JOINT MEMORANDUM ON RANG UNDANG UNDANG FARMASI
YB Datuk Seri Dr. S Subramaniam, Menteri Kesihatan Malaysia

18th April 2015

YB Datuk Seri,

We, the undersigned, humbly present the findings and conclusion of the National Forum on RUUF 2015 and Relevant Laws held on 18th April 2015 for the attention, consideration and action of Yang Berhormat.

A: The Forum has noted the following:

1. The present system of dispensing of medicines by doctors/physicians is an accepted practice in Malaysia. This is also true of developed nations like Singapore, Hong Kong (SAR) and, parts of the USA, Australia and UK.
2. Our existing system is a proven integrated system of care that is cost saving, convenient one-stop service, patient-centric and preferred by the public.
3. To date, the opponents of this existing system have not produced any proper studies indicating the ill-effects or negative aspects of this system in Malaysia.
4. On top of this, the proposal for separation of prescription and dispensing (D/S) is not supported by any evidenced-based studies whatsoever.
5. Furthermore, there have also been no proper research studies on the issue of doctors dispensing medicine in relation to developments and innovations in the pharmaceutical industry which has made dispensing non-technical. The practices of dispensing have been made simpler and less technical by the pharmaceutical industry with the production of pre-packed medicine and ready-to-use mixtures – negating the need for apothecary. Dispensing now is thus easily achieved in a physician-based practice.
6. Issues raised in support of D/S such as over treatment (e.g antibiotics) and poly-pharmacy occurs in both systems, regardless of whether doctors dispense or otherwise.
7. The Poison’s Act 1952 & its Regulations permits dispensing by doctors and also by paramedics working in government health centres and private sectors, 1 Malaysia Clinics and estate hospitals.
8. The National Drug Policy (DUNAS) 2012 endorsed the dispensing of medicines by doctors with the definition of dispensing as per the Poison’s Act 1952 and also the relevant provision in the PHFSA 1998 & its Regulations (2006).
9. Countries where dispensing is separate usually have a third party payment system – such as social health insurance. Even in Singapore where there is a health financing system, dispensing by general practitioners continues to be permitted. In Malaysia, private healthcare service is fee-for-service, paid out-of-pocket by patient or by private funds. Thus patient’s preference is paramount. Enforcing D/S is an infringement of the rights of the patient.
10. The consequences of separation will result in:
   - Fragmentation of care
   - Liability issues
   - Increase in cost (Korean example)
Inconvenience to the patients
So, it is very pertinent that the Forum have questioned what is the real reason for this move to change a practice that has been well accepted by the public.

11. Countries tend to lean towards legislation only when issues and problems cannot be solved administratively. Development in our healthcare system is path dependent. The continued use of a product or practice is based on historical preference or use. Any change that threatens the stability of the social system will be resisted unless there is support from the public. This holds true even if newer, more efficient products or practices are available due to the previous commitment made.

B: The Forum would like to bring to YB’s attention, the following concerns:

1. There is neither a policy statement regarding the issue of dispensing by doctors, dental practitioners and veterinary surgeons, nor the negative effects of this arrangement in the DUNAS 2012. However, in the RUUF 2015, by virtue of power bestowed upon the Competent Authority (CA) in the classification of medicines based on profession (“implied D/S” for Group B/C poisons) it will have the effect of effectively taking away or severely curtail the dispensing role of doctors in private sector. This also affects others like the dental practitioners and veterinary surgeons in private facilities. At the same time, it is unclear on its effect on the role of paramedics in government facilities and estate hospitals who will continue to dispense under a new provision to be registered pharmacy assistants. There is thus a fundamental flaw in the proposed Bill.

2. This implied provision of D/S in the RUUF also infringes on the legal right and duty of the medical, dental and veterinary professions. Its inclusion in the RUUF indicates a lack of transparency and good governance as it was done without proper consultation with stakeholders and in a covert manner.

3. The proposed new classification of “Pharmacist Only Medicinal Products” (POMP) is a dangerous move. It will create a monopoly in the supply of many medications, including psychotropic drugs (currently listed in Group B Poisons) used in the medical/dental/veterinary practices. The power of the CA is absolute in this matter and the proposed Evaluation Committee function has been designated merely as the secretariat.

4. We accept that in the event of lacunae in existing laws, new and better regulations will be needed to fill a genuine unmet need, but this should not be driven by parties with vested interest.

5. The RUUF 2015 is the creation of an omnibus pharmacy law which will vest too much power on one individual and one professional group, resulting in autocracy, monopoly and interference with the practice of other professions and professional groups. The Ministry had been duly advised against this in a workshop by the WHO Consultant in Health Legislation to Malaysia in 1989. The reasons stated were:
   - Amalgamation of laws is cumbersome
   - Complex involvement of many parties
   - Contradictory overlapping of legislation
• Ultra vires state laws (may happen)

In the Consultant’s Report, the sensitive issue of prescription and dispensing had been duly highlighted.

6. The RUUF 2015 (as its name suggests) should be confined to revamping of the Registration of Pharmacist Act 1951, to improve the regulation of pharmacists and their practice and should not be allowed to infringe into the regulation of the practice of other professions.

7. Deficits in the other three acts namely Poisons Act 1952, Sales of Drugs Act 1952 and the Medicines (Advertisement and Sales) Act 1956 should be addressed by specific amendments accordingly as per WHO Consultant’s advice.

8. Any enforced withdrawal of dispensing function of doctors, dental practitioners and veterinary surgeons is the first step by the pharmaceutical industry to control the import, supply, access, sales and price of medicines. There is also an avalanche of associated downstream vested business in prescription by pharmacists, walk-in health centres and monopoly of the industry by big business to the detriment of quality patient/animal care.

C: The Conclusion of the Forum is:

The current system of physician-based dispensing has worked well for the patients and the rakyat, There is absolutely no evidence to suggest that it is failing and so “if it ain’t broken, don’t fix it” is prudent and common sense policy.

D: We the undersigned hereby urge YB Datuk Seri:

1. To adhere to the policies and spirit arrived at, in the DUNAS 2012. Dispensed medicine should continue to be defined as per Poisons Act 1952 ie: "dispensed medicine" means a medicine supplied by a registered medical practitioner, registered dentist or veterinary surgeon under and in accordance with section 19 or supplied, for the purpose of the medical, dental or animal treatment, of a particular individual by a licensed pharmacist on the premises specified in his license” and also in accordance to what was discussed in the preparation of the 8th Malaysia Plan for the pharmaceutical industry.

2. To review the controversial provisions of the RUUF2015 and to require proof from evidence-based research, studies and stakeholders’ consultations (not briefings) to safeguard the following:
   i. Availability, quality, safety and efficacy,
   ii. Timely access to affordable medicines,
   iii. Quality use of medicines (QUM),
   iv. A responsible and viable medicines industry that serves the public and not any particular interest group,
   v. Ensure that public preference, and patient’s choice will not be compromised,
vi. Ensure that the move will not inconvenience the public,
vii. Ensure that it will not increase the cost of healthcare and
viii. Ensure transparency and good governance with the provision of appropriate check
and balance provisions in the proposed Bill so that decisions on the above would
not be vested in the hands of only one individual or professional group.

3. To expunge from the proposed RUUF 2015 all and any clauses that directly or indirectly
remove/hinder or diminish the legal duty and rights of doctors, dental practitioners, veterinary
surgeons and all authorised professionals/paramedics as provided for in the Poisons Act 1952 to
dispense Group B and C poisons.

4. To ensure that any proposed changes will not infringe on the rights of the patient and animal
owners to exercise his informed choice of medicines and treatment.

5. To implement checks and balance in the provisions of the RUUF to ensure that all decisions
with regards to classification of medicines should not be vested in the hands of only one
individual or one professional group.

6. In view of the aforesaid, we urge YB to either retract RUUF 2015 or to fully declassify it, in
order to obtain proper consultation and consensus from all stakeholders.

Signed on: This 18th Day of April 2015

Federation of Private Medical Practitioners’ Associations Malaysia
Perak Medical Practitioners’ Society
Private Medical Practitioners’ Association KL/Selangor
Private Medical Practitioners’ Society Kedah/Perlis
Private Medical Practitioners’ Society, Pahang
Private Medical Practitioners’ Society, Penang
Private Medical Practitioners’ Society Johor (Pro term)
Society of Private Medical Practitioners Sarawak

Malaysian Medical Association
Pertubuhan Doktor-Doktor Islam Malaysia
Malaysian Dental Association
Malaysian Veterinary Council
Medical Practitioners’ Coalition Association Malaysia
Sabah Doctors Coalition On Pharmacy Bill
Veterinary Association Malaysia
Malaysian Small Animal Veterinary Association
MDA Eastern Zone

Copy to:

YAB. DATO’ SRI MOHD NAJIB BIN
TUN HAJI ABDUL RAZAK,
PERDANA MENTERI MALAYSIA