



Why is my child being offered an “off label” vaccine?

A guide for parents

Like all medicines, vaccines have to have a license or authorisation before they can be given to members of the public. Sometimes, however, healthcare provider may tell you that the vaccine that your child is being offered is ‘off-label’. This leaflet explains what this term means and why it’s important that you understand why the vaccine is still recommended.

How does a vaccine get a licence?

All vaccines used in the UK are authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA). Vaccines will only be submitted to the MHRA after they have been trialed by the manufacturers on their target audience (which can be children or adults) and fully tested to see that they are:

- **acceptably safe** – they do not cause other illnesses or make existing illnesses worse and that any side effects produced are generally tolerable – like pain at the injection site or headaches, nausea and rashes
- **effective** – they offer good protection against the disease they are designed to protect against, and
- **manufactured** to a high standard of quality.

This exhaustive testing process – from the first batch of a vaccine being made in a laboratory to its use in the general population – can take more than 10 years.

Only when this information has been reviewed and accepted by the MHRA or EMA, will the vaccine be given a license and be produced and promoted by the manufacturers for general use. Amongst other things, the license specifies who can receive the vaccine, how many doses are required, what side effects may occur and how the vaccine should be handled and stored.



What does it mean for a vaccine to have a license?

It means that the vaccine has been approved for use in certain patients to protect against certain diseases. So a vaccine can be licensed for use in babies, but not older children, or in adults but not children.

There are many possible scenarios in which a vaccine could be used but the trials done before licensing can't study every possibility.

This means that vaccines are invariably given licences that restrict their use in certain ways – it would not be ethical to delay granting a license whilst every possible scenario was studied because in the meanwhile many people would be denied the benefits of immediate protection. When a vaccine is used in a way other than that described in its license, this is called 'off label'.

Why is my child being offered an off-label vaccine? Is it safe and effective?

As has been stated, all vaccines currently used in the UK are licensed, so being described as off-label doesn't mean a vaccine is unlicensed. It just means that it's being used in people for whom the license wasn't originally given – in teenagers instead of adults, for example – or in a slightly different way – for example at a different schedule.

The vaccine is still safe and effective. So these 'off-label' vaccines aren't unlicensed – they're licensed for different patients, conditions or schedules.

Who decides if my child should have an off-label vaccine?

Sometimes, after the MHRA has licensed a vaccine, circumstances change – such as an outbreak of a disease in a different age group – or new information comes to light – for example from independent studies on the length of protection from the vaccine. Decisions may need to be made to use the vaccine outside the strict terms of the license, so that as many people at risk can be vaccinated as quickly as possible.

These decisions are normally taken by the Joint Committee on Vaccination and Immunisation (JCVI) which is made up of many independent experts on all aspects of vaccination in the UK. Usually, they involve recommending that a vaccine that is licensed for one purpose or in one group of patients can be used off-label for another purpose or in another group of patients. Once these decisions are made, GPs and other suitably qualified professionals can offer the vaccine 'off-label'.



Can you give me some examples of where vaccines have been used off-label successfully?

MenB vaccine for infants

In 2015, the meningococcal B (MenB) vaccine was introduced into the UK routine childhood schedule to protect babies against meningococcal B disease which is a major cause of meningitis and blood poisoning. The vaccine is licensed as a 3 dose schedule in babies aged 2 months of age, followed by a booster dose at around one year of age.

However, after expert consideration of all the available evidence, the JCVI recommended that 2 doses at 2 and 4 months, with a booster at 12 months, would protect babies just as well as the licensed schedule. So one of the infant doses was dropped even though the license stated that 4 doses should be given. The schedule recommended by the JCVI is working well as around 250 cases of MenB disease were prevented in the first 3 years of the programme.

HPV vaccine for teenagers

A further example is the HPV vaccine which is given to 12- to 13-year-olds at school to protect them against cancers caused by infection with the Human Papillomavirus (HPV). Based on studies in young adult women, the vaccine was originally given as a 3 dose schedule over a 6 month period. Subsequent studies, however, suggested that in younger individuals, 2 doses given 6 months apart, were as effective as the 3 dose course in young adults.

Because of this evidence that younger individuals respond very well to vaccines and, in order to make the schedule work within the school terms, JCVI recommended that the second dose can be given between 6 months and 2 years after the first, even though giving the doses more than 6 months apart is considered 'off-label'.

Whooping cough vaccine for pregnant women

Another example is the use of a whooping cough vaccine in pregnant women. In the years running up to 2012, there was an increase in the number of whooping cough cases, with many cases occurring in babies too young to be vaccinated. An urgent decision on how best to prevent deaths and serious illness in young babies was required.

In 2012, JCVI agreed that the best way to protect these very young babies was by vaccinating pregnant women with pertussis (whooping cough) vaccine. This would ensure that babies were born with high levels of antibody from their mothers.

2 vaccines were suitable for boosting whooping cough protection in adults but neither had been tested on pregnant women because such women are excluded from most clinical trials.

However, data on the extensive use of similar vaccines suggested that the vaccine would be safe and effective.

The vaccine was therefore offered 'off-label' to pregnant women and around 70% of mothers now receive the vaccine. The vaccine quickly resulted in a significant fall in the number of whooping cough cases and deaths in babies, and detailed studies have shown that the vaccine is safe for the mother and the pregnancy.

It can be seen, therefore, that 'off-label' can have several meanings.

In these examples, and in all other cases, the decision to use vaccines 'off-label' has been taken in the best interests of those recommended the vaccine and the wider public.

What if I don't want my child to have an off-label vaccine?

'Off-label' may be the only way that the vaccine is available on the NHS and refusal may delay your child becoming protected.

JCVI and your healthcare professional will only recommend that your child has an off-label vaccine for a very good reason – so you should bear this in mind when making your decision.

Where can I get more information?

The Medicines and Healthcare products Regulatory Agency (MHRA) has comprehensive information on this topic at:

www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities

