INTERVIEW GUIDE FOR THE NATIONAL REGULATORY AUTHORITY

GENERAL INFORMATION

Date of interview _____/_____/_____ Interviewer's name: _____

Country: _____ Person interviewed: _____

Position: _____ Length of time in the position: _____

EVALUATION CRITERIA	YES	NO	NA	COMMENTS - OBSERVATIONS
1. What are the six basic regulatory functions in relation to the EPI?				
1.1 Vaccine registry				
1.2 Access to laboratory tests and/or batch releases				
1.3 Authorization and monitoring of clinical trials				
1.4 Periodic inspections of manufacturers and distributors				
1.5 Oversight of promotion and advertising				
1.6 Post-marketing surveillance (ESAVI)				
2. What is the batch release process in the country?	Specify how long the process takes.			
3. What steps are taken for quality control of vaccines?	Specify.			
4. How do the national regulatory authority and the EPI coordinate?	Specify.			
5. What role do you play in safe vaccination (investigation of ESAVI)?	Specify.			

DRAFT

CONCLUSIONS AND RECOMMENDATIONS