INDIAN DRUG MANUFACTURERS' ASSOCIATION

B-4/115 (2nd floor), Safdarjung Enclave, New Delhi 110 029

Phone : 91-11 - 26171367
91-11 - 41650726
Fax : 91-11 - 26171369

E mail : idmadelhi@gmail.com
akmadan.idma@gmail.com
Website : www.idma-assn.org

INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH

5th January 2015

Dr. V. M. Katoch,
Secretary, Dept of Health & Director General, ICMR
INDIAN COUNCIL OF MEDICAL RESEARCH,
P. O. Box No 4911; Ansari Nagar
New Delhi 110 029

Sub: National List of Essential Medicines (NLEM)

Dear Sir,

We thank you for the kind invitation extended to us when we met you on the 22nd December 2014. As suggested by you, we are sending our Note on NLEM.

Essential medicines are those that satisfy the priority healthcare needs of majority of the population. The essential medicines list needs to be country specific addressing the disease burden of the nation and the commonly used medicines at primary, secondary and tertiary healthcare levels. The medicines in National List of Essential Medicines (NLEM) should be available at affordable costs and with assured quality. The medicines used in the various national health programmes, emerging and reemerging infections should be addressed in the list.

The first National List of Essential Medicines of India was prepared and released in 1996. This list was subsequently revised in 2003 (first revision) and then once again in 2011 (second revision). Revision of NLEM 2011 was also based on the two important national reference documents i.e., Indian Pharmacopeia 2010 and National Formulary of India, 4th Edition, 2010. While the former deals with the standards of identity, purity and strength of medicines the later provides the information on rational use of medicines particularly for healthcare professionals.

It is our humble suggestions that if the NLEM is to be meaningful, and serve its primary intent: address the disease burden at all levels of healthcare, then it must be based on including medicines for diseases & disorders which are most common in India. By common it is meant that such medical conditions must be considered whose incidence is more than a specific cut off percentage. This would make the lists of medicines incorporated in NLEM for treatment of diseases & disorders more scientific and have sound basis.

Another suggestion is to incorporate only ONE prototype / medically best-suited drug of a class of drug in the NLEM. For example, in the NLEM 2011, omeprazole CAPSULE and pantoprazole INJECTION feature in NLEM 2011 which is most appropriate since the former is a prototype of proton pump inhibitors whist the latter is currently the best PPI widely advocated for parenteral administration for acute management of gastritis. Now if all dosage forms of pantoprazole were ALSO to be included in the NLEM, it would be meaningless since there is no need to give status of 'essential PPI' to both omeprazole as well as pantoprazole ORAL formulations since only one of these is adequate for the medical professional to manage the patient.

Similar would be the case with *quinolone* antibacterials – incorporate ciprofloxacin or ofloxacin as per the experts' consensus but NOT both! Amongst cephalosporins (third generation, oral) the NLEM, for example, can have cefixime or cefpodoxime but NOT both. For ARB anti-hypertensives, may be losartan but *not additionally* telmisartan or such other. This is should be the guiding principle when any class of drug is considered for inclusion in NLEM *if the medical condition for which it is intended fulfills the criteria of being classified as common disease / disorder of national concern.*

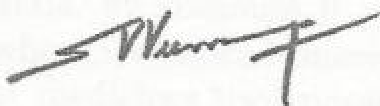
It would be worthwhile mentioning here that the WHO List of Essential Medicines (LEM) of 2011 and 2013 has 359 and 374 drugs only (15 additional medicines). Such basis should be a guiding factor when the NLEM is revised.

Lastly, there must be an effort and effective endeavor to delink the NLEM from the drugs to be incorporated under the DPCO. The list of drugs to bring under the DPCO could have some agents common to NLEM but considering the NLEM as the sole criteria defeats the purpose for which the same has been prepared. This is because the Pharma industry instead of focusing on making available essential drugs for national cause shy away due to non-viability. Essentiality should be the criteria for deciding on NLEM and not Sales or span of control of pricing.

It is suggested that the Government could focus the DPCO on having the 50 most essential drugs which being considered for free supply to all health centers. This would make DPCO symbiotic which Govt. intentions and also indirectly give the NLEM the due focus from the medical professionals, which is its intent and purpose.

Thanking You

Yours sincerely



S V VEERAMANI
President

Dr R K SANGHAVI
Chairman – Medical Subcommittee