Australian Government

Department of Health and Ageing

Australian Technical Advisory Group on Immunisation

Elizabeth Hart
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Dear Ms Hart

I refer to your email of 11 March 2013 regarding measles, mumps and rubella (MMR) vaccine. I apologise for the delay in responding.

The Australian Technical Advisory Group on Immunisation (ATAGI) provides technical advice to the Minister for Health on the medical administration of vaccine available in Australia. ATAGI is also responsible for producing the Australian Immunisation Handbook and making recommendations regarding the scheduling of vaccines on the National Immunisation Program Schedule.

ATAGI's recommendations are based on the best scientific evidence available from both published and unpublished literature. Where empiric evidence is unavailable, recommendations are formulated using the best available expert opinion relevant to the Australian context.

With respect to your comments regarding the recommendation that individuals receive two doses of measles-containing vaccine, it is important to note that while measles immunity induced by 1-dose vaccination provides long-term immunity in most recipients, approximately 5% of recipients fail to develop immunity after 1 dose. Following a second vaccine dose, approximately 99% of recipients will be immune to measles.

High vaccination coverage is vital to maintain measles elimination, with rates for each new birth cohort of > 95% for a single dose and >90% required for 2 doses. A recent increase in imported measles cases in Australia and subsequent outbreaks highlights the importance of continued high 2-dose vaccine coverage.

Consideration must also be given to the immunogenicity conferred by other components of the vaccine – while clinical trials of mumps-containing vaccine also indicate 95% seroconversion after a single dose of MMR vaccine, outbreak investigations and post-marketing studies have reported on dose vaccine effectiveness to be between 60 and 90%. Protection against mumps is greater in two-dose vaccine recipients, who have seroconversion rates up to 100%.

To enable a vaccine to be marketed in Australia, a sponsor is required to submit an application accompanied by scientific and clinical data to support the quality, safety and efficacy of the vaccine for its intended use. The Therapeutic Goods Administration (TGA) undertakes thorough evaluation of the data submitted by vaccine sponsors and will usually seek the advice of an independent expert advisory committee, the Advisory Committee on Prescription Medicines, before making a decision to approve or reject a new vaccine.

To further ensure the continued safety of the Australian public, the TGA also undertakes post-market monitoring of approved therapeutic goods, including vaccines. The primary focus of the post-marketing vaccine safety monitoring is to capture and investigate safety issues related to marketed vaccines and to ensure vaccine sponsors have appropriate mechanisms in place to identify safety concerns that may arise once a vaccine is marketed in Australia.

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In addition, for vaccines supplied in Australia, every batch is reviewed by TGA prior to release. This review may include laboratory testing, which provides independent assurance of the statements of the manufacturer. For imported products, the release of these batches by the TGA-equivalent Government organisation in the country of origin, which may include testing, provides additional assurance which is considered in the Australian release process. Further information on the regulation of vaccines is available on the TGA website at: http://www.tga.gov.au/safety/alerts-medicine-seasonal-flu-101008.htm#regulation

Immunisation service providers and health professionals in all states and territories are mandated to report a concern regarding a patient who has experienced an adverse event following vaccination. These are provided directly to the TGA or via state/territory health departments. The information provided to the TGA is used to confirm the safety profile of vaccines demonstrated during clinical trials and ensure the safety profile outside controlled conditions, ie in the field, is as expected.

With respect to the new combination measles, mumps, rubella and varicella (MMRV) vaccine, assessment of this vaccine included clinical studies where MMRV vaccine was administered as the second dose of MMR-containing vaccine (after a first dose of MMR vaccine) in children 15 months to 6 years of age.

Information about the safety of vaccines, including the potential for adverse events following vaccination is available on the Immunise Australia Website at: www.immunise.health.gov.au

ATAGI does not recommend serological testing for immunity to measles, mumps, rubella or varicella before or after routine administration of the 2-dose childhood schedule of these vaccines. However, serological testing for measles can be performed in cases where a history of natural immunity or 2 doses of vaccine administration is uncertain for adults and adolescents. Serology is also indicated in special situations such as pre-pregnancy planning.

While vaccination in Australia is strongly encouraged, it is not compulsory. This means that an individual is able to choose whether or not to immunise themselves or their children against a disease on the basis of personal, philosophical, religious or medical beliefs.

While eligibility for the Family Tax Benefit Part A supplement is now linked to a child immunisation status, provisions exist to enable parents to apply for an exemption to these requirements. Further information about immunisation exemptions is available on the Department of Human Services website at: www.humanservices.gov.au

I trust this information is of assistance.

Yours sincerely

Professor Terry Nolan
Chair, ATAGI
27 May 2013