

Official Statements, Guidelines and Documents

Position paper of the College on "Classification of vaccines, toxoids, antivenoms and immunoglobulins"

Vaccines and venoms are currently not controlled nor prescription items. The Registration Committee of the Pharmacy and Poisons Board, having reviewed trends elsewhere and the existing controls on vaccines, recommended that all vaccines for human use should be classified as "prescription-only medicines". However, this met with opposition from the pharmacists who suggested that there should be no control over the use of vaccines and that they should be freely available to all as over-the-counter drugs. After discussion, the Poisons Committee decided to put them as pharmacy items, i.e. to be sold at registered pharmacies and doctors' prescription is not required. The list in question consists of vaccines, toxoids, antivenoms and immunoglobulins.

Since many of these items are related to paediatric practice, the College thus appointed an expert panel to review this issue. After careful deliberation of the matter, the College holds the view that such products should be classified as "prescription-only" medicines and not "pharmacy-only" items. A position paper explaining our views and recommendation has been submitted to the Pharmacy and Poisons Board for consideration.

Views on Classification of Vaccines, Toxoids, Antitoxins, Antivenoms and Immunoglobulins for Human Use as "Prescription-only Medicines"

The Hong Kong College of Paediatricians welcomes the review and recommendation by the Registration Committee of the Pharmacy and Poisons Board to classify all vaccines, toxoids, antitoxins, antivenoms and immunoglobulins for human use as "prescription-only medicines". However, we do not support the decision by the Poisons Committee of the Pharmacy and Poisons Board to classify these products into "pharmacy-only" medicines, instead of "prescription-only" medicines.

A close scrutiny of immunization practices in overseas countries revealed that vaccines are regulated as immunobiologics and strictly require prescription by registered doctors for dispensing and administration. The classification of vaccines as "**prescription-only medicines**" is standard in China, Japan, Korea, Australia, New Zealand, Israel, United Kingdom, Germany, Denmark, Sweden, Norway and the United States, to mention but a few. It is universally recognized that

immunization practices, including the sale of vaccines, are liable to potential harm and abuse if not properly regulated and monitored by physicians or health officials. Hence, the decision to classify vaccines as "pharmacy-only" medicines is totally unacceptable and distinctively in contrary to reputable practices elsewhere.

Benefits and risks are associated with the use of all immunobiologics. No vaccine is completely safe or effective. Vaccine components are well recognized to cause allergic or adverse reactions in some recipients. These reactions can be local or systemic, and can include mild to life-threatening anaphylaxis or anaphylactic-like responses. The potential side effects of the commonly used vaccines warrant medical assessment prior to their administration.

Apart from potential adverse events or vaccine injury, "**vaccination**" itself is not synonymous with "**immunization**". Although these two terms are often used interchangeably by lay people, vaccination only denotes the physical act of administering any vaccine or toxoid, whereas immunization is a more inclusive term denoting the process of successfully inducing or providing immunity artificially by administering an immunobiologic in an appropriate manner, i.e. following a strict **medical protocol**.

Successful immunization is never equivalent to the simple act of dispensing and then giving the shot. Likewise, the purchase of vaccines over-the-counter cannot be regarded as equivalent to the prevention of infectious diseases.

The entire process of immunization should be integrated with other preventive services as part of a comprehensive child healthcare programme. There are many issues for consideration in the implementation of a successful and effective immunization programme, including

- the choice of the type of vaccine compatible with the current recommended immunization schedule;
- the selection of the right product offering the best efficacy and least side-effects;
- the proper storage and handling in accordance with manufacturers' specifications;
- an accurate and individualized assessment of the indications, precautions and contraindications on the use of vaccine;
- an opportunity for informing the vaccinees or their parents and guardians of the risks and benefits of a particular vaccine and answering all questions and concerns that may arise;
- the proper advice on the observation of adverse events and the likely time frame for their occurrence;
- the mechanism for monitoring and managing immediate reactions after proper

- administration;
- the recommendation of alternative solution and course of action for specific groups of recipients or special circumstances;
- the proper documentation and maintenance of immunization records;
- the advice on subsequent immunization schedule and the manner of follow-up; and finally
- the application of an organized practice-based programme with a tracking system capable of producing efficient reminders and recalls to avoid fragmentation of preventive care.

Thus, it is imperative that fully qualified healthcare providers be involved in overseeing the immunization process to assure strict adherence to the specifications as outlined above. The registered doctor is best qualified to fulfill the requirement for individualized pre-immunization screening and assessment preceding the prescription of a vaccine. Furthermore, establishment of the patient-doctor relationship will provide an opportunity for doctors to identify children for the required vaccines and administer appropriate immunizations in a timely fashion. The need for a doctor's prescription would provide the recipient of the chance for early intervention and avoid unnecessary or inappropriate immunizations.

Determination of the indications and contraindications of immunizations is often not straightforward. Healthcare providers, other than the medical professionals, often inappropriately consider certain conditions or circumstances to be true contraindications or precautions, thus needlessly deferring the required immunizations. They may blindly follow a schedule for general use which at times should be modified to suit individual needs. Alternatively, they may recommend vaccines which the recipients clearly do not need (e.g. already immune) or the administration of which can even be harmful (e.g. use of live vaccines to immunocompromised patients or healthy individuals with immunocompromised household contacts). Doctors are thus the best persons to ascertain an individual's immune status and recommend an appropriate schedule.

The sale of immunobiologics as "pharmacy-only" medicines is also subjected to misuse and abuse, such as self-injection of immunoglobulin by otherwise healthy individuals as a tonic for "boosting" immunity.

Inappropriate immunization by non-qualified personnel adds to vaccine failures, further undermining the effectiveness of infectious disease prevention. The most desirable immunization practice is one in which the decision to immunize is based on physician recommendation and performed under medical supervision, with medical follow-up if necessary.

As responsible healthcare professionals, we must uphold the standard practice of **"DO NO HARM"**. Our recommendation is straight forward and in line with worldwide trend and practices, i.e. *vaccines and other immunobiologics must be classified as "prescription-only medicines" to safeguard the health of our community*"

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