Pharmacogenomics Information in Official Drug Labelling

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INTRODUCTION

The US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are continually updating drug labels and Summary of Product Characteristics (SmPC) with pharmacogenomic (PGx) information. Harmonisation of PGx information in drug labelling between regulatory bodies facilitates clinical implementation of PGx.1-2

AIMS

To compare PGx information in official drug labelling between the US FDA and the EMA:

➢ Inclusion of PGx information within headings and sub-headings of drug labels and SmPCs
➢ Quality of PGx information in drug labels and SmPCs

METHOD

| Drugs with PGx implications in 4 disease categories available on Maltese Government Formulary identified | Most recent drug label and SmPC of each drug retrieved | Presence of PGx information in drug labels and SmPCs compared | Previously developed PGx information quality scoring scale adapted and reviewed |

| Mean quality score (out of 9) for FDA drug labels and EMA SmPCs calculated for each disease category and compared statistically | 9-criterion quality scoring scale applied to assess quality of PGx information in drug labels and SmPCs |

RESULTS

• The FDA drug label and EMA SmPC of 70 drugs with PGx implications were retrieved and compared. All FDA drug labels contained PGx information while 7 EMA SmPCs did not.

• Comparable PGx information between the FDA and EMA was included in Indications, Precautions, Contraindications, Interactions, Adverse reactions and Pharmacology (p<0.05). More PGx information was included in FDA drug labels than EMA SmPCs in Dosage and administration (FDA 29, EMA 18). Specific populations (FDA 13, EMA 4) and as Boxed warnings (FDA 8, EMA 1) (p<0.05).

• The mean quality score (out of 9) for the FDA drug labels was significantly higher than that of the SmPCs for the 4 disease categories (p<0.05).

CONCLUSION

This comparative analysis showed that PGx information was not included in all EMA SmPCs compared to the corresponding FDA drug labels and the quality of PGx information in FDA drug labels was higher compared to EMA SmPCs. The findings indicate the need for continued harmonisation between the FDA and the EMA with respect to presence and quality of PGx information in drug labels and SmPCs.

REFERENCES