

# IMMUNISATION AWARENESS CAMPAIGN 2001

## EPI(SA) & AVENTIS PASTEUR PARTNERSHIP



# EPI(SA) FACT SHEET IMMUNISATION IS SAFE



## 1. INTRODUCTION

When the World Health Organisation (WHO) began its immunisation programmes in 1974, less than 5% of the world's children were immunised. Twenty-six years later, it increased to 75% of children. Millions upon millions of children's lives have been saved and the burden of vaccine-preventable diseases has been considerably reduced. While many diseases have disappeared from the public eye, paradoxically the debate about safety of immunisation is still very much alive.

Lack of public confidence in immunisation programmes has resulted in a concomitant drop in vaccine coverage levels (in some countries by 25% by the mid 1990s).

Global communications, increasing consumer awareness, greater scientific knowledge and more open debate about health matters have all contributed to greater public scrutiny of healthcare issues and more scepticism about the intrinsic value of immunisation.

## 2. DISEASE BURDEN VERSUS RISK

Emphasis on Adverse Events Following Immunisation (AEFI) rather than lives saved and a lighter disease burden have contributed to fanning emotional responses without necessarily balancing the facts. The number of groups that actively seek information and knowledge about the risks and benefits of medicinal products has burgeoned as one public health crisis leads to another.

Vaccine-associated adverse events have drawn public attention and criticism. It appears that the public focus has shifted from acute risk of deadly diseases to longer-term concerns about quality, safety and equity.

The risks of disease and complications resulting from withholding immunisation, should be communicated to parents and communities. Health care workers need also be reminded of the great benefits of immunisations.

No child should be denied immunisation without serious thought as to the consequences, both for the child and the community.

## 3. VACCINE SAFETY AND QUALITY

Over the years, the WHO and its partners have deployed continuous efforts and resources to improve safety of immunisation. New delivery technologies including the auto-disable syringe (which does not allow re-use of the syringe) have been introduced.

Each country has a National Control Authority (NCA) that assesses the quality of vaccines, whether locally produced or imported, and ultimately authorises or rejects their public use. WHO considers a vaccine to be of good quality provided that an independent NCA has controlled the vaccine in accordance with the requirements defined by the WHO. There should be no remaining problems related to the vaccine quality. All vaccines used within the national immunisation programmes should, as a minimum, meet the WHO quality requirements.

## 4. EPI(SA) VACCINES

Vaccines are tested for safety and efficacy in clinical trials and then in mass trials before being registered and made available in South Africa. All vaccines are evaluated by the NCA in South Africa, namely the Medicines Control Council (MCC) to ensure efficacy, quality and safety prior to registration and approval for marketing.

All vaccines used in the EPI(SA) Programme are manufactured according to strict safety guidelines. These vaccines meet World Health Organisation (WHO) standards of quality, safety and efficacy.

Vaccine batches intended for use in the country are tested at the National Control Laboratory (NCL) in Bloemfontein, prior to release. After introduction into the immunisation schedule there is ongoing surveillance of safety and efficacy through trials and post marketing surveillance by the MCC, EPI Programme and Vaccine Suppliers.

The EPI Programme in South Africa introduced a active surveillance system for Adverse Events Following Immunisation (AEFIs), 1995, in all the provinces.

The purpose of the EPI system for AEFIs is to

- improve the quality of immunisation services;
- to increase public acceptance of immunisation; and
- to ensure that any such event is handled in a way that is acceptable to the patient, the parents and the vaccinators.

AEFIs may range from the common redness and soreness at the injection site, to rare, serious conditions such as the potential risk of a severe allergic reaction in 1:100 000 to 1:1 000 000 doses of measles vaccine. AEFIs may also be:

1. Programme – related
2. Vaccine – induced
3. Coincidental
4. Unknown

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## 5. IMMUNISATION SAFETY PROJECT

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In order to keep pace with new science, new technology and public concerns, WHO has created the Immunisation Safety Priority Project, which will focus on:

- ensuring vaccine safety from clinical trials through the point of use
- research and development of safer and simpler vaccine delivery systems
- expanded access to safe and effective delivery technologies and their disposal
- identification and management of risks related to immunisation

In the heated debates that immunisation provokes, it is important to consider the risk/benefit ration and to put AEFIs into perspective. Vaccines are known to be among the safest and most cost effective health interventions.

Reports linking immunisation to an AEFI that are later proven to be a coincidence and unjustified continue to occur. These unfounded reports which have not been fully investigated, have a potential to do a lot of harm to the image of the programme. Arguments against immunisation derive their power from unjustified scares and misconceptions. It is important to remember that the **RISK** of the **DISEASE** is far higher than the **RISK** of giving the **VACCINE**.

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## 6. ROLES AND RESPONSIBILITIES

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It is the joint responsibility of governments, regulatory authorities, the pharmaceutical industry, health care providers and communities to report any untoward events related to immunisation. There is a need to respond with facts and empathy to the concerns of parents and communities.

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## 7. CHALLENGES

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The approach requires a combination of a caring attitude towards parents and infants, up to date knowledge and a positive attitude towards immunisation. There is no need to be defensive about immunisation. It is a known fact that the *vaccine-preventable diseases are severe and immunisation prevents them!*

New challenges in the field of vaccine development and vaccine safety lie ahead. More complex vaccines are being developed and tested that may require increasingly sophisticated screening and monitoring systems. At the same time, these vaccines should reduce delivery schedules, simplify delivery technologies and offer good price/benefit ratios in overall public health terms.

Other than improved housing, sanitation and clean water supply, vaccines have had unparalleled success in reducing the incidence of death and disease. Paradoxically, this success may result in an undue emphasis on vaccine side effects.

Risk communication offers a set of tools for explaining risks in proportion to benefits. When we refer to the safety of any drug, we are talking about relative safety, that is safety relative to the alternative of not using vaccines.

The EPI Programme will continue to work with all partners to improve all aspects of immunisation, such as vaccine safety, training and work with the industry to improve delivery technologies.

It is by improving the quality of health care and keeping in mind the benefits that preventive health measures such as immunisation can offer, that tomorrow's world will be a healthier place.

The Department of Health will continue to promote the benefits of immunisation to all South Africans, all health care workers and the health care providers.

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