PhAMA

'Innovative Medicines for Malaysia'

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MALAYSIAN ASSOCIATION of PHARMACEUTICAL SUPPLIERS

Position Paper on Good & Services Tax (GST) on Medicines

Why All Medicines Should Be Accorded GST 'Zero-Rate' Treatment in Malaysia

INTRODUCTION:

Medicines are essential and critical 'goods' for all Malaysian and the Pharmaceutical Association of Malaysia (PhAMA), the Malaysian Organization of Pharmaceutical Industries (MOPI) and the Malaysian Association of Pharmaceutical Suppliers (MAPS) are steadfast to strongly uphold a system that put patients' healthcare first and policies that ensures the sustainability of a healthcare system which prioritises long term health outcomes for Malaysians.

The industry is very concern on the GST 'Zero-rated' treatment accorded to the National Essential Medicine List (NEML) issued by the Ministry of Health because it represents only a fraction of the total medicines available. The NEML covers only a low number of therapeutic areas and furthermore, most medicines listed in the NEML are older medicines indicated for treatment in those few therapeutic areas. As such, it is important to note that many key life-saving medicines, excluded from the NEML, will be costing more with the inclusion of GST beginning April 2015.

Under the current NEML 4th Edition issued by the Ministry of Health on 29th September 2014, consisting of 320 chemical compounds, has put-up only 500 medicines in specific measured doses or in forms of packaging that will be GST 'zero-rated'.

This means all medicines that are NOT included in the NEML list of the 500 medicines (in its specific doses or in forms of packaging) will be subjected 6% GST effective 1st April 2015. Effectively, as the brands of medicines listed under the NEML only include approximately 2,900 brands, it represents only a quarter (approximately 25%) of the total medicines available. Currently, there are between 11,000 to 12,000 registered medicine brands in Malaysia that has been registered and approved by the Ministry of Health.

WHY NATIONAL ESSENTIAL MEDICINE LIST IS NOT SUITABLE TO BE USED AS GST 'ZERO-RATE' LIST FOR MEDICINES?

As the limitation of the NEML list of medicines has been described to cover only a fraction of the total number of therapeutic areas, the NEML was developed principally to make available a list of essential medicines that satisfy the priority healthcare needs of the population. Essential medicines are selected with due regard to their public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness.

World Health Organization designated that *'Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.'* This is to ensure that basic medicines needs of the population are met within a healthcare system in the country.

As such, the NEML, which was developed based on WHO Essential Medicines and the nation's basic medicines needs for its healthcare system, does not provide a comprehensive medicines list to effectively treat all diseases or illness of the population.

<u>IMPLEMENTING GST ON MEDICINE NOT ALIGNED TO MAKING MEDICINE AFFORDABLE UNDER THE 'MALAYSIAN NATIONAL MEDICINES POLICY' AND WORLD HEALTH ORGANISATION RECOMMENDATION:</u>

Over the years, Malaysian Government has adopted a sound policy in its 'National Medicines Policy' that incorporates a sub-strategy that ensure the *'Supply of medicines shall continue to be exempted from taxes and duties'* in meeting its national strategy of 'Affordability of Medicines', which reads:

> *'Medicines needed for quality health care shall be affordable to all. Cost shall not become a barrier to ensure that medicines are available to the population. Efforts shall be taken to promote healthy competition towards fair, transparent and sustainable cost-effective treatments.'*

This move has been recognized globally and by the World Health Organization as an exemplary nation that has been proactively implementing policies and strategies that addresses the affordability of medicines for the population.

However, with the introduction of GST on medicines, the Government seems to have retracted from its own National Medicines Policy, in which, the Malaysian Cabinet had endorsed since October 2006 to address the affordability of medicines.

At the global front, the World Health Organization has been actively calling on nations who have introduced tax/tariffs on medicine to reduce those tax/tariffs. By eliminating duties and taxes on medicines, it is clear that medicine prices can be reduced and made more affordable. It is therefore, discouraging to note that Malaysia has taken the opposite path to subject medicines to taxation.

<u>INEQUALITY TAX TREATMENT ON MEDICINES:</u>

Medicines are approved, by competent Health Authorities around the world including the Ministry of Health Malaysia, based on its safety, quality and efficacy. The efficacy of each particular medicine provides an indication of the capacity for beneficial change (or therapeutic effect) of a given intervention to the patient for the treatment of a particular disease or illness. As such, as each approved medicine provides an unique therapeutic effect to the patient, it is unjust to accord some medicines the GST 'Zero-rate' and subject other medicines with the GST 'Standard rate' of 6%.

The inequality of tax treatment under the GST is discouraging as vast majority of approved innovative medicines, which provide patients with the most advance therapeutic options to disease treatments, are excluded from the GST 'Zero-rated' list. These medicines include majority of the most advanced innovative medicines that will treat patients with Chronic Diseases such as Diabetes, Hypertension, Cancer, Cardiovascular Diseases; Genetic-disorder illnesses; and against severe infections.

PATIENT HEALTHCARE SPENDING AND CARE IMPACTED:

Under the current taxation regime in Malaysia, medicines are not subjected to any taxes i.e. sales tax or import duties. In this light, GST would be a totally new tax on the entire Pharmaceutical Industry, in which would have a direct impact on the cost of medicines burdening consumers and patients with higher costs at a point when they are most vulnerable. Based on Table 1, it is estimated that with the implementation of GST come 1st April 2015, patients are required to pay an additional RM180 million for their medicines per annum to treat their illnesses. This additional RM180 million in medicine cost is the direct impact of the 6% GST incurred on medicines prices in the private sector.

Whilst, the industry is cognizant of the Government's intention to minimize the increased cost burden faced by Malaysian post GST implementation, the GST 'Zero-rate' accorded to the NEML only covers 23% of the medicine spent for the private sector. This, as such, does not provide much relief to patients in addressing the inflationary cost of living and overall healthcare.

2014 *(estimated sales values based on IMS Data)*	*(RM million)*	**Government Sector** *(RM million)*	**Private Sector** *(RM million)*
Total Annual Pharmaceutical Sales	6,136	2,241	3,895
Total Essential Medicine	1,953	1,055	898
Taxable portion of Medicines	-	nil	2,997
Potential 6% GST revenue	-	nil	**180**

Table 1: Sales value of Pharmaceuticals in Malaysia based on IMS Data, Malaysia

GST ON MEDICINES WILL FURTHER STRAIN GOVERNMENT'S HEALTHCARE BUDGET AND FACILITIES

As GST remained out-of-scope for all Government Healthcare Facilities and the fact that Public Healthcare for Malaysian continue to be substantially subsidised, the industry believes that, with the rise in the healthcare cost in the private sector (as the consequence of the implementation of 6% GST), there will be high possibility of a shift of private sector patients seeking treatment moving to Government Healthcare Facilities.

The shift of patients seeking treatment from private healthcare facilities i.e. Hospitals and Clinics moving to the Government Hospitals, Health Clinics and 1Malaysia Clinics will have an immediate impact on the patient load within the Government healthcare system.

It is estimated that, if patient load were to increase by a mere 5% in the Government Healthcare Sector, an additional medicine cost of RM195 million would be incurred by the Government. This is the direct cost of 5% medicines sales within the Private Sector in Table 1 being transferred to Government Sector.

Besides incurring increased medicine expenditure, Government Healthcare Facilities will be impacted by higher cost of hospitalization expenditure and resources utilization, as well as, limiting healthcare professionals' attention to treating patients. These will lead to further strain to the Government's ability to provide quality healthcare for Malaysians.

With the implementation of GST on Medicine, the Government will inevitably incur higher expenditure in Healthcare, negatively impacting its budget by over RM195 million as oppose to potentially gaining a revenue of approximately RM180 million from GST collection from medicines.

TAX ON MEDICINES DOES NOT DRIVE ECONOMIC DEVELOPMENT

Medicine can contribute importantly to improved human capital, through reductions in pain and suffering and improvement in the quality of life and indeed of life expectancy. Taxing the medicines which restore and maintain peoples' health is thus a tax on economic potential, contrary to both economic development objectives and to public health goals.

In fact, the priority in raising public revenue through taxes on public health should be targeted at the widespread external diseconomies of risky and unhealthy behaviour, such as smoking, alcohol and unhealthy diet, rather that taxing directly on health-promoting medicines.

COMPLEXITY OF IMPLEMENTATION OF GST 'ZERO-RATE' ON NEML IN THE PRIVATE SECTOR

The implementation of GST on medicines will bring about numerous complexities to the sale of medicines at the retail end of the private sector, especially with the introduction of the GST 'Zero-rate' on NEML.

As the application GST 'Zero-rate' is only specifically accorded to NEML medicine brands with reference to the Ministry of Health's registration number i.e. 'MAL' registration number listed by Treasury, all retail pharmacies and pharmacies in private hospitals must match the over 2,900 medicine selling unit individually in their respective billing systems to ensure compliance with the GST implementation.

However, as pharmacies are mandated to itemise the medicines it dispense in the billing to patients the Generic Medicine Name i.e. International Non-proprietary Name (INN), dosage form and strength and NOT the specific Brand name and 'MAL' codes of the medicine, the issue of providing the information required in the GST tax invoice to consumers becomes extremely difficult as medicines listed under the NEML are sold at, not just licensed pharmacist but, in all retail outlets in Malaysia, as the NEML includes 'over-the-counter' medicines and supplements i.e. vitamins.

These inconsistent requirements make the entire implementation of the GST 'zero-rate' for NEML extremely complex and will lead to retail non-compliance. As such, this will inevitably expose pharmacists and the general retail trade to penalties for incorrect returns under Section 88 of the Goods And Services Tax Act 2014 – which carry hefty fines and imprisonment upon conviction.

INDUSTRY's RECOMMENDATION:

The industry continues to stand consistent to its collective recommendations made by the Malaysian Organization of Pharmaceutical Industries (MOPI), Malaysian Association of Pharmaceutical Suppliers (MAPS) and PhAMA to the Ministry of Finance in February 2014, which is to have ALL medicines registered under the Ministry of Health with the 'MAL' product registration code ending with 'A' and 'X' to be accorded the GST 'zero-rate' to ensure minimal impact and to avoid the unintended consequences on Healthcare cost onto patients.

It is unfortunate that, as at today, the inclusion of the 6% GST will be mandatory effective 1st April 2015 and will be charged on medicines (other than medicines listed under the NEML) at the respective supply chain transactional points till it reaches patients. On this note, the industry members will be unable to take responsibility for the additional cost to patients associated with the implementation of GST.

The industry will continue to work with the Government in resolving the GST issue on medicines and we seek the support of the Ministry Of Finance and Royal Malaysian Customs to accord the GST 'Zero-rated on all medicines which are critical for all Malaysians.

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