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PGEU GPUE

Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

PGEU Response to EDQM Consultation on Automated Dose Dispensing (ADD) Guidelines

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 32 European countries. In Europe over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.

PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.

The Pharmaceutical Group of the European Union (PGEU) welcomes the European Directorate for the Quality of Medicine's (EDQM) Draft Guidelines on ADD and welcomes the opportunity to respond to this consultation. In particular, the PGEU welcomes the recognition of the crucial role the pharmacist can play in ADD production and management.

However, following the collection of feedback from PGEU member associations, the PGEU is concerned that the guideline is too specific and prescriptive in certain places and as such does not reflect pharmacy practice across Europe. The overwhelming majority of responses indicated that a "one size fits all" approach would not be appropriate in this instance due to the variation of practice across Europe, and in fact, may pose an unnecessary burden on pharmacies / ADD sites. The organisation and delivery of health services in the EU remains a Member State competence, however several recommendations within this draft guideline directly conflict with this principle and require reflection or rewording.

In conclusion, in order to adequately reflect pharmacy practice across Europe, the PGEU recommends that pharmacist and pharmacy organisations be involved earlier on, and more directly in future EDQM consultations affecting pharmacy practice.

Below are the excerpts which the PGEU recommends reflection or rewording:

D: Licensing

Concerning lines;

238-242,

An ADD site may receive an exemption from requiring a manufacturing authorisation if it is a pharmacy. In general, to be classified as a pharmacy, a site should only be supplying ADD medicines to patients of the pharmacy, and other pharmacy activities should occur at the site i.e. the supply of medicines directly to patients/carers and associated patient care activities.

247-248,

….it is recommended that national authorities provide a specific authorisation/licence for ADD activities that occur in manufacturers or pharmacies.

and 260-263

If an ADD site is operating on a smaller scale and fulfils the relevant requirements, it may operate as a pharmacy and these guidelines and the relevant principles of GMP and GDP required to ensure that the quality, safety and efficacy of the ADD medication is maintained should be applied.

We suggest deleting and three paragraphs, as these recommendations are very prescriptive and would be more appropriate for national or even local guidelines, as opposed to European guidelines. Specifically concerning lines 247-248, PGEU recommends that there be no licensing requirements other than the standard pharmacy licencing according to national legislation. It is important for European level guidelines to respect the principle of subsidiarity when concerning the organisation and delivery of health services. As such it is suggested to leave such decisions to national competent authorities discretion.

Part One:

4. Personnel and Training

Concerning lines;

304-305,

An organisational chart for the ADD site should be in place and should contain clear definitions of roles, duties, responsibilities and job descriptions

310-311,

The ADD site should have an appropriate number of staff with the necessary qualifications and practical experience to ensure that ADD is carried out effectively.

318-319,

Every ADD site should have a designated pharmacist who is responsible for the management of all activities relating to the pharmaceutical process at the ADD site.

and 321-323

…be available at the ADD site during all activities involved in dose dispensing and should supervise critical steps and take critical decisions personally.

Regarding lines 304-305 and 310-311, these recommendations are very prescriptive and would be more appropriate for national or even local guidelines, as opposed to European guidelines.

Concerning lines 318-319 and 321-323, whilst the training, skills, knowledge and activities performed by a pharmacist in the EU are laid out by Directive 2005/36/EC and amending Directive 2013/55/EC, these are minimum training requirements and Member States ultimately retain sovereignty over the organisation and delivery of their health services. Indeed, feedback from members indicated that several national level systems regulating the activities of the pharmacist and pharmacy staff would be in direct conflict with this recommendation.

As such, PGEU recommends deleting this text or rephrasing to the following; "Owners or operators of ADD sites shall ensure staff and operations are adequately in place according to the applicable legislation and practice"

C:Training

375-379,

The ADD site should provide training for all personnel involved in storage, warehousing, deblistering, dispensing, control and supply and those accessing those areas (including technical, maintenance and cleaning personnel), and for other personnel whose activities could affect the quality of the product. Training should be standardised for all ADD sites as far as possible, however the content and extent of training may vary depending on the scale and setting of the ADD site.

Regarding lines 375-379, it is also very prescriptive for a European guideline to describe the training requirements of staff in an ADD site, as this list above may not be exhaustive and may vary between country depending on their national requirements. Additionally, herein lies a contradiction in that the text recommends standardisation as far as possible, but then acknowledges that training may vary due to the scale and setting of the ADD site. This is true for both within and between Member States.

As such, PGEU recommends deleting this text or replacing it with the following text; "Owners or operators of ADD sites shall ensure adequate training is in place according to the applicable legislation and practice"

D. Elements of Introductory ADD Training for Different Staff:
Pharmacist(s)

403-416

Specific training on quality systems, risk management, validation, stability, medicine suitability, GMP, GDP, ADD standards and any other area the responsible pharmacist identifies as a gap in knowledge. Pharmacists should engage in continuing professional development in ADD appropriate to their role. They should receive training in the ADD process and the patient care elements of ADD to ensure their knowledge is maintained at the highest level.

Pharmacy Technician(s): *Specific training on critical control points, quarantine, corrective and preventative actions, validation, documentation systems, and the "Plan Do Check Act (PDCA) principle" and any area in which they operate where a gap in their knowledge is identified.*

Other staff: *The purpose of medicinal products and ADD, hygiene, equipment, procedures, instructions, records, labelling, principles of one direction flow, critical square area (only one medicine or label in a certain space) and double checks.*

Regarding lines 403-416, according to Directive 2005/36/EC and amending Directive 2013/55/EC, the title of "pharmacist" and the training, skills, knowledge and activities are described for Member States to implement in curricula and relevant education, training and practice. Many pharmacists across Europe participate in relevant further training and update of their knowledge, for example via Continuing Professional Development (CPD).

As such, PGEU recommends deleting specific training lines or replacing with the following text; "Owners or operators of ADD sites shall ensure adequate training and support is in place for ADD staff according to the appropriate competence"

6. Prescriptions

527-531

A prescription, or other valid authority, to supply medicinal products via ADD, written by an authenticated doctor or healthcare professional with the authority to prescribe, must be available at the ADD site prior to dispensing. In some countries, where two entities are involved, the prescription is transferred into a medication order prior to dispensing and this order is transferred to the ADD site. In this instance a copy of the prescription should also be supplied.

Concerning lines 527-531, providing a copy of a prescription (and not the original) in order to begin the dispensing process may actually be considered an illegal practice in some Member States. As such, PGEU recommends deleting the text for the second and third sentences. (In blue).

536-538

Non-prescription medicinal products, vitamins and food supplements do not require a prescription, however if they are to be included in ADD, they should be included in the prescription and order for the ADD medication.

Regarding lines 536-538, by definition, a non-prescription medicinal product does not require a prescription. However, the licensing of medicinal products can sometimes differ between Member States (for example, one molecule requires a prescription in country A, whereas the same presentation does not require one in country B). Additionally, there are often issues relating to reimbursement and co-payment concerning some non-prescription medicines, in that a prescription co-payment may be required or some non-prescription medicines, vitamins and supplements are not reimbursed when included on a prescription.

As such, PGEU recommends deleting this text.

7. MEDICINAL PRODUCTS: TRACEABILITY, SUITABILITY AND STABILITY

B. Suitability of Medicinal Products and Packaging Materials for ADD

Medicinal Products

597-600 *A medicinal product which does not have information on its suitability for ADD included in its marketing authorisation, should only be removed from the manufacturer's original packaging (e.g. deblistered) for use in ADD if sufficient, accurate data is available to make a suitability assessment*

Regarding lines 597-600, this could potentially mean that the pharmacist would be responsible for collecting the necessary product stability information from the manufacturer. This could restrict access of medications to patients or cause delay to treatment. This is an unnecessary burden on pharmacists and potential hindrance to access to treatment and therefore PGEU suggest this text be deleted.

605-619

The release by the responsible pharmacist should be based on a documented and suitably verified risk assessment of the medicine's suitability taking into consideration, if available:
• Data provided by the marketing authorisation holder, either in the medicinal product's Summary of Product Characteristics (SmPC) or other available data;
• Data or lists provided by a national or local competent authority.

If the above information is not available, the decision to include a medicinal product in ADD must be based on a risk assessment performed by the ADD site. This risk assessment should assess the potential risks to the quality, safety and efficacy of the medicinal products and take into consideration:
• Data from recognised international sources, e.g. from competent authorities in another country;
• Data from literature or reference books, e.g. Ph. Eur. (European Pharmacopoeia), BP (British Pharmacopoeia), USP (US Pharmacopoeia) or other reputable sources.

A more extensive risk assessment is required prior to the inclusion of a medicine with little available stability data and/or a new medicinal product in an ADD system.

Concerning lines 605-619 as this text now reads, this could potentially mean that the pharmacist would be responsible for performing an additional risk assessment at the ADD site. This is an unnecessary burden on pharmacists and therefore PGEU suggests this text be deleted.

637-650

In addition, the following decisions should be taken and documented by the responsible pharmacist:

• If medicinal products which have potential for misuse or abuse, e.g. controlled drugs or psychotropic medicines, can be included. These medicinal products should only be included if adequate procedures to prevent their misuse/abuse are in place.

• If vitamins, minerals and other food supplements can be included in ADD. Where these products are available as authorised medicinal products these must be used in preference to any unauthorised version. Caution should be exercised with unauthorised supplements.

• If split units of medicinal products can be dispensed. Only tablets scored for dividing, or tablets with appropriate information from the marketing authorisation holder on their suitability for splitting, should be split for ADD. In principle split tablets should only be used if no authorised medicinal product or other alternative is available.

• If a medicine is suitable for inclusion in a multidose container or should be packaged alone. Medicines that may be considered unsuitable include unauthorised products such as supplements and split tablets, unstable medicines, controlled drugs and medicines that should not be handled.

Regarding lines 637-650, record keeping requirements in relation to ADD are a competence for Member States. As previously mentioned, there is a variation across the EU on the licensing and reimbursement of prescription and non-prescription medicines, vitamins and supplements. Additionally, the decision to use split formulations or products outside of their (or with no) Marketing Authorisation remains a decision for the individual pharmacist in practice on each occasion. The inclusion or exclusion of controlled substances or medications at higher risk of misuse or abuse for inclusion in ADD would be subject to the national legislation concerning narcotics.

As such, PGEU recommends deleting this text.

8. AUTOMATED DOSE DISPENSING PROCESS

H. Labelling and Information:

931-940

In ambulatory/primary care settings, the following information should be included on the final ADD medicines:
• Name of the patient;
• Dispensing pharmacy/ADD site;
• Medicinal product name, strength and form;
• Quantity of medicinal products;
• Administration and dosing instructions;
• Warnings and storage instuctions as applicable;
• Date of dispensing/Expiry date of the medication/Date and time of medication use;
• Identification or batch number or electronic code to ensure full traceability.

Concerning line 931-940, labelling and information requirements for dispensing are the responsibility of Member States provided they comply with the minimum labelling requirements stated by Directive

2001/83/EC on the Community Code for medicinal products of human use. However, Member States are entitled to set more restrictive labelling or information requirements.

As such, PGEU recommends deleting this text or rephrasing to "Owners or operators of ADD sites shall ensure labelling and information requirements are adequately in place according to the applicable EU and national legislation and practice".

11. QUALITY ASSURANCE:

1133-1136

C. Pharmacovigilance and Safety System and Data Collection: A specific pharmacovigilance and safety system for reporting ADD errors, incidents and adverse effects should be established. The system should be coordinated across Europe and encourage the sharing and analysis of data and comparison of the rate of errors, incidents and adverse effects with traditional dispensing.

Concerning lines 1133-1136, the pharmacovigilance of ADD medications would fall under numerous European pharmacovigilance legislation, that is to say; Directive 2010/84/EU, Regulation (EU) No 1235/2010, Commission Implementing Regulation No 520/2012 of 19 June 2012, Regulation (EU) No 1027/2012 and Directive 2012/26/EU amending Directive 2001/83/EC and Regulation (EC) No. 726/2004.

As such, a separate legislation and pharmacovigilance system for ADD is not necessary and the PGEU suggests deleting this text.

Part Two

14. ADD PRESCRIPTION/ORDER AND RESPONSIBILITY FOR PATIENT CARE

A. ADD Prescription/Order

1268

The treating physician can request that a patient's prescribed medication be dispensed via ADD.

1274-1276

Additionally, pharmacists may decide ADD is the most suitable method of providing medication to certain patients on the basis of a patient suitability assessment conducted in consultation with the treating physician and the patient/carer.

Concerning lines 1268 and 1274-1276, as pharmacists are recognised as being the experts in the use of medications, PGEU believes that pharmacists should be one of the primary actors in assessing patients for suitability for ADD in consultation with the other relevant healthcare professionals and patient/carer. In addition, several concepts seem to be confused here, i.e. the concept of a prescription or an order – i.e.

from a person with the authority to prescribe medicines on a prescription. Additionally, this text could also be confused to mean that ADD can be "prescribed". Two further concepts, i.e. a request to use ADD (e.g. by a patient or their carer) and a recommendation for a patient to use ADD i.e. from a healthcare professional (physician, pharmacist etc).

As such, PGEU recommends rewording this paragraph to (i) reflect the pivotal role pharmacists have to play in assessing (and recommending) the use of ADD for their patients and (ii) removing reference to "prescribing" or "ordering" of what could be confused as either medications (which is not relevant here as a professional's ability and entitlement to prescribe medicines should remain unaffected if it is intended the medicines are dispensed in ADD format), or prescribing / ordering of ADD itself (as issues relating to reimbursement are related to what is prescribed or not in many countries).

B. Responsibility for Patient Care

1292-1295

Patients should always receive their medication from the same pharmacy and should be managed by a healthcare team, which involves the same medical practitioner (or team of medical practitioners) and pharmacist (or pharmacy) for each dispensing, review and assessment.

Concerning lines 1292-1295, PGEU recognises that patients have free choice to obtain their medications from whichever pharmacy they prefer, and from the healthcare team which they prefer. Additionally, the Directive 2011/24/EU on the application of patients' rights in cross border healthcare foresees the possibility for patients to receive healthcare services in another Member State, therefore from another group of healthcare providers.

As such, PGEU recommends deleting these lines and instread emphasising the need for effective communication channels and systems between healthcare providers and between healthcare providers and patients/carers.

C. Healthcare Team

1326-1331

An ADD healthcare team should be established to ensure the patient-centric care of ADD patients. The team has responsibility for patient care and assessing the appropriateness of the use of ADD for each patient. This team should include the prescriber, who has knowledge of the patient's medical and care status and access to the patient's medical records, and the pharmacist, with their medicinal product knowledge and responsibility for reviewing prescriptions for therapeutic appropriateness and counselling.

Regarding lines 1326-1331, PGEU recognises that in addition to their extensive knowledge on the safe, effective and rational use of medicines, pharmacists are increasingly utilising new technologies (such as patient medication records, electronic health records and shared medical records) to improve their

knowledge of their patients' medical care status, for example to minimise the risk of interactions, side effects, allergies and duplication of therapy.

Furthermore, as Member States retain the competence for the organisation and delivery of their health services, it would be inappropriate for the guideline to suggest the establishment of an ADD healthcare team where existing legislation, guidance, standards, teams, structures and processes are already in place.

As such, PGEU recommends rewording the text to (i) include the emerging use of ICT in healthcare practice and to (ii) rephrase the reference to the creation of an ADD healthcare team (and all subsequent references) to reflect the fact that Member States retain competence in organising their health systems and emphasising the need for effective communication channels and systems between healthcare providers and between healthcare providers and patients/carers.

For example, it could be acknowledged that a multi-disciplinary group of healthcare professionals could be included for consideration when concerning ADD production, but the guidelines should avoid stating that a new team be created specifically for ADD.

15. PATIENT SUITABILITY:

A. General:

1364-1371

Prior to the provision of a dose dispensed system to a patient, alternative adherence supports should be considered, including:
• Simplification or tailoring of the medication regimen, e.g. removing unnecessary medication, altering times of administration or using combination products;
• Reminder charts;
• Visual aids, e.g. large font information sheets, magnifying glasses, pictograms;
• Memory aids, e.g. software applications, timed alarms or calls from a relative;
• Involvement of a carer or relative to help administer medication.

Concerning lines 1364-1371, these recommendations are overly prescriptive for a European level guideline concerning healthcare practice. The options available to patients with adherence issues vary across Europe and related to each individual Member States health system and practice. Additionally, it often is the case the one patient finds one intervention more suitable than another, even within Member States on an individual basis. As such, PGEU recommends deleting this text and making reference to the support, advice and services pharmacists can provide to patients and their carers concerning the most appropriate adherence support on an individual basis, as is done in practice currently.

17. REVIEW OF MEDICATION THERAPY, COUNSELLING, INFORMATION PROVISION AND EDUCATION

A. Review of a Patient's Medication Therapy

1458-1464

The healthcare team should carry out regular reviews to assess the pharmaceutical and therapeutic appropriateness of patients' medication therapy. A review involves considering each medicinal product individually and collectively, including screening for any potential therapy problems which may arise out of the use of the medicinal products. Both general and ADD specific patient care elements are to be considered as part of the review.

Regarding lines 1458-1464, PGEU acknowledges the expanding role of pharmacists in performing medication reviews and other services to support patients in taking their medicines safely, rationally and effectively.

18. DOCUMENTATION AND RECORDS

1542-1553

There should be documents (policies, procedures, specifications) and records in place for the following patient care processes:

- *Obtaining informed patient consent;*
- *Patient suitability assessments and reassessments;*
- *Prescription/ADD order management;*
- *Medication therapy review (individual and multidisciplinary);*
- *The provision of patient information leaflets and information on medication changes;*
- *Additional counselling;*
- *Data protection;*
- *Contracts and interactions/meetings with relevant healthcare professionals, e.g. physicians or other pharmacists;*
- *Pharmacovigilance.*

Regarding lines 1542-1553, documentation and record keeping requirements with regard to ADD are the responsibility of the Member State and may vary across Europe.

As such, PGEU recommends deleting these lines or rephrasing to "Owners or operators of ADD sites shall ensure documentation and record keeping requirements are adequately in place according to the applicable legislation and practice".

In conclusion, in order to adequately reflect pharmacy practice across Europe, the PGEU recommends that pharmacist and pharmacy organisations be involved earlier on, and more directly in future EDQM consultations affecting pharmacy practice.

END