Regulatory Considerations for Licensure

Dr. Jo White
EU regulatory framework for vaccines

- Marketing authorization granted after an evaluation of the risk-benefit ratio of the vaccine based on a dossier which presents the data collected during the product development and clinical trials.

- Compliance with good practices in the areas of manufacturing and clinical or laboratory testing is verified by regulatory agencies prior to approval of a marketing authorization.

- During vaccine development, the manufacturer must evaluate the needs of the pediatric population, and if appropriate, propose a pediatric DCP to the European Medicines Agency (EMA)—and then comply with the plan.
Regulatory Guidelines

- Always begin discussions early about your development plan to regulatory by submitting short outlines.
- Request face-to-face meetings early on.
- Try to get written confirmation from your group and the regulators as to what was agreed upon at the meeting.
- Regulators seem to have final say in claims contained in SPC. Usually conservative.
- Always notify any SAEs ASAP with adequate follow-up and open communications with medical monitor and medical personnel at the regulatory agency.
Registration or licensing

- Centralized Procedure
- Mutual recognition Procedure (MRP)
- National Procedures (for products licensed in one single country)
- Quality assessment—each batch of vaccines must still be assessed for quality before release for use. This is done by both the manufacturer and an official European control laboratory
- Pharmacovigilance—all vaccines and pharmaceuticals are monitored after release onto the market for adverse events. A summary of events is supplied to the registration board to assess if changes need to be made to the SPC
- Additional stability studies, further confirmatory safety or efficacy trials in populations that have not been studied yet.
Position Papers

- Publications
- Company Web site
- Presentations at meetings
- Journal and/or TV and radio ads