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DISCLOSURES

B. Calingaert, A. Gilsean, and C. Sweeney are full-time employees of RTI Health Solutions, which received funding from Bayer AG to conduct this study. The contract between RTI Health Solutions and the sponsor includes independent publication rights. C. Moeller, G. Schomakers, A. Sok, R. Holzmann, and F. Pisa are full-time employees of Bayer Pharma AG, the funder of this study.

BACKGROUND

- Cyproterone acetate (CPA) is a synthetic progesterone derivative with antiandrogenic properties indicated as monotherapy for moderate and severe signs of androgenisation in women (e.g., hirsutism, androgenetic alopecia, acne, and seborrhoea), reduction of drive in sexual deviations in men, and antiandrogen treatment of prostate cancer.
- Approved indications for CPA monotherapy differ among the various strengths and among countries in which CPA monotherapy products are authorised.
- In 2020, the special warning and precaution about meningioma risk was updated in the summary of product characteristics (SmPC) for CPA monotherapies, and a direct healthcare professional communication (DHPC) was distributed.

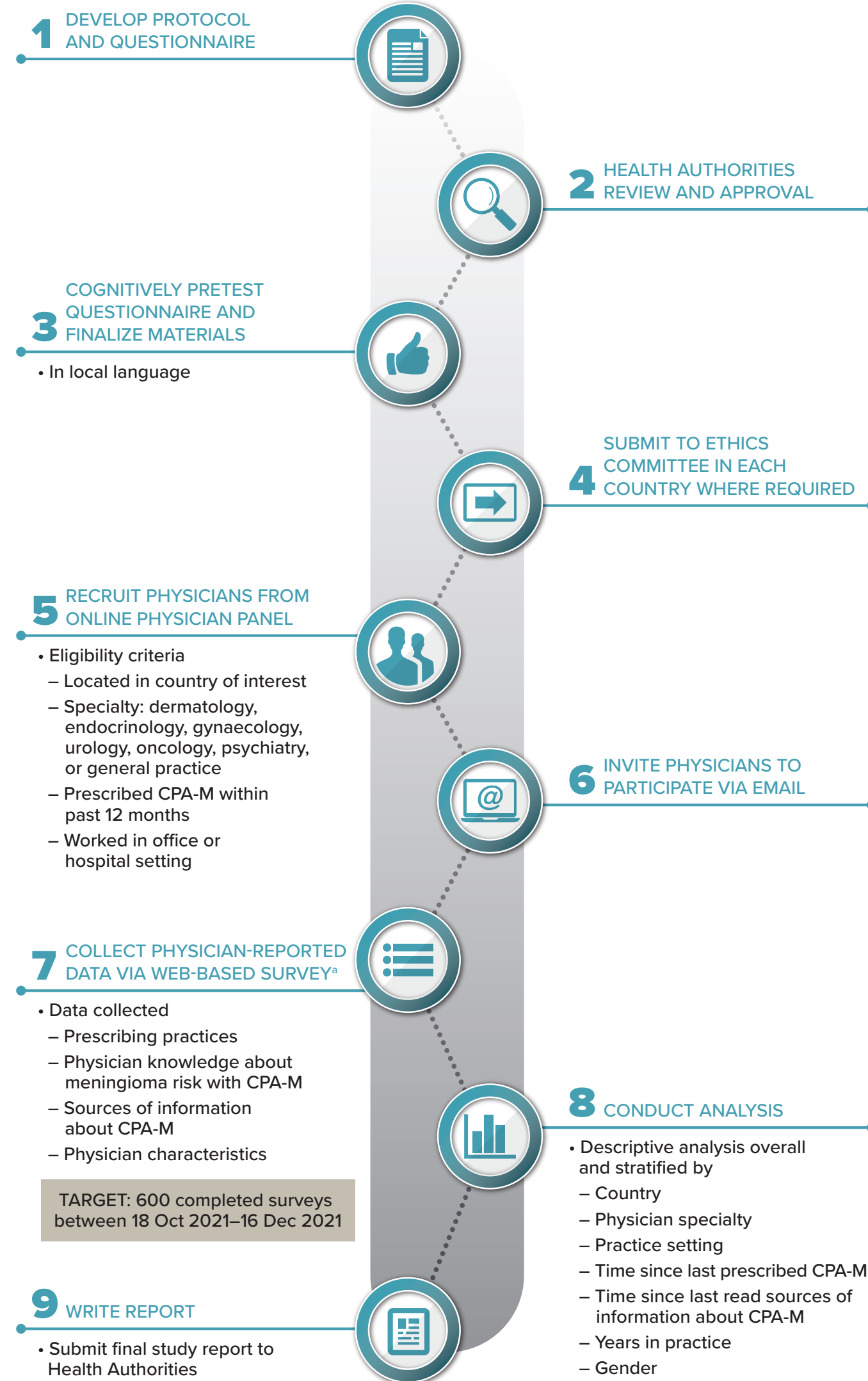
OBJECTIVE

- To assess physicians' receipt and knowledge of key safety information pertaining to meningioma risk with the use of CPA monotherapy.

METHODS

- Study Design:** Observational, cross-sectional physician survey conducted in France, Germany, Poland, Spain, and the Netherlands

Figure 1. Overview of Study Activities



CPA-M = CPA monotherapy. *While completing the survey, physicians were not able to go back to previous questions, prohibiting them from changing their answers based on subsequent questions.

RESULTS

Physician Characteristics

- A total of 613 physicians participated. The overall response rate was 5.8%, but participation was capped once the target sample size for each country was reached.
- Distribution by specialty aligned with predefined minimum recruitment targets (Figure 2).
- Most physicians reported having been practising medicine for 11-15 years (21%), 16-20 years (21%), or more than 25 years (21%), and only 4% reported that they had been practising for 5 years or fewer. The majority of physicians characterised their practice as either office-based (46%) or a university- or research-oriented/teaching hospital (33%) rather than another type of hospital (21%).
- 65% of physicians identified as male.

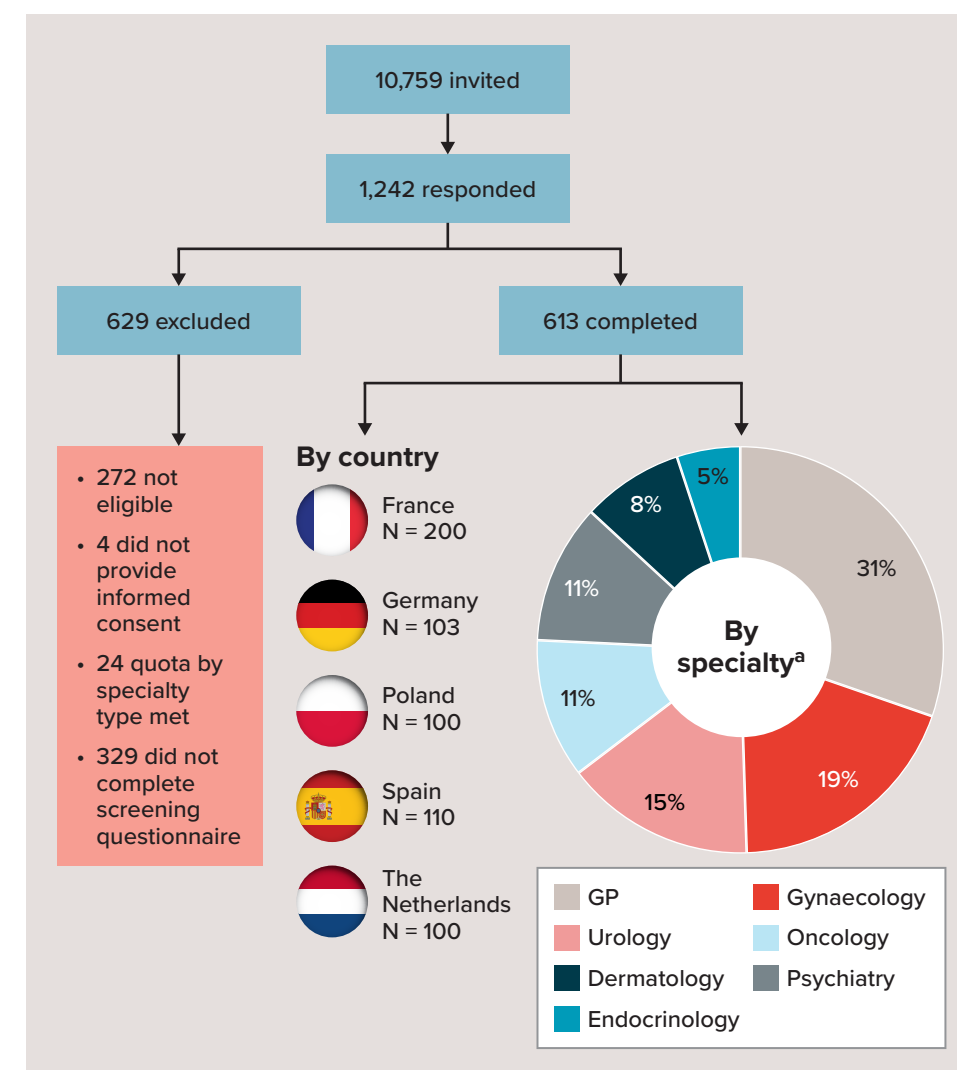
Knowledge Questions

- Overall, 43% of physicians correctly identified that information about meningioma in the special warning and precaution section was updated in 2020 for CPA monotherapy, with awareness highest among gynaecologists (62%) and endocrinologists (60%) and lowest among oncologists (30%) (Figure 3).
- 66% of physicians identified all 7 correct responses for the clinical signs and symptoms of meningioma, while knowledge of the individual signs and symptoms ranged from 72% to 92% (Figure 4).
- Overall, 85% of physicians knew that CPA monotherapy should be prescribed with the lowest effective dose, and 74% correctly responded that patients using CPA monotherapy should be monitored for meningiomas in accordance with clinical practice (Figure 5).
- 75% correctly indicated that the risk of meningioma increases with increasing cumulative doses of CPA monotherapy, and 73% correctly indicated that treatment with CPA-containing products must be stopped permanently if a patient is diagnosed with meningioma (Figure 6).

Receipt and Review of Revised SmPC and DHPC

- Overall, 42% of physicians reported receipt of the revised SmPC, and of those, 69% reported that they read it. Similarly, 40% reported that they received the DHPC, and of those, 82% reported that they reviewed it (Table 1).

Figure 2. Distribution of Physician Specialties by Country



GP = general practitioner. *3 participants selected "other" as their specialty.

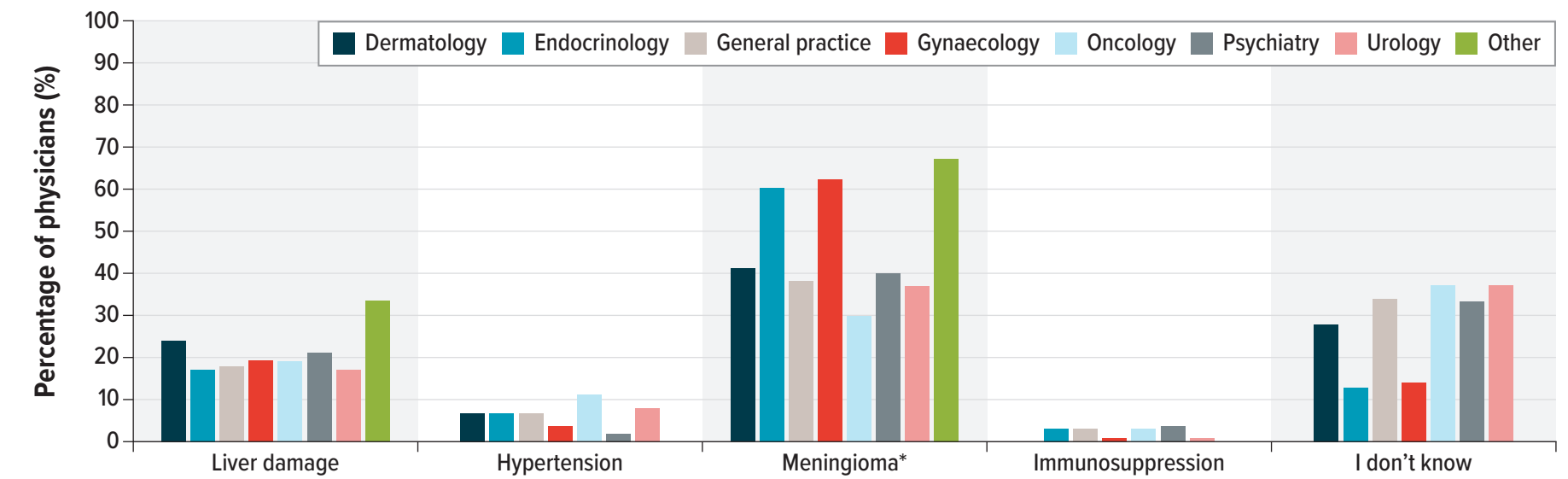
DISCUSSION

- The knowledge of the risk of meningioma associated with use of CPA monotherapy was high.
- Awareness of the recent updates in the warning and precautions implemented in the label was lower.
- The observed patterns of knowledge among the physicians were as expected—with greatest knowledge on the indicated use of CPA monotherapy relevant to the per-specialty indication and most important risks of meningioma and less knowledge on more complex aspects of safe use, especially correct use in indications that were not in the area of specialty of the respective physician (e.g., questions specific to the dosage of CPA monotherapy).
- Recall of the receipt of the educational materials is consistent with what was measured in a similar study.¹

CONCLUSIONS

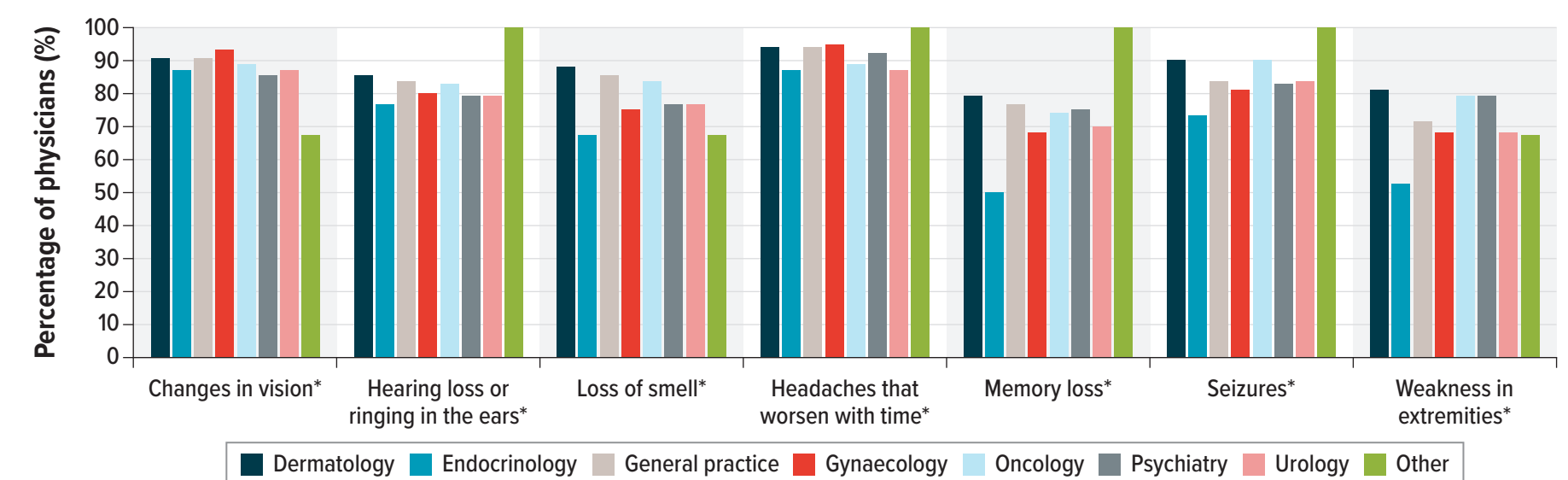
- Knowledge of the clinical signs and symptoms of meningioma, risk of meningioma, and actions to mitigate risk was high despite only 43% of physicians reporting awareness of the recent changes in the warning and precautions implemented in the label and less than half confirming receipt of the revised SmPC and/or DHPC.

Figure 3. What special warning and precaution was recently added in 2020 to the prescribing label for CPA monotherapy? (N = 613)



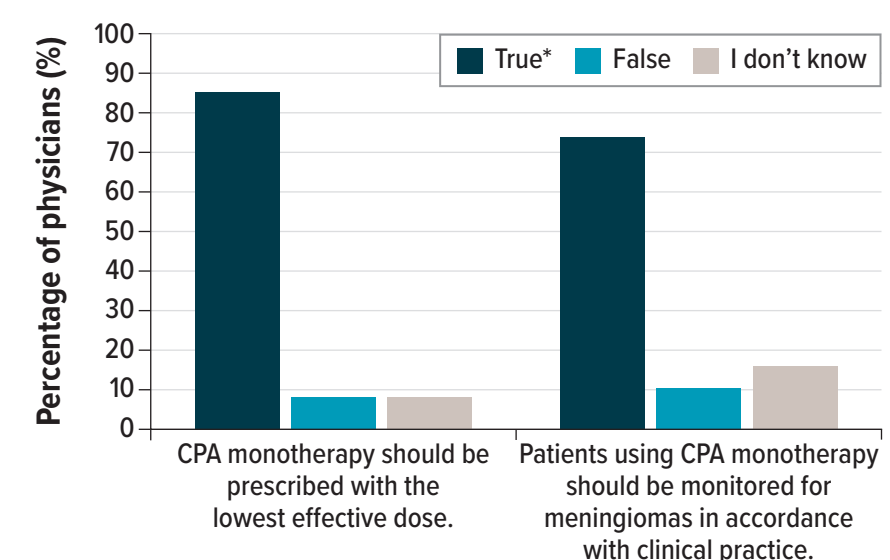
* Correct response is marked with an asterisk.

Figure 4. Which of the following may be clinical signs and symptoms of meningioma? (N = 613)



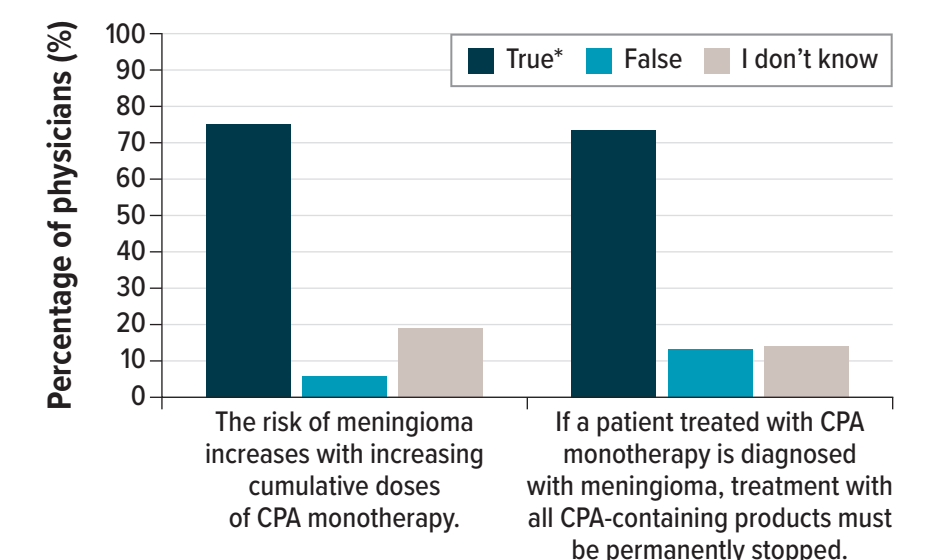
* Correct response is marked with an asterisk.

Figure 5. Please indicate whether each of the following statements about CPA monotherapy is true or false. (N = 613)



CPA = cyproterone acetate. * Correct response is marked with an asterisk.

Figure 6. Please indicate whether each of the following statements about CPA monotherapy is true or false. (N = 613)



* Correct response is marked with an asterisk.

Table 1. Receipt and Review of Revised SmPC and DHPC

	Number of physicians (%)					Overall, N = 613
	France, N = 200	Germany, N = 103	Poland, N = 100	Spain, N = 110	Netherlands, N = 100	
Revised SmPC						
Received	95 (48)	43 (42)	36 (36)	67 (61)	15 (15)	256 (42)
Reviewed ^a	60 (63)	27 (63)	25 (69)	54 (81)	10 (67)	176 (69)
DHPC						
Received	125 (63)	56 (54)	8 (8)	50 (45)	7 (7)	246 (40)
Reviewed ^b	102 (82)	48 (86)	5 (63)	42 (84)	4 (57)	201 (82)

DHPC = Direct Healthcare Professional Communication; SmPC = summary of product characteristics.

^a Percentages are based on the number of physicians who reported that they received the "SmPC."

^b Percentages are based on the number of physicians who reported that they received the "DHPC."

References

- Davis KH, Asimwe A, Zografos LJ, McSorley DJ, Andrews EB. Evaluation of risk-minimization activities for cyproterone acetate 2 mg/ethinylestradiol 35 microg: a cross-sectional physician survey. *Pharmaceut Med.* 2017;31(5):339-51. doi:10.1007/s40290-017-0203-9.

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