Vaccine activities at the Netherlands Vaccine Institute

Workshop India-Netherlands
Trivandrum, India

21-23 January 2010

Loek van Alphen

NVI is 5 years old, but has over 100 years of vaccine experience

Elements of our Mission:

- Assuring a reliable vaccine supply to protect the Netherlands' population against existing or emerging infectious diseases, caused either by nature or man

- Striving to increase access to relevant vaccine technology thereby contributing to internationally defined public health goals

Core activities

- **Core values**:
  - Over 100 years vaccinology know-how
  - Independent (State-agency under Ministry of Health)
  - Research, development, production and distribution of vaccines for vaccination programs in the public domain
  - Advice on and design of vaccination programs
  - Excellent infrastructure, including cGMP compliant plants

- **Expectation**:
  - Be an attractive partner for international organisations, public health institutes and industry in vaccinology areas, including:
    - **research and development**
    - **pilot-scale manufacturing**
    - **procurement**
    - **advisory services**

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Netherlands

VUmc + NVI nederlands vaccin instituut

Sweden

SMITTSKYDDSINSTITUTET
Swedish Institute for Infectious Disease Control

Norway

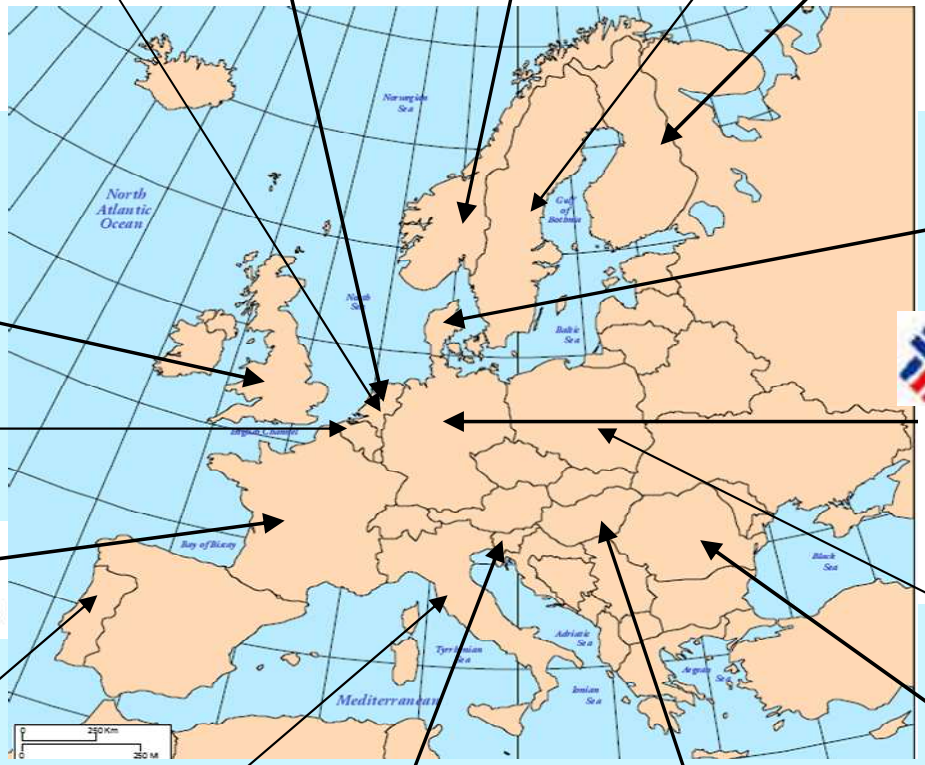
folkehelseinstituttet

KTL

Finland

United Kingdom

Health Protection Agency



STATENS SERUM INSTITUT

Denmark

Paul-Ehrlich-Institut
Bundesamt für Sera und Impfstoffe

ROBERT KOCH INSTITUT

Germany

Pasteur

Belgium

IPBS +

INSTITUT PASTEUR

France

NIPH +PZH

Poland

INSTITUTUL IC CANTACUZINO

Romenia

IBET+IBMC

Portugal

NOVARTIS VACCINES

Italy

IVZ RS

Slovenia

OEK

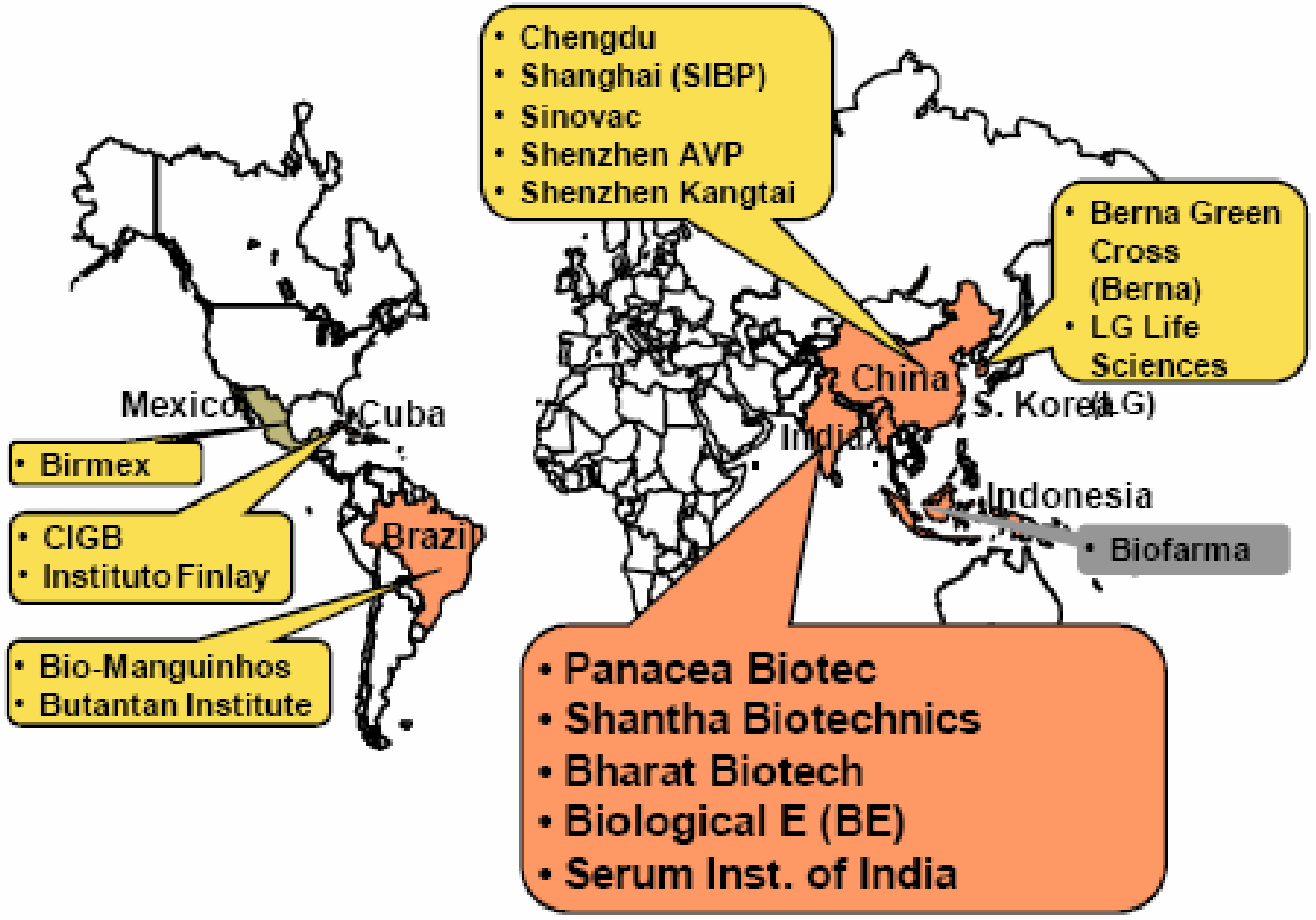
Hungary

DCVMN & NVI

- Several *PSVI* meetings organised by WHO
- Pre-establishment meeting Bilthoven, Netherlands, 2000 (see photo)
- Installation meeting in Bandung, Indonesia, 2001
- NVI is (with IVI) a DCVMN Resource Institute from its beginning

Ref: Poeloengan et al.; Vaccine 2002 May 15;20(16): pg 2150

Emerging manufacturers playing an increasing role in vaccine supply
M Kaddar DCVMN meeting Cape Town



Historic contributions to human vaccine development

- Many vaccine production technologies including Polio vaccine production technology were developed by NVI (now used world wide), and Hib vaccine was developed for emerging countries.
- Technology transfer for pediatric vaccine production to (former) developing countries like India, Indonesia and China. One-third of all vaccine worldwide is based on NVI technology and / or strain material.

Based on NVI technology the Serum Institute of India (Puna) is now producing close to 1 billion doses pediatric vaccines per year, thus serving 20% of all children worldwide!

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NEWS

Serum Institute of India obtains first ever Indian license for its Hib vaccine developed through technology transfer from the Netherlands Vaccine Institute

May 3, 2007

Serum Institute of India Ltd (SII Ltd) has developed a vaccine against Hib (Haemophilus influenzae type b) and obtained a license from the Indian Government for its indigenous production. The pilot process technology know-how came from the Netherlands Vaccine Institute (NVI). This is the first time that through intensive joint development and technology transfer a developing country vaccine manufacturer successfully develops a Hib vaccine and obtains a license for it.

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NVI and Polio eradication

- WHO is in the final phase of global polio eradication.
- The life oral polio vaccine (OPV) has to be phased out or replaced by inactivated polio vaccine (IPV) for safety reasons
- This may result in a great global demand for IPV
- NVI is one of the few routine producers of inactivated poliovaccine, and supplies bulk material for Indian companies
- After polio eradication wildtype viruses should be replaced by attenuated Salk- or Sabin-virus in the IPV production process for safety reasons.
- WHO has asked NVI to develop a Sabin-IPV vaccine process for technology transfer

Polio (IPV) production worldwide

IPV Market	World needs	NVI production
Now	80 million doses	10 million
Coming years and after eradication (Sabin-IPV)	> 200 million doses	> 40 million; Client wishes: > 100 million

What is in it for others

- Indian manufacturers:
  - Best ones are in the private sector
  - Are very competitive
  - Aim for the global markets,
  - have much difficulty in dealing with intellectual property (IP)
  - Have difficulty in finding access to technical know-how (this was NVI's major contribution in the Hib-project)

- With the help of MoEZ, NVI as innovative public institition and possibly also other Biotech players in the Netherlands can support India by using the NVI matchmaking and networking experience

- The vaccine demand for upcoming markets including India offers excellent selling and technology transfer opportunities

Research & Development Programs of NVI

The NVI R&D program includes major leads for:

- Meningococcal B – outer membrane vesicle vaccine.
- RSV - deletion mutant: life attenuated vaccine.
- Pneumococcal (pneumolysoid) protein subunit vaccine.
- Tuberculosis (immunosuppressive molecules deleted BCG mutants). Cooperation with free University of Amsterdam.
- ImSaVac adjuvant (superior to MPL) (Cooperation with ImSaVac BV).
- Needle-free delivery of vaccines: collaborations with Bioneedles (biodegradable implants) and Pharmajet (jet injector).
- Platform technologies on antigen identification, vaccine safety and lyophilization

All leads above are part of a 20 subjects patent portfolio.

NVI Collaboration in international public need perspective

I NVI in international perspective

II Technology transfer: Hib conjugate vaccine

III Polio vaccine production for eradicating the disease

III Research program offering possibilities for inventive collaboration