

# Vaccines and Biologics Work group Close out report

Rome HUG March 2006 Steve Hess, Bruce Cohen

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We are different from Pharma but not very different Very small packaging size – variety of delivery systems Cold chain requirements Unique end user requirements Inability to readily accept RFID (stability, if ever) 2D can work

We must <u>**not**</u> have a specific set of requirements for vaccines or biological products

There may be a business case to launch with vaccines and biological products

Our focus remains Patient Safety and medication error





# Wide variety of delivery systems

**Very small containers** Vials **Ampoules** Syringes (with and without diluents) **Unit dose pipettes Peel off label requirements Vs Permanent pressure** sensitive label Multi dose Vs Single does **Dry powder inhalers** Self inject devices





Time out of refrigeration issues

Record keeping requirements initiate the electronic record keeping process recording of lot and expiry and site of injection etc

Inability of the patient to self authenticate Primary and secondary packaging often separated

Variety of dispensing models





# **Needs and Next Steps**

Full Supply chain participation Hospitals or Physicians. National Registry and organization (CIRA/AIRA etc) Health authorities

Map the supply chain

Understand the user requirements Council of Nurses, WHO, ECHO

Understand the potential business benefits Standards can facilitate reimbursement

Need debate on; Logic on the product or as a pointer to the database





- Regularly schedule telecons
- 2 per month
- Revise our time schedule
- Focus on user requirements
- Focus on true requirements
- Solicit active supply chain participation
- Encourage debate





Thank you

To our meeting sponsors and organizers:

GS1 Italy

Pfizer

Ulrike







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Needs

Need a global sustainable system for all products not just vaccines and biological products
Why do we need a specific workgroup for vaccines/bio
Need to standardize the data for all products – no exceptions

Chicken and egg situation – no one reads the bar codes, why should we invest now?

AIRA participation

Auto an identification system

Smart tags for temperature monitoring system

Radioactive out of scope

