Official Journal of the European Union

C 212

English edition

Information and Notices

Volume 60

1 July 2017

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EN

[1] Text with EEA relevance.

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EUROPEAN COMMISSION

COMMISSION NOTICE

EU Guidelines for the prudent use of antimicrobials in human health

(2017/C 212/01)

Table of contents

1. **INTRODUCTION**

Antimicrobial resistance (AMR) is a priority for the Commission which adopted in 2011 an action plan against the rising threats from antimicrobial resistance. Progress towards more prudent use of antimicrobials in both humans and animals were key objectives. Guidelines on prudent use of antimicrobials in veterinary medicines were published in 2015 ([1]). In 2016 Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance called on the Commission and Member States to develop European Union guidelines on prudent use of antimicrobials in human medicine to support national guidelines and recommendations ([2]).

([1]) Guidelines for the prudent use of antimicrobials in veterinary medicine (OJ C 299, 11.9.2015, p. 7).

([2]) Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance. 17 June 2016 http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-antimicrobial-resistance/

These Guidelines on prudent use of antimicrobials in human health are based on a technical report prepared by the European Centre for Disease Prevention and Control (ECDC) with input from EU Member States experts and stakeholders, which should be referred to for details of the methodology used in creating the guidelines as well as for additional references ([3]).

These guidelines draw upon, among other sources, the Council Recommendation 2002/77/EC of 15 November 2001 on the prudent use of antimicrobial agents in human medicine ([4]) and on the WHO Global action plan on antimicrobial resistance ([5]).

2. **DEFINITIONS**

An antimicrobial is any substance of natural, semi-synthetic, or synthetic origin that in *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target ([6]). Antimicrobials with activity against bacteria are called antibacterial agents.

An antibiotic is a substance produced by, or derived (chemically produced) from a microorganism that selectively destroys or inhibits the growth of other microorganisms ([7]). The term 'antibiotic' is often used to refer to antibacterial agents.

Acquired antimicrobial resistance is the resistance of a microorganism to an antimicrobial agent that was originally effective for treatment of infections caused by this microorganism.

A multidrug-resistant organism is a microorganism that is not susceptible to at least one agent in each of three or more antimicrobial categories ([8]) (or two or more antimicrobial categories for *Mycobacterium tuberculosis*).

Antimicrobial therapy: empiric antimicrobial therapy is based on a reasonable informed clinical judgement regarding the most likely infecting organism; documented antimicrobial therapy is when the identity and antimicrobial susceptibility of the infecting organism is known as the result of appropriate diagnostic or reference testing.

Antimicrobial prophylaxis is the use of antimicrobials for the prevention of infections.

Prudent antimicrobial use is use which benefits the patient while at the same time minimises the probability of adverse effects (including toxicity and the selection of pathogenic organisms, like *Clostridium difficile*) and the emergence or spread of antimicrobial resistance ([9]). Other terms that have been used with the same purpose include judicious, rational, adequate, correct and optimal.

Antimicrobial stewardship is an organisational or healthcare system-wide approach to promoting and monitoring judicious use of antimicrobials to preserve their future effectiveness ([10]).

Antimicrobial stewardship programmes are coordinated programmes that implement interventions to ensure appropriate antimicrobial prescribing ([11]).

([3]) European Centre for Disease Prevention and Control. Proposals for EU guidelines on the prudent use of antimicrobials in humans. Stockholm: ECDC; 2017 http://ecdc.europa.eu/en/publications/_layouts/forms/Publication_DispForm.aspx?List=4f55ad51-4aed-4d32-b960-af70113dbb90&ID=1643

([4]) OJ L 34, 5.2.2002, p. 13.

([5]) World Health Organisation (WHO). Global action plan on antimicrobial resistance. Geneva: WHO; 2015. Available from: http://www.wpro.who.int/entity/drug_resistance/resources/global_action_plan_eng.pdf

([6]) World Health Organisation (WHO)/Food and Agriculture Organisation of the United Nations. Guidelines for risk analysis of foodborne antimicrobial resistance CAC/GL 77-2011. 2011. Available from: http://www.fao.org/input/download/standards/11776/CXG_077e.pdf

([7]) European Centre for Disease prevention and Control (ECDC), European Food Safety Authority (EFSA), European Medicines Agency (EMEA), Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Joint Opinion on antimicrobial resistance (AMR) focused on zoonotic infections. EFSA; 2009. Available from: http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1372.pdf

([8]) Magiorakos AP, Srinivasan A, Carey RB, Carmeli Y, Falagas ME, Giske CG, et al. Multidrug-resistant, extensively drug-resistant and pandrug-resistant bacteria: an international expert proposal for interim standard definitions for acquired resistance. Clin Microbiol Infect. 2012; 18: 268-281. doi: 10.1111/j.1469-0691.2011.03570.x

([9]) Dellit TH, Owens RC, McGowan JE, Jr., Gerding DN, Weinstein RA, Burke JP, et al. Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. Clin Infect Dis. 2007; 44: 159-177. doi: 10.1086/510393

([10]) National institute for Health and Care Excellence (NICE). Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use. 2015. Available from: https://www.nice.org.uk/guidance/ng15?unlid=577615908201652413485 7

([11]) Transatlantic Taskforce on Antimicrobial Resistance (TATFAR). Summary of the modified Delphi process for common structure and process indicators for hospital antimicrobial stewardship indicators. 2015. Available from: https://www.cdc.gov/drugresistance/pdf/summary_of_tatfar_recommendation_1.pdf

Prescribers are all healthcare professionals qualified to prescribe antimicrobials. In addition to physicians of all specialties and dental practitioners, the term may refer to prescribing nurses, pharmacists, clinical microbiologists, midwives, and other healthcare professionals, depending on local regulations.

3. SCOPE AND PURPOSE

The exposure of microorganisms to antimicrobial agents creates selective pressure that can lead to the development of resistance. Inappropriate use of antimicrobial agents accelerates the emergence and dissemination of resistance.

The goal of controlling antimicrobial resistance can only be achieved by combining strong infection prevention and control and the prudent use of antimicrobials. Infection prevention and control, including vaccination, contributes to a decrease in the number of infections, which leads to lower antimicrobial consumption and fewer opportunities for misuse.

These guidelines aim to reduce inappropriate use and promote prudent use of antimicrobials. The guidelines are complementary to infection prevention and control guidelines which may exist at national level.

These guidelines are intended to be used to inform and assist activities to promote the prudent use of antimicrobials in humans. They target all actors who are responsible for, or play a role in, antimicrobial use and whose contribution is necessary to ensure that antimicrobials are used appropriately. These guidelines include measures to be considered by Member States when developing and implementing national strategies to promote the prudent use of antimicrobials and elements of good practice to be followed by healthcare professionals. They include good clinical practice and the resources, systems and processes that authorities and actors should consider when developing and implementing strategies for the prudent use of antimicrobials in human medicine. They also identify activities that may be taken by international organisations and agencies in support of national strategy development and implementation.

These guidelines relate to the prudent use of antimicrobials in humans, with a special focus on antibacterial agents. Many of the points mentioned here also apply to other classes of antimicrobials such as antivirals and antifungals.

These guidelines do not cover specific medical conditions or specific antimicrobials.

These guidelines are without prejudice to provisions contained in national or EU law and are not binding on Member States or other parties. They contribute towards the Commission's overall strategy on AMR.

4. GUIDELINES

4.1. National, regional and local governments

National, regional and local governments, have the ultimate responsibility for developing, implementing, and supporting the policies, actions and structures necessary to ensure the prudent use of antimicrobials. Their responsibilities include legislation, regulation and auditing compliance with legal, policy and professional standards. Collaboration between government and other organisations including those responsible for delivering health care, regulators, organisations responsible for managing payments for health care as well as those responsible for professional education, is essential to the development and implementation of these policies.

National strategies to combat AMR should be developed which should be in line with the WHO Global Action Plan on AMR ([12]).

National strategies should include the following key elements to promote prudent use of antimicrobials in human medicine as part of multi-faceted interventions adapted to local conditions.

— Regulation of access and use of antimicrobials.

— Antimicrobial prescribing and stewardship

  — Antimicrobial stewardship programmes at all levels of care (community, hospital, long-term).

([12]) World Health Organisation (WHO). Global action plan on antimicrobial resistance. Geneva: WHO; 2015. Available from: http://www.wpro.who.int/entity/drug_resistance/resources/global_action_plan_eng.pdf

— Integration of national antimicrobial stewardship activities with infection prevention/control and vaccination; all activities should be based on the national antimicrobial resistance plans developed in accordance with the cross-sectoral 'One Health' approach ([13]).

— Qualitative and quantitative targets for improvement of antimicrobial prescribing.

— Timely availability of standardised open data on antimicrobial consumption for benchmarking and on antimicrobial resistance for informing clinical guidance in the community and hospital sector.

— A mechanism (e.g. a national committee or platform) for the development, implementation and monitoring of clinical guidance for infections; such a mechanism should address diagnostics, treatment, management and infection prevention and control.

— Education of health professionals.

Core components and measures for implementation:

Regulation of antimicrobials:

— Ensure access to the antimicrobials recommended in clinical guidance, by conducting a review of national market availability, implementing measures to support sustained market availability for both innovative and generic products and tackling shortages. At the same time, limit the use of last-resort antimicrobials to safeguard their effectiveness, by establishing restrictive measures for use.

— Ensure that information on the risks of antimicrobial resistance and inappropriate use of antimicrobials is included in the SmPC and in patient information leaflets.

— Review, or establish if not in place, the legal provisions on availability of antimicrobials over the internet.

— Ensure compliance with the regulations with regards to the dispensing of antimicrobials by pharmacies without prescription.

— Explore per-unit dispensing of antimicrobials taking into consideration all relevant guidelines and regulations.

— Consider the introduction of additional labelling of antimicrobial packages to highlight the risk of increasing antimicrobial resistance through unwarranted use.

Antimicrobial prescribing and stewardship:

— Provide guidelines and tools for the implementation of antimicrobial stewardship programmes covering the community, long-term care facilities and hospitals.

— Ensure an appropriate number of experts in the field of antimicrobial stewardship through education of a sufficient number of specialists in infectious diseases and clinical microbiology and other professionals.

— Monitor and audit the appropriate use of antimicrobials, including the introduction of relevant quantity and quality indicators and systems for monitoring these indicators. Ensure regular feedback of the results to prescribers.

— Ensure the introduction and monitoring of electronic antimicrobial prescribing systems that are preferably able to link clinical indication, microbiological and consumption data.

— Ensure availability of adequate microbiology services and diagnostics, including rapid and point-of-care diagnostic tests.

— Consider and, if appropriate, implement incentive systems for appropriate prescribing.

([13]) Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance 17 June 2016 http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-antimicrobial-resistance/

— Fund, design, implement and assess the outcome of national awareness and educational campaigns on antimicrobial use by targeting health professionals and the general public (including children, teenagers, students, older people and vulnerable groups).

— Promote behavioural interventions to reduce inappropriate antimicrobial prescribing.

— Explore motivational and system change approaches to optimise antimicrobial prescribing.

— Identify best practices on antimicrobial promotional activity in collaboration with the pharmaceutical industry, to ensure it aligns with promoting appropriate antimicrobial prescribing and dispensing.

— Introduce appropriate disposal systems in the community setting, and inform the general public on the correct disposal methods for antimicrobial drugs.

— Ensure availability of national clinical guidance for prophylaxis and management of infections based on national antimicrobial resistance patterns for the community, long-term care facilities, and hospitals.

— Develop clinical pathways and provide decision support tools to encourage appropriate testing and management.

— Ensure that national clinical guidance is reviewed and revised when there is a significant change in antimicrobial resistance, or if there is new evidence on the management of infections, or at regular intervals (e.g. every 2 to 3 years); national clinical guidance should take into consideration the last valid summary of product characteristics of a medicinal product (SmPC).

— Ensure accessibility of the guidelines to all prescribers by ensuring wide distribution, training and promotion.

— Ensure availability of guidelines for therapeutic and prophylactic antimicrobial prescribing for particular categories of clinical setting including dental practice.

Actions in education:

— Make sure that the competency of all healthcare professionals is guaranteed by continuous professional development activities on appropriate antimicrobial use.

— Ensure that antimicrobial stewardship is included in all specialty training curricula for clinical specialties.

— Include training on prudent antimicrobial use in medical, nursing, pharmacy, dentistry and midwifery schools. This training should include a strong practical component as part of an inter-professional approach.

— Introduce education on prudent antimicrobial use, antimicrobial resistance, vaccination and hygiene in primary and secondary education.

4.2. **Healthcare facilities (resources, systems and processes)**

Healthcare facilities are on the front line for the implementation of policies and procedures, and for the provision of surveillance and monitoring data, which are necessary to ensure prudent antimicrobial use. They are also a focal point for audits during which a facility is examined for compliance with policy and professional standards.

Healthcare facilities should focus on the following elements:

— Establish and provide the necessary funding and resources for antimicrobial stewardship programmes in each healthcare facility, linked with the infection prevention and control programme and/or the patient safety programme.

— Ensure timely access to clinical microbiology laboratory services and transmission of results.

— Promote the uptake of rapid diagnostic tools.

— Utilise validated rapid and/or point-of-care diagnostics for defined patient groups to complement clinical assessment and optimise antimicrobial treatment when available.

— Ensure information technology support for antimicrobial stewardship activities, including electronic prescription and introduce electronic decision support systems as tools to improve antimicrobial prescribing.

— Contribute to facility-wide, national and regional surveillance systems, studies and prevalence surveys of antimicrobial resistance and antimicrobial consumption, including molecular epidemiological investigations.

In community/primary care:

— Ensure that antimicrobial stewardship activities are in place, under the coordination and with active involvement of the healthcare professionals in these settings, as dictated by the level of care, identified areas of antimicrobial overuse and misuse, and by national and local provisions.

— Establish a multi-faceted approach including elements such as clinic-based education, patient information leaflets and posters, pharmacist counselling of patients on antimicrobial treatment, prescriber feedback and clinician training in communication skills.

— Ensure sufficient time for consultation to allow for proper assessment and counselling of patients.

In hospitals, the elements of antimicrobial stewardship programmes should include:

— An antimicrobial committee or similar formal organisational structure with senior management support.

— An antimicrobial stewardship team including ideally a clinician with training, expertise and professional involvement in the diagnosis, prevention and treatment of infections (if possible an infectious disease specialist), a hospital pharmacist and a microbiologist (if possible a clinical microbiologist). The composition of the team is dictated by the hospital size and level of care and by national and local provisions.

— Salary support and dedicated time for antimicrobial stewardship activities.

— Guidelines for the diagnosis and management of infections and for perioperative antimicrobial prophylaxis.

— Documentation in the patient records of indication, drug choice, dose, route and duration of treatment.

— A policy for pre-authorisation and or post-prescription review of selected antimicrobial prescriptions.

— Microbiology laboratory services for acute care hospitals should be provided on a 24/7 basis for critical specimens.

— The availability of facility-specific cumulative susceptibility reports for common bacterial pathogens against antibiotics that are recommended in the relevant treatment guidelines.

— An audit of perioperative antimicrobial prophylaxis indication, choice, timing and duration.

— An annual report on antimicrobial stewardship activities which includes an evaluation of effectiveness, reported to the management.

— Monitoring of quality indicators and quantity metrics of antimicrobial use with feedback to prescribers and prescriber actions agreed.

In long-term care:

— Ensure that antimicrobial stewardship activities are in place and are given dedicated time and management support, under the coordination and with active involvement of the healthcare professionals in these settings, as dictated by national and local provisions.

— Establish a multi-faceted approach which includes elements such as education of nursing and medical staff, audits of antimicrobial use, feedback to the prescribers, and targeting identified areas of antimicrobial overuse and misuse.

4.3. **Clinical microbiologists**

Clinical microbiologists play a key role in providing diagnostic information. At the same time, they have the expertise required to exercise effective infection control, take steps to prevent antimicrobial resistance and adequately treat infections. Furthermore, they provide advice and guidance on optimal diagnostic strategies for infections. Clinical roles depend on the setting, clinical training and national provisions. The roles outlined in this section may overlap with those outlined below for infectious disease specialists.

Clinical microbiologists should:

— Ensure that susceptibility testing and reporting are in accordance with treatment guidelines (selective reporting) and European (i.e. EUCAST) and national standards. Ensure timely diagnosis and communication of critical results (e.g. blood cultures).

— Provide facility-specific cumulative susceptibility reports for common bacterial pathogens against antibiotics that are recommended in the guidelines.

— Be available to clinicians for counselling on diagnostics of infectious diseases, including correct sampling and interpretation of test results, difficult-to-treat pathogens and complicated infections.

— As full members of the antimicrobial stewardship team, take on responsibilities that include coordination, planning, post-prescription review and feedback.

4.4. **Infectious disease specialists**

Infectious disease specialists are involved in the clinical assessment, investigation, diagnosis and treatment of patients with infections, which also includes the optimal use of antimicrobials. They also provide consultation on the prevention and treatment of healthcare-associated infections, e.g. infections in intensive care units and surgical site infections, and therefore play a central role in the prudent use of antimicrobials in the hospital.

Depending on setting, training and national provisions, there may be some overlap in the roles outlined in this section with those outlined above for clinical microbiologists.

Infectious disease specialists should:

— Be available for consultation on diagnostic evaluation and treatment of infectious diseases including difficult-to-treat pathogens and complicated infections, as well as appropriate antimicrobial use.

— As full members of the antimicrobial stewardship team, take on responsibilities that include coordination, planning, post-prescription review and feedback.

4.5. **Prescribers**

Prescribers are ultimately responsible for the decision to use antimicrobials in patient care. They also choose the type of antimicrobials used in patient care. Prescribers should therefore be provided with training, guidelines and information in order to be able to exercise prudence in the prescribing of antimicrobials. Information should also be given how prescribers can assess and manage patient expectations. Prescribers working in the community, hospitals, dental practice, or other settings, should be familiar with any specific guidance applicable to the situation in which they are working.

Prescribers should:

— Ensure that they are familiar with the relevant guidelines, the last valid SmPC and prescribing advice before prescribing an antimicrobial.

— Keep themselves up to date regarding antimicrobial prescribing; this can be achieved by attending training courses, being aware of guidelines, and following guidelines.

— Seek and take advice from specialists regarding antimicrobial prescribing.

When making the decision to prescribe an antimicrobial, prescribers should do the following:

— Make a diagnosis during an in-person patient consultation before prescribing antibiotics, except in exceptional circumstances.

— Ensure that appropriate microbiological samples are taken before starting antimicrobial treatment.

— Avoid antibacterial treatment when there is only evidence of viral infection or of a self-limiting bacterial infection.

— Avoid treatment for colonisation without evidence of infection after relevant clinical examination and diagnostic testing unless there is a clear indication in the guidelines.

— Use antimicrobial prophylaxis only when indicated in relevant guidelines.

— Avoid antimicrobial combinations unless there is a clear indication outlined in the guidelines

— If antimicrobial treatment is not considered necessary, give the patient advice about the expected natural history of the illness, the limited or absent benefit of antimicrobial treatment, and the potential unwanted side effects of antimicrobials such as diarrhoea and rash, recommendations for symptom management, as well as advice about actions in case of worsening clinical condition (safety netting).

When prescribing an antimicrobial, prescribers should:

— Select an antimicrobial in accordance with relevant guidelines, at an appropriate dose, for the shortest effective duration and with appropriate route of administration (preferably oral if possible).

— Consider relevant host factors: age, comorbidities (e.g. immunodeficiency), renal and hepatic function, pregnancy, breastfeeding, allergies, presence of prosthetic material, potential drug interactions, body mass index and risk factors for antimicrobial resistance (e.g. history of recent antimicrobial use, history of recent travel).

— Promote allergy testing for patients with a history of allergic reaction to beta-lactams, as a measure to promote use of first-line antimicrobials in non-allergic patients.

— Select an antimicrobial with a spectrum of activity as narrow as possible. Ensure timely administration of antimicrobial treatment for patients with severe infections. Examples: sepsis, severe community-acquired pneumonia.

— If possible, inform the patient and/or responsible caregiver about the reason for antimicrobial treatment and potential side effects and ensure that the patient understands the dosage and duration of treatment; this improves adherence and increases treatment success.

— Address the patient's expectations, questions and preferences as an essential component of patient-centred care and an effective intervention to promote the prudent use of antimicrobials.

— Reassess antimicrobial treatment and consider modification (e.g. de-escalation, discontinuation or switch to oral treatment) after 48–72 hours in hospitals and, in specific circumstances, in other settings in accordance with guidelines.

In the community, prescribers should:

— Refrain from prescribing antibacterials for viral or self-limiting bacterial infections.

— Consider delayed antimicrobial prescribing with appropriate safety netting for adults or children in specific circumstances and in accordance with guidelines. Example: delayed antimicrobial prescribing for acute otitis media or acute rhinosinusitis.

— Evaluate symptoms and use scoring systems or symptom checking lists to guide the need for diagnostic testing, antimicrobial treatment and urgent referral.

In hospitals, prescribers should:

— Document in the patient chart: indication, drug choice, dose, route and duration of treatment. Follow guidance for perioperative antimicrobial prophylaxis. Enhance timely and adequate source control for surgical infections and discourage using only antimicrobials instead of surgical treatment when there is a clear indication for surgical treatment.

— Evaluate the need for parenteral antimicrobials and switch to oral antimicrobials when possible, all in accordance with available clinical criteria.

— Therapeutic drug monitoring is recommended for adjustment of the dosing regimen in accordance with guidelines and in specific circumstances.

4.6. **Pharmacists**

Pharmacists in community and hospital settings have expertise in medicines and are the gatekeepers to the use of antimicrobials. As such, pharmacists can act as an important source of advice and information for patients and prescribers on the safe, rational and effective use of antimicrobials (including on side effects, adherence, adverse drug reactions, cautions & contra-indications, interactions, storage & disposal and rationale for treatment). To this end, they need to be provided with appropriate training, guidelines and information in order to be able to encourage prudence in the prescribing of antimicrobials and manage patient expectations. In the hospital setting, a pharmacist should be a member of the antimicrobial stewardship team and actively involved in antimicrobial management in the multidisciplinary care team. The role of the pharmacist includes assessing the prescription in accordance with local policies for antimicrobial use; reviewing the antimicrobial duration; counselling on the use of restricted antimicrobials; giving advice on dosage, preparation and administration (especially for special patient cohorts such as children); and advising patients on the proper use of antimicrobials. Pharmacists should also be involved in monitoring antimicrobial use.

Pharmacists should:

— Only dispense antimicrobials with prescription, unless specific provisions allow for regulated dispensation in specific circumstances.

— Ensure that the patient and/or the carer understands the dosage and duration of treatment as this can improve adherence and increase treatment success.

— Promote appropriate disposal of leftover antimicrobials.

— Notify adverse events related to antimicrobials in accordance with regulations.

— Participate in local, regional or national public health campaigns promoting the prudent use of antimicrobials.

— Provide advice to patients and health professionals with regard to contraindications, drug interactions and food–drug interactions.

4.7. **Nurses**

The role of nurses within the clinical team is critical because of their regular contacts with patients and their role in administering medicines. Nurses make sure that antimicrobials are taken according to the prescription; they also monitor the response to antimicrobials (including potential adverse effects). In general, nurses are responsible for the administration of antimicrobials and for monitoring the patient and patient safety.

The role of nurse prescribers is also critical.

Nurses should:

— Be actively involved in antimicrobial management as part of the multidisciplinary care team.

— Ensure timely administration of antimicrobials according to prescription.

— Provide advice and educate the patient on the proper use of antimicrobials.

— Utilise protocols and tools that enable you to independently detect patients with severe infections and then trigger diagnostic and treatment algorithms.

— Remind the clinician to reassess the antimicrobial treatment after 48 to 72 hours.

4.8. **Infection control practitioners**

Infection control practitioners play an essential role in the prevention and control of infections, many of which are associated with inappropriate antimicrobial use. Infection control practitioners can therefore support the prudent use of antimicrobials through the provision of advice and peer review.

Infection control practitioners should:

— Ensure coordination and collaboration between antimicrobial stewardship programmes and infection prevention and control programmes by highlighting the essential aspects of appropriate antimicrobial use in the prevention and control of healthcare-associated infections.

4.9. **Public/patients**

The knowledge, attitudes and behaviour of the public and patients can be of profound importance in establishing and ensuring the prudent use of antimicrobials, both in terms of expectations and normative pressures that these can exert on healthcare professionals and peers, and their adherence to medication schedules.

The general public and patients should:

— Inform themselves and, where needed, seek information from healthcare providers about appropriate antimicrobial use, antimicrobial resistance and adverse reactions to antimicrobials.

— Use antimicrobials only when prescribed.

— Refrain from using antimicrobials which have not been prescribed such as leftover antimicrobials, antimicrobials prescribed for another person, or antimicrobials obtained without a prescription.

— Return leftover antimicrobials to pharmacies and local collection, in accordance with local disposal regulations.

4.10. **Professional associations and scientific societies**

Professional associations and scientific societies represent the healthcare professionals and promote the professional and scientific development of their members, thus influencing clinical and laboratory practice.

Professional associations and scientific societies should:

— Cooperate closely with the regulatory authorities in all relevant domains to ensure that the proposed measures to promote the prudent use of antimicrobials are evidence-based and feasible.

— Promote prudent use of antimicrobials among their members through activities that include guideline development and training.

— Supporting information and awareness raising activities to promote prudent use of antimicrobials

— Avoid conflicts of interest and commercial consideration.

— Promote and conduct relevant research.

4.11. **Research funders**

Research is essential to reduce the current levels of, and rising trends in, antimicrobial resistance. In particular, translational research is needed to identify options for improving the ways in which we use existing antimicrobials. Research is also needed to explore how the risk of developing antimicrobial resistance can be mitigated.

Research funders and those responsible for research policy should:

— Promote research that assesses and compares behavioural change interventions for antimicrobial prescribing, taking into account cultural differences, in order to improve our understanding how rational antimicrobial prescribing practices can be achieved.

— Promote research on interventional studies for antimicrobial prescribing.

— Promote research on the potential of specific antimicrobials and antimicrobial classes to create a selective pressure toward antimicrobial resistance in microbiota.

— Promote clinical research studies on existing antimicrobials, including pharmacokinetic/pharmacodynamics studies, ensuring that studies sufficiently consider sex/gender and age factors across the lifespan.

— Promote research on diagnostic tools, including rapid and point-of-care diagnostics to support evidence-based guidelines for the role of diagnostics in appropriate antimicrobial prescribing.

— Promote research studies in antimicrobial therapeutic drug monitoring in special populations (e.g. critically ill patients, burned patients, paediatric patients, patients receiving continuous renal replacement therapy).

— Promote research on educational and awareness interventions which target the public and patients.

— Support activities to enable research to be translated into practice, systematic reviews and meta-analyses, and the use of research results to inform clinical guideline development and decision-making.

4.12. **Pharmaceutical industry**

The pharmaceutical industry is a key partner in the overall effort to ensure the prudent use of antimicrobials.

The pharmaceutical industry should:

— Ensure that marketing and promotional activities to healthcare professionals are in accordance with the EU legislation e.g. the advertising of a medicinal product to healthcare professionals must comply with the particulars listed in the summary of product characteristics and should encourage the rational use of the medicinal product.

— Ensure that financial incentives within companies are aligned with the stewardship principles laid out above.

— Ensure the monitoring of resistance and off-label use after launching new compounds in accordance with post-marketing obligations.

— Engage with national and international policymakers and regulators to support the development of policies that promote appropriate antimicrobial prescribing, including the design of novel reimbursement systems, adaptation of pack size and other processes that contribute to the goals of access and conservation.

4.13. **Diagnostics industry**

Diagnostic testing, including testing in microbiology laboratories but also point-of-care and novel diagnostics, provides essential information to avoid unnecessary antimicrobial use and optimise antimicrobial selection.

The diagnostics industry should:

— Address the different needs for diagnostics including point-of-care testing and surveillance.

— Collaborate with scientific societies and public health in the development of evidence-based guidelines on the use of tests for the diagnosis of infection, including novel diagnostics and point-of-care tests.

— Support studies on the effect of novel diagnostics on the prudent use of antimicrobials, and on the cost-effectiveness of diagnostics.

4.14. **International collaboration**

International cross-sectoral, inter-governmental and inter-organisational collaboration and coordination, both within and outside the EU is required to establish standards, systems and procedures necessary to ensure the prudent use of antimicrobials, the sharing of best practices, and the support of capacity development.

International collaboration should contribute to the following:

— Facilitate the coordination of response to cross-border threats relating to antimicrobial-resistant organisms.

— Design, implement and monitor antimicrobial stewardship interventions and campaigns to support appropriate antimicrobial use and reduce inappropriate antimicrobial use.

— Establish mechanisms for sharing best practice interventions on appropriate antimicrobial use and their impact on relevant qualitative and quantitative outcomes.

— Enable cooperation on the surveillance of antimicrobial consumption and antimicrobial resistance using a harmonised methodology with the aim of providing timely information regarding cross-border threats from resistant organisms, as well as providing valid and internationally comparable information on resistance and consumption.

— Harmonisation of clinical breakpoints and methods for antimicrobial susceptibility testing.

— Support the development of good evidence-based clinical practice guidelines that address the most common infections and are adaptable to local resistance patterns and available licensed antibacterials.

— Facilitate access to essential antimicrobials and diagnostic tests by supporting market availability and tackling shortages.

— Encourage, at the national level, the development of standards and adoption of selective reporting of microbiology results to optimise antimicrobial prescribing.

— Support the development of evidence-based guidelines on the use of rapid and point-of-care diagnostics.

— Promote and financial support of research and development of new antimicrobials and new point-of-care tests.

— Facilitate cross-sectoral collaboration in the animal health, food production and healthcare sectors regarding the surveillance of, and policies for, antimicrobial use.

Non-opposition to a notified concentration

(Case M.8474 — HNA/CWT)

(Text with EEA relevance)

(2017/C 212/02)

On 15 June 2017, the Commission decided not to oppose the above notified concentration and to declare it compatible with the internal market. This decision is based on Article 6(1)(b) of Council Regulation (EC) No 139/2004 ([1]). The full text of the decision is available only in English and will be made public after it is cleared of any business secrets it may contain. It will be available:

— in the merger section of the Competition website of the Commission (http://ec.europa.eu/competition/mergers/cases/). This website provides various facilities to help locate individual merger decisions, including company, case number, date and sectoral indexes,

— in electronic form on the EUR-Lex website (http://eur-lex.europa.eu/homepage.html?locale=en) under document number 32017M8474. EUR-Lex is the online access to European law.

([1]) OJ L 24, 29.1.2004, p. 1.

Non-opposition to a notified concentration

(Case M.8385 — Pillarstone/Famar)

(Text with EEA relevance)

(2017/C 212/03)

On 3 May 2017, the Commission decided not to oppose the above notified concentration and to declare it compatible with the internal market. This decision is based on Article 6(1)(b) of Council Regulation (EC) No 139/2004 ([1]). The full text of the decision is available only in English and will be made public after it is cleared of any business secrets it may contain. It will be available:

— in the merger section of the Competition website of the Commission (http://ec.europa.eu/competition/mergers/cases/). This website provides various facilities to help locate individual merger decisions, including company, case number, date and sectoral indexes,

— in electronic form on the EUR-Lex website (http://eur-lex.europa.eu/homepage.html?locale=en) under document number 32017M8385. EUR-Lex is the online access to European law.

([1]) OJ L 24, 29.1.2004, p. 1.

III

(Preparatory acts)

EUROPEAN CENTRAL BANK

Recommendation for a Decision of the European Parliament and of the Council amending Article 22 of the Statute of the European System of Central Banks and of the European Central Bank

(ECB/2017/18)

(presented by the European Central Bank)

(2017/C 212/04)

EXPLANATORY MEMORANDUM

I. INTRODUCTION

On 4 March 2015, the General Court delivered its judgment in Case T-496/11 *United Kingdom of Great Britain and Northern Ireland* v *European Central Bank* [1]. The General Court held that the European Central Bank (ECB) does not have the competence necessary to regulate the activity of clearing systems, including central counterparties (CCPs). For that reason, the General Court annulled the Eurosystem Oversight Policy Framework, published by the ECB on 5 July 2011, in so far as it set a requirement for CCPs to be located within a euro area Member State.

However, the General Court noted that Article 129(3) of the Treaty on the Functioning of the European Union provides for a simplified amendment procedure in respect of certain articles of the Statute of the European System of Central Banks and of the European Central Bank (hereinafter the 'Statute of the ESCB'). This enables the European Parliament and the Council, acting in accordance with the ordinary legislative procedure, and on a recommendation from the ECB or a proposal from the Commission, to amend Article 22 of the Statute of the ESCB. The General Court considered it would be for the ECB to request the European Union legislature to amend Article 22, should the ECB consider that having the power to regulate CCPs is necessary for the proper performance of the task referred to in the fourth indent of Article 127(2) of the Treaty.

Significant developments at both global and European level are expected to increase the risks posed by clearing systems, in particular CCPs, to the smooth operation of payment systems and implementation of the single monetary policy, ultimately affecting the Eurosystem's primary objective of maintaining price stability.

In view of the above, the ECB submits the present recommendation for a Decision of the European Parliament and of the Council amending Article 22 of the Statute of the ESCB. In accordance with Article 40.3 of the Statute of the ESCB, the Governing Council has adopted the recommendation by unanimity. It will be published in the *Official Journal of the European Union*.

II. GENERAL CONSIDERATIONS

Disturbances affecting CCPs can have an impact on the Eurosystem's primary objective of maintaining price stability through several channels. First, such disturbances can affect the liquidity position of euro area credit institutions, potentially disrupting the smooth functioning of euro area payment systems. This could lead to increased demand for central bank liquidity and possible challenges in implementing the Eurosystem's single monetary policy. Second, such disturbances can impair the functioning of financial market segments that are key for the transmission of monetary policy.

In 2012, the European Parliament and the Council adopted Regulation (EU) No 648/2012 [2] setting out, inter alia, the regulatory and supervisory framework to ensure that CCPs are safe and sound and comply at all times with stringent organisational, business conduct and prudential requirements. This regulatory framework includes collective supervisory arrangements in the form of colleges, which provide for the involvement of the Eurosystem, including under situations

[1] ECLI: EU:T:2015:133.

[2] Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories (OJ L 201, 27.7.2012, p. 1).

of stress in which the stability of the currency may be at risk. Moreover, in the light of the growing systemic importance of CCPs, the European Commission has adopted a proposal for a Regulation on a framework for the recovery and resolution of CCPs ([1]).

Significant developments at both global and European level are expected to increase the risks posed by clearing systems, in particular CCPs, to the smooth operation of payment systems and implementation of the single monetary policy, ultimately affecting the Eurosystem's primary objective of maintaining price stability.

First, the withdrawal of the United Kingdom from the European Union will have a major impact on the Eurosystem's ability to carry out its tasks as central bank of issue for the euro. At present, CCPs established in the United Kingdom clear significant volumes of euro-denominated transactions: the estimated daily values of euro-denominated repos and open positions in euro-denominated interest rate swaps are respectively EUR 101 billion and EUR 33 trillion (around 99 % of the Union market) ([2]). Thus, a significant disturbance affecting a major UK CCP could lead to a severe decrease in liquidity within the euro area. The Eurosystem's ability to monitor and manage the risks posed by UK CCPs will be adversely affected if UK CCPs are no longer subject to the regulatory and supervisory framework for Union CCPs under Regulation (EU) No 648/2012. Moreover, the current arrangements between the ECB and the Bank of England for information exchange and cooperation regarding UK CCPs with significant euro-denominated business build upon, but cannot replace, collective supervisory arrangements in the form of colleges established under Regulation (EU) No 648/2012. In the future, UK CCPs may instead be subject only to the regime applicable to third-country CCPs under that Regulation.

Second, central clearing has become increasingly cross-border in nature and systemically important. At the September 2009 summit in Pittsburgh, G20 leaders agreed that all standardised OTC derivative contracts should be cleared through a CCP. This commitment was reaffirmed by the G20 leaders in June 2010, and implemented in the Union by Regulation (EU) No 648/2012. Moreover, the integration of Union financial markets has meant that CCPs have evolved from primarily serving domestic needs and markets to constituting critical infrastructures in Union financial markets. These developments have led to a dramatic increase in the scale and importance of CCPs in the Union and globally.

Third, on 13 June 2017, the European Commission presented its legislative proposal to ensure financial stability and the safety and soundness of CCPs that are of systemic relevance for financial markets across the Union ([3]). The Commission's proposal seeks to introduce more integrated supervision by the supervisors and responsibilities for the central bank of issue in order to support the development of deeper and better integrated capital markets. It also seeks to address the issues raised by the withdrawal of the United Kingdom from the Union and to ensure that CCPs playing a key systemic role for Union financial markets are subject to safeguards provided by the Union legal framework.

In this context, in order to ensure that the Eurosystem as central bank of issue for the euro can carry out the role envisaged by the legislative proposal, it is of utmost importance that it has the relevant powers under the Treaty and the Statute of the ESCB. The Eurosystem should have the power to monitor and assess risks posed by CCPs clearing significant amounts of euro-denominated transactions. This should include, in particular, the regulatory powers to adopt binding assessments and require remedial action, in close cooperation with other Union authorities, in response to risks affecting the Eurosystem's basic tasks and primary objective. Moreover, where necessary to protect the stability of the euro, the ECB should have the regulatory powers outside the framework of Regulation (EU) No 648/2012 to adopt additional requirements for CCPs involved in the clearing of significant amounts of euro-denominated transactions.

In the light of the above, the ECB considers that the grant to it of the power to regulate clearing systems, in particular CCPs, is necessary for the proper performance of its basic tasks referred to in the first and fourth indents of Article 127(2) of the Treaty.

([1]) Proposal for a Regulation of the European Parliament and of the Council on a framework for the recovery and resolution of central counterparties and amending Regulations (EU) No 1095/2010, (EU) No 648/2012, and (EU) 2015/2365 (COM(2016) 856 final).

([2]) LCH.Clearnet Ltd CPMI-IOSCO public quantitative disclosure information, January 2017.

([3]) Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 1095/2010 establishing a European Supervisory Authority (European Securities and Markets Authority) and amending Regulation (EU) No 648/2012 as regards the procedures and authorities involved for the authorisation of CCPs and requirements for the recognition of third-country CCPs (COM(2017) 331 final).

Recommendation for a

'DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Article 22 of the Statute of the European System of Central Banks and of the European Central Bank

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 129(3) thereof,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Article 40.1 thereof,

Having regard to the recommendation of the European Central Bank,

Having regard to the opinion of the European Commission (*),

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The basic tasks to be carried out through the European System of Central Banks (ESCB) include the definition and implementation of the monetary policy of the Union and the promotion of the smooth operation of payment systems. Safe and efficient financial market infrastructures, in particular clearing systems, are essential for the fulfilment of these basic tasks.

(2) In order to achieve the objectives of the ESCB and to carry out its tasks, the European Central Bank (ECB) and national central banks may provide facilities, and the ECB may make regulations, to ensure efficient and sound clearing and payment systems within the Union and with other countries.

(3) On 4 March 2015, the General Court delivered its judgment in *United Kingdom* v *ECB*, Case T-496/11 ([1]), which held that the ECB does not have the competence necessary to regulate the activity of clearing systems. The General Court stated that Article 129(3) of the Treaty enables the European Parliament and the Council, acting in accordance with the ordinary legislative procedure, and on a recommendation from the ECB, to amend Article 22 of the Statute of the European System of Central Banks and of the European Central Bank (hereinafter the 'Statute of the ESCB'). The Court concluded that 'it would be for the ECB, should it consider that the grant to it of a power to regulate infrastructures clearing transactions in securities is necessary for proper performance of the task referred to in the fourth indent of Article 127(2) TFEU, to request the EU legislature to amend Article 22 of the Statute, by the addition of an explicit reference to securities clearing systems.'

(4) Significant developments at both global and European level are expected to increase the risk that disturbances affecting clearing systems, in particular central counterparties (CCPs), threaten the smooth operation of payment systems and implementation of the single monetary policy, ultimately affecting the Eurosystem's primary objective of maintaining price stability.

(5) On 29 March 2017, the United Kingdom of Great Britain and Northern Ireland notified the European Council of its intention to withdraw from the European Union. The withdrawal of the United Kingdom will lead to a fundamental change in how certain systemically important euro-denominated clearing activities are regulated, overseen and supervised, thereby adversely affecting the Eurosystem's ability to monitor and manage risks to the smooth operation of payment systems, and implementation of the Eurosystem's monetary policy.

(6) Central clearing is becoming increasingly cross-border in nature and systemically important. Given their diverse membership and the pan-European nature of the financial services they provide, CCPs are of key importance to the Union as a whole, and in particular to the euro area. This is reflected in Regulation (EU) No 648/2012 of the European Parliament and of the Council ([2]), which establishes collective supervisory arrangements in the form of colleges, composed of the relevant national and Union authorities, including the Eurosystem in its role as central bank of issue for the euro.

(7) In order to address these issues, on 13 June 2017 the Commission presented its legislative proposal to ensure financial stability and the safety and soundness of CCPs that are of systemic relevance for financial markets across the Union. In order to ensure that the Eurosystem as central bank of issue for the euro can carry out the role

(*) Not yet published in the Official Journal.

([1]) ECLI: EU:T:2015:133.

([2]) Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories (OJ L 201, 27.7.2012, p. 1).

envisaged by the legislative proposal, it is of utmost importance that it has the relevant powers under the Treaty and the Statute of the ESCB. In particular, the Eurosystem should have regulatory powers to adopt binding assessments and require remedial action, in close cooperation with other Union authorities. Moreover, where necessary to protect the stability of the euro, the ECB should also have the regulatory powers to adopt additional requirements for CCPs involved in the clearing of significant amounts of euro-denominated transactions.

(8) Article 22 of the Statute of the ESCB is part of Chapter IV 'Monetary functions and operations of the ESCB'. The tasks conferred therein should accordingly only be used for monetary policy purposes.

(9) For these reasons, the ECB should be granted regulatory competence over clearing systems, in particular CCPs, by means of an amendment to Article 22 of the Statute of the ESCB,

HAVE ADOPTED THIS DECISION:

Article 1

Article 22 of the Statute of the ESCB is replaced by the following:

'*Article 22*

Clearing systems and payment systems

The ECB and national central banks may provide facilities, and the ECB may make regulations, to ensure efficient and sound clearing and payment systems, and clearing systems for financial instruments, within the Union and with other countries.'

Article 2

This decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.'

Done at Frankfurt am Main, 22 June 2017.

The President of the ECB

Mario DRAGHI

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Euro exchange rates [1]

30 June 2017

(2017/C 212/05)

1 euro =

	Currency	Exchange rate		Currency	Exchange rate
USD	US dollar	1,1412	CAD	Canadian dollar	1,4785
JPY	Japanese yen	127,75	HKD	Hong Kong dollar	8,9068
DKK	Danish krone	7,4366	NZD	New Zealand dollar	1,5554
GBP	Pound sterling	0,87933	SGD	Singapore dollar	1,5710
SEK	Swedish krona	9,6398	KRW	South Korean won	1 304,56
CHF	Swiss franc	1,0930	ZAR	South African rand	14,9200
ISK	Iceland króna		CNY	Chinese yuan renminbi	7,7385
NOK	Norwegian krone	9,5713	HRK	Croatian kuna	7,4103
BGN	Bulgarian lev	1,9558	IDR	Indonesian rupiah	15 209,34
CZK	Czech koruna	26,197	MYR	Malaysian ringgit	4,8986
HUF	Hungarian forint	308,97	PHP	Philippine peso	57,575
PLN	Polish zloty	4,2259	RUB	Russian rouble	67,5449
RON	Romanian leu	4,5523	THB	Thai baht	38,744
TRY	Turkish lira	4,0134	BRL	Brazilian real	3,7600
AUD	Australian dollar	1,4851	MXN	Mexican peso	20,5839
			INR	Indian rupee	73,7445

[1] *Source*: reference exchange rate published by the ECB.

COURT OF AUDITORS

Special Report No 10/2017

'EU support to young farmers should be better targeted to foster effective generational renewal'

(2017/C 212/06)

The European Court of Auditors hereby informs you that Special Report No 10/2017 'EU support to young farmers should be better targeted to foster effective generational renewal' has just been published.

The report can be accessed for consultation or downloading on the European Court of Auditors' website: http://eca.europa.eu

NOTICES FROM MEMBER STATES

Commission information notice pursuant to Article 16(4) of Regulation (EC) No 1008/2008 of the European Parliament and of the Council on common rules for the operation of air services in the Community

Repeal of public service obligations in respect of scheduled air services

(Text with EEA relevance)

(2017/C 212/07)

Member State	United Kingdom
Route concerned	Dundee to Heathrow Airport Dundee to Gatwick Airport Dundee to Luton Airport Dundee to London City Airport Dundee to Southend Airport
Original date of entry into force of the public service obligations	26 March 2017
Date of repeal	2 May 2017
Address where the text and any relevant information and/or documentation relating to the public service obligation can be obtained	Dundee City Council 18 City Square Dundee DD1 3BY UNITED KINGDOM Tel. +44 1382433860 Email: karen.lawson@dundeecity.gov.uk

Commission information notice pursuant to Article 16(4) of Regulation (EC) No 1008/2008 of the European Parliament and of the Council on common rules for the operation of air services in the Community

Repeal of public service obligations in respect of scheduled air services

(Text with EEA relevance)

(2017/C 212/08)

Member State	United Kingdom
Route concerned	City of Derry to Heathrow Airport City of Derry to Gatwick Airport City of Derry to Luton Airport City of Derry to London City Airport City of Derry to Southend Airport
Original date of entry into force of the public service obligations	26 March 2017
Date of repeal	2 May 2017
Address where the text and any relevant information and/or documentation relating to the public service obligation can be obtained	John Kelpie Chief Executive Derry City & Strabane District Council 98 Stand Road Derry BT48 7NN UNITED KINGDOM

V

(Announcements)

ADMINISTRATIVE PROCEDURES

EUROPEAN COMMISSION

Call for applications 2017

for the 'Altiero Spinelli Prize for Outreach: Spreading Knowledge about Europe'

(2017/C 212/09)

The Directorate-General for Education, Youth, Sport and Culture has launched a call for applications for a European Union 'Altiero Spinelli Prize for Outreach: Spreading Knowledge about Europe'.

The aim of the call is to reward outstanding contributions that enhance citizens' understanding of the EU, broaden the ownership of the European project, inspire citizens and build trust in the EU.

There will be six first prizes of EUR 50 000, six second prizes of EUR 30 000 and 10 third prizes of EUR 17 000.

Registration of intention to apply is compulsory by **16 August 2017**.

The deadline for applications is **2 October 2017**.

All relevant information and application forms are available at: https://ec.europa.eu/education/calls/altiero-spinelli-prize-contest-2017_en

PROCEDURES RELATING TO THE IMPLEMENTATION OF COMPETITION POLICY

EUROPEAN COMMISSION

Prior notification of a concentration

(Case M.8539 — KPS/DexKo)

Candidate case for simplified procedure

(Text with EEA relevance)

(2017/C 212/10)

1. On 16 June 2017, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ([1]) by which KPS Capital Partners, L.P. ('KPS', USA) acquires, within the meaning of Article 3(1)(b) of the Merger Regulation, control of the whole of DexKo Global, Inc. ('DexKo', USA) by way of a purchase of shares.

2. The business activities of the undertakings concerned are:

— KPS is a US-based investment management fund with investments in a diverse array of industries, including basic materials, branded consumer, healthcare and luxury products, automotive parts, capital equipment and general manufacturing,

— DexKo is a US-based designer and manufacturer of trailer axles and running gear components. It offers trailer axles and brakes, hubs and drums, chassis, suspension components, and other running gear components.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved. Pursuant to the Commission Notice on a simplified procedure for treatment of certain concentrations under the Council Regulation (EC) No 139/2004 ([2]) it should be noted that this case is a candidate for treatment under the procedure set out in this Notice.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

Observations must reach the Commission not later than 10 days following the date of this publication. Observations can be sent to the Commission by fax (+32 22964301), by email to COMP-MERGER-REGISTRY@ec.europa.eu or by post, under reference M.8539 — KPS/DexKo, to the following address:

European Commission
Directorate-General for Competition
Merger Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

([1]) OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').
([2]) OJ C 366, 14.12.2013, p. 5.

Prior notification of a concentration

(Case M.8459 — TIL/PSA/PSA DGD)

(Text with EEA relevance)

(2017/C 212/11)

1. On 23 June 2017, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 [1] by which Europe Terminal NV ('ET', Switzerland) a wholly-owned subsidiary of Terminal Investment Limited Sàrl ('TIL', Switzerland) and Kranji (Netherlands) Investments BV ('Kranji', Netherlands) a holding company controlled by PSA International Pte Ltd ('PSA', Singapore) acquire within the meaning of Article 3(1)(b) of the Merger Regulation joint control over PSA DGD NV ('PSA DGD', Belgium) by way of purchase of shares.

2. The business activities of the undertakings concerned are:

— for PSA: PSA is an operator of shipping terminals. It is mainly active in the provision of stevedoring services at ports, with a particular focus on providing terminal services for containerised liner ships,

— for TIL: TIL is a terminal operating company indirectly jointly controlled by MSC Mediterranean Shipping Company Holding SA and certain financial investment vehicles managed by Global Infrastructure Management, LLC. TIL invests in, develops and manages container terminals around the world, often in joint ventures with other major terminal operators,

— for PSA DGD: PSA DGD operates a container terminal in the Deurganck dock in the Port of Antwerp. It is a pre-existing company currently solely controlled by Kranji.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

Observations must reach the Commission not later than 10 days following the date of this publication. Observations can be sent to the Commission by fax (+32 22964301), by email to COMP-MERGER-REGISTRY@ec.europa.eu or by post, under reference M.8459 — TIL/PSA/PSA DGD, to the following address:

European Commission
Directorate-General for Competition
Merger Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

[1] OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').

OTHER ACTS

EUROPEAN COMMISSION

Notice concerning a request pursuant to Article 35 of Directive 2014/25/EU — Suspension of a deadline

(2017/C 212/12)

On 30 January 2017 the Commission received a request pursuant to Article 35 of Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC [1]. The first working day following receipt of the request was 31 January 2017 and the initial period available to the Commission for deciding on this request was of 105 working days.

This request, made by Eneco BV and NV Nuon Energy, concerns retail of electricity and gas in the Netherlands. The relevant notice was published on page 7 of OJ C 85 of 18 March 2017. The initial deadline was 6 July 2017.

Pursuant to Annex IV, point 2, of Directive 2014/25/EU, the Commission may require the Member State or the contracting entity concerned or the competent independent national authority or any other competent national authority to provide all necessary information or to supplement or clarify information given within an appropriate time limit. On 24 March 2017 the Commission asked the Dutch authorities to provide additional information by 17 April 2017 at the latest.

In the event of late or incomplete answers, the initial deadline shall be suspended for the period between the expiry of the time limit set in the request for information, and the receipt of the complete and correct information.

The final deadline will therefore expire after 53 working days after the receipt of the complete and correct information.

[1] OJ L 94, 28.3.2014, p. 243.

Notice concerning a request pursuant to Article 35 of Directive 2014/25/EU — Suspension of a deadline

(2017/C 212/13)

On 30 January 2017 the Commission received a request pursuant to Article 35 of Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC [1]. The first working day following receipt of the request was 31 January 2017 and the initial period available to the Commission for deciding on this request was of 105 working days.

This request, made by Eneco BV, NV Nuon Energy and DONG Energy A/S, concerns production and wholesale of electricity in the Netherlands. The relevant notice was published on page 6 of OJ C 85 of 18 March 2017. The initial deadline was 6 July 2017.

Pursuant to Annex IV, point 2, of Directive 2014/25/EU, the Commission may require the Member State or the contracting entity concerned or the competent independent national authority or any other competent national authority to provide all necessary information or to supplement or clarify information given within an appropriate time limit. On 24 March 2017 the Commission asked the Dutch authorities to provide additional information by 17 April 2017 at the latest.

In the event of late or incomplete answers, the initial deadline shall be suspended for the period between the expiry of the time limit set in the request for information, and the receipt of the complete and correct information.

The final deadline will therefore expire after 53 working days after the receipt of the complete and correct information.

[1] OJ L 94, 28.3.2014, p. 243.

ISSN 1977-091X (electronic edition)
ISSN 1725-2423 (paper edition)

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

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