region as well as providing a more straightforward path to market in the region for manufacturers of medical devices.
113. Successful introduction and implementation of the AMDD will require regulatory agencies of each of the ASEAN Member States to have a thorough understanding of both the underlying philosophies of the Global Harmonization Task Force and the basic building blocks which, when integrated, provide a robust and adaptable framework aimed at ensuring citizens of each of the ASEAN Member States have timely access to safe and effective medical devices. This series of training will help ASEAN medical device regulators forge a common understanding and interpretation of the provisions of the AMDD.

Assessment questions for Section II Substantive Consumer Protection Issues

1. Enumerate barriers to achieving universal healthcare in ASEAN
2. Describe the role of consumer agencies in healthcare service issues
3. Articulate a framework for analysis of consumer issues in healthcare service delivery
4. Identify and express priority areas for action in relation to healthcare services including:
 - a. developing and implementing consumer policies, laws and action plans
 - b. monitoring and enforcing of policies, laws and codes of conduct
 - c. developing effective redress mechanisms
 - d. developing and implementing awareness and education programmes
 - e. undertaking research and development
5. Classify and categorise general areas of concern with healthcare services
6. Outline and discuss the limitations in available data and different stages of development throughout the AMS
7. Contrast and restate elements of consumer centred approach to healthcare policy
8. Nominate strategies for empowering consumers in improving healthcare service delivery
9. Analyse barriers to implementation of universal healthcare
10. Tabulate healthcare issues by reference to root causes of consumer detriment



Further Reading Section II Substantive Consumer Protection Issues

1. Road – Mapping Capacity Building Needs in Consumer Protection in ASEAN (AADCP II 2010)
2. Country Reports Road – Mapping Capacity Building Needs in Consumer Protection in ASEAN (AADCP II 2010)
3. Global Health Action, volume 7, Progress Towards Universal Health Coverage in ASEAN 2015
4. Journal of the American College of Cardiology 2010 Use of Herbal Products and Potential Interactions in Patients with Cardiovascular Diseases
5. Journal of gastroenterology and hepatology 2000 Herbal Hepatotoxicity: an Expanding but Poorly Defined Problem
6. ASEAN Post – 2015 Health Program Agenda, ASEAN 2015
7. A Guide to Good Practice – Principles and Practice in Product Regulation and Market Surveillance ISO October 2012
8. A Healthy Caring and Sustainable ASEAN Community joint statement, 12 ASEAN health ministers meeting, 18 September 2014, Hanoi Vietnam



III. Pre Market Intervention/Protection for healthcare services

Learning objectives and outcomes of Section III

This section provides the context and modalities for pre-market intervention in healthcare services. Common forms of premarket intervention are described together with their strengths and weaknesses.

Following completion of the train the Trainer sessions, participants should be able to:

- explain the context and modalities for premarket intervention in healthcare services
- discuss and design common forms of premarket intervention
- contrast existing consumer protection mechanisms with those of other AMS.
- analyse the domestic need for measures in their AMS

III.1 The ASEAN Context

114. A critical element in the evolution of comprehensive consumer policies for ASEAN is the incorporation of measures to protect the consumers of healthcare services. As the comprehensive analysis of laws policies and practices in relation to health care services detailed above disclose, all AMS have some form of regulation of some of these services but much more is needed.
115. Schemes in place range from those which are comprehensive efficient and effective to those which are not much in evidence. Throughout the 10 AMS, there is a wide variation in practice reflecting, no doubt, the differential stages of development and capacity within the governments, professions and civil society actors.
116. The existence in all AMS of some regulation of health-care services suggests that there are significant opportunities for pre- market intervention which has the goal of establishing norms of ethical and competitive behavior in such a way that consumer complaints are less likely to arise or where they do remedies are made available.
117. This section of the training module identifies possible pre-market interventions which, if implemented, will lead to the gradual lessening of consumer the categories of consumer complaints which appear in the table. The goal of pre-market intervention is to prevent complaints and add to the enhancement of consumer welfare in these sectors.



118. Regulation, licensing or regulation of health-care providers and standards for medical devices are common method for pre-market intervention.
119. The use of licensing and regulation to control the practice of healthcare providers is common throughout ASEAN member states. However, in many countries large parts of the healthcare sector are not covered by regulations and where they are covered are often not subject to any monitoring or enforcement. Unlike other areas of consumer policy covering goods and services, it is not surprising that regulation of health-care providers prior to them engaging in market activities is seen as a desirable way of preventing incompetent or unqualified providers and dangerous untested or other equipment failing to meet standards doesn't get to the market in the first place From a policy perspective, the decision to use premarket regulation and whether or not there is a role for government to resolve an issue and if so what type of regulation or licensing requirement will best achieve the desired policy objectives.
120. Key determinants for health care regulation include where consumers lack information about a service or a product and the consequences of a poor consumer choice as a result of the poor information must be high. An alternative rationale is that the impact on third parties must be high with limited ability to remedy and no scope for a market solution and where a broad government policy rationale exists with significant consequences in the absence of government intervention, or the ability to remedy the issue is poor and no scope for market solution is available.
121. In the case of faulty diagnostic equipment or harmful pharmaceuticals or traditional medicines, many consumers may be seriously affected and the magnitude of potential harm increases the need for premarket regulatory interventions.
122. Common forms of premarket intervention in relation to health services include:
- Licensing of healthcare providers
 - Mandatory standards for pharmaceuticals, complementary medicines and even traditional medicines
 - Mandatory standards for diagnostic and healthcare equipment
 - Codes of practice for manufacturing of drugs and other healthcare products
 - Import controls on a wide range of healthcare goods
 - Requirements for regular retraining for healthcare operators
 - Restrictions on the class of person who can engage in certain health-care service provision
123. Pre-market schemes are a suitable means of dealing with a sector in which substantive consumer protection issues such as misleading advertising, deceptive marketing and dangerous goods arise. Healthcare services is an area of complexity and many services require high expertise and pro market interventions such as regulation



schemes are a useful measure.

124. In the less developed AMS there is little or no evidence of effective implementation and enforcement of licensing rules while in a number of AMS systems are highly developed and quite successful. The training module identifies elements in licensing schemes which are more likely to assist them in achieving their goals while minimising negative elements.
125. A key determinant in success is the availability of adequate resources and personnel to monitor and enforce scheme rules. Throughout the developed world, licensing schemes depend on close relationship with professional bodies for their administration and typically they take the form of co-regulation

III.2 Pre-market intervention schemes in Health Care Services:

III.2.1 Dealing with consumer problems which arise from relationships between healthcare service providers and patients (business-related activities related to the rendering of health care services)

126. Throughout ASEAN, every jurisdiction has mandatory requirements for professional training and registration of at least some healthcare professionals. The Country reports Annexed to this Module spell out the specific legislative instruments through which medical professionals and in some cases nurses and other healthcare providers are regulated. Typically doctors, nurses and higher levels of clinical therapists require mandatory training.
127. Mandatory standards for pharmacists and in a number of AMS practitioners of complementary medicines and even traditional medicines also must conform to educational and performance standards.
128. In a number of AMS there are mandatory standards for healthcare professionals who use certain specified diagnostic and healthcare equipment. However, this is sporadic and there is little evidence of monitoring the quality of such regulation.
129. Codes of practice for a range of healthcare professionals can be found throughout the AMS and these can often form a cost-effective form of premarket intervention. Depending on its content, codes of conduct can act as premarket or post-market forms of intervention.
130. As ASEAN moves to more liberalisation in trade between member states this is extending to mutual recognition of professionals. An important form of premarket intervention to protect consumers of healthcare service professionals use the specification of certain standards in relation to those foreign professionals practising in the AMS. Typically, performance standards will only relate to a few key professions such as doctors, specialist clinicians nurses and therapists.



131. Requirements for regular retraining for healthcare operators and also act as a form of premarket consumer protection. However, as such schemes typically only apply to existing practitioners, it can also be described as a post-market form of intervention.
132. Restrictions on the class of person who can engage in certain health-care service provision is an important form of pre-market intervention as it can prevent undesirable or unqualified persons from becoming health care service providers in the first place.

III.2.2 Consumer protection issues in the area of health-care products, pharmaceuticals and medicaments (generic or branded) medical devices, traditional medicines.

133. Licensing of healthcare products particularly pharmaceuticals, therapeutic goods and equipment used in the provision of healthcare services is a vital part of the premarket intervention dimension of consumer protection. To be effective however, there is a need for regular market inspections and monitoring to ensure that pharmaceuticals and medical devices are in fact tested prior to the presence in the market. Elsewhere in this report problems of fake drugs and poor quality products have been found on the market which suggests poor implementation of this important form of premarket intervention.
134. Mandatory standards for pharmaceuticals, complementary medicines and even traditional medicines are to be found in a number of AMS. As with licensing schemes for therapeutic goods and equipment, mandatory standards are only going to be of use if there is the comprehensive monitoring and enforcement regime to ensure nonconforming products are removed from the market quickly.
135. Mandatory standards for diagnostic and healthcare equipment should include clear performance specifications and regular retesting as diagnostic and health care equipment requires constant maintenance and recalibration to be safe and effective.
136. Codes of practice for manufacturing of drugs and other healthcare products are designed to ensure that facilities used in the production of healthcare products are themselves safe and effective. It is considerably cheaper and from a consumer point of view, preferable to have premarket intervention to prevent the production of products which are either unsafe or ineffective.
137. Import controls on a wide range of healthcare goods is a desirable state of affairs however in many AMS the capacity of central governments to monitor imported equipment is very low and this form of premarket intervention is implemented in a patchy way around ASEAN.
138. Requirements for regular recertification of equipment and reregistration of any therapeutic goods which may undergo technological or formulation change is an essential



mechanism for premarket intervention. Restrictions on the class of products which may be used such as prohibition of known dangerous all band drugs or devices is a further tool in the premarket intervention scheme.

III.2.3 Consumer protection issues in hospitals, clinics and other facilities

139. Licensing and regular inspection of all public and private hospitals and clinics at which therapeutic services are provided is the primary form of premarket intervention for facilities used in healthcare provision
140. Mandatory standards are essential to underwrite any licensing inspection scheme is described the first point above. The absence of rigorous and mandatory standards means that inspections and any subsequent enforcement action will be unsuccessful and lead to a false sense of security.
141. Licensing or other regulatory controls over premises which provide healthcare services should also be used to control the types of pharmaceuticals, complementary medicines and even traditional medicines provided to consumers
 - Mandatory standards for diagnostic and healthcare equipment is a basic yet often ignored premarket intervention in ASEAN
 - Codes of practice for operating and managing premises from which healthcare services are provided should include objective, measurable and measured indicators.
 - Import controls on a wide range of healthcare goods should also apply to hospitals and clinics and other premises used for the provision of therapeutic services
 - Requirements for regular staff training and assessment of the competency and effectiveness of staff is an important premarket intervention.
 - Restrictions on the class of person who can own or operate facilities used for provision of healthcare services is another possible measure to prevent fraud or consumer detriment.



Assessment questions for Section III Premarket Intervention/Protection for Healthcare Services

1. Explain the meaning of premarket intervention?
2. Why is premarket intervention superior to post-market intervention?
3. Give examples of effective premarket intervention in healthcare services in your AMS
4. Explain the context and modalities for premarket intervention in healthcare services
5. Discuss and design common forms of premarket intervention
6. Contrast existing consumer protection mechanisms with those of other AMS.
7. Analyze the domestic need for measures in your AMS.

Further Reading for Section III Premarket Intervention/Protection for Healthcare Services

1. Risk Assessment for Regulatory System Design UNECE 2012
2. A Guide to Good Practice – Principles and Practice in Product Regulation and Market Surveillance ISO October 2012
3. ASEAN Post – 2015 Health Program Agenda, ASEAN 2015
4. A Healthy Caring and Sustainable ASEAN Community joint statement, 12 ASEAN health ministers meeting, 18 September 2014, Hanoi Vietnam



IV: Post Market Intervention

Learning objectives and outcomes of Section IV

Section IV provides the context and modalities for post-market intervention in healthcare services. Common forms of post-market intervention are described together with their strengths and weaknesses. Particular emphasis is given on investigation of breaches of laws and codes of conduct, the need for consumer awareness and education, international cooperation and other suitable measures.

Following completion of the Train the Trainer sessions participants should be able to:

- discuss the merits of pre-and post- market intervention in the context of improving healthcare outcomes for consumers
- specify areas for intra-ASEAN cooperation in implementation of **post-market** measures
- interpret for local context principles for investigation of breaches of laws and codes
- evaluate current measures being undertaken for post-market ASEAN Member States

IV.1 ASEAN Context: The Role of consumer agencies

142. Unlike other areas of consumer protection, such as controlling misleading and deceptive conduct by marketers of goods and services, the health care role of consumer agencies in ASEAN is quite limited.
143. Typically, professional or specialist regulatory bodies are credit the entry of healthcare professionals and also operate disciplinary and regulatory systems which might seem removed from practice as well. Assessment of competence and malpractice is itself a specialist task and consumer agencies have little role throughout ASEAN in this process.
144. Where consumer agencies do have some jurisdictions it is usually limited and incomplete. However, there are examples from Malaysia, Thailand and Singapore where consumer agencies are playing a greater role in the protection of the interests of consumers of healthcare services.
145. Malaysia, Thailand and Singapore all have agencies which permit complaints against some healthcare professionals to be submitted and adjudicating however the jurisdiction



for findings of incompetence and/or the granting of damages and compensation are rather limited.

IV.1.1 Market surveillance

146. It is rare for consumers to know as much about the quality of goods and services as the provider. In any event consumers will rarely have sufficient knowledge prior to choosing a particular doctor or lawyer. In most AMS the relative scarcity of doctors and lawyers ensure that the usual processes of choice are in any event limited.
147. As it is very difficult for consumers to know in advance of a purchase whether or not the services of high-quality – and even in some cases after-the-fact, consumers may not achieve their objectives. Most healthcare services fall into the category of services for which a consumer is obliged to take the quality of the service on trust since he or she may not possess the expertise to determine whether the service has been appropriately supplied.
148. Possible post market interventions to achieve improved consumer welfare in healthcare through market surveillance:
 - Establishing patient safety should be a priority in the national health policy plan and in all health programs there should be specific accountability and responsibility for such measures
 - Establishing national multi – disciplinary patient safety involving professional and non- government organisations groups is a positive way of consulting stakeholders and getting feedback about priorities
 - Surveillance can take form of operational research and evidence-based interventions where current incidents and complaints do not disclose a problem, external research might.
 - Identifying key government departments and other bodies will be responsible execution of post market interventions
 - Developing legal and regulatory frameworks as well as assisting enforcement for quality consumer safety
 - Establish dedicated quality and patient safety Department in the Ministry of health
 - Encourage third-party players to support and provide incentives patient safety
 - Educating and engaging the media society partners to act as lookouts and mentors for the public at large.

IV.1.2 Consumer fraud and deception



149. Compounding the lack of knowledge or information possessed by consumers about the quality and competence of the health care service providers are problems associated with fraud or deliberate false and deceptive behavior.
150. In many of the regional reports listed above there was substantial evidence of misleading and deceptive conduct by health care service providers which led to consumers suffering loss or damage
151. While many aspects of consumer complaints can and should be dealt with by the healthcare service provider or through a self-regulatory or industry code, there are exceptions. One such exception is where the trader engages in consumer fraud or deception. As markets and self-regulation depend to a large extent on people operating in good faith, issues of fraud and deception require swift intervention and punishment by regulators in order to maintain market integrity and prevent loss or damage to consumers.
152. So where providers of services deliberately set out to mislead or deceive consumers a higher rationale for intervention exists. In a number of AMS the only remedy for consumers in such cases is the use of criminal fraud statutes which though apparently a strong sanction, are almost never applied and so the case for more effective remedies is clearly apparent.

IV.1.3 Impact on third parties

153. Inadequate market surveillance or regulation of health-care service providers throughout the AMS can lead to considerable losses for consumers. In the case of dangerous medical equipment, fake or expired pharmaceuticals or incompetently marketed traditional medicines an incompetent provider could cause widespread loss and damage which would cause harm to many third parties who are not involved in the original purchase transaction

IV.1.4 Post market intervention/protection

154. Investigation and enforcement by regulatory bodies of the rules for pharmaceuticals, medical devices or traditional medicine and for breaches of standards is a crucial part of consumer protection system. Sanctions for breaches will range from reprimands through compensation and mandatory retraining programs to disbarment or cancelation of the right to continue marketing healthcare services by the party in breach.



155. Other measures to give effect to sanctions include public warnings and in AMS where laws allow, group proceedings or class actions for compensation. As the country reports above note, however, there is relatively little evidence of the use of these tools and in the case of the less developed AMS almost none. It remains important for consumer protection that such powers remain in the rule book and that authorities are equipped to use them where necessary. It is also necessary to recognise that resource and personnel constraints mean there will never be sufficient enforcement of such measures.
156. A further limitation of the enforcement model for action against the providers of health services is that throughout the AMS there is a cultural reluctance to complain. In the Road mapping report it was stated in relation to a number of AMS that consumers prefer to “suffer in silence” rather than make formal complaints about health care service providers.

IV.1.5 Consumer Awareness and Education

157. An essential step in reforming markets for healthcare services is the engagement of consumers in the process. From a policy perspective, the best form of consumer protection is aware consumers operating in fair and informed markets. Where consumers are aware of their rights and responsibilities and critically aware of risks to themselves, problems may be avoided.
158. Establishing a culture of safety and improving communications requires much better integration of consumer policy with healthcare services and requires individuals responsible for consumer care and safety. It also means ensuring that Healthcare service managers, clinicians and all levels of healthcare engage with consumers and are held accountable
159. There are certain necessary steps to empowering consumers to act in their own interests and avoid problems. Where problems arise consumers are still able to act in their own interests to resolve them quickly.
160. Establishing a culture of safety and improving communications links to establish:
- Ensure that consumers are informed and empowered to exercise their rights
 - Obtaining informed consent for treatments and procedures carrying risk to consumers
 - Seeking consumers participation in decisions regarding their care
 - Communicating with consumers in the cultural context in the language they can understand
 - Involving consumers and their families in their own care



- Creating an enabling environment in which individuals feel safe to report incidents and near misses
- Local mechanisms to collaborate and set policies and procedures involving consumers
- Seek to focus on human factors including interdisciplinary consumer centred care, team training, improving communication and handover and transfer protocol
- Involving patients and consumer advocates in healthcare service design and delivery
- Identify and protect consumer rights and understand consumer satisfaction/experience in healthcare process

IV.2 Protecting Consumers of Health Care Services

161. To be effective in the protection of consumers of health care services, officials need to be equipped with adequate skills and resources to monitor and force existing laws as well as to design new policies and rules as circumstances dictate. The Country reports disclose that across ASEAN there are gaps in compliance, information, and best practice or implementation mechanisms for consumer protection in health care services they derive from a survey, key informant interviews, roundtable discussions in the 10 AMSs and the ASEAN committee on Consumer Protection Workshop 2010
162. Consumer agencies in the AMSs: As in other countries, are sometimes not the lead government agencies responsible for regulation or consumer protection in the field of healthcare services. The critical task of the needs assessment in this project was to understand the responsibilities of each agency, to match these to the specific regime for health care services and to determine capacity building requirements for responsibilities they have outside those areas.
163. Identifying and sharing best practice: A number of AMSs already possess laws, codes and regulatory schemes dealing with health care services. This training module will identify them and establish effective twinning arrangements of partnerships between those with the competencies and those without.
164. A core function for a consumer agency is effective compliance and law enforcement: Across all of the training activities, agency staff need to understand the investigation principles and enforcement methodologies without which they cannot gain general compliance with laws and policies.
165. The legislation regulating health care services in AMS may not be incorporated in the principal Consumer Protection Act. Legislation and codes in each AMS needs to be assessed to ensure that it provides clear standards for healthcare services.
166. Information sharing and mutual support amongst a community of officials is a key issue in the long-term success of this project. The module will explore the extent to which this project might assist in the development of an ASEAN facility for Consumer Protection



which is anticipated in the Roadmap

167. The international community of consumer affairs officials is a strong and growing one. The training module will seek ways to integrate officials from AMSs in the training and development programs of professional bodies such as the Society of Consumer Affairs Professionals (SOCAP) and the International Consumer Protection and Enforcement Network (ICEPEN)
168. Most AMSs incorporate consumer protection in national development plans. Singapore, Thailand, Malaysia and the Philippines have comprehensive laws while Brunei Darussalam, Cambodia and the Republic of the Union of Myanmar have recent and basic consumer laws. The module will need to accommodate these differences in consumer policy development.
169. This section of the training module extracts from the earlier ASEAN consumer protection project, material setting out various mechanisms for post market intervention. The project which was completed in 2014 led to the identification of a range of models, case studies and implementation guidelines.
170. Information presented in this section of the training module has been adapted from another ASEAN consumer protection project. There are 4 source documents each of which can be found on the ACCCP website. They are:
 - Assessment Framework for Complaint Handling and Redress Schemes
 - Assessment Report on Internal Complaint Handling Systems and External Redress Schemes
 - Development of Complaint and Redress Mechanism Models in ASEAN
 - Guidelines for Selection of Models
171. There are many possible models for the establishment of consumer redress schemes in ASEAN Member States. This section sets out proposed models for possible implementation in ASEAN. They derive from models currently to be found in Australia and AMS; this section describes their key features and provides a number of examples.
172. Information presented in this chapter has been drawn from the extensive interviews undertaken by the project Team in Thailand, Malaysia and Singapore in March 2013. In addition, extensive references have been made to the documents listed at the end of this report and to the complaint handling systems and redress schemes in operation in Australia, South Korea and elsewhere in the world.



Assessment questions for Section IV Post-Market Intervention/Protection for Healthcare Services

1. Explain the meaning of premarket intervention?
2. Why is premarket intervention superior to post-market intervention?
3. Give examples of effective premarket intervention in healthcare services in your AMS
4. Explain the context and modalities for premarket intervention in healthcare services
5. Discuss and design common forms of premarket intervention
6. Contrast existing consumer protection mechanisms with those of other AMS.
7. Analyse the domestic need for measures in your AMS

Further Reading for Section IV Post-Market Intervention/Protection for Healthcare Services

1. Risk Assessment for Regulatory System Design UNECE 2012
2. A Guide to Good Practice – Principles and Practice in Product Regulation and Market Surveillance ISO October 2012
3. ASEAN Post – 2015 Health Program Agenda, ASEAN 2015
4. A Healthy Caring and Sustainable ASEAN Community joint statement, 12 ASEAN health ministers meeting, 18 September 2014, Hanoi Vietnam



V. Redress Mechanisms.

Learning objectives and outcomes of Section V

Section V describes the wide range of steps and measures which can be taken in obtaining redress. A spectrum is described which starts with internal complaint systems in the service provider's organisation through to external redress or enforcement by regulatory authorities.

A major component of this chapter is the elaboration of models for codes of conduct, complaint handling systems, external redress systems and a range of other consumer protection mechanisms.

Following completion of the train the Trainer sessions participants should be able to:

- evaluate models for consumer protection against specifically identified problems for healthcare service delivery
- differentiate the application of models for the state of development and available resources in their AMS
- contrast measures taken in their AMS with those of other AMS
- analyse existing data from enforcement agencies and complaint handling bodies to determine gaps in consumer protection provision

V.1 The ASEAN context

173. Each AMS has a different starting place as some have very well developed and implemented complaints systems and redress schemes'. Set out below is a diagram showing the necessary steps in the construction of a scheme to be implemented by the health care services providers themselves as a means of reducing the number of complaints which arise in the first place, provide remedies for affected consumers and relieve the State of part of the regulator burden.
174. The process is a journey to best practice in which current measures to protect consumers of health care services need to be re-evaluated and compared to those in other AMS and suitable reference countries on a regular basis to ensure that once they reach best practice, they remain at that level. With the fast pace of development in ASEAN it would be highly desirable to establish and maintain data bases of measures and experiences to share in relation to Models and their implementation.
- Stage of economic development
 - Regulatory capacity
 - Strength of the government sector
 - Degree of market development in the AMS
 - Presence of an active civil society



- Progress will depend on many factors, including:
 - Pressures of competition in ASEAN markets
 - Presence of international lawyers and doctors
175. There is no single model which will suit all AMS in all circumstances as Models have been developed to solve different problems and AMS are themselves different from one another International experience shows that where traders are actively engaged in the design and implementation of complaint and redress schemes, better levels of commitment and outcomes result. For ASEAN such an approach also fits the culture of respect and consensus in which professions operate.
176. The schemes can be applied to a range of markets but in this module they have been tailored for application to health care service providers. There are many possible models for post market consumer protection in the health care services sphere. The appendix to this module provides guidance on selection and implementation of the best one for each profession in each AMS.
177. The models incorporate the elements from various approaches including:
- ADR
 - Ombudsman
 - Arbitration
 - Mediation
 - Group actions
 - Cross border access to justice
178. As current levels of consumer protection vary amongst AMS and as levels of resource and expertise differ, there is no single model which will suit all AMS. Guidelines therefore set out steps which may be taken to assess the current consumer protection framework of an AMS; and to identify possible steps which, if implemented, will lead to better or best practice levels of protection for consumers of health care services.
179. The initial step is to determine the stage of development and implementation of regulation and establishment of agencies for implementation which best describes current approaches to regulation of health care service providers.
- Little or no measures for consumer redress
 - Basic professional admission/striking off provisions for gross negligence or dishonesty
 - Agreement within the jurisdiction on the need to respond to consumer complaints against health care providers
 - Growing consumer pressure with the establishment of complaint and redress schemes
 - Professional associations involvement in complaints handling systems and



redress schemes

- Government intervention or threats to establish consumer redress schemes
- Creation of industry ombudsman or other industry based schemes
- Best practice complaint systems and redress schemes

180. In part as a response to the shortcomings of a more extensive investigation and enforcement based approach to dealing with market problems in ASEAN, a project was undertaken to develop more regionally appropriate models to deal with consumer complaints.
181. The goal of regulatory licensing schemes is to enhance consumer welfare by restricting entry to a trade or profession to those with suitable qualifications and character. However, a pre-market scheme will not prevent licensed healthcare providers from anti-consumer behaviour and so schemes of post market intervention are also necessary
182. Guidance and implementation of complaints handling scheme. The following suggestions will be appropriate for AMS who have little or no current measures in operation up to those with well-developed schemes. Implementing complaints handling systems for professional bodies.
183. The first stage of the implementation of internal complaint handling systems for healthcare services bodies is to undertake a survey of members and consumers to determine the existence of and extent of consumer problems
184. The survey should seek to assess the adequacy of existing internal complaint handling systems and to cross reference that with government records about complaints from the health care sectors examined. In the event that the survey shows current internal complaint handling systems are not present or are inadequate, then further implementation of model one should be considered.
185. The second stage is to meet with representatives of government departments responsible for regulation of health-care services and the general consumer agency collect and summarize information about the complaints they have received in these sectors and then meet with market participants about complaints handling systems encouraging them to implement ISO 10002 using the collected complaints data as a bargaining tool.
186. It may be useful to run workshops on ISO 10002 through the national body responsible for standardisation. The government should consider developing and implementing a policy that if healthcare service providers do not have their own schemes which meet the principles and features for external redress schemes developed by an agreed date that they will mandate redress schemes for them.



Assessment questions for Section V Redress Mechanisms in Healthcare Services

1. Evaluate models for consumer protection against specifically identified problems for healthcare service delivery.
2. What steps are needed to assess market problems and suitable remedies in your AMS?
3. Are you aware of the development of any cross-border or regional redress mechanisms?
4. What is the goal of regulatory licensing?
5. Differentiate the application of models for the state of development and available resources in their AMS
6. Contrast measures taken in their AMS with those of other AMS
7. Analyse existing data from enforcement agencies and complaint handling bodies to determine gaps in consumer protection provision

Further Reading for Section V Redress Mechanisms

1. Models for Internal Complaint Systems and External Consumer Redress Schemes in ASEAN. December 6, 2013 FEMAG
2. Development of Complaint and Redress Mechanism Models in ASEAN: guidelines for the selection and implementation of complaint and redress models December 6, 2013 FEMAG
3. Road – Mapping Capacity Building Needs in Consumer Protection in ASEAN (AADCP II 2010)



ANNEXES



ANNEX 1: Seven models for redress mechanisms

MODEL 1: Internal complaint handling systems

Internal complaint handling refers to systems designed and implemented by organisations (public and private) such as a business firm or a government agency that provides services to the public to deal with expressions of dissatisfaction about some aspect of the goods or services provided by the organisation to consumers or to the public. An internal complaint handling system has a multiplicity of purposes, which can deliver benefits for all the participants. Such a system provides an opportunity for consumers of goods or services to have their voice heard on those occasions when:

- The organisation fails to deliver its goods or services;
- They are delivered in a manner that is unacceptable to the consumer;
- The goods or services are faulty;
- The organisation fails to meet its own standards of service, or those considered generally acceptable for the industry in which the organisation operates;
- The organisation fails to meet an undertaking; or
- The organisation acts in a manner that the consumer considers to be injurious to his or her interests.

In addition, an internal complaint handling system provides a unique opportunity for an organisation to find out what its customers think of it, both good and bad. It can be a window into the minds of its customers and can avoid tarnishing the reputation of an organisation by voicing their complaints in the wider community. An organisation will fail to discover what customers think is wrong with it until there is a critical mass that compels attention. Finally, an internal complaint handling system is an essential ingredient of a service quality program. Research has shown that effectively handling a complaint will lead to greater levels of loyalty and customer satisfaction than if there had been no problem at all.

Far from being a burden on businesses or government agencies, an effective internal complaint handling system can add great value.

168. Key Features of Model 1: Internal Complaint Handling Systems

- Implemented by businesses and government agencies providing services to resolve consumer complaints
- Should embody the principles and features of complaint handling systems (appendix 3)
- May be voluntary or required by law or regulations
- Appropriate for organisations of all sizes
- Guidance in implementation can be found in international standard iso 10002

169. Example of internal complaint handling systems



Thailand National Health Security Office (NHSO): Public Organization to respond to the public good management system www.nhso.go.th. The Thailand National Health Security Office was established in 2002, set up as a public organization to create health security for 48 million Thai citizens, whereby. 'Every person born as Thai should feel secure irrespective of being sick or not'. The NHSO is responsible for the implementation of the Thai universal coverage system for health care and is responsible to develop the service system which is easily accessible, effective and efficient. NHSO has implemented an information system for communications and has a highly evolved and efficient complaint handling system.

NHSO has a highly developed, well-resourced and well supported complaint handling function. Operating from the head office building in Bangkok, well trained and enthusiastic call centre staff manage large workloads in an efficient and effective manner. The complaint handling system draws on international benchmarks and is subject to rigorous quality assessment and review at periodic intervals.

As NHSO is a large organisation and the elaborate systems in place are not wholly transferable to the experience of small agencies or organisations in AMS which have a less sophisticated legal system and capacity for implementation. However, for the purposes of modelling complaint handling systems, NHSO is a very good example of the application of international principles converted to effective domestic operation. Thailand faces many challenges with a significant refugee and non-Thai speaking population, rural and remote areas where poverty and transport are problematic and great development challenges exist. This complaint handling system therefore faces some of the significant challenges for other areas of ASEAN to which sees recommended models may be applied.

170. The provision of multiple channels

An important conceptual element in the structure of complaint handling system is to provide multiple channels for consumers to express their dissatisfaction with elements of the service they have received. Known as channels for complaint, the NHSO provides three main channels for complaint received. They are illustrated in the following figure



MODEL 2. Self-regulatory external consumer redress schemes.

The least formal external consumer redress schemes are those implemented by some industry associations. They may be described as ‘self-regulation’ or ‘informal industry regulation’. Such schemes are established by agreement or contract between members of an industry and seek to provide consumer redress through establishment of norms of conduct which may be expressed in a code of practice or may include mediation and the use of persuasion, rather than enforcement, to encourage members to provide compensation or some other redress to a complaint. Typically, the powers of the association will be no more than persuasive although sometimes contractual remedies can be found which give a small measure of enforceability to determinations.

Governance of informal industry associations is typically by a Board or Committee established by member organisations and empowered to levy fees on industry members to finance the association. Rules and procedures are set out in the agreement between members and will define jurisdictional limits, matters to be taken into account in the exercise of its role, and details of funding operations.

Self-regulatory schemes can be brought into existence very quickly and with an absolute minimum of formality. Terms of reference and procedures can be very flexible and change as needed without bureaucratic processes.

As such schemes are purely voluntary, and at most engage a contractual relationship between members, the determinations are typically not enforceable. One weakness is that rules and procedures are set at the standard that members of the Association are prepared to accept - which is often very low. A further weakness of voluntary schemes is that Governments and consumer groups will generally have little or no role in the establishment or oversight. Weaknesses of self-regulatory external consumer redress schemes often lead to their transition to statutory schemes or industry Ombudsmen schemes which are underpinned by licence conditions, regulation or legislation.

The success or failure of self-regulatory schemes to provide adequate levels of redress to consumers will depend upon the extent to which the schemes incorporate the principles and features of best practice external redress systems. Although there are structural characteristics of self-regulation which tend to make it unsuccessful, there are nonetheless examples of schemes that are very effective. AMS considering encouraging the implementation of self-regulatory external consumer redress schemes should consider strengths and weaknesses. This matter is dealt with in more detail in the Guidelines paper.

Key Features of Model 2: Self-regulatory external redress schemes

- Set up with little formality
- Usually used in the early stages of consumer policy and law implementation



- Tend to relatively low standards of performance
- Unless they are based on contractual arrangements between industry members, such schemes are usually not enforceable
- There is no stakeholder engagement particularly with consumers and governments
- Generally held in low regard by consumers and some governments
- Considered to be just an interim step in development of consumer redress schemes



Model 3 Statutory complaints bodies

By definition, statutory complaints bodies are established by legislation and most commonly with legislation specific to the industry to be regulated. Such bodies are frequently used for regulation of the conduct of professions and they may obtain redress for consumers while investigating consumer complaints, however, their objectives are often more of a public interest nature such that obtaining redress for individuals is secondary to maintaining overall high levels of commercial or professional conduct. Schemes of this sort are not really redress schemes in the fullest sense, however, on occasion individual redress can be provided to consumers.

Special purpose or industry specific regulators, on the other hand, often have a consumer redress power or may oversee the establishment of self-regulatory or co-regulatory bodies which have this function. Most countries with a general consumer law have a consumer protection, compliance and enforcement agency, many of which have as part of their mandate redress for consumers.

In most cases statutory complaints bodies form part of a larger government department or agency committed to fair trading or consumer protection. Functions often include investigation of claims of breaches of consumer law, maintenance of product safety and, commonly, such agencies will supervise licensed professions, and may deal with building and disputes against tradespeople. In relation to industry specific regulators, these are often associated with a Department of State with primary policy or regulatory responsibilities for an industry sector such as energy or telecommunications.

Industry specific regulators will almost always have industry specific legislation and staffing and resources to deal with licensing, research, sometimes economic regulation, and matters relating to consumer protection. Funding can either be provided by direct appropriation from the national budget or, as in the case of a number of industry specific regulators, operating costs are recovered from the regulated industry through levying of licence or operating fees.

Key Features of Model 3: Statutory complaints bodies

- Jurisdiction usually covers most economic activity
- Some are established to deal with a specific industry or practice
- Generally, part of a larger government agency responsible for consumer policy and law enforcement
- May also be linked to industry regulators and small claims courts

Examples of statutory complaints bodies

- *Korea Consumer Agency* – www.kca.go.kr



- The Korea Consumer Agency is a government organisation established in 1987 by the Consumer protection Act. Its founding principle is to protect consumer rights and interests, to promote rational consumption and to contribute to the sound development of the national economy.

Key functions are:

- The Korea Consumer Provide consumer counselling and redress
- Conduct tests and inspection and investigation on standards, quality and safety of products and services
- Research and process consumer protection policies and laws
- Collect and provide information on rationalisation and safety of consumption
- Provide education/training on consumer protection
- Conduct comprehensive research to enhance national life
- Investigate and enforce consumer protection laws
- Handle consumer related complaints

Agency is a mature consumer agency with more than 25 years of experience in development and implementation of consumer policy. The agency embodies modern management and policy structures to achieve its goals and provides within its system of operation adequate opportunities for early mediation, fact-finding, escalation of matters that are serious or intractable and follow-up.

Key Features of Element B: Licensing schemes

- Such schemes are rapidly growing around the world in service industries such as telecommunications, energy, banking and finance
- Usually combined with elements of model 4: adr schemes
- Enables governments to identify specific areas of poor industry practice to be improved
- When properly implemented and well-funded they can provide successful consumer redress
- ASEAN has a number of good example of such schemes
- Guidance in establishment and implementation can be found in the list of Source documents

Examples of licensing schemes

The Communication and Multimedia Consumer Forum of Malaysia (CFM) www.cfm.org.my CFM is responsible for the administration of the General Consumer Code of Practice (GCC) for the Communications and Multimedia Industry Malaysia. The GCC was registered as a voluntary industry self-regulatory code in 2003. The GCC is binding on and requires compliance of all licensees under the Communications and Multimedia Act 1998 (CMA) Under the code it is mandatory for licensed operators, specifies a comprehensive complaint handling regime which deals with:



- Visibility and accessibility
- Special needs
- Responsiveness
- Charges
- Further recourse
- Suspension of charges
- Internal data collection and analysis
- Review
- Changes to complaint handling processes
- Retention of records
- Audit of the complaints handling processes of the service providers and of the consumer forum

Alternative dispute resolution (ADR) techniques

A common and desirable feature in Government established external consumer redress schemes is the use of alternative dispute resolution (ADR) techniques to provide redress. ADR techniques provide an alternative to going to court to resolve disputes. There are many variations in the way it can be applied but the underlying principle is that ADR provides a low-cost, speedy and relatively informal way of resolving consumer complaints. The most common application of ADR is the industry Ombudsman scheme described below.

Industry Ombudsman schemes.

Independence strongly underpins the way schemes/offices undertake their ADR roles. In practice, this means –

- Following the principles of 'natural justice' or fair hearing allowing each party a fair opportunity to explain their perspective
- Allowing each party equal opportunity to provide any further information that may be relevant to the investigation
- Not pre-judging a complainant
- Avoiding personal conflicts of interest
- Avoiding the deliberate withholding of information, so that one party can obtain a better outcome.

Industry Ombudsmen schemes are independent, impartial redress bodies which may be established under legislation or by voluntary contractual arrangements within an industry. Such schemes form part of the classification known as '*Alternative dispute resolution schemes*'. They are so named as they are established as an alternative route to redress rather than forcing a consumer to file an action in a court of law.

The goal of industry Ombudsmen schemes is to provide accessible, informal and speedy



alternative to courts. Typically, they are free of charge to consumers and while processes are impartial, they seek to redress the imbalance of resources and expertise between consumers and service providers such that parties do not require - and are often not permitted - to be represented by a lawyer.

The governance structure can vary among different industry Ombudsmen schemes. The most common schemes have a single level structure and such schemes are governed by an independent Board of consumer representatives and industry appointees. The role of the Board is to monitor the performance of the industry Ombudsman scheme and provide directions to the Ombudsman on policy matters, set the budget and review the terms of reference including the jurisdictional limits of the scheme.

The Board does not get involved in the detail of cases which come before the Ombudsman as that would prejudice the independence of the Ombudsman. An important feature of such a scheme is that decisions made by the Ombudsman are independent of any interference from the Board. A single Board or council governing scheme is considered best practice and is preferable to a dual layer in that it invests matters of governance of the scheme (apart from those that are the responsibility of the Ombudsman) squarely in the hands of a body made up of an equal number of industry and consumer representatives with an independent chair.

Key features of alternative dispute resolution (ADR)

- **ACCESSIBILITY**
- The scheme makes itself readily available to customers by promoting knowledge of its existence, being easy to use and having no cost barriers.
- **INDEPENDENCE**
- A feature of the decision-making process and administration of the scheme are independent from scheme members.
- **FAIRNESS**
- The scheme produces decisions which are fair and seen to be fair by observing the principles of procedural fairness, by making decisions on the information before it and by having specific criteria upon which its decisions are based.
- **ACCOUNTABILITY**
- The scheme publicly accounts for its operations by publishing its determinations and information about complaints and highlighting any systemic industry problems.
- **EFFICIENCY**
- The scheme operates efficiently by keeping track of complaints, ensuring complaints are dealt with by the appropriate process or forum and regularly reviewing its performance.
- **EFFECTIVENESS**
- The scheme is effective by having appropriate and comprehensive terms of reference and periodic independent reviews of its performance.



Examples of alternative dispute resolution

Financial Ombudsman Scheme (FOS) – Australia www.fos.gov.au

The Financial Ombudsman Service sets out to 'fairly and independently' resolve disputes between consumers — including some small businesses — and member financial services providers. Membership of the Financial Ombudsman Service is open to any financial services provider carrying on business in Australia.

Independent dispute resolution processes cover financial services disputes including banking, credit, loans, general insurance, life insurance, financial planning, investments, stock broking, managed funds and pooled superannuation trusts. The scheme also covers estate planning, estate management and trustee services, and is free to consumers.

FOS, in common with other industry Ombudsmen schemes which employ alternative dispute resolution methodologies, is an alternative to going to court. There is no need to obtain legal or other advice when lodging a dispute and FOS can help consumers with the dispute process. Consumers unhappy with financial, insurance or investment products or services can complain to the financial services provider and ask for a resolution of a dispute in accordance with its own complaint handling scheme. Also, in common with similar schemes, all financial services providers who are members of the FOS are required to have a consumer complaints system.

Where a consumer is dissatisfied with the results of a complaint to a member financial services provider, FOS provides a conciliation process or investigation of the dispute that will result in a written decision on cases which is binding on the financial services provider.

Codes of conduct

Over the past 25 years, there has been a discernible international trend to convert purely self-regulatory consumer redress schemes into ones that have a legislative or regulatory underpinning and so become an element of the Government established external dispute resolution schemes. The causes of the shift are mainly dissatisfaction by consumers with the standards and outcomes of voluntary schemes. Typically, remedies were very limited, slow to obtain and schemes were underfunded. Many industry and public sector codes of conduct now have legislative or regulatory underpinning to ensure their enforceability.

The choice of mechanisms for providing legislative or regulatory underpinning are quite wide with some regulations which call up the previous self-regulatory or voluntary scheme and deem it to be an enforceable regulation of government. In other cases, laws or regulations have built on previous provisions but added enforcement and accountability mechanisms. Still others are fully enshrined in legislation but often disregard previous



unregulated versions.

Common features of such schemes are that they are specific to a particular industry or form of conduct sought to be the subject of redress, and that public authorities are assigned the responsibility of administering or enforcing them. Another common feature is that they confer rights on consumers to take action under the provisions that might be enforced in small claims courts or in the court system more generally.

Key advantages of providing regulatory or legislative underpinning for codes are that they can retain some of the industry connection and dynamism which comes from engaging industry associations with rule-making but with the added advantage of ensuring wider coverage and a more certain possibility of redress for consumers using such schemes.

Key features of codes of conduct

- Fast replacing voluntary or industry association redress schemes around the world
- Many different models depending on the circumstances of the industry concerned
- Usually specific to a particular industry or sector
- Deal with common consumer problems that arise within a specific industry
- Often administered by an industry specific regulator
- Usually specify standards of conduct required by a business
- Regulatory backing allows full industry coverage



MODEL 4: Public sector redress body (also known as Ombudsman)

The fastest growing and most effective vehicle for redress of complaints against governments as providers of services is the public sector redress body or Ombudsman scheme. For the sake of simplicity and consistency in this report such external redress bodies will be described as 'Public sector Ombudsmen schemes'.

They are most commonly established by legislation with the objectives of:

- Resolving public complaints efficiently, fairly and effectively;
- Reporting and recommending solutions to resolve systemic problems of administration;
- Improving resolution rates of complaints by government agencies;
- Determining the root cause of complaints and seeking to reduce the incidence of them;
- Proposing administrative innovation which may improve service and reduce complaints;
- Providing advisory services to agencies in order to improve the effectiveness of public complaints management systems; and
- Providing advice to governments on ways to improve public administration.

Public sector Ombudsmen are usually appointed by the government or by parliament but with a significant degree of independence. They are charged with representing the interests of the public by investigating and addressing complaints of maladministration or violation of rights. In some countries an Inspector-General, Public Advocate or other official may have duties similar to those of a national Ombudsman, and may also be appointed by the legislature. Below the national level an Ombudsman may be appointed by a state, local or municipal government. Although falling well short of the minimum standards of independence required to meet the definition of an Ombudsman, sometimes unofficial Ombudsmen may be appointed by, or even work for, a corporation such as a utility supplier or a newspaper, for an NGO, or for a professional regulatory body. It is not recommended that any such approach be adopted by ASEAN Member States.

It should be noted that the mere use of the term 'Ombudsman' does not mean that the body meets the reasonably strict international standards for use of that term. In fact the international Ombudsman movement has taken great pains to set out a functional definition of 'Ombudsman' to distinguish it from the very many pale imitations.

Whether appointed by the legislature, the executive, or an organization (or, less frequently, elected by the constituency that he or she serves), the typical duties of an Ombudsman are to investigate complaints and attempt to resolve them, usually through recommendations (binding or not) or mediation.

Ombudsmen also aim to identify systemic issues leading to poor service or breaches of people's rights. At the national level, most Ombudsmen have a wide mandate to deal with the



entire public sector, and sometimes also elements of the private sector (for example, contracted service providers). In some cases, there is a more restricted mandate, for example with particular sectors of society. More recent developments have included the creation of specialised Children's Ombudsman and Information Commissioner Agencies. In some jurisdictions an Ombudsman charged with the handling of concerns about national government is more formally referred to as the 'Parliamentary Commissioner' (e.g. the United Kingdom Parliamentary Commissioner for Administration, and the Western Australian State Ombudsman).

In many countries where the Ombudsman's remit extends beyond dealing with alleged maladministration to promoting and protecting human rights, the Ombudsman is recognised as the national human rights institution. The post of Ombudsman had, by the end of the 20th century, been instituted by many governments and by some intergovernmental organizations such as the European Union.

Most commonly, seeking redress from an Ombudsman is free of charge and in general, an Ombudsman is a state official appointed to provide a check on government activity in the interests of the citizen, and to oversee the investigation of complaints of improper government activity against the citizen.

If the Ombudsman finds a complaint to be substantiated, the problem may be rectified, or an Ombudsman report is published making recommendations for change. Further redress depends on the laws of the country concerned, but this typically involves speedy determination of a decision or sometimes financial compensation. Ombudsmen in most countries do not have the power to initiate legal proceedings or prosecution on the grounds of a complaint.

The major advantage of an Ombudsman is that he or she has extensive investigative powers, examines complaints from outside the offending state institution, thus avoiding the conflicts of interest inherent in self-policing and the perception of bias. However, the Ombudsman system relies heavily on the selection of an appropriate individual for the office, and on the cooperation from officials within the apparatus of the state.

In Australia, at the Federal, State and Territory level, an Ombudsman is an official who is appointed by the government with a significant degree of independence and answerable to Parliament and who is charged with representing the interests of the public by investigating and addressing complaints of maladministration or violation of rights. At the national level, the Commonwealth Ombudsman's (www.Ombudsman.gov.au) office handles complaints, conducts investigations, performs audits and inspections, encourages good administration, and carries out specialist oversight tasks.

Key features of MODEL 4: Public sector Ombudsman

most such schemes cover administrative actions of the government some extend jurisdiction



**Australian
Aid**



to contractors on behalf of governments independence from the government is an important element usually have no powers of enforcement for decisions can however, require production of documents needed for investigations sometimes include anti-corruption and human rights functions goal is to provide redress and also deal with systemic issues of poor administration Examples of public sector ombudsmen

Ombudsman of the Republic of Indonesia www.ombudsman.go.id

The Ombudsman of the Republic of Indonesia is an example of a fully independent redress scheme for dealing with complaints about government administration.



MODEL 5: Small claims courts or tribunals (also known as consumer claims tribunals or civil and administrative tribunals)

Small-claims courts are widely known in many countries, while they are relatively new to ASEAN member states. Some have limited jurisdiction to hear civil cases between private litigants. Courts authorized to hear small claims may also have other judicial functions, and go by different names in different jurisdictions. For example, it may be known as a County or Magistrate's court. These courts can be found in Australia, Brazil, Canada, England, Singapore, Wales, Ireland, Israel, New Zealand, Scotland, South Africa, Hong Kong, and the United States.

The jurisdiction of small-claims courts typically encompasses private disputes that do not involve large amounts of money. The routine collection of small debts forms a large portion of the cases brought to small-claims courts, as well as evictions and other disputes between landlords and tenants, unless the jurisdiction is already covered by a tenancy Board.

A small-claims court generally has a maximum monetary limit to the amount of judgments it can award, often in the thousands of dollars. By suing in a small-claims court, the plaintiff may sometimes be required to waive any right to claim more than the court can award. The plaintiff may or may not be allowed to reduce a claim to fit the requirements of this venue. Schemes vary in procedure and jurisdiction. And in the case of small claims courts in Australia, the UK and New Zealand, claimants might forego part of an outstanding claim in order to bring the matter within the monetary jurisdiction of the small claims court.

The rules of civil procedure, and sometimes of evidence, are typically altered and simplified to make the procedures economical. A usual guiding principle in these courts is that individuals ought to be able to conduct their own cases and represent themselves without a lawyer. Rules are relaxed, but still apply to some degree. In some jurisdictions, corporations must still be represented by a lawyer in small claims court while it is common in Commonwealth countries that lawyers are prohibited from participating in hearings. Expensive court procedures such as interrogatories and depositions are usually not allowed in small claims courts, and practically all matters filed in small claims courts are set for hearings unless they are resolved by preliminary mediation. Under some court rules, should the defendant not show up at a hearing and not have requested postponement, a default judgment may be entered in favour of the plaintiff.

Winning in the small claims court does not automatically ensure payment in recompense of a plaintiff's damages. This may be relatively easy, in the case of a dispute against an insured party, or extremely difficult, in the case of an uncooperative, transient, or indigent defendant. The judgment may be collected through wage garnishment and liens.

Most courts encourage parties with disputes to seek alternative dispute resolution, if possible, before filing suit. For example, the Small Claims Tribunal of Singapore provides guidelines for resolving disputes out of court. Both parties can agree on arbitration by a third party to settle their dispute outside of court. Though small claims court judgments can be appealed, arbitration awards cannot.



The movement to establish small claims courts typically began in the early 1960s, when other forms of complaint resolution such as civil courts were increasingly seen as costly and inefficient and officials felt it desirable to have such a court to allow people to represent themselves without legal counsel.

Key features of Model 5: Small claims tribunals

Designed for swift and inexpensive redress for consumers
Most do not permit legal representation
Usually suggest or require mediation prior to adjudication
Tend to have modest monetary limits for jurisdiction
Employ ADR techniques
Judgements usually enforceable in the courts

Examples of small claims tribunals

Small Claims Tribunal – Singapore www.app.subcourts.gov.sg

Chaired by a District Judge, the Singapore Small Claims Tribunals are part of the subordinate Courts in Singapore.

Established in 1985 under the Small Claims Tribunal Act, the tribunal was introduced to provide a quick and inexpensive forum to the resolution of small claims between consumers and suppliers and has a jurisdiction up to S\$10,000, or if both parties consent S\$20,000. Each year there are around 13,000 hearings while many more potential matters are settled through the provision for prehearing mediation.

The tribunal is currently investigating online dispute resolution schemes such as those operating in the United Kingdom with a view to further streamlining and making more efficient its operations.

Procedures employed at the tribunal encourage initial contact with the supplier and where a hearing proceeds, legal representation is not permitted. The tribunal is supported by community Justice Centres which provide consumer advice. Debt enforcement remains the consumer's obligation and decisions are binding on both parties, subject to appeal to the High Court of Singapore.



MODEL 6: Private organisation to improve consumer complaint systems

Government consumer protection authorities have the primary responsibility for establishing policy for consumer complaint handling and redress schemes. Governments alone however, cannot hope to achieve high levels of compliance in systems over which they have no direct control. Also needed are businesses with a firm senior management commitment to serving customers well and to the swift resolution of consumer complaints when they occur. Internationally, there are a number of organisations of consumer protection officials from businesses and government who band together to improve the standard of complaint systems and compliance with them.

While not at 1st glance a model for either complaint handling or redress schemes, the establishment and support for such a private organisation with the capacity for it improve the management of consumer complaints should be regarded as a legitimate aspirations for AMS.

Key features of Model 6: Private organisation to improve consumer complaint systems

- made up of representatives from businesses and government agencies who deal with consumer complaints
- provide best practice training on consumer support functions (e.g. complaints handling)
- requires senior management support to be successful
- highly effective in those countries in which they operate strong domestic and international networks
- consistent with building a responsible and responsive business sector

Example of private organisation to improve consumer complaints systems *Society of Consumer Affairs Professionals (SOCAP) - Australia* www.socap.org.au SOCAP is a non-government organisation made up of an extensive membership of businesses, government officials, consumer representatives, and academics committed to the goal of improved customer service. SOCAP has been at the forefront of development of complaint handling systems by organisations, as part of an international network. SOCAP Australia prides itself on providing members with research, networking opportunities and other tools to achieve best practice in complaint handling, complaints prevention and consumer affairs.

SOCAP Australia has been at the forefront of promoting corporate complaint handling particularly with the undertaking of its joint survey with American Express on consumer attitudes to complaint handling released in 1995. That survey was a watershed in making the case for companies to establish effective complaint handling systems and, in that sense, has internalised consumer protection within companies. The launch of the Australian Standard on Complaint handling AS 4269 (now replaced by AS ISO 10002) at about the same time has also assisted companies in developing effective complaint handling systems.

Although not strictly a model for complaint handling systems, nonetheless we propose that ASEAN Member States consider the development of an ASEAN consumer affairs



professional association made up of:
individual consumer affairs officials involved in administering consumer protection laws;
members of consumer groups in ASEAN countries;
consumer affairs/customer services professionals in business

The organisation would aim to encourage strong networking and a cooperative approach to complaint handling and redress sharing ideas so that emerging problems arising out of the creation of borderless markets and technological advances can be dealt with effectively. As currently envisaged, this professional organisation would be independent of government and have no government affiliation.

Even though such a body would not be an arm of government, it would be appropriate for governments employing members to support the organisation through various means such as sending officers to an annual conference.

The aims of the organisation could include:

- Creating an ASEAN network of consumer affairs officials;
- Encouraging best practices in consumer policy regulation and administration; Developing ASEAN consumer protection policies;
- Encouraging the development and harmonisation of consumer protection laws; Encouraging agencies to exchange research,
- Opening up training programs to overseas officials and commit themselves to the use of technology for interagency communication;
- Advocating cost effective consumer remedies and encouraging business to adopt consumer responsive, market sensitive, mechanisms for dealing with consumer problems. Communication between members could be via a variety of means including an annual conference, regional conferences, regular newsletters, and the internet.



MODEL 7: Cross-border redress: ASEAN regional facility for cross-border complaints management

Consumer protection is an essential tool in building up a people centred ASEAN economic Community. The ASEAN Economic Blueprint demonstrates that AMS are mindful that consumer interests and welfare have to be taken into account in measures implemented to achieve an integrated economic region.

Consumer protection laws ensure fair competition and the free flow of correct information in the marketplace. At present, Brunei Darussalam, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand and Vietnam have principal consumer protection legislation. The remaining ASEAN Member States are planning or are in the process of drafting their consumer protection policies and laws. Meanwhile, consumer protection elements in these countries are covered by other legislation in order to achieve consumer protection objectives.

Consumer protection is a new area of regional cooperation. As initiated under the ASEAN Economic Community (AEC) Blueprint, the ACCP was established in August 2007. The ACCP, and its three Working Groups, serve as the focal point for the implementation and monitoring of regional arrangements and mechanisms to foster the sustainable development of consumer protection in ASEAN.

In order to steer the implementation of initiatives and commitments under the AEC Blueprint, a strategic approach towards consumer protection has been adopted by the ACCP⁷.

This approach contains policy measures and detailed priority actions with specific timeframes for implementation, including the development of a:

- Notification and information exchange mechanism by 2010;
- Cross border consumer redress mechanism by 2015; and
- Strategic roadmap for capacity building by 2010.

Malaysia, as the Chair of the Working Group on Cross Border Consumer Redress, is in the final stage of developing a comprehensive website on cross border consumer redress for the ASEAN region. This website will serve as the main reference point for matters pertaining to consumer redress, including: Information on basic cross border redress mechanism (handling complaints);



About the consultant:



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⁷ www.aseanconsumer.org

