# Innovation: MHRA's speedy approval of high dose flu vaccine demonstrates flexibilities in national applications

## The issue

Influenza vaccines are known to be less effective in the over-65 age group, since the immune system is less vigorous in older people. Advancements have been made in flu vaccine technology which can enhance the vaccines' protective effect in this age range, compared to those which are known to be effective in the under-65s.

The Department of Health and Social Care and the Joint Committee on Vaccination and Immunisation (JCVI) in the UK expressed a desire that such vaccines be made available to the UK public as soon as possible, and preferably in time for the 2019 to 2020 flu season.

## How the MHRA helped

An application for a flu vaccine by Sanofi Pasteur, which is designed to be effective in the over-65 age group, was approved by the MHRA in a very short timescale and became available for the 2019 to 2020 flu season. This was achieved despite additional complexities to the supply chain because of changing legislation. This is one of three newer vaccines that JCVI recommends for use in the over-65 age group.

Most flu vaccines are made to a specific formula. Due to the desire to enhance its effect in older people, this formula has been optimised for the over-65 age group, resulting in a product which is more effective in older people than the standard flu vaccine.

This meant that the changes needed to be thoroughly evaluated to ensure they did not change the safety profile of this vaccine compared to the well-established safety profile of other, more conventional flu vaccines.

Whilst developing the product and preparing the regulatory submission, Sanofi Pasteur sought advice on scientific and regulatory aspects which were specific to its product.

Because this was a purely national application, managed by the MHRA without involvement of other regulatory bodies, it was possible to be extremely flexible regarding the timeframe and co-operation between the various groups to achieve the desired outcome.

Hugo Fry, Sanofi UK Country Chair & General Manager of Sanofi Pasteur said:

"It's exciting to see the MHRA increasingly thinking creatively on how to be a fast, balanced, light-touch yet scientifically robust regulator in order to

create and capitalise on opportunities for faster product approvals. The accelerated approval of our TIV High Dose influenza vaccine is a great example of this and clearly demonstrates their agility, flexibility and willingness to collaborate with industry".

## Outcomes

Through close collaboration working with the MHRA, Sanofi Pasteur was granted a UK licence for Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose (TIV High Dose).

The process took just seven months, compared with a standard review time of 12 months for national approvals. The UK is the only European country where TIV High Dose is approved.

The MHRA's Licensing Director, Dr Siu Ping Lam, said:

"This is further evidence of the MHRA's ability to deliver in an agile and flexible way, and enhances our standing as a world-leading, innovative regulator, to enable time-critical preventative medicines to be available earlier and timely for the protection of our patients".

## How we can help you

Contact the Innovation Office to find out more about accessing expert knowledge, guidance and experience that could help you develop ideas and save time and money.

Use the hashtag #HealthInnovation to find out more.