The prescription (Rx) to over-the-counter (OTC) switch has become a common practice in the global pharmaceutical market (1, 2). It must be invariably preceded by a highly regulated and scientifically rigorous process (2). In the United States (US), for instance, a medicine to be switched must be effective, must have a wide safety margin and consumer-friendly labeling to ensure a proper use (2, 3). In the European Union (EU), however, the policy guidance document (4) emphasizes that properties of drugs which are considered for a switch include the following rules: they should be characterized by a low toxicity in general, low or a very low risk of serious type A reactions and serious type B reactions respectively, and should have no interactions with commonly used medicines (1, 4).

There are many reasons why pharmaceutical companies apply for the switch of their medicines from Rx to OTC (5). Switches are frequently a logical extension for life-cycle management of the product or give the originator company a chance to develop a defense strategy against generic competitors (5). Moreover, switches improve access to medications, may contribute to savings for healthcare payers and may positively influence a turnover in pharmacies (1, 5–8). Nevertheless, there are some doubly registered medicines (when there is the same medicine available with and without a prescription), which makes switches somewhat vague (2).

From the consumers’ point of view, there are several advantages of switches likewise. Easier access to medicines (3) may result in lower drug
prices and may contribute to significant cost savings related to avoided general practitioners (GP) visits (6). Although OTC medicines should be safe, some may lead to significant side effects (1). Therefore there have been reverse but rare switches from OTC to Rx (e.g. ketoprofen in the form of a gel) (2). Nevertheless, the number of Rx-to-OTC switches increases and the OTC drug market has been growing, thus the turnover of OTC pharmaceuticals is globally expected to exceed USD 178 billion by 2024 (9). Despite that market analyses frequently refer to the richest countries like the USA, Jakovljevic and Getzen (10) notice that low and middle-income countries are also likely to be significant contributors to the global health care market.

In Poland, one of top twenty OTC drug markets (11) and classified as the 4th leading nation in the EU in terms of medicinal purchases (2), the total value of pharmacy market in 2017 was EUR 7.45 billion (according to the average exchange rate of EUR 1 = PLN 4.28 presented by the National Bank of Poland on February 4, 2019). OTC drugs accounted for nearly EUR 2.6 billion (12). By comparison, the value of the German OTC drug market is EUR 5.7 billion, EUR 1.2 billion in Spain, EUR 1 billion in Argentina or EUR 30 billion in the USA (1, 12, 13).

Despite the number of OTC drug purchases in Poland, about 50% of Poles use OTC medications for the first time without consulting healthcare professionals (14). Considering this and the number of newly Rx-to-OTC switched medicines the aim of this study was to determine pharmacists’ opinions about Rx-to-OTC switches including double registration of medicines.

MATERIAL AND METHODS

The study was conducted in pharmacies from Greater Poland, which is the third-largest region in Poland in terms of population size. A study tool was an anonymous questionnaire comprising seven closed-ended questions and a short socio-demographic section.

Before the right analysis, the pilot study was conducted in 10 pharmacies. The gathered questionnaires were not finally included, because after the pilot study the possible variants were simplified. The questions content and possible variants of the answer are presented in Table 1. Pharmacies as potential study participants were selected from the list of pharmacies in Greater Poland. The participation was voluntary and the personal data were not requested. Incentives were not offered to partici-

pants. The questionnaire was delivered by direct contact (visit to the pharmacy) and left in the pharmacy to be filled in the meantime. Potential participants were requested to return questionnaires by e-mail or if such was the participants’ expectation, the filled-in questionnaire was personally collected from the pharmacy. In case of no reply, the request to fill in the questionnaire was reiterated by a phone call. It might be easy to connect the completed questionnaire with the e-mail address of the pharmacy, but it was not our aim to collect and then to present these data. It could be considered as a pharmacy advertising which is strictly forbidden in Poland (15).

Pharmacists frequently indicated that the filled questionnaire would be a common point of view of all of the pharmacy’s staff, thus the study is a direct group survey and from each pharmacy one questionnaire was expected. If the pharmacy took part in the study we marked the address on the list to avoid the repetition of our request.

We assumed to deliver 400 questionnaires, but some of the potential respondents refused to join the study particularly because of their dislike of such studies and of being too busy to take part in the project. Finally, 232 questionnaires were received and all of them were included in the study.

Moreover, we obtained data from the PEX PharmaSequence, a consulting and market research company with a nearly 20-year focus on the pharmaceutical market and the healthcare sector. These data (supported by a permission to use them for scientific purposes) came from 5500 Polish pharmacies and concerned the turnover of doubly registered medicines (furaginum 0.05 g, omeprazole/pantoprazole 0.02 g, loratadine 0.01 g/desloratadine 0.005 g, cetirizine 0.01 g/levocetirizine 0.005 g, ibuprofen 0.2 g, loperamide 0.002 g).

RESULTS

Considering the answers presented in Table 1, Rx-to-OTC switches were negatively evaluated by the majority (81.5%) of study participants. Besides, 75% of respondents indicated that if the medicine had previously been available only on prescription, special care should be taken and the patient should be advised about possible side effects of the switched medicine. Among opinions related to the question which of the listed medicines should be available only on prescription, the most frequent answer was “furaginum” chosen by 60.8% of respondents and followed by “omeprazole/pantoprazole” (27.2%) and “naproxen” (24.6%). In the case of the “other” option, where respondents could indi-
Table 1. Questions content and answers provided in the study.

<table>
<thead>
<tr>
<th>Question</th>
<th>Question content</th>
<th>Possible answers</th>
<th>The percentage of answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>How do you evaluate the Rx-to-OTC switch phenomenon?</td>
<td>&quot;positive/negative&quot;</td>
<td>18.5%/81.5%</td>
</tr>
<tr>
<td>2</td>
<td>Do you think that pharmacists should advise the patients that the drug had been previously available as a prescription brand and that the patient should take extra care when using this medicine?</td>
<td>&quot;agree/disagree&quot;</td>
<td>75.0%/25.0%</td>
</tr>
<tr>
<td>3**</td>
<td>Which medicine should be available as an Rx-only brand instead of the current double registration?</td>
<td>&quot;loperamide&quot;, &quot;furaginum&quot;, &quot;omeprazole/pantoprazole&quot;, &quot;loratadine/desloratadine&quot;, &quot;cetirizine/levocetirizine&quot;, &quot;ibuprofen&quot;, &quot;naproxen&quot;, &quot;other&quot;, &quot;none&quot;</td>
<td>&quot;furaginum&quot; - 60.8% &quot;omeprazole/pantoprazole&quot; - 27.2% &quot;naproxen&quot; - 24.6%</td>
</tr>
<tr>
<td>4**</td>
<td>Which of the switched or doubly registered medicines was sold most frequently?</td>
<td>&quot;loperamide&quot;, &quot;furaginum&quot;, &quot;omeprazole/pantoprazole&quot;, &quot;cetirizine/levocetirizine&quot;, &quot;ibuprofen&quot;, &quot;naproxen&quot;, &quot;other&quot;, &quot;none&quot;</td>
<td>&quot;ibuprofen&quot; - 81.3% &quot;loperamide&quot; - 50.4% &quot;omeprazole/pantoprazole&quot; - 47.8%</td>
</tr>
<tr>
<td>5**</td>
<td>Which medicine should be available outside pharmacies?</td>
<td>&quot;none&quot;, &quot;ibuprofen&quot;, &quot;loperamide&quot;</td>
<td>&quot;none&quot; - 45.3% &quot;ibuprofen&quot; - 45.3% &quot;loperamide&quot; - 13.8%</td>
</tr>
<tr>
<td>6</td>
<td>Do you think that medicines with double registration should be reimbursable in their Rx forms?</td>
<td>&quot;agree/disagree&quot;</td>
<td>64.2% / 35.8%</td>
</tr>
<tr>
<td>7</td>
<td>What is (if exists) the most important drawback of the double registration phenomenon?</td>
<td>&quot;development of the uncontrolled self-medication&quot;, &quot;decrease of the patients awareness about medicines&quot;, &quot;patients' confusion about the medicine safety&quot;, &quot;it has no drawbacks&quot;</td>
<td>44.4% 37.1% 16.8% 1.7%</td>
</tr>
</tbody>
</table>

Source: based on the custom-made questionnaire. * there are presented 3 most frequently chosen answers (in these questions there was an option to select 3 answers). & in question 3, 4 and 5 possible answers were common.
cate their own example, the most popular answer (5.2%) was “sildenafil”.

From double registered and listed in the study medicines, ibuprofen and loperamide turned out to be most frequently sold. Apart from the turnover and the market share of doubly registered medicines, the respondents would frequently (45.3%) answer that “none” (of the listed in the questionnaire) medicine should be available for out-of-pharmacy sale. However, the same percentage (45.3%) of study participants indicated “ibuprofen” as an example of medicine which could be considered for out-of-pharmacy access.

Study participants also claimed that the most important drawback (chosen by 44.4%) of the double registration of medicines is the development of uncontrolled self-medication associated with inappropriate use of medicines. Further disadvantages of Rx-to-OTC switches are presented in Table 1.

Data obtained from a consulting and market research company allowed us to provide information about the market share of selected medicines with a double registration. For “omeprazole/pantoprazole”, “loratadine/desloratadine”, and “cetirizine/levocetirizine” categories, we observed that significantly more packages were sold in the Rx class compared to OTC class, while for “furaginum”, “ibuprofen”, and “loperamide” the market share was reversed. Detailed results are presented in Table 2.

**DISCUSSION**

A continuous increase in the number of OTC medicines has been observed in Europe and the USA since the late 1980s (16). It might be related to Rx-to-OTC switches which are frequently welcomed by regulators and retailers, due to the improved access to pharmacotherapy and cost-effectiveness for third-party payers (5). To change the status of medicines and make them available without prescription several factors must be taken into consideration, including safety and efficacy of self-treatment as well as possible misuse of switched medicines (17–19). Considering this, it might be surprising that the majority of study participants presented a negative attitude towards Rx-to-OTC switches, indicating the need to provide special and additional information concerning, for instance, possible side effects of Rx-to-OTC switched medicines.

Nonetheless, such an attitude of Polish pharmacists may result from the common access of OTC medicines in Poland. Apart from pharmacies, some OTC medicines might be available from herbal shops, groceries and petrol stations (2, 19). In light of the inevitable growth of the OTC drug market and an increase in the number of RX-to-OTC switches, it could be advisable to create classes of OTC drugs. In Germany, for instance, there are pharmacy-only and general sales drugs (1). In countries such as Canada, Australia, and New Zealand, however, there are three classes of OTC medicines: pharmacist-only, pharmacy-only, and general sales (20). The implementation of similar classes in Poland could emphasize the advantages of switches instead of their drawbacks. Besides, it would be convergent with the results of this study because many respondents answered that “none” of medicines should be available for out-of-pharmacy sale. This may be related to the risk of the development of non-medical

**Table 2.** The market share of selected medicines characterized by a double registration (2016).

<table>
<thead>
<tr>
<th>The medicine - the international name and the dosage</th>
<th>The value of sales (gross) EUR</th>
<th>The number of packages sold</th>
<th>The value of sales (gross) EUR</th>
<th>The number of packages sold</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBUPROFENUM 0.2 g</td>
<td>1,589,621.23</td>
<td>998,740</td>
<td>26,231,633.96</td>
<td>9,354,559</td>
</tr>
<tr>
<td>FURAGINUM 0.05 g</td>
<td>3,494,648.35</td>
<td>2,620,513</td>
<td>14,402,528.3</td>
<td>4,807,461</td>
</tr>
<tr>
<td>LOPERAMIDUM 2 mg</td>
<td>1,102,566.27</td>
<td>618,814</td>
<td>14,034,926.89</td>
<td>6,968,535</td>
</tr>
<tr>
<td>OMEPRAZOLUM/PANTOPRAZOLUM 0.02 g</td>
<td>128,515,622.17</td>
<td>40,428,195</td>
<td>15,630,192.69</td>
<td>5,805,302</td>
</tr>
<tr>
<td>CETIRIZINUM 10mg/LEVOCETIRIZINUM 5 mg</td>
<td>34,291,513.21</td>
<td>9,716,133</td>
<td>7,192,031.13</td>
<td>4,195,250</td>
</tr>
<tr>
<td>LORATADINUM 10 mg/DESLORATADINUM 5 mg</td>
<td>25,949,687.74</td>
<td>4,825,494</td>
<td>3,868,074.76</td>
<td>1,540,316</td>
</tr>
</tbody>
</table>

Source: based on data obtained from the PEX PharmaSequence company.
use of medicines, which may also contribute to the health and economic consequences (1, 17, 20).

Another possible cause of the pharmacists’ reluctance to Rx-to-OTC switches is the very frequent advertising of OTC medicines (2, 21). Pharmaceuticals belong to the most heavily advertised goods in terms of advertising budgets, thus the overwhelming scope of information coming from media may contribute to miscomprehension. It is confirmed by the observation that more than 30% of Poles make their OTC drug choices based on advertising (19). Therefore, medicines can be misused or overused by the patients who, wrongly convinced that they know everything about medicines or fail to read OTC drugs’ leaflets (2).

Furthermore, double registration of medicines seems to cause some confusion and may contribute to the ambivalent attitude of Polish pharmacists towards switches. It can be deemed justifiable because, according to legislation on access to various categories of medicines, pharmaceuticals available on prescription may cause danger to human life if used inappropriately or misused (2). On the other hand, guidance on pharmacological features of medicines indicates that OTC medicines should be characterized by low toxicity and general safety (1). Thus, some inconsistencies between legal regulations may lead to doubts on the safety of these medicines in self-medication and on potential general sales. However, it might be considered surprising that many participants claimed that medicines with double registration should be still reimbursable in the Rx category. This point of view may result from the belief that in some cases the analyzed medicines might be used by chronically ill patients or as an alternative therapy to previously used medicines (22–24). Thus, the significance of the affordability of these medicines.

OTC medicines are used by approximately 90% of Polish citizens (2). For example, reclassification of fenspiride hydrochloride and inosine pranobex contributed to a significant increase in the turnover of these medicines in Poland (2). Moreover, as presented in this study, the Rx-to-OTC switch of e.g. furaginum changed the market share of this substance with an overwhelming superiority of the OTC category compared to the Rx class (Table 2). It may result in increased public health care spending on pharmaceuticals, which for instance in Serbia increased in less than a decade from EUR 339 million to EUR 742 million (25).

However, in the case of some antihistamines or proton pump inhibitors (Table 2) the switch did not change their market shares significantly and in 2016 majority of packages in Poland were still sold in the Rx category. Despite this and the fact that some switches are considered controversial or may result in the misuse of medicines (17, 26), reclassifications may contribute to better economic results of a pharmacy. It might be related to freely created prices, profit margins, and market competition of OTC medicines. The phenomenon should be also supported by the affordability of switched medicines because out-of-pocket expenditures became dominant in many Central and Eastern European countries. Hence equitable access to medicines as well as sustainable financing of pharmaceuticals are for individuals (27).

The study has some limitations. First of all, it could be advisable to consider more substances, such as ketoprofen or sildenafil. It could be also interesting to examine opinions about significant increases in the retail prices of switched medicines. Sometimes it seems difficult to logically explain to patients why pharmaceuticals offered in the same packaging sizes, forms, and dosages and branded by the same pharmaceutical company are a few times more expensive in the OTC class than those in the Rx category. In addition to this, it seems that this study would be of more value if we decided to evaluate the patients’ opinions on reclassified medicines and ask them about expected trends in the field.

CONCLUSIONS

The current scope of Rx-to-OTC switches is considered a controversial phenomenon that may lead to the development of uncontrolled self-medication. Double registration of medicines is also frequently moot. Furaginum was indicated as the substance which should be available as an Rx-only brand instead of double registered medicine. The Rx-to-OTC switch generally leads to an increase in sales in the OTC category instead of Rx class. In the case of Rx-to-OTC switches, additional information about possible side effects and/or interactions should be provided to the patients who might inappropriately use medicines.

Acknowledgments

The authors would like to thank decision-makers from PEX PharmaSequence who disinterestedly shared their market data. They had no role, however, in study design, data collection, and analysis, decision to publish, or preparation of the manuscript.
Conflict of interest

Nothing to declare.

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Received: 13.02.2019