



BAUSCH + LOMB

A company of Valeant Pharmaceuticals International, Inc.

Final countdown for EU-Serialization

useful knowledge for saving time

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AGENDA



- Bausch+Lomb
- Experience
- Useful advice
- Conclusion





Vision Care	Pharmaceuticals	Surgical
Contact lenses & eye care	Medicines for eye diseases	Aids & implants



- Berlin Pharma plant >600 employees
 - Eye Drops, gel & ointment, nasal spray
 - Rx & OTC –worldwide



EXPERIENCE



securPharm Member	Serialization equipment	IT Infrastructure
Since 2013	Level 1-2 (TQS HC-A)	Level 3-5 ongoing
		

Source: OCS CHECKWEIGHERS- Track&Trace

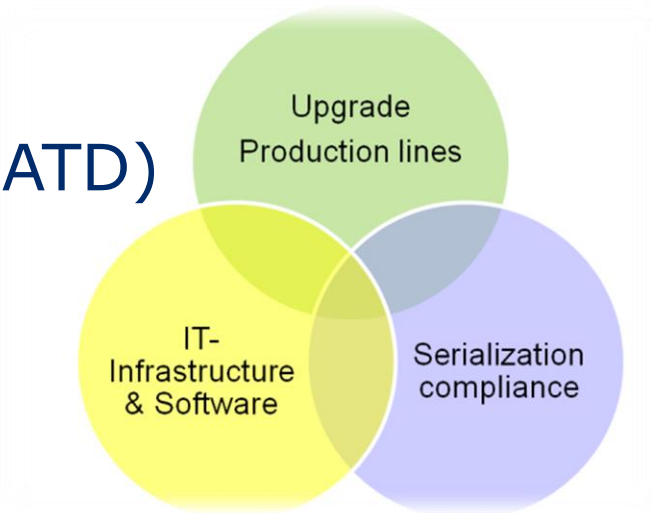


The Global Language of Business

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- Definition of Standards for
 - Tamper evident guideline (ATD)
 - Artwork guideline
 - Printing guideline
 - Data management



USEFUL ADVICE –ATD GUIDELINE



Glue/peroration method

PRO

As per DIN EN 16679

>10 years experience

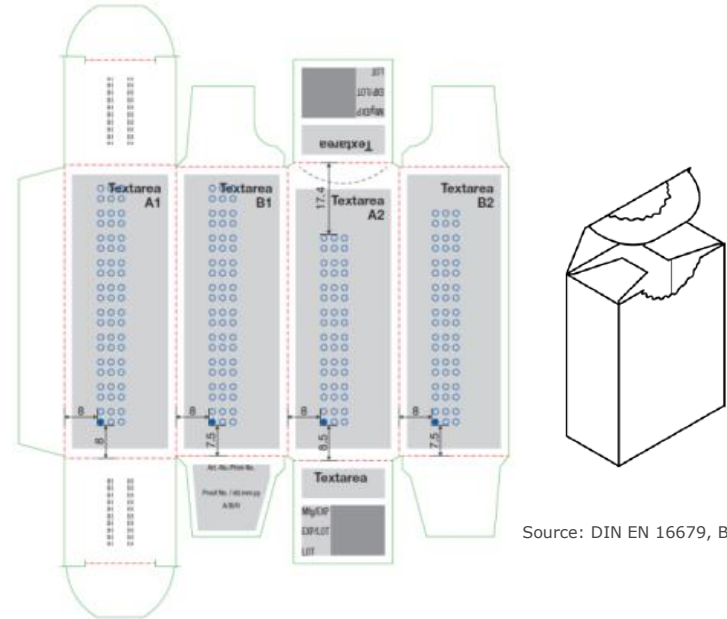
Save for all storage conditions

CON

Additional flap should be a bit smaller

Enlarge distance perforation -> braille

Text-free area around perforation



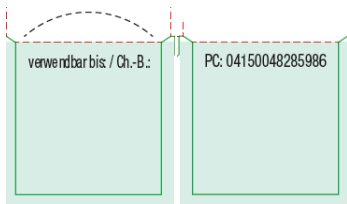
Source: DIN EN 16679, Beuth Verlag

USEFUL ADVICE – ARTWORK GUIDELINE



Put fixed data into the artwork - saving errors in production

Fixed text of artwork



Fixed text

**GTIN/NTIN
(Prefix "PC")**

EXP

LOT

Market

Austria

Switzerland

Germany

France

Spain

Nordics

Germany (verwendbar bis)

Germany (Ch.-B.)

NTIN rules

908888+PZN+check digit

7680+Swissmedic code

4150+8-digits PZN+check digit

3400+CIP/ACL code+check digit

847000+Codigo national

704626+Vnr.+check digit



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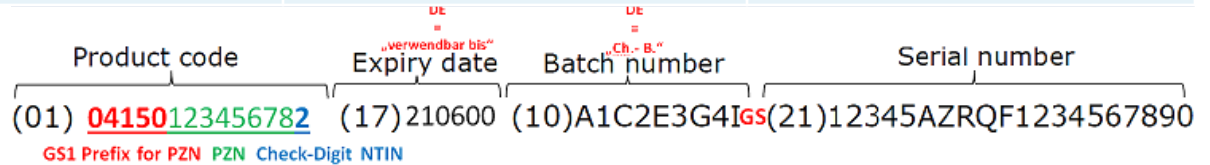
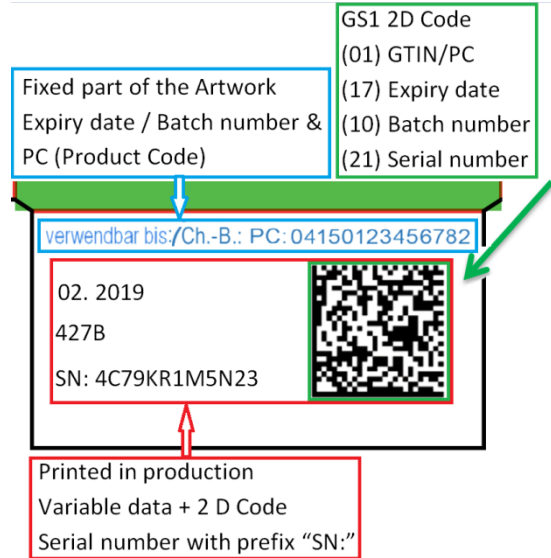
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USEFUL ADVICE – PRINTING GUIDELINE



Element	Human readable variable data	2D code ECC200 (FNC1 Prefix)
Product code (PC)	Not needed if it is part of the artwork	(01) GTIN/NTIN
Expiry date (EXP)	MM.YYYY	(17) EXP YYMMDD (DD=00)
Lot/ Batch number (LOT)	Batch number	(10) LOT (+GS)
Serialnumber (SN)	SN:Serialnumber (Prefix "SN")	(21) SN



USEFUL ADVICE – DATA MANAGEMENT



Data for production

- Company ID
- Product information
- Market
- Type/size of packaging
- Packing scheme
- Order size

- Sample size
- Printing layout
- Application Identifier (AI)
- Product code
- Reimbursement number
- EXP/LOT
- Serial number

Quality Agreement

- Contract national system
- EU hub
- Sampling taking
- Mono/multilingual package
- Code content
- Code quality

- SN scheme
- SN handling
- SN upload
- Market release
- Recall

CONCLUSION



- Network/exchange of experience –>
saves time and avoids expensive mistakes
- Take care of your experts inhouse
- Train the involved people early and regularly

Contact Information



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