Science For A Better Life

Clinical Study Synopsis

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The study listed may include approved and non-approved formulations or treatment regimens. Data may differ from published or presented data and are a reflection of the limited information provided here. The results from a single trial need to be considered in the context of the totality of the available clinical research results for a drug. The results from a single study may not reflect the overall results for a drug.

Title	Study to Evaluate Physician Knowledge of Safety and Safe Use Information for Diane-35 and Its Generics in Europe: An Observational Post-Authorisation Safety Study
Keywords	Diane-35 and its generics; post-authorisation safety study; evaluation of risk minimisation measures; physician survey
Rationale and background	At the request of the European Medicines Agency (EMA), a Dear Healthcare Professional Communication, a patient information card, and a prescriber checklist were developed and distributed to increase awareness and understanding about risks associated with Diane-35 (cyproterone acetate 2 mg/ethinylestradiol 35 µg) and its generics (CPA/EE). In addition, the current study was conducted to address the EMA's request to evaluate the understanding and use of these materials, which were distributed in addition to the routine risk minimization measures (RMMs), (i.e., Summary of Product Characteristics [SmPC], Patient Information Leaflet [PIL]).
Research question and objectives	The primary objectives were to measure whether physicians received the Dear Healthcare Professional Communication, the Patient Card, and the Prescriber Checklist, respectively, and to evaluate their awareness and understanding of the key safety messages.
Study Design	The study was a joint, observational, cross-sectional study among physicians with recent experiences with CPA/EE. Bayer was responsible for liaising with the generic companies and was requested by the PRAC to take the lead in the consortium that was formed. Physicians who had recently prescribed CPA/EE within the previous 6 months were considered eligible. Physician specialty was considered when selecting the sample in each country based on the CPA/EE prescribing patterns in each country. The study targeted recruitment of up to 25% dermatologists in each country. The following physician specialties were recruited in each country: · Austria and the Czech Republic: gynaecologists and dermatologists · The Netherlands: general practitioners and dermatologists · France and Spain: general practitioners, gynaecologists, and dermatologists Eligible physicians were invited to complete a web-based questionnaire regarding their knowledge of key safety information included in the educational materials.
Setting	Austria, the Czech Republic, France, the Netherlands, and Spain
Subjects and Study Size, including dropouts	Physicians were eligible to participate if they had prescribed CPA/EE within the previous 6 months. Across the five countries, 11,102 physicians were invited to participate, of whom 1,347 responded. Of these, 363 were ineligible, 6 refused consent, 154 did not respond to the consent question, 55 were excluded because the study had achieved its target for their specialty, 10 did not fulfil the definition of a completed questionnaire, and

	759 physicians completed the questionnaire.
Variables and Data sources	Data were obtained through questionnaire responses.
Results	The percentage of physicians who reported receiving at least one of the three educational materials was 51.0%: 45.5% received the Dear Healthcare Provider Letter (DHPL), 16.2% received the Patient Card, and 16.9% received the Prescriber Checklist. Knowledge was highest (≥ 80% of physicians) for symptoms of possible deep vein thrombosis, pulmonary embolism, and cerebrovascular accident; most important risk factors for thrombosis; instructions of use in smokers; and approved indication for moderate to severe acne. A smaller percentage of physicians (69.2%) was aware of the approved indication for hirsutism. Knowledge was variable with 65.2%-98.9% of physicians reporting correct responses for risky time periods/special situations. The percentage of physicians who responded correctly was variable for contraindications (59.3%-98.8%), symptoms of possible myocardial infarction (42.8%-98.8%), other general risk factors for thrombosis (42.2%-96.8%), instructions related to immobilization (47.0%-97.2%), and selected concomitant medical conditions (44.7%-95.5%). Approximately 48% of physicians responded correctly to the question regarding prescribing CPA/EE for acne only after failure of topical therapy or systemic antibiotics. For most questions, knowledge did not vary by physician specialty, receipt of educational materials, number of patients prescribed CPA/EE in the last 3 months, and number of years practicing medicine.
Discussion	Knowledge of thromboembolism risk was 80% or higher. Knowledge was variable for topics that were more complex or less frequently encountered in which physicians might consult additional references. The knowledge about prescribing CPA/EE after failure of other acne treatments was approximately 48%.
Marketing Authorisation Holder(s)	Bayer Pharma AG
Names and affiliations of principal investigators	Elizabeth Andrews, MPH, PhD RTI Health Solutions Research Triangle Park, NC Kim Davis, MS, BS RTI Health Solutions Research Triangle Park, NC