Region Hovedstadens Apotek

PSQ 11464

Application of a supplier qualification program for primary packaging materials regulated as medical devices

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WHAT WAS DONE?

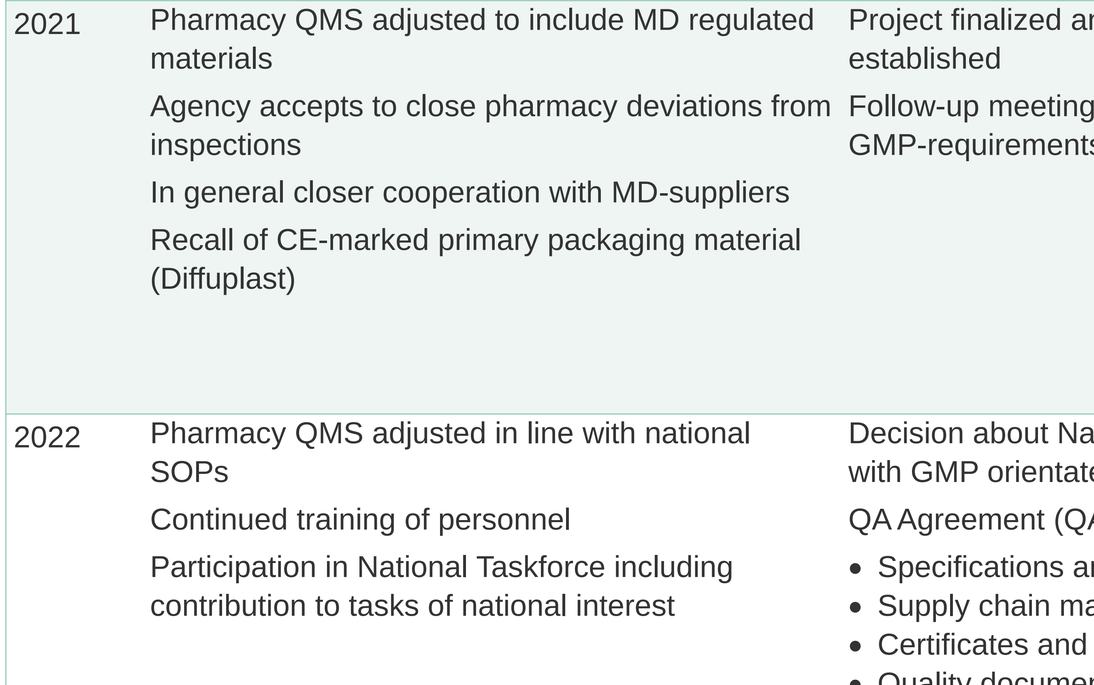
Several actions to combine Good Manufacturing Practice (GMP[1]) and Medical Device Regulations (MDR[2]) were implemented. Among others, comprehensive training programmes were conducted, and quality standards as well as supply chain mappings were included in quality management systems.

WHY?

The Danish Medicines Agency enforced that the Quality Management System (QMS) for the hospital pharmacies must include primary packaging systems regulated by MDR (CE-products). Immediate actions were necessary as these packaging systems are a prerequisite for supply to patients of vital medicines like Total Parental Nutrition (TPN) and ready-to-use products such as antibiotics, cytostatics and pain reliefs.

Examples: CE-marked devices

Year	Regional pharmacies	National pharmacy lead	National task force
2019	Agency enforce GMP-requirements for CE-products with TPN-bags as example Immediate corrections and references to national initiatives	Establishment of Task Force with members from pharmacies and Amgros Dialogue with the Agency in relation to immediate corrections and planned corrective actions	Fast development of general MDR/CE competences for members of taskforce Benchmarking with pharmacies in other countries
2020	Local specifications and SOPs as required Training in MDR/ISO/CE requirements and workshops with actual cases rolled out to all pharmacies	Project plan approved with budget Contract with MD-consultant Contact to a MD-supplier (pilot) Status meeting with the Agency	Data collection in relation to CE-products including datasheets, supply chains and certificates Preparation of training materials for course and workshops Support to pharmacies as required
2021	Pharmacy QMS adjusted to include MD regulated materials Agency accepts to close pharmacy deviations from inspections In general closer cooperation with MD-suppliers Recall of CE-marked primary packaging material (Diffuplast)	Project finalized and permanent national task force established Follow-up meetings with the Agency where mandatory GMP-requirements for CE-products were determined	GMP-audit of MD-supplier #1 (pilot) Establishment of shared standards e.g., supply chain mapping and specifications Contact to manufacturers of ‘combination products’ Establishment of national archive for documentation in relation to CE-products and MD-suppliers Integration of new MD-related requirements with other GMP activities as process validation, test for integrity and rationale for shelf-life
2022	Pharmacy QMS adjusted in line with national SOPs Continued training of personnel Participation in National Taskforce including contribution to tasks of national interest	Decision about National Tender for elastomeric pumps with GMP orientated QAA (Won by MD-suppler #2). QA Agreement (QAA) includes: • Specifications and data sheets • Supply chain mapping • Certificates and declarations • Quality documentation as rationales for expiry dates and test for leachables (LE) • GMP requirements as related to change control, complaints recalls and audits	Determination of GMP requirements in tender for elastomeric pumps (QAA) GMP-audit of MD-supplier #2 Open courses in ISO 13485, MDR and relevant ISO standards National SOPs for, among others: • Specifications • Supply chain mapping • Safety issues (esp. LE) • Archiving



Supply chain mapping for: *(name as stated on package, product-family and item numbers)*

Prepared by: | **Date:** | **Edition:**

INTENDED USE:
NB! Scope for CE-certificates, Declaration of Conformity and Product characteristics.

MANUFACTURER
Name and address:
ISO 13485, Certificate No. and expiry date:

LEGAL MANUFACTURER
Name and address:
EC Certificate + Declaration of conformity No. with expiry date:

SUPPLIER
Name and address:
Quality Agreement:

STERILISATION STERILE
Name and address:
Method and standard (ISO or similar):
Quality System (ISO 13485 or similar). Certificate No. and expiry date:

ADDITIONAL REMARKS: *(the most important references and supplementary documentation). Description of controls by receipt.*

WHAT HAS BEEN ACHIEVED?

Agreements with the Agency in relation to GMP related requirements.

Knowledge of supply chains and established cooperation with suppliers, facilitate a quick and effective response to e.g., recalls or regulatory enforcements.

Ability to meet ad-hoc requests for drugs packaged in medical devices.

Established QAA including GMP requirements ready for future tenders on medical devices intended for use as packaging materials.
Experiences with GMP audits of medical device suppliers in a GMP context.

WHAT NEXT?

More medical devices as transfer-sets, syringes, utensils and gloves to be included in the supplier qualification program.

References

[1] Volume 4 of "The rules governing medicinal products in the European Union" (EudraLex) especially section 5.27.

[2]REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC