Introduction: Guidelines caution prescribers and patients against chronic benzodiazepine use (BZD). Nevertheless, BZD use among nursing home residents remains high. We focused on individual residents and explored benefit and harm of chronic BZD use, willingness to try, and barriers against the discontinuation of chronic BZD use by questioning the general practitioner (GP) and the nurse.

Patients (or Materials) and Methods: In this cross-sectional study, we selected nursing home residents with at least 3 months of BZD use. A resident-specific questionnaire was addressed to the GP and nurse. For every resident, the GP and nurse had to score 8 barrier statements on a 10 point Likert scale. Additionally, we collected 10 general attitudes scored by GPs and nurses. The questionnaire was based on an expert meeting and was pretested.

Results: We received data from 109 chronic BZD users. GPs and nurses indicated that the BZD still had the desired effect in, respectively, 87% and 83% of the residents, and that except for dependence; there were no observed side effects in 75% and 70% of the residents. Overall, GPs had higher barriers than the nurses. Nevertheless, the willingness to stop among GPs was higher (respectively 33% vs. 21%). Both caregivers were willing to stop in 13% of the residents. The most common barriers against discontinuation was for both caregivers the fear that initial problems will come back and the preference of a pharmacologic treatment instead of a nonpharmacologic treatment. The GPs perceived the resident’s motivation as a larger barrier than the nurses (median, 9 vs 7; \( P = 0.001 \)) and indicated more often that discontinuation of BZDs can lead to an increase in care burden (median, 8 vs 6; \( P = 0.028 \)). Of all 10 general statements, the most common attitude among both GPs and nurses was that the longer the resident takes the medication, the more difficult it is to stop (median, 8), and the resident’s old age makes it difficult and unnecessary to stop. Nurses, in contrast to the GPs, indicated that there is little knowledge on alternative strategies to handle troubles when stopping BZDs (median, 7 vs 2; \( P < 0.001 \)) and little scientific information available for stopping (median, 6 vs 2; \( P = 0.004 \)). The scores for resident-specific barriers were higher than for general statements.

Conclusion: The perceived effectiveness, the absence of side effects and the presence of dependence in most residents that use BZD chronically, result in a low willingness to stop. Implementation of discontinuation initiatives have to address different barriers of different parties requiring multidisciplinary evaluation of residents.

Disclosure of Interest: None declared.

PP224—ViEWs of clinical and non-clinical professionals on information about older patients needed for rational drug prescription at time of authorisation

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Introduction: The ICH E7 guideline for studies involving geriatric patients intends to improve the knowledge about medicines in that population. As a legislative document, it might not reflect the needs of health care professionals. This study investigated what information health care professionals, regulatory agencies, and pharmaceutical industries actually consider necessary for rational drug prescribing to older individuals.

Patients (or Materials) and Methods: A 29-item questionnaire was composed, focusing on the representation of older individuals in trials, the pharmacokinetics, efficacy and safety, and the convenience of use of medicinal products. Forty-three European physicians, pharmacists, ethicists, regulators, and professionals from the pharmaceutical industry, all specialized in medication for older individuals were included. A second questionnaire was composed of 11 control items and 5 new items, based on comments. Median scores, differences between clinical and nonclinical respondents, and the consistency of responses were analyzed.

Results: Thirty-seven (86%) respondents returned the initial questionnaire: 23 clinicians and 14 nonclinical professionals. The second was returned by 21 clinicians and 10 nonclinical professionals (31/37 [84%]). There were no significant differences between respondents regarding 10 control items. Information about 32 (94%) of the 34 items was considered necessary. Information about age-related differences in adverse events, locomotor effects, drug–disease interactions, dosing instructions, and information about the proportion of included 65+ patients was considered necessary by most respondents. The clinicians considered information significantly more important than did the nonclinical respondents about the inclusion of 75+, time until benefit in older people, anticholinergic effects, drug–disease interactions, and the convenience of use.

Conclusion: This study reveals that items considered necessary are currently not included in the ICH E7 guideline or its supplement, the Q&A document; namely, information about effects on the locomotor system, drug–disease interactions, and dosing instructions. Also, clinicians’ and nonclinicians’ opinions differed significantly in 15% of the items. Therefore, all stakeholders should collaborate to improve the availability of information for the rational prescribing of medicines to older individuals.

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PP226—Available and clinically applicable information for rational prescribing to older patients in European and American handbooks

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Introduction: Health care professionals in daily practice use national handbooks for rational prescribing of medicines to older patients. The study objective was to investigate the availability and clinical applicability of such information in European and American handbooks. Patients (or Materials) and Methods: The Belgian Repertorium, German Rote Liste, British National Formulary (BNF), Dutch Farmacotherapeutisch Kompass (FK), and American Physician’s Desk Reference (Concise Monograph and Product Label [PL]) were analyzed. All 35 nongeneric medicines for diseases frequently present in older people with a first European centralized approval between 2008 and 2011 and an FDA approval before October 2012 were included. A 19-item checklist, based on the ICH-E7 criteria, was used.
to study the availability of information about the studied population, clinical experience, pharmacokinetic properties, and drug–drug interactions. Using the Systematic Information for Monitoring score, available information was considered clinically applicable if it provided information that could be applied in clinical practice. Missing information was either a statement that information was absent, unjustifiably nonavailable information, or hollow statements (e.g., “caution in older patients”). Descriptive statistics (frequencies) were applied using SPSS 20.0.

Results: The availability of relevant and clinically applicable information ranged between 10% (Belgian Repertory and BNF) and 20% (FK), except for the PL (mean, 66%). The PL, which is comparable to the European SmPC, appeared a more extensive document (7–32 pages) than the other handbooks (2 pages). In the handbooks, most information was present about drug–drug interactions (range, 30%–75%). Information about patient characteristics and about experience in older people was present in <7% of the handbook texts, except for the PL (48% and 81%, respectively). Clinically applicable information (what to monitor, critical value, how to respond) concerning renal impairment ranged from 4% to 29%.

Conclusion: This study found that the availability and clinical applicability of information about older people for rational prescribing of medicines is incomplete in the investigated European and American handbooks. Because these handbooks are the primary documents that guide prescribing in actual medical practice, the availability and clinical applicability of the information on older individuals should be improved.

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PP229—CHRONIC TREATMENT WITH PRAVASTATIN IMPROVES THE IMPAIRED NITRIC OXIDE–MEDIATED NEUROGENIC AND ENDOTHELIN-DEPENDENT RELAXATION OF CORPUS CAVERNOSUM IN AGED RATS

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Introduction: The aim of this study was to investigate the effect of chronic pravastatin treatment on diminished corpus cavernosum (CC) function associated with aging.

Patients (or Materials) and Methods: Male rats were divided into 3 groups as young rats (12–14 weeks old), aged rats (72–80 weeks old), and aged rats given 10 mg/kg/d of pravastatin in drinking water for 6 weeks. Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were monitored by tail-cuff method. Total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides, and testosterone levels were estimated in blood. NO-mediated endothelium-dependent and neurogenic CC relaxation were evaluated by acetylcholine (ACh, 0.1 nM–100 µM) and electrical field stimulation (EFS, 30 V, 5 ms, 2–32 Hz), respectively. Changes in protein expression levels of eNOS, p-eNOS, and nNOS were assessed by immunohistochemistry.

Results: In aged rats, NO-mediated both endothelium-dependent and neurogenic CC relaxation was significantly impaired as compared with young rats. Besides, eNOS and nNOS expressions decreased significantly in CC from aged rats compared with those from young rats. The diminished relaxation in response to ACh or EFS as well as reduced expressions of eNOS, p-eNOS and nNOS in CC of aged rats were improved by pravastatin treatment. SBP, DBP, and plasma levels of total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides, and testosterone did not change with aging or pravastatin treatment.

Conclusion: The present results suggest that chronic pravastatin treatment enhances NOS activity and NO-mediated relaxations in the rat CC, and this effect does not seem to be associated with lipid-lowering effect of this drug.

Disclosure of Interest: None declared.

PP228—ADVERSE REACTIONS IN CHILDREN ARE NOT THE SAME IN ADULTS: ANALYSIS OF SPONTANEOUS REPORTS IN 2011–2012 IN CRIMEA, UKRAINE

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Introduction: Adverse drug reactions (ADR) in children are an important medical problem. The ADRs in pediatrics are not the same in adults. Our aim was to define such specificity for periods of childhood and to compare found results with ones of adults.

Patients (or Materials) and Methods: ARCADe (Adverse Reactions in Crimea Autonomy Databases) was used for search of ADRs and their analysis. Classification of age stages of American Academy of Pediatrics was used. It defines babies (0–1 y.o.), toddlers (1–3), preschool (3–5), and grade-school (5–12) periods of childhood, and teenagers (12–18). The pharmaceutical groups and drugs were determined using WHO ATC index. WHO classes and Naranjo algorithm was used in causality and FDA criteria in seriousness assessment.

Results: The total amount of ARCADe records in 2011–2012 period is 2528. Amount of ADR reports for pediatric groups: babies, 187 (7.4%); toddlers, 138 (5.5%); preschool, 52 (2%); grade-school, 100 (4%); and teenagers, 52 (2%). Other reports were about reactions in adult patients (n = 1999, 79%). The amount of reports informing about ADR in male decreases with age. In babies, toddlers, and preschool children, ADRs in males are more often (55%–60%); in schoolchildren and teenagers, the ratio for males and females is 1:1, in adults ADRs in females are more frequent (60%). The most frequent clinical presentation of ADR in all groups is skin rash with different severity (including Lyell’s syndrome). In babies, rashes were found in 89.3% of cases; in toddlers, in 77.5%; in preschool and grade-school children, in 75% and in 56%; and in teenagers, in 63.5%. In adults, the frequency of rashes was lower (42%). The incidence of fever varied from 3.2% in babies to 11.4% in preschool children; then in teenagers and adults it decreases to 3.8% to 4%. The seriousness of ADRs was maximal in toddlers (75%), less in babies (71.7%); in other groups it was equal to adult rates (66%). The products caused ADRs most frequently in pediatric groups as well as in adults were antibacterial drugs. For them there was trend to decrease from babies (36.1%) to adults (36.7%) while in teenagers and adult patients the leader drug from this group was ceftriaxone (13.5% and 4.7%); in babies and toddlers ADR was mostly caused by ceftazidime (21.9% and 12.3%). In preschool children, the leader was ibuprofen (7.7%)