Highlights of the Guidelines on best practice for the automated dose dispensing process, and care and safety of patients.

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Definition and providers of Automated dose dispensing

Automated dose dispensing (hereafter: ADD) is the dispensing of one or more medicinal products into an ADD container or pouch for a patient to take at a particular date and time. It is performed using a method involving an automated process. ADD services are applied to serve the needs of patients in institutional setting across northern Europe and to patients in ambulatory care. Manual dose dispensing (MDD) is excluded from the scope of the guidelines.

Scope and Purpose of the guidelines.

The guidelines propose standards and approaches to regulating and providing automated dose dispensing (ADD) services across Europe. The guidelines are not legally binding but serve as a framework that can be used by ADD providers and the national authorities. The proposals in these guidelines form a suitable basis for legislation and standards.

Advantages and risks of ADD

ADD has been associated with reduced distribution costs, fewer errors and better medication adherence. However, the benefits claimed for ADD have not been extensively investigated in international literature.

There are risks associated with the application of ADD. The re-packaging and re-labelling of medical products associated with ADD poses risks for quality and integrity. Quality defects and errors have been reported. Factors to be considered are for example the stability of the medicinal products, criteria for the suitability of their use in ADD, the continuation of supply of medicinal products that are no longer needed and the design and monitoring of the ADD process and the control / release through the responsible pharmacist.

There is no common set of standards available to guide regulators, providers and patients on how ADD should be carried out and how it should be regulated. Besides, there are significant disparities concerning ADD in different countries which can create inconsistencies.

ADD suppliers

ADD services are provided by a variety of suppliers such as licensed manufacturers, companies / sub-contractors and by large and small-scale hospital and community pharmacies. ADD should only be carried out at a licensed site, i.e. a licensed manufacturer, pharmacy or company / sub-contractor, which is decided on a national basis. Regardless of the scale of the production or the setting in which the ADD site operates, the supply of effective and safe medicines to patients should in any case be guaranteed.

Good manufacturing practice (GMP)

In the case that the ADD site is a licensed manufacturer, GMP and, if applicable, Good distribution practice (GDP) must be adhered to. If an ADD site is operating on a smaller scale and fulfills the relevant national requirements, it may operate as a pharmacy and the relevant principles of GMP and GDP should be applied. The principles of Good manufacturing practice are stated in European Directive 2003/94/EC.

Most of the guidelines are applicable irrespective of the setting of the ADD site or the scale of the ADD activity at a site.

The guidelines consist of two parts:

1. standards for the ADD process and operations;
2. patient care activities, including a suitability assessment for all patients prior to supplying medicines via ADD.

Ad 1. Standards for the ADD site and operations (part one)

The standards in part one of the guidelines relate to personnel and training, premises and equipment, prescriptions, traceability, suitability and stability of the medicinal products, the ADD process, prevention of cross-contamination, validation of equipment, machines and computerised systems, distribution, supply to patients and recall, quality assurance and documentation. Concerning these topics guidance is given to improve quality systems, reduce or avoid risks and to pack medicinal products at the benefit of the patient.

Ad 2. Patient care activities (part two)

This part deals with the incorporation of ADD into the patient care process. Multidisciplinary teams should regularly review and manage all of the patient's medicines. For the patient suitability assessment all members of the healthcare team should be involved including the patient/carer.

It should not be assumed that all patients in a particular setting, e.g. hospital or long-term institutional care, are suitable for ADD.

Challenge to improve national standards for ADD for the benefit of the patients

The proposals in these ADD guidelines form a suitable basis for legislation and standards. GMP, GDP and relevant legislation in place in other countries should also be considered. It is essential for each country to assess whether, and how, to set standards for ADD sites. In this way the necessary quality improvement can be achieved in all countries where ADD is applied at the benefit of the patient.

ADD guidelines are developed by a working group of experts at the Council of Europe/EDQM.

The ADD guidelines have been developed by a working group of experts from industry, academia, pharmacy and government from across the region of the Council of Europe. They have been discussed and reviewed by stakeholders via a consultation. Finally the ADD guidelines have been approved by the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care, coordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM – Council of Europe).

References

1. Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC) – EDQM (Council of Europe)
(link: https://go.edqm.eu/PC)
2. Automated dose dispensing (ADD); Guidelines on best practice for the ADD process, and care and safety of patients; Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care. (The ADD guideline can be downloaded free of charge: https://register.edqm.eu/freepub)