

Declaration of Free and Informed Consent

to be signed by all persons over 18 capable of freely giving their consent

This form is to be filled in by candidates for vaccination prior to the administration of the **Pandemrix** (GSK) vaccine against influenza A/H1N1.
Two copies are to be signed, one to be retained by the doctor.

As the conditions under which Pandemrix (GSK) is being launched depend on the real-time collection of data regarding the vaccine's safety and effectiveness during the course of the 2009-2010 A/H1N1 influenza pandemic, it follows that this vaccination programme corresponds *de facto* to a research project on human subjects, requiring therefore each participant's free and informed consent.

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Consequently, I the undersigned certify that:

- I have been made aware of the **risks incurred** by this vaccination against the A/H1N1 virus, knowing that a large-scale study will take place during this current vaccination campaign 2009-2010, in order to establish whether the product presents, at its current stage of development, any side-effects in either the short, medium and/or long term;
- I have been informed that my doctor is under obligation to consign **personal data** relating to me (last name, first name, national register number together with the reference of the manufacturing batch of the product injected) to a centralised electronic data-bank called "e-health" under the auspices of the Belgian government; my doctor will likewise be required to supply additional data relating to the safety of the product over the coming years;
- I have been informed that the manufacturer of the vaccine has obtained **legal immunity** in the event of the appearance of side-effects, and that I will therefore have no means of appeal against the company GSK; I have also been informed that in the event of unspecified damages relating to this vaccine being brought against me, the law protects the administrator of the vaccine against any legal or administrative proceedings.

I have taken good account of the pros and cons of this vaccine, including the conditions under which it is being launched which constitute a counter-indication for vaccination with Pandemrix, a product containing squalene. I have fully understood the possible consequences, the risks and the benefits associated with this vaccine, and I agree to be vaccinated in full knowledge of these facts.

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Signature of patient

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Signature of the responsible M.D.

Date:

Place: