

# THE VALSARTAN SAGA: SCIENCE, MYTHS AND REALITIES

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## INTRODUCTION

The detection of N-nitrosodimethylamine (NDMA), a potential human carcinogen in the manufacture of the valsartan active pharmaceutical ingredient, led to the withdrawal of several contaminated valsartan medicinal products.

## AIMS

To identify the science, myths and realities of the valsartan saga situation.

## METHOD

- Part 1: Involved an in-depth analysis of the significance of the NDMA impurity in valsartan medicines through a literature search of NDMA-related peer-reviewed articles and scientific documents.
- Part 2: Consisted of conducting semi-structured interviews with four main stakeholders involved in the management of the sequelae of the safety recall of valsartan medicines in Malta (Superintendent of Public Health, Malta Medicines Authority, Central Procurement and Supplies Unit and the NHS Medicines Distribution Department).
- Part 3: Involved distribution of self-administered structured questionnaires to healthcare professionals (pharmacists and physicians) using convenience sampling.

## RESULTS

- The stakeholders collaborated in the best interest of patients to devise and implement a healthcare strategy in view of the valsartan saga.
- It was concluded to emphasize that the health risk of discontinuing valsartan is higher than any potential risk presented by the NDMA impurity.
- 31 of 42 healthcare professionals claim that patients stopped the administration of Valsartan before being prescribed an alternative medicine causing unnecessary cardiovascular risk.

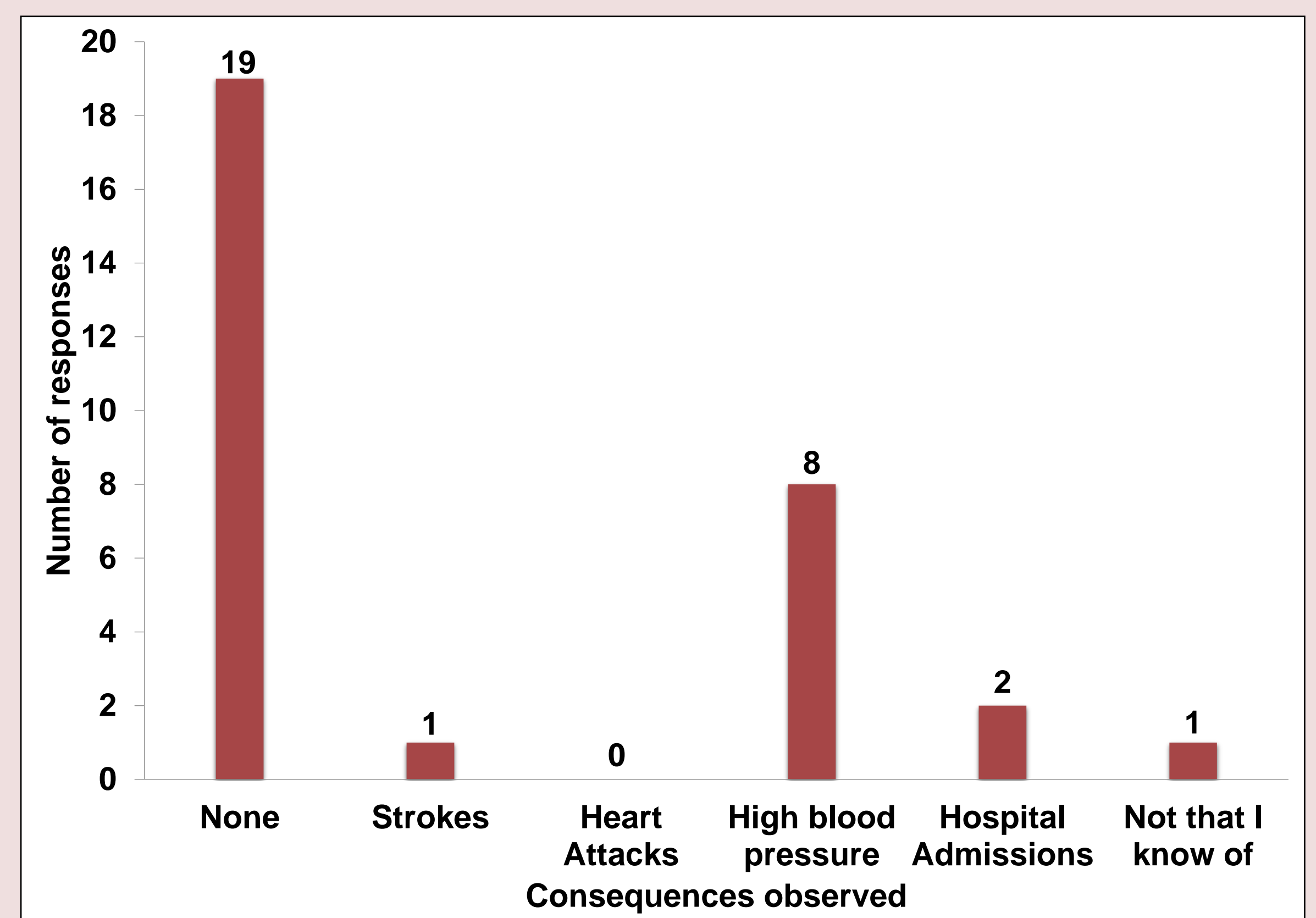


Figure 1: Consequences of stopping the valsartan medicine abruptly, observed by the healthcare professionals (N=42)

## CONCLUSION

The science behind the valsartan saga is that the presence of the NDMA impurity was due to the formation of a tetrazole ring in the new manufacturing process. The myths related to the valsartan saga are that patients could die from cancer after taking the contaminated valsartan medicine. The realities of the valsartan saga are that alternative medicines were supplied to patients to replace the contaminated valsartan medicinal products. It is recommended that patients should be more educated on the benefit to risk ratio of stopping any medicine abruptly without prior consultation with a pharmacist or physician.