FOURTH PERSON DIES IN SWEDEN FROM SWINE FLU JAB: NO END IN SIGHT

News - Highlighted News

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The news that a fourth person has died after taking the "swine flu" jab in Sweden is focussing attention on the failure of the Swedish Medical Products Agency (MPA) to halt the "swine flu" programme even as reports of serious side effects flood in.

The Swedish drug regulator has allowed the "swine flu" jab campaign to be launched even though there is no safety or efficacy data on the vaccine. GlaxoSmithKline's Pandemrix with mercury and squalene has been given approval under new and lax European Union regulations formulated by the European Medicines Agency, (EMEA) for a "pandemic emergency" that do not require safety or efficacy data.

The EMEA derives three-quarters of its funding from pharmaceutical companies.

The "swine flu" jab has been authorised for use only on condition that governments and companies implement "post-authorisation" studies to check it is safe and effective. However, the MPA in Sweden appears to have limited its role in collecting data on death and damage to spontaneous reports from doctors and patients.

In addition, there appears to be no accurate data available on how many people have been given the "swine flu" jab in Sweden.

The MPA has said it has no such data and the SMI has said that its system for collecting data on vaccines is flawed.

EU's own guidelines on "post authorisation" studies highlight the need to collect accurate data on "vaccine exposure".

http://www.emea.europa.eu/pdfs/human/pandemicinfluenza/35938109en.pdf

"The basis for the assessment of an association between A/H1N1 influenza vaccines and severe adverse events should be Observed-to-Expected analyses. For this purpose, data will be needed on vaccine exposure and the expected number of cases. It is therefore crucial that background incidence rates on AESIs are collected as early as possible, before the vaccine is introduced on the market. Vaccine manufacturers

should actively liaise with public health and regulatory authorities in countries where its vaccine(s) will be used in order to explore the availability of such data. Use of large electronic databases could be used if available. If data are not available, they could be extrapolated from other countries. Background incidence rates should be provided with any specific signal evaluation. "

MPA officials have given their view in the media that the deaths of Swedes directly after the "jab" were not linked to the "swine flu" vaccine but due to underlying medical conditions. Just how independent and effective will their investigation be if they are making this statement before conducting any inquiry or without adequate data?

Gunilla Sjölin-Forsberg from the MPA said in an email that the MPA was fulfilling all its requirements under the EMEA recommendations. She also revealed that there will be no study on the "swine flu" jab in Sweden. The only study on Pamdemrix will be carried out in the UK.

However, the question that needs to be to asked is whether there are personnel and financial links between the MPA officials and pharmaceutical companies. Have private or financial interests among MPA officials motivated them to allowed a drug classified as a bioweapon to come onto the market and to collude with pharmaceutical companies to evade responsibility for the harm this drug does to others by bending the regulations.

As a result of the gross negligence at a minimum of the MPA officials, millions of Swedes, especially children and maternity cases, are being exposed to death and damage from this jab.

These MPA officials must be held accountable.

This is Sjolin-Forsberg's email:

"MPA has implemented all parts of the EMEA recommendations for agencies concerning the pharmacovigilance plan. Spontaneous reporting is encouraged and a standardized reporting form published on our website. Cases of adverse events of special interest are specifically searched for and we also receive reports directly from consumers.

To further clarify: the MPA has implemented all parts of the EMEA recommendations for agencies concerning the pharmacovigilance plan. Spontaneous reporting is encouraged and a standardized reporting form published on our website. Cases of

adverse events of special interest are specifically searched for and we also receive reports directly from consumers. As for post-authorisation studies the EMEA request is that the MAH (marketing authorization holder) puts in place a prospective cohort study in at least one European Member state. This will be done in UK and for more information I suggest you contact the MHRA. These described actions summarizes the recommendations from EMEA.

In addition to this, a Swedish registry study is being implemented covering a significant portion of vaccinated people.

http://www.emea.europa.eu/pdfs/human/pandemicinfluenza/35938109en.pdf

CHMP Recommendations for the Pharmacovigilance Plan as part of the Risk Management Plan to be submitted with the Marketing Authorisation Application for a Pandemic Influenza Vaccine

Adopted by CHMP in November 2006

Revision 1.0 adopted by CHMP on 25 June 2009

Revision 1.1 adopted by CHMP on 24 September 2009

1. INTRODUCTION

The CHMP Guideline on dossier structure and content for pandemic influenza vaccine marketing authorisation application (CPMP/VEG/4717/03) specifies that, as part of the post-approval commitments, Marketing Authorisation Holders (MAHs) should have protocols in place at the time of authorisation of the mock-up vaccine to ensure that immunogenicity, effectiveness and safety of the final pandemic vaccine are adequately documented during use in the field (i.e. during the pandemic), since there will be only limited immunogenicity and safety data and no efficacy data at the time of licensing.

iv) The basis for the assessment of an association between A/H1N1 influenza vaccines and severe adverse events should be Observed-to-Expected analyses. For this purpose, data will be needed on vaccine exposure and the expected number of cases. It is therefore crucial that background incidence rates on AESIs are collected as early as possible, before the vaccine is introduced on the market. Vaccine manufacturers should actively liaise with public health and regulatory authorities in countries where its vaccine(s) will be used in order to explore the availability of such data. Use of large electronic databases could be used if available. If data are not available, they

could be extrapolated from other countries. Background incidence rates should be provided with any specific signal evaluation.

4.5. Post-Authorisation Safety Study

Very limited knowledge on safety will be available from A/H1N1 influenza vaccines before use. Additional pharmacovigilance activities for the vaccines used during pandemic are therefore needed to assess safety. Given differences in the vaccination policy between member states in terms of type of vaccine used, target population prioritised for vaccination, setting of vaccination and surveillance systems already in place, it is considered that a single method cannot be proposed.

A minimum requirement is that each MAH puts in place a prospective cohort study for each vaccine, for which specifications are described below. The design of the prospective cohort study of exposed subjects and of other additional pharmacovigilance activities should be presented in the risk management plan.