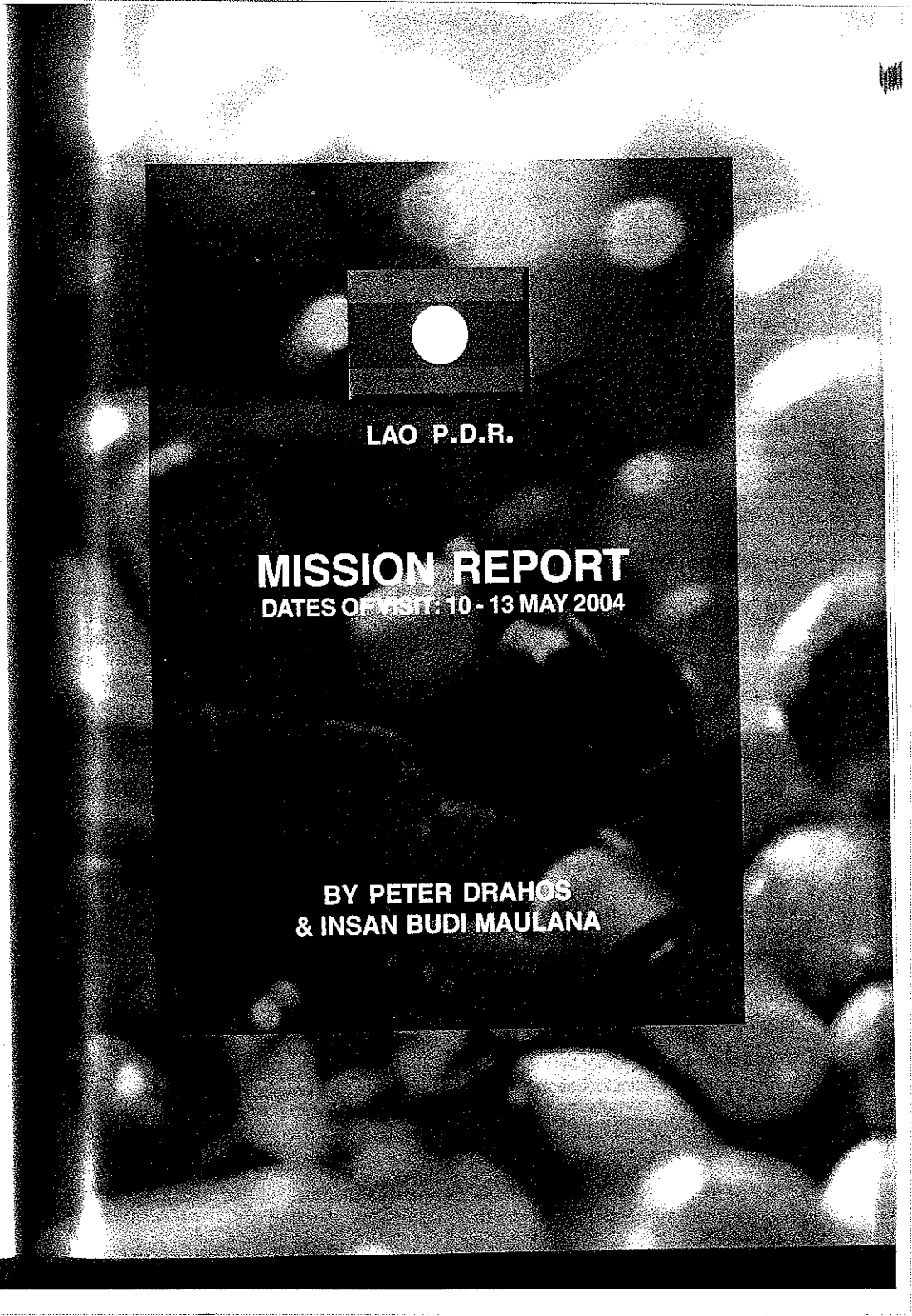
In 1987, the Ministry of Justice enacted a Ministerial Decree concerning well-known trademark protection, even though the Trademark Law No. 21 of 1961 did not provide any provision to support the above decree. However, the cited decree was acknowledged as part of regulation in trademark law, especially for protecting the owner of well-known trademark from counterfeiters. This decree was no longer in force after the previous trademark law was amended by the Trademark Law No. 19 of 1992 which provided well-known trademark protection as an implementation of Article 6 bis of the Paris Convention.

The Indonesian Patent Law provides Compulsory License and Government Use provisions. It is also supported by the Doha Declaration. Therefore, we consider that these laws are our references and sufficient reasons for taking legal action for issuing a "joint decree" if the Government does not enact government regulations on Compulsory License and Government Use as soon as possible. We believe that the "Joint Decree" is the last resort for the Food and Drug Agency and the Ministry of Health, and could be issued anytime by the Food and Drug Agency and the Ministry of Health if they face emergency situation in the field of public health in certain region.



1. CONSULTATIVE PROCESS

Monday, 10 May

We met with Dr Chantone Khamsibouheung, Deputy Director of the National Committee for the Control of AIDS Burea. Dr Bounlay Phommasack, the Chair of the NPCC was too busy to see us. The morning was taken up with planning the workshop. In the afternoon we met with Ms Khamnhong Sichathavong, the Deputy Director in the Department of Intellectual Property, Standardization and Metrology in the Science, Technology and Environment Agency. Ms Sichathavong was able to give us a preliminary briefing on the state of Lao's patent and trade mark law.

We also held a brief meeting in the afternoon with John Biddle and Daodeuane Duangdara from the PriçeWaterhouseCoopers (Lao P.D.R.). They receive few inquiries from their clients about intellectual property issues.

Tuesday, 11 May

The scheduled meeting with Dr Khiene Phansoulivong from the Ministry of Foreign Affairs did not take place. He was overseas. We met with Mr Vilavath Thepphitak from the Ministry of Justice, but this Ministry it transpired is not involved in issues of intellectual property.

We met with Thierry Dumont from MSF and obtained a briefing on the HIV situation in Lao P.D.R. In the afternoon we met with Savengvong Douangsavanh and Sourisak Sounvoravong from the Food and Drug Department.

We also met with Prof Sithat Insisiengmay, the Director of the Center for Laboratory and Epidemiology. He was not familiar with the intellectual property issues, but he was able to give us a picture of the diseases that represent the big killers in Lao P.D.R. These are malaria, diarrhea, acute respiratory infections and various parasitic diseases. Denghi fever is a big problem and TB is making a comeback.

Wednesday 12 May

We met with Ms Songkan Anoulath who works in the Secretariat on WTO Accession in the Ministry of Commerce and Mr Saybanalith Sayanongkhandy, a Trade Officer in the Foreign Trade Department of the Ministry of Commerce. This was a useful meeting in which we gained some understanding of the WTO process in Lao P.D.R. as well as information about the status of the bilateral agreement with the US.

We also met with Mr Makha Chanthala from the Department of Intellectual Property and Mr Nheune Sisavad, the Director General of the Department of Intellectual Property in the afternoon.

Thursday 13 May

The whole day was devoted to a workshop organized by the National Project Coordinator Committee (NPCC). In the morning there were 3 ten-minute presentations covering HIV/AIDs in Lao P.D.R. (from NCCAB), an ARV treatment pilot project (from MSF) and a briefing from the WHO representative.

The rest of the morning was taken up by a presentation from the two consultants. They covered TRIPS, compulsory licensing, parallel importation, Doha Declaration and the para 6 solution, data protection, patenting issues raised by pharmaceuticals and the implications of the bilateral agreement with the US. They emphasized the need for coordinated planning if Lao P.D.R. was to satisfy its needs for medicines on the basis of importation.

In the afternoon there were presentations from the Food and Drug Department and a briefing on the WTO accession process. The workshop ended with a discussion of options and the country report.

2. PHARMACEUTICAL INDUSTRY IN LAO P.D.R.

Unfortunately we were not able to arrange any interviews with local companies engaged in pharmaceutical production in Lao P.D.R. We were told that there were about 6 local companies, three of which were involved in traditional medicine. Data from the Food and Drugs Bureau suggests that Lao P.D.R. is largely dependent upon the importation of medicines. Roche does have a representative in Lao P.D.R.

3. CURRENT STATE OF IPR LAW

In 2002 the Prime Minister passed the Decree on Patent, Petty Patent and Industrial Designs (No. 01/PM, January 17, 2002).[1] This Decree has been amplified by means of the Regulation on the implementation of Decree Patent, Petty Patent and Industrial Designs, No.3222/STEA-PMD, February, 18 2003. There is also a Decree on Trademarks (No. 06/PM, January 18, 1995) and an implementing regulation, the Regulation on Registration of Trademarks, No. 466/STEA-PMO, March 07, 2002.

4. REGISTRATIONS UNDER CURRENT LAW

There are more than 10,000 trademark registrations in Lao P.D.R. A significant number relate to Class 5 (pharmaceutical products). In June 2004 the Science and Technology and Environment Agency, which has a Registry Unit for patents, will begin accepting patent applications. To date no patent has been issued in Lao P.D.R.

Applications will not be examined in Lao P.D.R. There are 4 people in the patent division and only two of those are examiners. In those cases where the patent application reveals that the patent has been examined elsewhere, the Registry will accept the results of that application. Otherwise it will send the application to an examining office such as China or Korea.

5. PATENT DECREE: A PUBLIC HEALTH PERSPECTIVE

The present Patent Decree provides a rudimentary framework for the protection of inventions. The Decree maximizes the rights of patent owners. For example:

> Article 10 of the Decree excludes methods of treatment of the human and animal body, but not diagnostic and surgical methods. Also not excluded are plants, animals and the biological processes for their production.
>
> Article 18 of the Decree gives the patent owner the right of importation and Article 19 only restricts that right in cases where the act took place before the grant of the patent.
>
> Use of the patent without the authorization of the patent holder is severely circumscribed. Article 20 allows government use of the patent or use by a third party in cases of anti-competitive practice. Article 21 allows the Registry

[1] *Decrees are regulatory instruments issued by the Prime Minister's Office. In certain sectors, intellectual property being an example, they may be the only form of regulation. Decrees represent a form of subordinate legislation. They rank below laws which can only be passed by the National Assembly. However their creation does not depend on an enabling law.*

to issue a non-voluntary licence in cases of lack of exploitation or insufficient exploitation in Lao P.D.R. However the patent owner may escape issue of a non-voluntary license if he shows justification for non-exploitation. Given the size of the domestic market in Lao P.D.R. this would probably be possible in most cases.

In short, the current Decree offers patent owners of pharmaceutical products and processes a high degree of protection with few restrictions on their rights. We were told that this Decree was drafted by the IP Office, with the assistance of WIPO. So far this Decree has not had an impact on Lao P.D.R., because Lao P.D.R. has not been a position to accept patent applications.

6. THE DRAFT IP LAW

6.1. The Legislative Process

Lao P.D.R. is in the process of replacing its current decrees in intellectual property with a law that will take the form of an IP Code. According to our discussions with the IP Office, the IP Code has been drafted. We were unable to obtain clarity on the role that WIPO has played in the drafting process, except that it seems that WIPO has offered some assistance. One person in the IP Department told us that WIPO had sent a model patent law to Lao P.D.R. in 1998. (It is also worth noting that in its answers to WTO members Lao P.D.R. has stated that "All intellectual property laws are based on WIPO model laws".)[2] The draft has not been seen by the other people that we interviewed. An internal meeting in the IP Office has taken place concerning the draft. The next stage is consultation with various ministries (Industry, Justice, Commerce, Culture Finance, Customs, Agriculture and Health).

[2] *See WT/ACCC/LAO, p168.*

The draft will also be sent to the provincial administrations for their comments and then finally to the National Assembly. The aim is to have the IP code enacted by 2006.

Our conclusion was that to date the Health Department or the Food and Drug Department have had no opportunity to feed into this process. We raised the issue of the Health Department's participation in process at the workshop and recommended that the Health Department, the Food and Drug Department and the IP Office along with people from the Ministry of Commerce form a core group to track the passage of this legislation.

6.2. Status Politics

It is not possible to be confident that departments outside of the Intellectual Property Department will have a significant influence on the shape of the IP Code. One person we spoke to explained that steering a piece of legislation through the National Assembly was seen to be a very significant achievement. Once a department has draft language there is some reluctance to alter it, to share information about it in case this triggers too much interference. Moreover, in the case of IP there is the complicating factor that this legislation is integral to Lao's plans for WTO accession and the desire of Lao P.D.R. to achieve normal trade relations with the US.

Our discussion with the IPO left us in doubt that the IP Office understood that intellectual property law could have a significant impact on access to medicines. More generally there was an understanding that moving quickly on the implementation of IP law might not necessarily be advantageous for Lao's economy. The real question, however, is to what extent this sensitivity will translate into action.

7. THE US-LAO P.D.R. BILATERAL

In 1997 the US and Lao P.D.R. negotiated and signed a bilateral trade agreement. This agreement never came into operation. On the 18th of September of 2003 the US and Lao P.D.R. signed a revised bilateral. We were not able to obtain a copy of this revised bilateral, but were told that the intellectual property provisions were the same as those negotiated in the 1997 agreement (which is available on the USTR's website). From a public health perspective, the key points about this bilateral are as follow:

Article 18(1) obliges Lao P.D.R. to protect all inventions in any field of technology. Under Article 30 Lao P.D.R. must enact implementing legislation within 27 months of the bilateral agreement coming into force. It follows that if the US Congress approves this agreement Lao P.D.R. will not be able to take advantage of paragraph 7 of the Doha Declaration that allows LDCs to suspend Sections 5 and 7 of Part II of TRIPS so far as pharmaceutical patents are concerned till at least 1 January 2016.

Article 18.2 offers the US the option of protecting pharmaceutical patents in Lao P.D.R. in existence in the US up to 17 years prior to the date of agreement. Article 18.8 gives Lao P.D.R. the option of not having a compulsory licence provision and Article 18.10 gives Lao P.D.R. the option of extending patent terms.

Article 20 requires that undisclosed test data submitted by companies during the process of obtaining market approval for pharmaceutical products be protected for a minimum of five years.

One reason for the US imposing these tough conditions on Lao P.D.R. may be that it is worried about the possibility of generic companies in Viet Nam or Thailand investing in Lao P.D.R. if Lao P.D.R. were to take advantage of the Doha Declaration. The local pharmaceutical manufacturers are state-owned, expect for one which is a joint venture with a Vietnamese firm.

7.1. The Broader Context

Lao P.D.R. has signed this bilateral. It is desperate to achieve normal trade relations with the US (currently the US is the second biggest investor in Lao P.D.R.). A number of the people we interviewed spoke about the importance of achieving 'NTR' with the US. Clearly the decision to commit Lao P.D.R. to achieving NTR has been taken in the upper reaches of the political decision-making process. The potential cost to Lao P.D.R. of departing from the IP standards set out in the bilateral would be that Congress would not approve the agreement. Realistically health officials will have to operate in the parameters set by the bilateral agreement.

8. REGISTERING MEDICAL PRODUCTS: THE FOOD AND DRUG DEPARTMENT (FDD)

The interviews at the FDD turned up the following information. There are about 6 local manufacturers of drugs in Lao P.D.R. Raw materials come mainly from China and India. Some rough calculations on the part of the FDD suggest that about 45% of the registered pharmaceutical medicines that are consumed in Lao P.D.R. are produced locally. However, much of the population relies on traditional medicine. There are about 240 local products registered and 760 registered imported products. The imported products come principally from Thailand (356), France (78), Viet Nam (74) and Malaysia (52).

The FDD does have a regulation that covers drugs that have been donated from overseas to persons within Lao P.D.R. These drugs still require the approval of the FDD, but the system for approval is fast. Potentially the owner of a registered drug could prevent the importation of donor drugs. Thus far, however, there have been no complaints to donor importation from the commercial owners of drugs.

To date the FDD has been involved in one incident concerning intellectual property. The Indian company CIPLA sought to register a product that Roche claimed was the subject of a patent owned by Roche. This patent was not registered in Lao P.D.R. Roche complained to the FDD. Since the patent was nearing expiry, the FDD waited until it had expired and then registered the CIPLA product.

The FDD is aware that intellectual property issues may well complicate their work. The FDD said that to date there had been no communication between them and the IP Office on these matters.

9. OPTIONS FOR LAO P.D.R.

At the workshop that was held we proposed a number of options for consideration by the government officials that attended. These options were based on the assumption that Lao P.D.R. would remain a small market with a limited number of local manufacturers and would therefore have to continue to import medicines. We also assumed that Lao P.D.R. would probably gain WTO accession and that Congress would probably approve the bilateral.

9.1. The Doha Declaration

As a LDC, Lao P.D.R. could, in acceding to the WTO, take advantage of paragraph 7 of the Doha Declaration. However as explained earlier, the bilateral with the US prevents Lao P.D.R. from exercising this right. But this does not prevent Lao P.D.R. from asking the US to waive its obligation under the bilateral with respect to pharmaceutical patents and data protection.

9.2. Compulsory Licensing

The provision on compulsory licensing in the bilateral basically follows Article 31 of TRIPS. Obviously Lao P.D.R. should enact a TRIPS compliant compulsory licensing provision and decline the option (suggested in the bilateral) of not having a compulsory licensing provision. Before Lao P.D.R. enacts the patent law, however Lao P.D.R. could review and get useful information from their neighbour in the ASEAN region how could the other ASEAN Member Countries' experience in enacting and implementing compulsory licensing. Spirit and friendship among the ASEAN Member Countries could assist Lao P.D.R. when they would like enact the patent law which also provide compulsory license and government use provisions. Furthermore, the compulsory licensing provision make it clear that a license could be satisfied by means of importation.

9.3. Parallel Importation

This issue provoked some discussion since the economics of parallel importation is complex with arguments for and against national or international exhaustion. Our basic point was that while price discrimination in favour of developing countries is highly desirable it is not clear that using intellectual property (national exhaustion) is the best way to achieve this. The problem is that the doctrine of national exhaustion places consent to importation in the hands of the IP owner. It might be better for developing countries to negotiate price

reductions with pharmaceutical companies and then use export controls to ensure that the purchased products are not diverted into higher-paying markets. Under this approach there would be no need to follow the risky strategy of placing the power over importation in the hands of the intellectual property owner.

9.4. The Paragraph 6 Solution

We explained the nature of this solution and pointed out that Lao P.D.R. could take advantage of this solution as a WTO member. We also pointed out that it was important that developing countries begin to consider how they might implement this solution as importers. Here we pointed out that a country might recognize the solution in its law. For example, the National Assembly could enact a provision in its law that recognized the principle of the para. 6 solution by providing such as: importing a pharmaceutical product that is protected by patent in Lao P.D.R. and such product has been entered to the market in a state by the eligible patent holder provided that such product is imported in accordance to the prevailing laws and regulations.

Furthermore, Lao P.D.R. could also provide compulsory licenses in accordance with Article 31 of TRIPS by putting in their future patent law such as:

a. Compulsory license application may also be filed at any time after the patent being granted with the reason that the patent has been implemented by patent holder or licensee in the form and in such a manner as damaging public interest. Otherwise, if the Government is of the opinion that a patent in Lao P.D.R. is very important to public interest, however the government directly or by appointing other party may use the concerned patent.

b. The decision to use or act a compulsory license to a patent shall be determined by minister after hearing the considerations among institution who responsible on the concerned field.

c. Additionally, in a decision of the Lao Patent Office regarding the grant of a compulsory license, the following matters shall included:

- compulsory license shall be non-exclusive in nature;
- the reasons for granting the compulsory license;
- evidence, including convincing information or explanation which be the basis for the granting of compulsory license;
- the period of compulsory license;
- royalties to be paid by the compulsory licensee to the patent holder along with the method payment thereof;
- conditions of the expiry of compulsory license and matters which may result in cancellation;
- compulsory license shall be used mainly to provide local market demands; and
- other matters necessary to protect fairly the interests of the related parties.

One of the features of importing pharmaceuticals into a country is that it is a bureaucratically complex process in which it is easy for the importer to be tripped up in some way. By way of example in the Philippines, the government itself ran into a problem relating to the importation of medicines that were unregistered and therefore deemed counterfeit under a rule in its medical registration law. In Lao P.D.R., the MSF representative took us through the 9 steps and approvals that were required to

bring in ARVs, such as: ministry of health, ministry of trade and industry, ministry of finance, customs, etc.

In order to deal with potential problems we suggested that consideration be given to enacting a provision that overrides any rule that would otherwise prevent the successful use of the paragraph 6 solution. The idea behind such a provision is that it would send a signal to a judge to interpret the relevant rule in a way that was consistent with the spirit of the paragraph 6 solution. For example:

> For the purposes of implementing paragraph 6 of the Doha Declaration the use of a compulsory license or notification shall override all other provisions in this law or other laws, decrees, regulations that are inconsistent with the implementation of that compulsory license or notification.

9.5. The Health-IP Working Group

Perhaps the most important priority is the formation of a core group made up of representatives from health, the IP Department, the Ministry of Commerce and the Food and Drug Department. Our impression was that the workshop we held was the first time that there had been an exchange of information on intellectual property and health issues. It is vital that these departments continue to co-operate and co-ordinate throughout Lao's WTO accession process. We also gained the impression that Lao P.D.R. was weak in infrastructures and human resources, therefore they need support from other countries especially from the other ASEAN Member Countries, and improving their coordination inter-departmental and cooperation funded by an outside donor. If we are right in this, then it is likely that the National Project Coordination Committee (NPCC) will have problems in implementing the term of this and other projects.

10. CONCLUSIONS

a. Lao P.D.R. is a small LDC that has very limited manufacturing capacity. In the foreseeable future it will have to meet its medicines requirements through importation.

b. Intellectual property law is undergoing something of a transition in Lao P.D.R. Lao P.D.R. is seeking WTO accession. Normalising trade relations with the US is a matter of priority. Lao P.D.R. has signed a bilateral with the US that limits the capacity of Lao P.D.R. to take advantage of the flexibilities in TRIPS. Congress is yet to ratify this agreement. In particular, the bilateral will make it difficult for Lao P.D.R. to take advantage of the Doha Declaration.

c. As our report makes clear the current Patent Decree offers patent owners of pharmaceutical products and processes a high degree of protection with few restrictions on their rights. We were told that this Decree was drafted by the IP Office, with the assistance of WIPO. So far this Decree has not had an impact on Lao P.D.R., because Lao P.D.R. has not been a position to accept patent applications. As part of the WTO accession process, Lao P.D.R. has drafted new IP legislation with some input from WIPO. The draft legislation was not made available to us, but given that Lao P.D.R. has a bilateral with the US, one can assume that this draft legislation will not be especially suitable for Lao P.D.R. from a public health perspective.

d. Perhaps the most important priority for Lao P.D.R. is the formation of a core group made up of representatives from Health, the IP Department, the Ministry of Commerce and the Food and Drug Department. Information exchange on IP and health issues is not taking place at the moment. Lao P.D.R., as an LDC, would also benefit greatly from a co-ordinated ASEAN approach to IP and health issues.

Regional Workshop on Intellectual Property Laws
Related to Public Health in the ASEAN Region
Bali, Indonesia, 10-12 December 2004

Recommendations

- The major challenge in the ASEAN Region is how to encourage (in the context of the ASEAN structure, objectives, and vision and existing agreements) Member Countries[1] to adopt laws (review and amend existing or legislate one) with corresponding implementing regulations and administrative rules to facilitate the use[2,3] of the TRIPS flexibilities/safeguards and operationalise them to improve access to medicines.

- In this regard, the ASEAN should consider the following (as) priority undertakings in the region:

  1) Facilitate the review and amendment, as necessary, of laws of importing and exporting ASEAN countries for the implementation of Doha Declaration Para 6.

  2) Develop and formalize an ASEAN guidelines on key administrative and implementation areas that would facilitate effective implementation of TRIPS flexibilities i.e. compensation in compulsory licensing, data protection, competition policy, administrative issues around compulsory licensing, and implementation of Doha Declaration Para 6.

  3) Strengthen intra-country coordination among Departments/Ministries involved in IPRS and Public Health – to include private sector i.e. pharmaceutical industries, etc.

  4) Strengthen inter-country coordination:
     - On networking and information sharing.
     - Initiate efforts towards regional purchasing of drugs to reduce price.
     - Monitoring the progress of the implementation of the TRIPS and assisting the member countries facing the difficulties.

  5) Create and maintain permanent (utilizing existing group of ASEAN experts) to provide technical assistance on all aspects of IP and access to medicines[4].

  6) Review the ASEAN Work Program II on HIV/AIDS (AWPII) and develop an AWPIII to include the issues on access to affordable drugs and TRIPS.

Note:
With cooperation from ASEAN dialogue partners.

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[1] Member Countries, together, can advance shared public health objectives.
[2] I.e. Thailand's IP Code has a Bolar provision.
[3] Malaysia and Indonesia have issued government use authorization for HIV/AIDS drugs – crucial steps in helping lower prices and deliver the medicines to people who need them.
[4] ASEAN Member Countries are engaging in trade negotiations, which often involved IP. This ASEAN group of experts can provide technical assistance to member countries to strengthen their capacity and develop strategic positions in the context of trade negotiations with parties outside of the region.

Regional Workshop on Intellectual Property Laws
Related to Public Health in the ASEAN Region
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