Challenges and practical solutions to a successful implementation of the safety features in the hospital environment

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State of readiness

Manufaturers

Wholesalers

Distribution

Hospital Pharmacy

- ✓ *Update and accessibility of data on the legality of suppliers and authorized customers for the distribution of medicines*
- ✓ Incorporation of technology to the storage and dispensing of medicines in the Pharmacy Services, or the technological renewal for the adaptation to the new regulation
- ✓ The improvement of the electronic systems of data exchange with suppliers

WG IV: Implementation of the Falsified Medicines Directive in the hospital setting[1]

Adopted 25 September 2018 by the Member State expert group on the safety features[2]

Executive summary

The deadline for the entry into application of the safety features is fast approaching. Hospitals must be ready to decommission safety features by 9 February 2019. Hospitals should start preparations early to ensure they have the necessary equipment and personnel to comply with the requirements of the Falsified Medicines Directive and Commission Delegated Regulation by this date.

Decommissioning in hospitals can be accomplished by scanning individual unique identifiers or, if agreed with suppliers, by scanning aggregated codes. Although aggregation through the repository system will not be ready by 9 February 2019, some manufacturers and wholesalers may be able to provide grouped unique identifiers to hospitals.

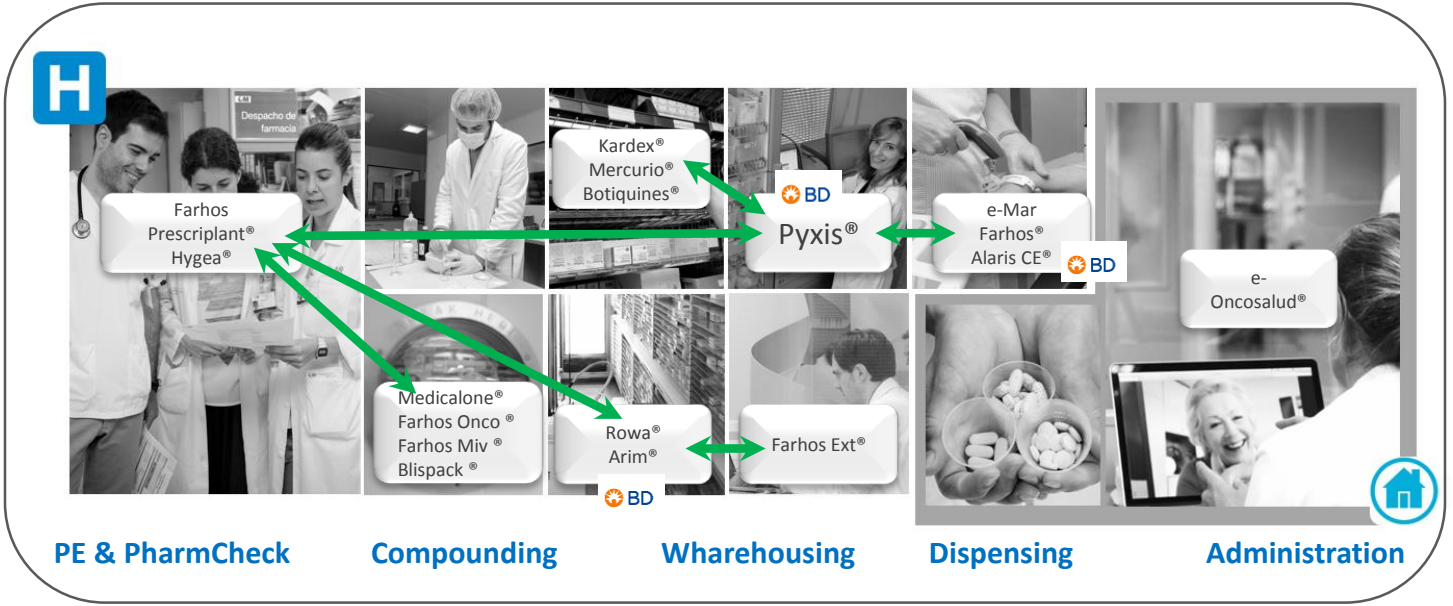

Autoridades nacionales
Sistema Español de Verificación de Medicamentos
SEVeM
Servicios Farmacia Hospitales
REPOSITORIO NACIONAL DE VERIFICACIÓN
SNS Farma
nodofarma
Verificación
Farmacias
Sistema Mayorista
emvo
European Medicines Verification Organisation
Nodo Europeo
TACS
OBP
Distribuidor paralelo

Evolution of the process in the furture

End-to-end

Traceability

IT SYSTEMS SUPPORT MEDICATION SAFETY



- ✓ The use of data for other purposes, such as <u>pharmacovigilance and monitoring of health outcomes</u>

- ✓ Accessibility to the pharmacotherapeutic history by the patient, being able to consult what medications have been dispensed and / or administered, where and when

Evolution of the process in the furture

The standardization of bar codes at European level as a first step to implement solutions for the identification of the drug in its primary labeling, at least through the standard product code (mandatory by the FDA since 2006)

This would make it possible to provide greater security to the Medication Use Process in the Pharmacy Department and that the medication could be scanned at each step of the process of preparation, dispensing and administration

ISMP Beste Practice 11

When compounding sterile preparations, perform an independent verification to ensure that the proper ingredients (medications and diluents) are added, including confirmation of the proper amount (volume) of each ingredient prior to its addition to the final container

The fulfillment of the regulation generates great uncertainties and opportunities.

Is essential to create an agile framework of collaboration of industry, government, professionals and citizens to promote activities that provide real value to the health system and patient safety.

Thank you very much