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THE VALSARTAN SAGA: PHARMACISTS COMPETENCE TO RESOLVE THE THERAPEUTIC CHALLENGE

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INTRODUCTION

In June 2018, a safety alert by the European Medicines Agency notified that some valsartan medicines were contaminated with the genotoxic impurity, N-nitrosodimethylamine (NDMA). NDMA was formed as a side product during the synthesis of the active pharmaceutical ingredient. Actions were taken to recall potentially impacted valsartan medicines.

AIM

To investigate the competence of the pharmacist in assessing and addressing the risks versus benefits associated with the use of valsartan medicines potentially contaminated with NDMA.

METHOD

A symposium was organised to evaluate the competence of the pharmacists in the application of scientific knowledge to the therapeutic challenges in the valsartan saga

A concise 32 slide interactive presentation with 9 questions was prepared after a literature search of valsartan-related peer-reviewed articles and scientific documents was conducted.

The responses given by the pharmacists in the interactive discussion were recorded by the Mentimeter. The results obtained indicated of the competence shown by pharmacists.

RESULTS

26 pharmacists (16 females, 10 males; age 22 to 45) from different pharmaceutical work backgrounds (10 hospital, 12 community, 4 industrial pharmacists) participated in the symposium.

Number of pharmacists agreeing with the statements presented	Statement
18 (60%)	NDMA is a probable human carcinogen found to cause cancer in animals
22 (84%)	Not all sartans contain a tetrazole ring
20 (77%)	The formation of NDMA occurred during the synthesis of valsartan
20 (77%)	NDMA is unlikely to bioaccumulate
7 (27%)	The half-life of valsartan is 6 hours
6 (24%)	1.5mcg/day is the tolerated limit for daily exposure to NDMA
24 (88%)	Drinking water, ham, bacon and cigarettes are contaminated with NDMA
20 (77%)	Advised that valsartan should not be stopped abruptly until alternative treatment is available
24 (92%)	Would recommend switching patients to another sartan as early as possible

CONCLUSION

The results show that pharmacists can benefit from added value educational interventions to enhance their scientific knowledge in certain areas, such as in the pharmacokinetics and the clinical relevance of the threshold of NDMA impurities in valsartan which should point to a toxicological concern of NDMA impurities. However, pharmacists showed a minimal necessary competence to deal wit

REFERENCES

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