

TRACEABILITY

Traceability Law # 11903 14/01/09

Regulation (RDC) # 59 24/11/09

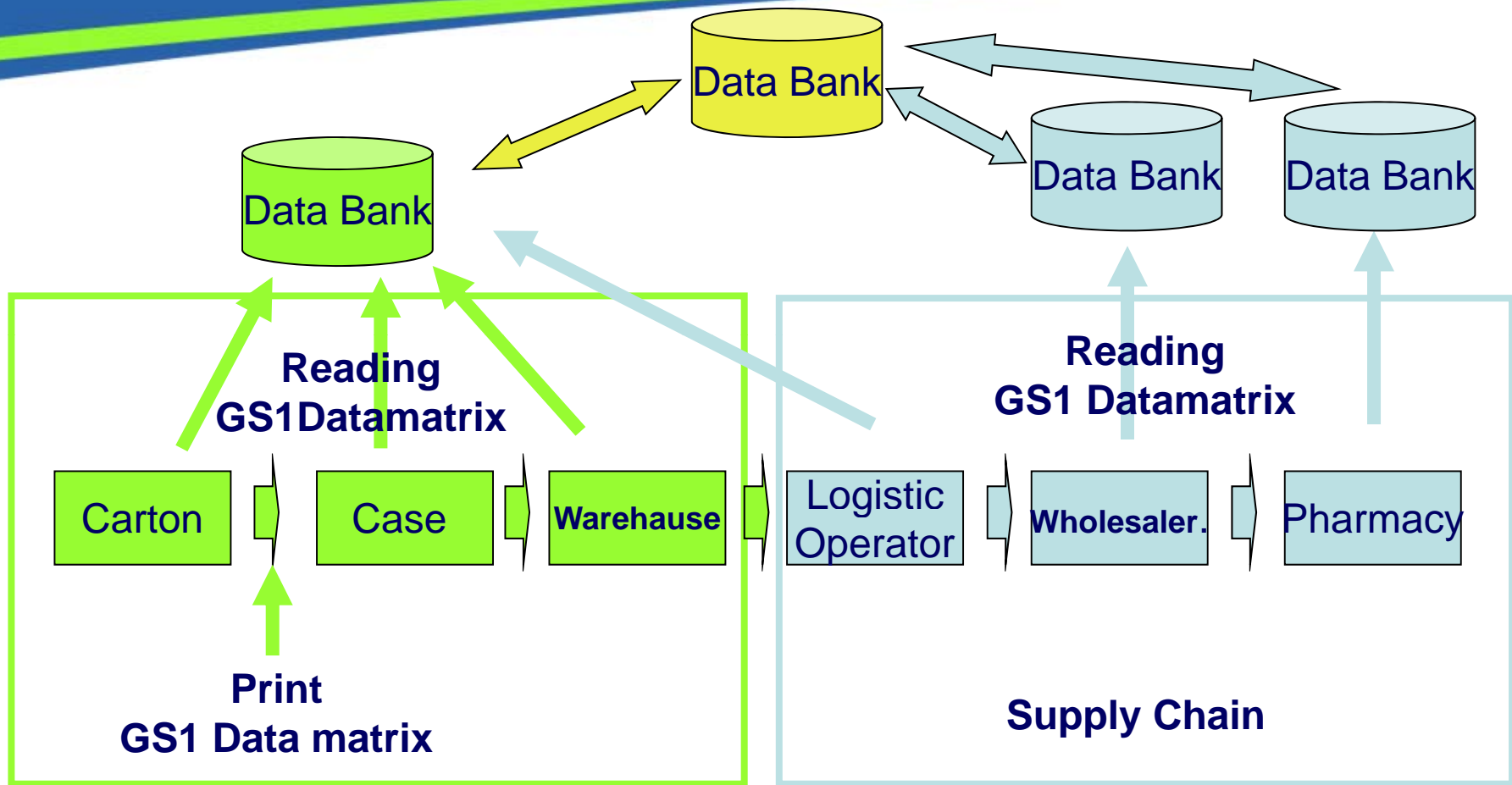
Regulation (RDC) # 01 14/01/10

Eduardo Lopes 03-2010

Traceability

- General Issues
- Pilot practical Issues

Traceability



Human readable data



General issues

- Final customer benefits - Human readable IUM*
- Data bank architecture – It's not defined
- Data bank security – Information property ,ethics
- International compatibility
- Imported products
- Final packaging simplification
- Data flow – Fast development in the coming years
- Simplify others identification/ anti counterfeiting devices

* IUM – Serial number

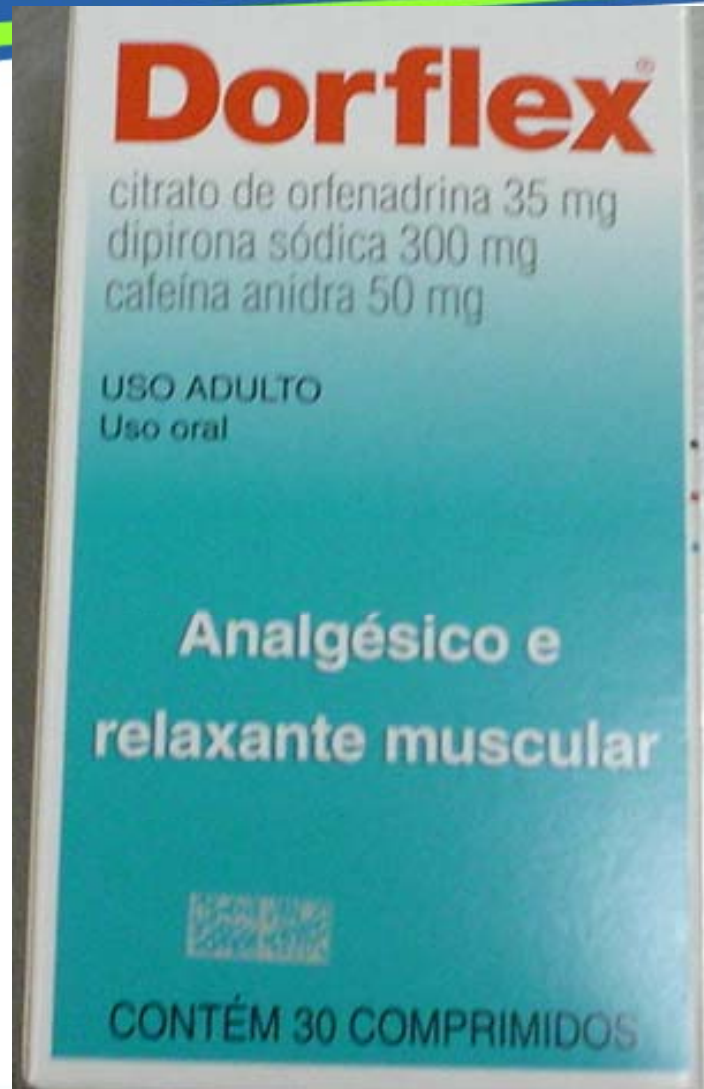
Pilot experience



sanofi aventis

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Pilot experience



Pilot experience – Practical issues

- Line speed – Printer and reader fast enough
- Vibration – Must be small
- Contrast – It's necessary changes in the art
- Reading Interferences – Others codes
- Case geometry to provide filiations –
Guarantee relation units/ case
- Safe GMP system – Must be read to be included
- Events out of the line – Sampling have to be recorded



 Thank you!!!

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