



GOVERNMENT OF GIBRALTAR

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GIBRALTAR GOVERNMENT SWINE FLU VACCINATION PROGRAMME

Introduction

Early on in the Swine Flu outbreak, and while the vaccine was still being developed the Gibraltar Government Civil Contingency Committee made a strategic decision to procure 60,000 doses of the swine flu vaccine, enough for the whole Gibraltar population.

The product purchased by the Gibraltar Government is the one manufactured by GlaxoSmithKline ("GSK") under the brand name Pandemrix®. This vaccine is now fully licensed by both the European Union and the European Medicines Agency, making it ready for use.

The manufacturing process has now begun and Gibraltar has received its first batch of the vaccine. Under the terms of the Government's agreements with GSK, the vaccine will arrive in Gibraltar in periodic batches from now until the end of March 2010. Accordingly, and as previously indicated, the Government is now making a statement about its vaccination programme.

Vaccination is voluntary

The decision whether or not to receive the vaccine is up to each individual, and parents will of course decide in respect of their minor children. This Statement by the Government is intended to assist people in making an informed decision. The medical information and assessments in this Statement have been contributed by the Government's Director of Public Health drawing on the best available knowledge and advice from the European Union, the United Kingdom, World Health Organisation and other international medical sources.

Is there a need for the vaccine ?

It has been asked whether, given the "mild" nature of the disease, the vaccine is really necessary. In addition, experience until now is that its incidence in Gibraltar has been low, there have been no serious cases and there is no evidence as yet of any person to person transmission to any significant extent in Gibraltar.

Against these considerations must be set the following:

- Gibraltar's experience so far is untypical of other countries. The Government's containment policy has been extremely successful in Gibraltar, very unlike all other

countries. This has been possible because considerable resources have been invested locally to back up the containment policy and because the general public in Gibraltar have responded and co operated with the Medical advice given. The continuation of these circumstances cannot be taken for granted and they could therefore change.

- the disease has to date been mild in all known cases in Gibraltar and in the great majority of cases in other countries, but in a small minority of cases in other countries it has been unexpectedly aggressive. The problem is that as yet there is no test to identify those people who might be seriously affected if they get swine flu.
- pandemics have historically been far worse in the second wave and it is now believed that the second wave has begun in the UK, USA and other countries. The number of swine flu cases in late October in other countries is already exceeding the averages for regular winter flu. The number of cases in which the effects have been more serious have increased in the UK very recently. Such statistics are closely monitored by the Government and advice will be updated accordingly.
- the virus is still changing and could still become a more dangerous one.
- It is thought that many elderly people who appear to be naturally immune to swine flu today are so because they might have had flu of a similar type 30 to 40 years ago and have therefore developed immunity. Therefore, younger people who neither get the swine flu now nor receive the vaccine will not enjoy similar immunity in the future.

There is some evidence of a drop in the number of people coming forward to receive the seasonal flu vaccine. This may be because they are waiting for this new vaccine. But it must be understood that the swine flu vaccine does not effective protection against seasonal flu, and vice versa.

Is the Vaccine Safe?

Another important matter that people will wish to take into consideration is safety. Is the vaccine safe? Ordinarily, population vaccination programmes are only delivered when the safety profile of a vaccine has been fully investigated, in animal models, human trials and multi-centre programmes.

The swine flu vaccines (all brands) have received limited human trialling and few population trials. Therefore, this vaccine programme is being considered for implementation in unusual circumstances, but this is a situation faced by all countries at the present moment. Nevertheless, similar vaccination programmes are proceeding in most first world countries.

The GSK Pandemrix[®] vaccine is modelled on the already existing avian flu and Human flu vaccines. In effect therefore, only the Swine Flu virus particles are new, while other components of the vaccine are already familiar and in safe and tested use. It is important to emphasise that this vaccine does not contain live virus and therefore cannot itself cause influenza.

The Government is advised and believes that the vaccine is safe, on the following grounds:

1. It is based on killed virus particles and therefore cannot itself cause the disease.
2. Apart from the swine flu virus particles, the ingredients of the vaccine are based on components that have already been safely used in the seasonal flu and avian flu vaccines in large populations.
3. Safety trials involving up to 5000 people using the vaccine (without the swine flu particles) have been in progress for several months and are the principal basis for the licensing of the full vaccine by the EMEA (European Medicines Agency).
4. The EMEA license granted to the vaccine lays down specific monitoring that has to be carried out around the world after the vaccine begins to be used , namely the

manufacturer must perform a study on 9,000 patients across all age groups, recruited at the start of the vaccination campaign and must provide every month a comprehensive Safety Update Report on any adverse reports notified by patients and doctors.

5. There is no indication that this vaccine may cause any untoward medical complications.
6. Co-administration with another vaccine: Trials show that there is no problem in taking this vaccine with other vaccines.

In summary, while the scientific world is not presently in a position to make an unequivocal assertion of safety, every trial carried out so far appears to have shown a good level of safety within the parameters of that trial. More evidence of safety would be ideal, but by the time that it becomes available it may be too late to prevent the disease and its possibly serious complication and consequences.

Some countries have apparently elected to administer the vaccine to pregnant women without the adjuvant (ie a less concentrated version of the vaccine), but there is no evidence that such a vaccine would be fully effective. Accordingly, after careful consideration the UK has decided to use the full vaccine in pregnant women as the real risks of severe disease far outweigh any imagined risks. The Gibraltar Government intends to adopt the same practice.

Accordingly, on the basis of the best scientific and medical evidence and advice available today, the Government believes the vaccine to be safe.

Who can receive the vaccine and what is the recommended dosage?

All persons over the age of 6 months can receive the Pandemrix vaccine, except for those persons (a) with clinical allergy to the constituents of the vaccine (which will be established by the nurse prior to administering the vaccine) and (b) who have encountered allergic reactions to influenza vaccines in the past.

Following advice to the UK Government from the Joint Council on Vaccination and Immunisation, the following vaccination schedule is recommended:

- Persons below the age of 10 require two half-doses of the vaccine spaced apart by three or more weeks; and
- Persons aged over 10 years require only one full dose of vaccine.
- Persons with problems in their immune systems require two doses.

The Government constantly monitors latest emerging international advice on the question of effective dosage.

What is the Government's vaccination programme strategy, and why?

In developing a Programme strategy, a crucial factor which affects how countries design their Programme is whether the quantity of vaccine they acquire is enough to cover their whole population. If there is not going to be enough vaccine for everyone, then the foremost debate is about who is to be left out. This leads to profound ethical, political, economic and several other implications, of which the clinical consideration is but one. Prioritisation is then vital.

Where countries are able to secure vaccine for all their population, as the Gibraltar Government has done, the picture is markedly more relaxed. The purpose of prioritisation is then only to determine the reasonableness of the delay between the first and the last recipient. If the whole population can be vaccinated rapidly, then the issue of prioritisation becomes much less important. This is the case in Gibraltar, where the Government's purchase of vaccine for the whole population, and the resources that will be deployed to deliver the vaccination programme means that prioritisation is very much less important.

Nevertheless, it is still good practice to reach first those groups that are at exceptionally high risk of contracting the disease (clinical grounds) or of spreading it to the vulnerable population (health protection grounds). Thus, the Gibraltar Government's Immunisation Strategy and programme is a combination of whole and quick population coverage together with priority given to groups by clinical risk.

Priority groups

The following ordering of groups is the prioritisation reflected in the Gibraltar immunisation Programme:

Priority	Groups
1	Health Care and Essential Workers
2	Pregnant women
3	High Risk Groups
4	Children of School age (5-19 yrs)
5	Children aged 6mths - 5yrs
6	Young adults aged 20-29yrs
7	Adults aged 30-64 years
8	Older persons

Health Care and Essential Workers are prioritised for a variety of reasons, including:

- personal risk: they are the most exposed persons in society, encountering high concentrations of infective persons as well as high frequencies of contact
- public health: they have the capacity to spread the disease, not just when infected but also by carriage
- clinical risk: they are regularly exposed to numbers of vulnerable persons, who cannot be vaccinated
- capacity: their loss from the workforce due to illness has a double impact because of the consequences to the continued delivery of essential public services

Accordingly the Health Care and Essential Workers category at this stage includes all employees of the Gibraltar Health Authority, RGP police officers, fire fighters, electricity and water workers.

Pregnant women: There is now a consensus that pregnant women should be vaccinated as a priority. This is not because they have any greater risk of catching the disease, but because its impact on them is sometimes more severe. Any influenza can be more severe in pregnant women, but swine flu appears to be no more so. The risk of severity is greatest in the third trimester.

High Risk groups : The following groups of persons have been identified as being at above average risk of contracting the disease or suffering a more severe form with complications. The definitions are clinical and in case of doubt, should be decided by a doctor, but the vast majority of persons with chronic disease are generally

familiar with their illness. Within this group, persons under 65 years may be at higher risk and are thus accorded a higher relative priority.

High risk groups	For example
Chronic respiratory disease	<ul style="list-style-type: none"> • Severe Asthma • A chest complaint or breathing difficulties, including bronchitis and emphysema
Chronic heart disease	<ul style="list-style-type: none"> • A heart problem
Chronic renal disease	<ul style="list-style-type: none"> • A kidney disease
Chronic liver disease	<ul style="list-style-type: none"> • A liver disease
Chronic neurological disease	<ul style="list-style-type: none"> • A neurological condition, e.g. multiple sclerosis (MS) or cerebral palsy • A stroke or a transient ischaemic attack (TIA)
Diabetes	<ul style="list-style-type: none"> • Diabetes
Immune disorder	<ul style="list-style-type: none"> • Lowered immunity due to disease or treatment (such as steroid medication or cancer treatment) • A problem with the spleen (e.g. sickle cell disease), • Removal of the spleen.

Others : Infants under 6 months are not recommended to receive the vaccine and it will therefore not be offered to them. The highest attack rates for swine flu have been in the pre-school and 5-19 age groups. Adults aged 20-29 years represent the next group in terms of disease attack rates globally. After this age the risk drops progressively. The oldest age groups (65+) have the lowest risk and therefore the lowest priority in receiving pandemic swine flu vaccine - this is in sharp contrast to the high levels of risk and morbidity they experience from seasonal human influenza, making them the top priority group for that vaccine.

When will vaccination actually start, and how will I know where and when I should go?

Vaccination will start on the 16th November and will be administered and delivered at a specially prepared facility in the ex – NAAFI depot at Waterport (next to Customs House).

A home delivered leaflet and media advertisements will inform you, by reference to your prioritisation category and other personal details of the time and date when you should attend at the Immunisation Centre if you wish to be vaccinated.

Parents with more than one child will, if they so wish, be able to bring all of their children to be vaccinated at the same time, on any of the dates appointed for any of their children. This will avoid the need for multiple visits. The parents themselves however will need to come separately on the different dates in accordance with their individual prioritisation categories.