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EDQM issues Automated Dose Dispensing (ADD) Guidelines

Many hospitals and pharmacies across Europe are becoming increasingly interested in automated dose dispensing (ADD) services. ADD is an automated process, which allows one or more medicinal products to be dispensed into a container/pouch for a patient to take at a particular date and time. The approach is becoming ever more popular in Europe because it addresses the rise in polypharmacy and complex medication regimens, both of which are particularly associated with ageing populations.

The EDQM has issued its Guidelines on 'Best Practice for the Automated Dose Dispensing (ADD) Process and Care and Safety of Patients'. These Guidelines take into consideration the diversity of practices across Europe, and aim to ensure that ADD care is provided to a consistently high standard, and that medicines continue to be supplied safely to patients.
Up till now, there was no common set of criteria or standards available in Europe to guide regulators, providers and patients on how ADD should be carried out and how it should be regulated which can result in avoidable inconsistencies and disparities in the provision and regulation of ADD in different countries.

The Guidelines were drafted by a working group of experts from government, academia, pharmacy and industry from countries across Europe and were then reviewed and updated following an EDQM expert workshop. Following stakeholder consultation and final approval from the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and its subordinate body, the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC) the guidelines have now been finalised. The importance of the patient care element is stressed, in particular its strong link to the public health protection activities of the EDQM's Committee of Experts (CD-P-PH/PC).

These guidelines are non-binding and are seen as a vehicle for promoting best practices, standards and approaches in regulating and providing ADD services. They should be read in conjunction with any regulations, standards and guidance already in force at national level, and in the event of discrepancies between the two, national legislation takes precedence. National authorities may accept alternative but comparable methods to achieve the standards laid down in the guidelines. The aim is not to impose specific requirements on national authorities or ADD sites, but to provide best practices for the ADD process that will support national competent authorities and other stakeholders across Europe.

In short, the ultimate goal of these guidelines is to ensure the safe use of medicines providing the best possible medication outcome for patients.

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Note for the Editor: Further information is available on the internet site **https://www.edqm.eu/**
The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation, patients and consumer health issues.

[1]There are thirty-nine members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom and the European Union.*