

THE RESULTS OF THE SURVEY ON ADDITIONAL RISK MINIMISATION MEASURES' MATERIALS

The State Agency of Medicines of the Republic of Latvia, Riga, Latvia, 2015



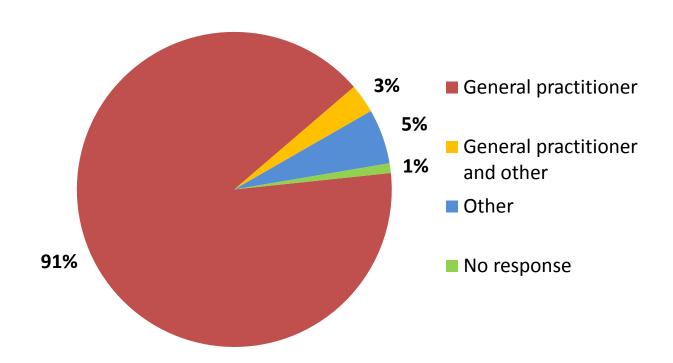
An overview of the survey on additional risk minimisation measures' materials

☐ Conducted by: the State Agency of Medicines (SAM);
☐ A period: 13 March — 30 April 2015;
☐ The aim of the survey: to find out how well healthcare professionals are supplied with additional risk minimisation measures' materials — SAM approved direct healthcare professional communications (DHPC) and educational materials on risk minimisation (further - educational materials) and to get information regarding usefulness of these materials and suggestions for improvements;
☐ Respondents: 301 respondents (94% - general practitioners (20% of the amount of total general practitioners in Latvia in 2015)*; 6% - other healthcare professionals);
☐ A method: an online survey (<i>Google Drive</i>) and a printed survey disseminated during the conference organized by the Latvian Association of Rural General Practitioners.

^{*}Data: 26/06/2015, source: Health Inspectorate of Latvia, The Register of Medical Persons and Medical Support Persons

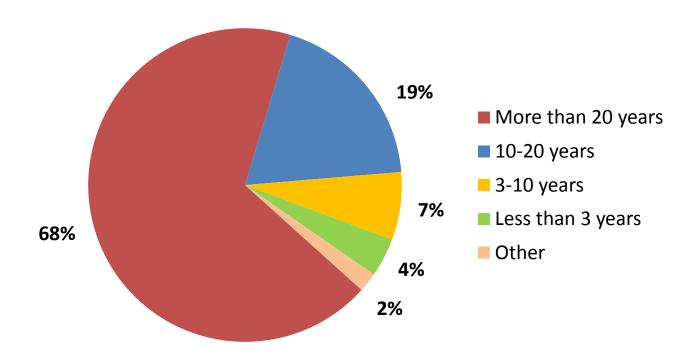


Respondents' speciality (-ies)



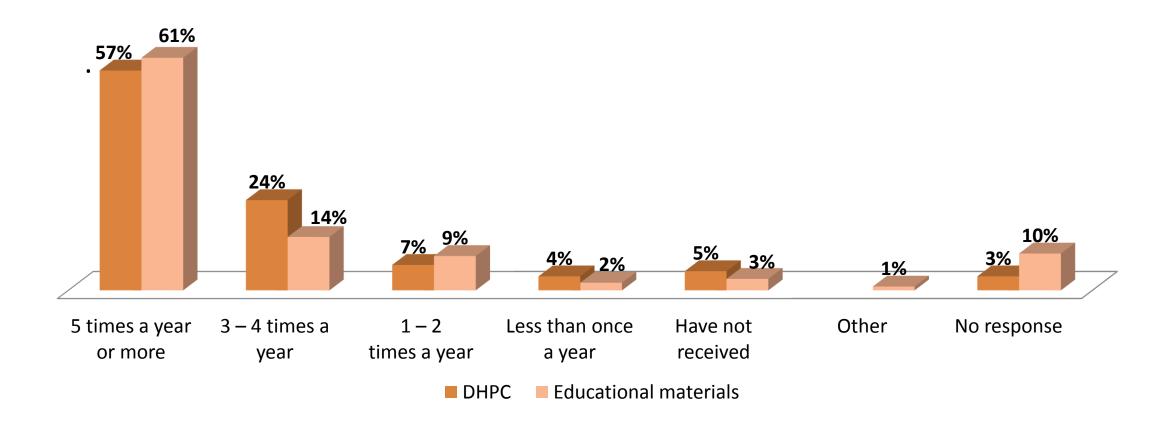


Length of practice of the speciality (-ies)



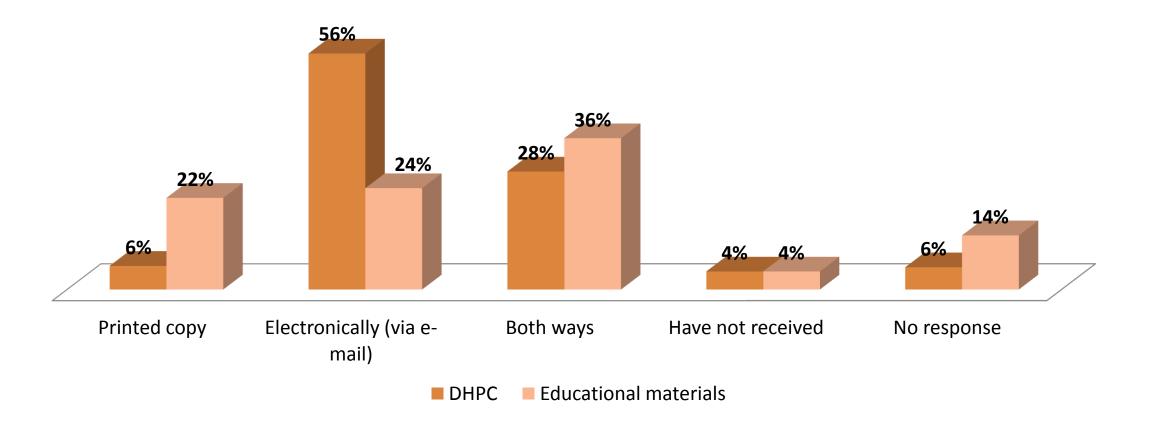


How often do respondents receive the materials?



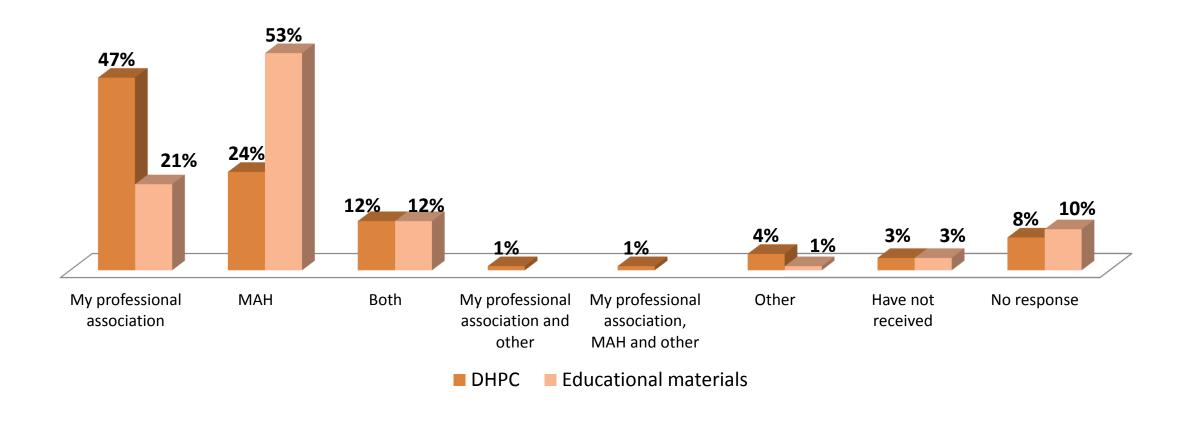


Delivering options





Who delivers the materials?





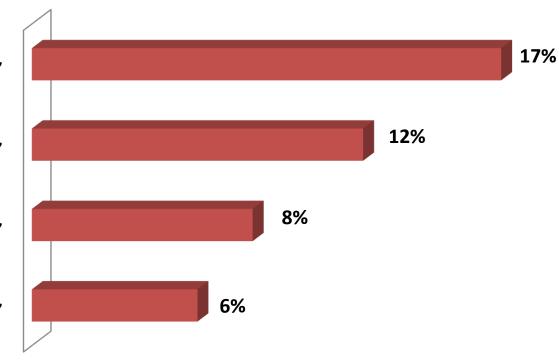
Sources of information respondents use in their practice

A summary of product characteristics, a package leaflet, DHPC, educational materials, a SAM website

A summary of product characteristics, a package leaflet, DHPC, educational materials

A summary of product characteristics, a package leaflet, educational materials

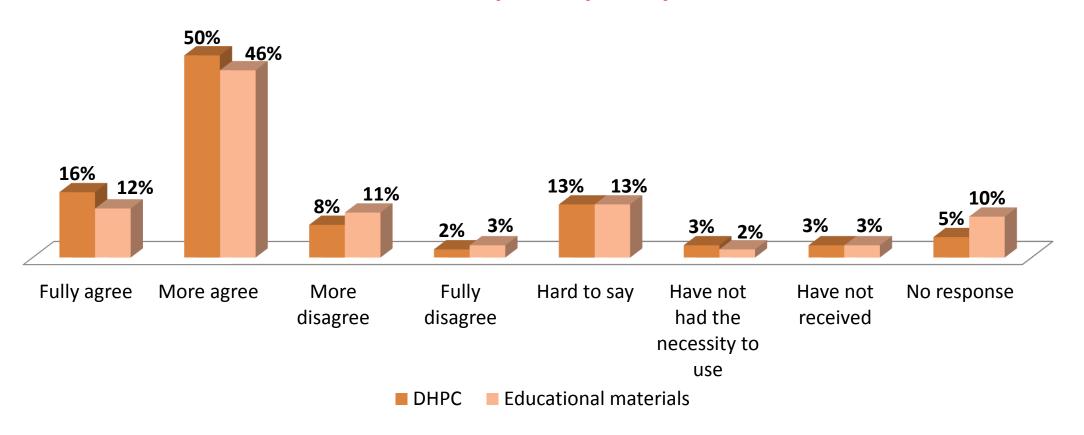
A summary of product characteristics, a package leaflet, DHPC



^{*} Other different combinations of the materials mentioned above – 57%

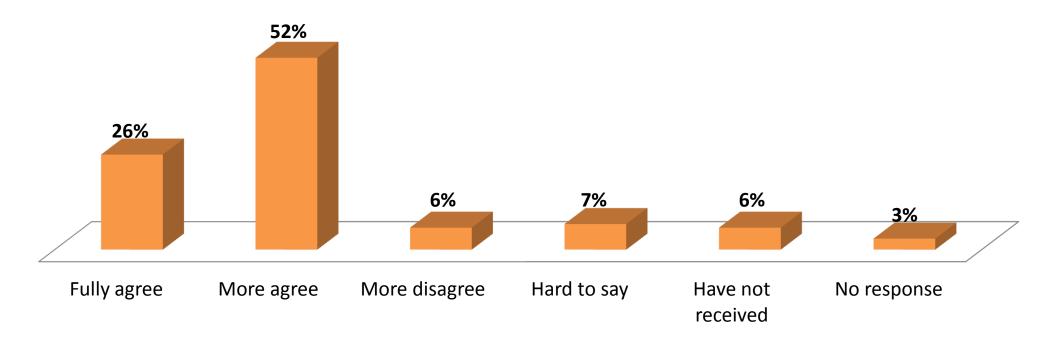


Opinions regarding the statements 1.1. «The received DHPC and/or educational materials change my prescription practices»





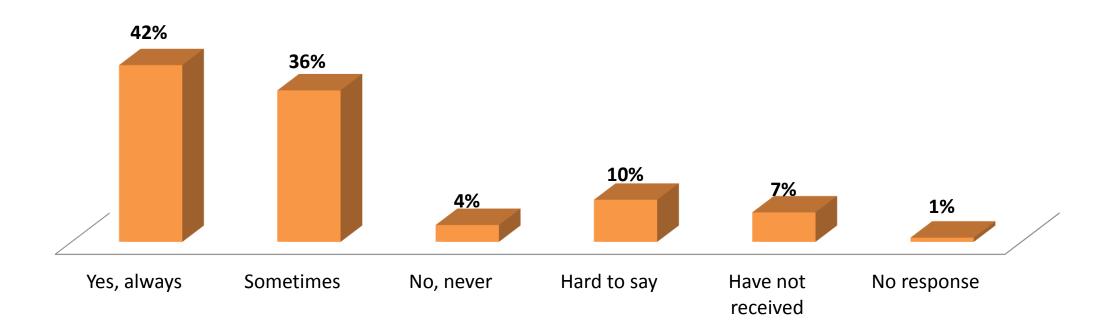
1.2. «The materials for patients included in the set of educational materials help in communication with patients, thus, promoting safe use of medicines»



^{*} Materials intended for patients can be given only by a doctor or a pharmacist.

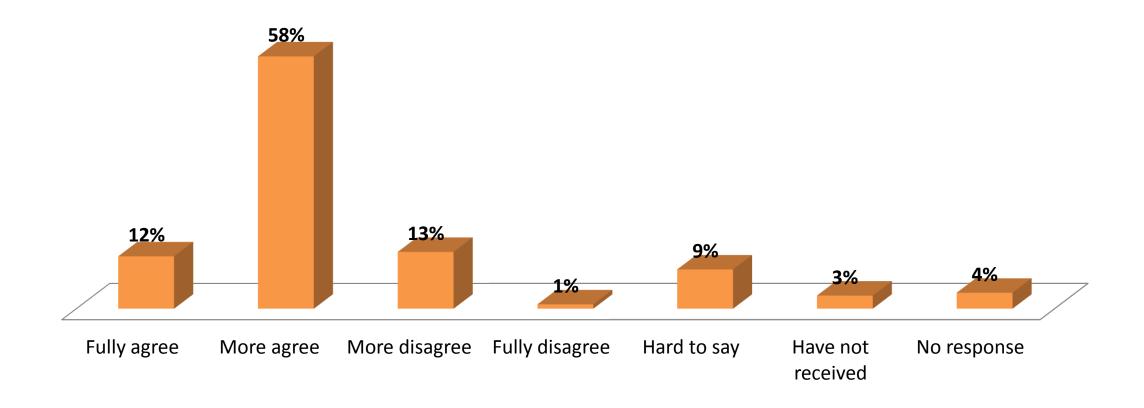


1.3. «A number of printed copies of educational materials (including educational materials for patients) delivered is sufficient»



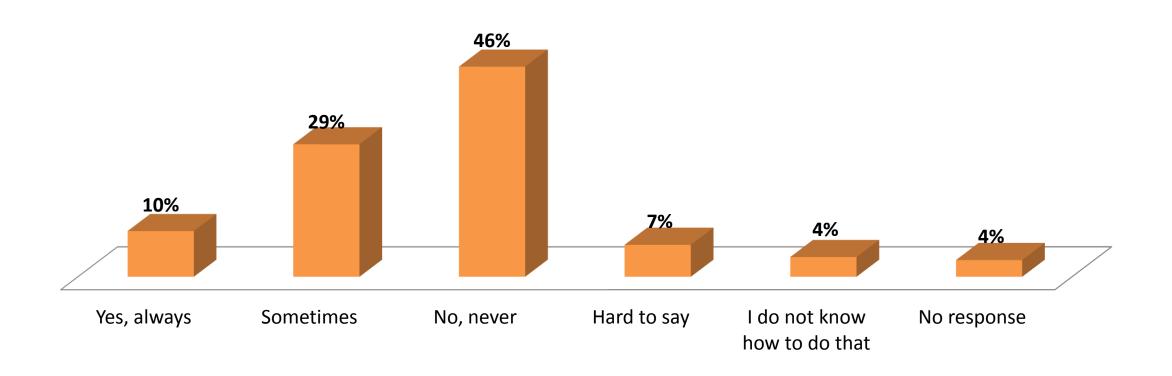


1.4. «Educational materials can be easily understood»



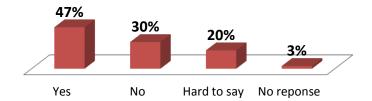


Do respondents make sure whether the received materials have been approved by the SAM on the website of the SAM www.zva.gov.lv?

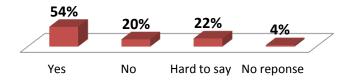


Received DHPCs in 2014/2015 (mentioned in the survey)

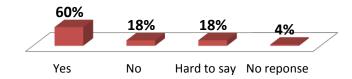
1. "Medicines containing valproic acid and related compounds: risk of pathological outcome of pregnancy" - approved by SAM on 10.12.2014.



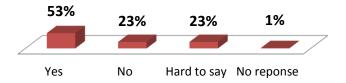
3. "Important additional safety data in the summary of product characteristics of carvedilol containing medicines" - approved by SAM on 21.08.2014.



2. "Domperidone (Motilium, Domperodon Actavis, Oroperidys): new recommendations for minimisation of cardiac risk" - approved by SAM on 22.08.2014.



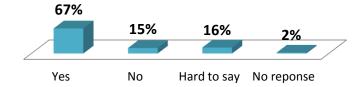
4. "Transdermal fentanyl patch: a reminder regarding potential life-threatening harm from accidental exposure to transdermal fentanyl patches" - approved by SAM on 16.06.2014.



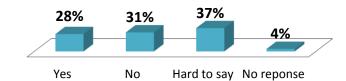


Received educational materials in 2014/2015 (mentioned in the survey)

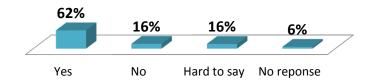
1. For the medicinal product Pradaxa – approved by SAM in June 2014?



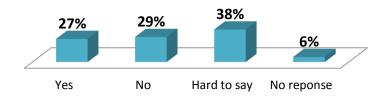
2. For the medicinal product Eliquis – approved by SAM in December 2014?



3. For intravenous iron preparations – approved by SAM in December 2014?



4. For the medicinal product Ebetrex (methotrexate)– approved by SAM in October 2013?





The most useful received materials: examples

All received materials were useful (51 respondents) • Provided useful information regarding medicines safety;
DHPC: "Domperidone (Motilium, Domperodon Actavis, Oroperidys): new recommendations for minimisation of cardiac risk" - approved by SAM on 22.08.2014.: • I have a lot of patients who must use these medicines;
"Educational materials for the medicinal product <i>Pradaxa</i> " - approved by SAM on 06.2014: • Useful when choosing between medicines <i>Pradaxa</i> and <i>Xarelto</i> ;
"The most useful were <u>practical educational materials</u> that I used <u>after the operation of varicose veins</u> ."



Suggestions

- ☐ To include only the key message(s) - clear and brief statements (in both DHPC and educational materials);
- Request to continue to deliver;
- Necessity for independent information from the pharmaceutical industry.

