

GLOBAL VACCINE SAFETY BLUEPRINT 2.0 BACKGROUND RESEARCH

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Organization

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Acronyms

AE: adverse event

AEFI: adverse event following immunization

AFRO: Regional Office for Africa

CIOMS: Council for International Organizations of Medical Sciences

EMRO: Regional Office for the Eastern Mediterranean

EPI: Expanded Programme on Immunization

EURO: Regional Office for Europe

GACVS: Global Advisory Committee on Vaccine Safety

GVAP: Global Vaccine Action Plan

GVSII: Global Vaccine Safety Initiative

HPV: human papillomavirus

ICH: International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

ITAGs: Immunization Technical Advisory Groups

LMICs: low and middle-income countries

NGOs: non-governmental organizations

NRAs: National Regulatory Authorities

PAHO: Pan American Health Organization/ Regional Office for the Americas

PBRER: Periodic Benefit-Risk Evaluation Report

PMS: post marketing surveillance

PPI: public-private information

PV: pharmacovigilance

SDGs: Sustainable Development Goals

SEARO: Regional Office for South East Asia

UHC: universal health coverage

WHO: World Health Organization

WPRO: Regional Office for the Western Pacific

Executive Summary

In 2012, the Global Vaccine Action Plan (GVAP) for 2011-2020 was endorsed by 194 Member States at the World Health Assembly, serving as a framework to guide immunization efforts through 2020. The Global Vaccine Safety Blueprint was created alongside GVAP to set objectives for building the capacity of vaccine safety in low and middle-income countries (LMICs) to better detect, report, and analyse adverse events. As the GVAP comes to an end in 2020, the World Health Organization (WHO) is working with stakeholders to develop a new framework, Immunization Agenda 2030, in the context of the Sustainable Development Goals (SDGs) and the changing immunization landscape. This serves as an opportune time to also evaluate the impact and strategic direction of the Global Vaccine Safety Blueprint and its implementation mechanism, the Global Vaccine Safety Initiative (GVSII). For that purpose, background research was conducted in 2019 to obtain input from vaccine safety experts, national regulatory officials, immunization program managers, global agencies, industry, non-governmental organizations (NGOs), and others.

This report serves to synthesize the findings of that research and provide recommendations for the drafting of the Global Vaccine Safety Blueprint 2.0. Information collected from more than 200 stakeholders that work in vaccine safety indicated that many of the challenges discovered during the creation of the first Global Vaccine Safety Blueprint in 2011 remain. Additionally, new challenges

While capacity has improved, **many of the same challenges from Blueprint 1.0 persist**. These challenges include: low detection and reporting; investigation of safety signals; epidemiologic methods for active surveillance; lack of clarity in roles and responsibilities at the country level for National Regulatory Authorities (NRAs), Expanded Programmes on Immunization (EPIs) and industry; and a need for more information-sharing between countries.

With reference to the next Blueprint, respondents highlighted the **necessity of addressing vaccine hesitancy** and of understanding the distinction between real and perceived vaccine safety concerns among the general public, noting that these challenges are becoming a consistent part of the vaccine landscape. Better vaccine safety data will assist with addressing this emerging challenge, but many respondents also noted the importance of using social networks as a tool to share scientific and accurate vaccine safety information to proactively combat the rise of misinformation. Stakeholders noted that it is critical to **empower consumers with scientific information and the risks and benefits** of vaccines to build vaccine confidence.

As the world faces an increasing number of ongoing conflicts, disease outbreaks and other emergencies, stakeholders would like to see these emerging challenges for vaccine safety

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