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Pharmacogenetic Testing for Drugs used in Malignancy

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INTRODUCTION

The inclusion of pharmacogenetics information in official drug labelling is increasing. Inadequate harmonisation between regulatory bodies is reported. [1]

AIM

To compare pharmacogenetics information in official drug labelling of oncology drugs between major regulatory bodies.

METHOD

Identification of drugs with pharmacogenetic implications used in malignancy from the Government Formulary List (GFL)[2]

→ Identification of drugs with 'Testing required' label annotation from Pharmacogenomics Knolwedgebase (PharmGKB)[3]

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Comparison of pharmacogenetics information in:

- US Food and Drug Administration (FDA) drug label
- European Medicines Agency (EMA) Summary of Product Characteristics (SmPC)

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Consultation with 7 oncologists at Sir Anthony Mamo Oncology Centre regarding use of pharmacogenetic testing for the identified drugs

RESULTS

- 80 drugs indicated for use in malignancy on the GFL (November, 2018); 22 have pharmacogenetic implications
- 14/22 drugs with 'Testing required' label annotation on PharmGKB (November, 2018)
- Comparison between FDA drug label and EMA SmPC for the 14 drugs with 'Testing required' label annotation showed agreement between regulatory bodies for 6 drugs and differences between regulatory bodies for 3 drugs. Comparison was not possible for 5 drugs since only the FDA drug label is available (Table 1)
- Oncologists stated that pharmacogenetic testing is being requested before prescribing for the 14 drugs annotated as 'Testing required'

Table 1. Comparison between FDA drug label and EMA SmPC for drugs used in malignancy (N=14)

Agreement between FDA drug label and EMA SmPC (n=6)	Non-agreement between FDA drug label and EMA SmPC (n=3)	FDA drug label only (n=5)
Dabrafenib: I, W, D	Lenalidomide	Anastrazole: I
Erlotinib: I, D	*FDA - Testing required*: I, W	Exemestane: I
Everolimus: I	*EMA– Informative*: I	Letrozole: I
Imatinib: I, D	Rasburicase	Tretinoin: I, W
Trametinib: I, D	*FDA –Testing required*: CI, W	Tamoxifen: I
Trasutuzumab: I, D	*EMA– Actionable*: CI	
	Rituximab	
	FDA—Informative: I	
	EMA– Testing Required: I	

I Indication CI Contraindication W Boxed/Special Warning D Dosage

CONCLUSION

Differences in pharmacogenetics information between FDA drug labels and EMA SmPCs for drugs used in malignancy were identified. The findings point to the need for enhanced regulatory harmonisation of pharmacogenetic information in official drug labelling for oncology drugs.

REFERENCES

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