GA N° 668353 H2020 Research and Innovation

Deliverable N°: D2.2 Title: PGx-guidelines therapeutic recommendations and risk-assessments in English

WP N° and Title: WP2 - Towards shared European Guidelines for PGx

Lead beneficiary: P6-KNMP

Type: Report

Dissemination level: Public

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Duration: 60 months

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Actual submission date: 24/01/2017 (Month 13)

Comment: [e.g. explanation for delay]

Introduction

Since 2005 the Dutch Pharmacogenetics Working Group (DPWG) of the KNMP has been developing pharmacogenetic guidelines in the Netherlands. These gene-drug interactions are drafted in Dutch and distributed to healthcare professionals by Z-Index. The guidelines are displayed at the secure website *Kennisbank* and available in computer systems through the incorporation in the database *G-Standaard*.

To make these pharmacogenetic guidelines suitable for European use, all documentation has been translated to English by a certified translation agency. This includes the risk analyses (also called risk assessments, with recapitulations of the studies and justification of choices), recommendation texts and background information per gene.

To make sure the guidelines are usable at all implementation sites, we performed several inventarisations:

- Are the products available at the implementation sites? Are the suggested actions do-able?
- Are there any other (European) pharmacogenetic guidelines known or in use?
- For which gene-drug combinations should we create guidelines in the next few years?

Updated or new risk analyses are now only available in English. Recommendation text are still all in Dutch, but translations in English are performed by the contracted translation agency for these new and updated guidelines. During the project there is a DPWG meeting every 3 months, where changes in the guidelines database are endorsed. These changes are translated and entered into the *G-Standaard*.

All translated text has been checked by KNMP for errors and inconsistencies. This includes a scientific check: is the meaning in the context still correct? Are numbers and calculations correct?

Results

All 90 pharmacogenetic guidelines have been translated and entered into the *G-Standaard*. The risk analysis are available at http://www.g-standaard.nl/risicoanalyse/. The G-Standaard structure and texts are integrated into the GIMS system. The *G-Standaard* is updated every month. For the production of report for the physician, only the pharmacogenetic guidelines with therapeutic recommendations (action is needed) are displayed. The other guidelines are available in the full report, so a physician knows these drugs have been evaluated but the pharmacogenetic variant was not relevant.

In 2016, 9 new guidelines have been composed (this includes 3 therapeutic recommendations for carbamazepine with different HLA-variants) and 21 guidelines have been updated.

Summary/Conclusions

All pharmacogenetic guidelines available in 2016 have been translated. For the next years the guidelines will be updated and translated continuously.