Reply

Multidose preparations have definite place especially in the public sector of resource contrained countries like India. They save cost, space, and make economic sense. Extra amount in a given multidose vial is to cover for any losses incurred during preparing a dose form the multidose vial. This cannot be used as an additional dose, unless the addition amount makes one full dose in terms of quantity.

However, this should not be promoted by the manufacturers as an additional benefit to the vaccinator/doctor. The onus does not entirely lay with the company alone, but the practitioner is also equally responsible for indulging in such unethical practices. This sort of malpractice should not be a valid reason to justify discontinuation of preparation and marketing of multi-dose vials. This should at best be viewed as merely a cheap marketing gimmick. If a company is found indulging in such unethical practices to promote sales of their multi-dose preparations, the same must be brought in the knowledge of IAPCOI immediately, so that a befitting letter can be written to the erring company.

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Newer Vaccines – Indian Scenario

1. Is there any criteria laid down by Government of India regarding the introduction of a new vaccine in India? Are newer vaccines as recommended by IAP-COI, approved by WHO?

2. What is the scientific basis for the many recently launched combination vaccines?

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Reply

A vaccine must be licensed first by the appropriate authority for the use in the country. The vaccines/ drugs licensing authority in India, i.e. National Regulatory Authority (NRA) is Drugs Controller General of India (DCGI) which is approved by WHO also. For licensing of a new vaccine, the vaccine manufacturer should conduct the phase I, II, and III trials and must submit their results to NRA for its approval.

There are both central and state licensing authorities. Good clinical practice (GCP) and ethical guidelines (by ICMR) for approval exist. Licensing of products in India is by the Central Licensing Approval Authority (CLAA). The Drug Technology Advisory Board (DATB) approves introduction of vaccines into the immunization services, while all vaccine approval and clinical trials is by the CLAA. The state licensing authority inspects and grants licensing for retail.

Imported products are considered on a case-by-case basis; if trials meet the requirements of the NRA, there is no insistence on clinical trials in the country for registration. The advisory committees that review the information follow published guidelines, directed by a responsible person. External clinical experts may be asked for advice on a case-by-case basis.

After licensing, the vaccine manufacturer should undertake a large post-marketing surveillance (Phase IV) to further ensure the safety of their products. Any complaint regarding the safety, efficacy, etc of the licensed vaccine should be directed to NRA. Once the vaccine is licensed in the country, it can be used both by the private as well as the public sector. All the vaccines recommended by IAP-COI are approved by WHO.

The combining of multiple related or unrelated antigens into a single vaccine is not a new concept. Several combination vaccines have been in use including the trivalent influenza accines, diphtheria, pertussis and tetanus toxoids (DTwP, DTaP, DT, Td, Tdap), the polio vaccines, MMR and meningococcal