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WHAT CAN WE LEARN FROM CONSUMERS' UNDERSTANDING OF DRUG INFORMATION AND SAFETY?

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Abstract: Objective: To analyse consumer perspectives regarding drug information and safety and opinions on consumer reporting of adverse drug reactions (ADR). Methods: A voluntary survey was conducted in a population ≥ 18 years of age in Asturias, a region in northern Spain. The survey was designed to be completed in a face-to-face street interview or completed independently by the consumers. The survey consisted of structured questions organized in four sections: I) Demographic data, II) Use of medicines, III) Reading and understanding of the patient information leaflet (PIL) and IV) Awareness and perception about direct consumer reporting of ADR. Key findings: A total of 402 surveys were given and analysed; 295 were completed independently and 107 were completed in street interviews. Of the total responders, 82.3% had taken some drug(s) in the previous three months, although only 62.4% had done so by medical prescription. A quarter of respondents claimed that they never read the PIL of medicines, 12.7% that they sometimes read it, and 61.4% that they always read this information. A high percentage (82.8%) of respondents reported that they were not aware of consumer reporting of ADR, and 86.1% stated their agreement with this option. Conclusions: Consumers have great interest in useful information about all aspects involved in the use of medicines. This includes consumer reporting of suspected ADR, which is still unknown to many consumers.

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Introduction

Medical practice has always been guided by ethical principles. The principle of autonomy takes into account the rights of individuals to actively participate in the decisions involved in their own health and, by extension, the right to access sufficient information to be able to carry out this activity[1]. In recent decades, demographic, economic, technological and educational changes in the population have resulted in a new model of patient who is better informed and is an active player in self-care and shared decision-making[2]. The concept of a "patient-centred approach" is directly related to the concept of "patient empowerment", which refers to patients shedding their passive role and playing an active part in decision-making processes that impact their health and quality of life[3].

One of the most significant recent changes in pharmacovigilance is the formal leading role of patients[4] or, in a wider sense, consumers[5]. The aim of spontaneous reporting systems is to detect new signals, and in order to do that, pharmacovigilance centres need many good-quality reports[5]. There is evidence to show that new and novel adverse reactions can be detected through consumer reporting[6]. European legislation that came into effect in July 2012[7] urges member states to develop tools to facilitate the direct spontaneous reporting of suspected adverse drug reactions (ADR) by patients. Until then, in Spain, spontaneous ADR reporting was mainly based on reports of health professionals to the health authorities[8,9]. In compliance with the abovementioned European legislation, in 2013, the Spanish Ministry of Health, Social Services and Equality published a new directive[10], and the Spanish Agency of Medicines and Medical Devices developed an electronic format to collect reports of suspected ADR directly from consumers, which is also available through a direct link from its website. This option was published in a safety warning in January 2013[11]. Consumer reporting of ADR gives new perspectives on consumers' own unfiltered experiences of the side effects of drugs in a way that is not otherwise available[12-15]. The growing numbers of patient reports indicate European patients' high motivation to report ADR and suggest that the new European Union pharmacovigilance legislation has made a positive impact by empowering patients[16].

However, to our knowledge, in Spain, no promotional campaign concerning this issue and directed towards the public has been developed, nor have the results of direct patient reports of ADR to the Spanish Agency of Medicines and Medical Devices been published. Furthermore, to date, no studies on consumer awareness and perception regarding information on drug safety have been performed in Spain. Therefore, the aim of our study was to analyse the perspectives of consumers on medicine information and safety and on direct patient reporting of suspected ADR.

1. Methods

The study was carried out by researchers of the University of Oviedo in the Principality of Asturias, Spain, as part of a research project aimed to foster spontaneous reporting of ADR by consumers. This project (65/2012) was approved by the Clinical Research Ethics Committee. The Principality of Asturias is a region located in northern Spain, with an area of 10,603.57 km^2 and a total population of 1,034,449 inhabitants.

A voluntary survey of people ≥ 18 years of age in the Principality of Asturias in the cities of Oviedo, Gijón and Avilés and the towns of Langreo and Cangas del Narcea was conducted between May 2014 and May 2015. Based on the study published by Krska et al[17], a survey written in Spanish was developed. At the top of the first page of the final questionnaire, a box explaining the subject and aim of the survey was included. All members of the research team contributed to the development of the questions. At the beginning of the study, two researchers worked together to deliver the first 50 surveys. After this pilot period, the survey was reviewed by the research team, and some corrections were made to the content and order of questions.

The questionnaire was designed to be completed in a face-to-face street interview or independently by consumers. In the street interviews, the people surveyed were randomly selected by the researcher. At the beginning of the interview, the survey was presented as part of a research project at the university, and the subject and the aim of the study were explained. Self-completed surveys were mainly completed in social centres in collaboration with the person in charge. In Spain, there is a network of social centres aimed at the whole population that provide activities

related to social information delivery, entertainment and community sociocultural promotion. In each of these centres, a non-specific large number of survey forms were left, and 1-2 weeks later, a researcher collected the completed surveys. Of these, only 7 were declared null for lack of completeness (missing information) or for methodological reasons (age < 18 years).

The survey consisted of structured questions organized in 4 sections: I) Demographic data: age, sex and level of education, including a question on health education; II) Use of medicines: 6 closed questions; III) Reading and understanding of the patient information leaflet (PIL): 1 open and 2 closed questions; and IV) Perception and awareness towards direct reporting of suspected ADR: 6 closed questions. The level of education was classified as follows: a) high education (ISCED 2011[18], levels 5-8), b) upper secondary studies (ISCED 2011, levels 3-4), c) lower (compulsory) secondary or primary studies (ISCED 2011, levels 1-2) and c) no education (ISCED 2011, level 0).

A preliminary analysis of the results was conducted with the first 264 responses. To record the survey results, a data matrix was created with Microsoft Excel 2010. Definition of study variables, filtering of data and statistical analysis were performed by syntax with IBM SPSS Statistics 22. Age was treated as a discrete and metric variable and presented as median [range]. Other metric variables were expressed as the mean ± standard error of the mean (SEM), and categorical variables were expressed as frequencies and percentages. Pearson's chi-squared (χ^2) test was used to compare proportions for categorical variables, and a *t*-test was used to compare means with metric variables. The level of statistical significance was set at $p \leq 0.05$.

3. Results

3.1. Demographic data

Of the population asked to participate, only 23 people declined to participate in the study. A total of 487 surveys were returned, but 85 were excluded from the analysis: 77 because respondents had some type of health education and 8 due to incomplete information. Of the remaining 402 analysed surveys, 295 were completed

by the respondents and 107 were completed by the researcher, according to the information provided by the respondent. Table 1 shows the demographic details of the surveyed population compared with the overall Spanish population according to the 2011 census data [19].

3.2. Use of medicines

The results obtained in this section are summarized in Table 2. Of the total number of respondents, 331 (82.3%) had taken some drug(s) in the previous three months, but only 251 (62.4%) had done so by medical prescription. The use of drugs without versus with medical prescription was significantly ($p < 0.01$) higher among respondents aged 18-45 years [125 (75.8%) vs 75 (45.5%)] and 46-65 years [139 (84.7%) vs 109 (66.5%)] compared to respondents aged 65 or more years [64 (95.5%) vs 64 (95.5%)]. The consumption of non-prescribed medicines was mainly self-medication [48 (11.9%)] or based on the pharmacist's advice [18 (4.5%)]. On the other hand, although the total use of drugs, both prescribed and non-prescribed, was similar for all educational levels, the consumption of prescribed drugs was significantly higher ($p < 0.01$) in the surveyed population with lower educational levels [17 (89.5%) in respondents with no education vs [60 (46.5%) in those with higher education].

Most respondents stated that when taking a medicine, they knew what it was for [365 (90.8%)] and with what frequency they should take it [367 (91.3%)] (Table 2). The level of knowledge of these two items was higher in the surveyed population aged 65 years or older [66 (98.5%) and 65 (97.0%)] than in the population aged 18-45 years [142 (86.1%) and 143 (86.7%)]. However, a slightly lower percentage of respondents [336 (86.6%)] declared they knew the intended duration of drug treatments when taking a drug. Awareness of the duration of drug treatments was lower in the group of respondents aged between 18-45 years [121 (73.3%)] than in other age groups [145 (88.4%) – 64 (95.5%)] ($p < 0.01$).

3.3. Reading and understanding the patient information leaflet

A quarter [100 (24.9%)] of respondents claimed that they never read the PIL, whereas 51 (12.7%) sometimes read it and 247 (61.4%) always read this information (Table 3). Of those who always read the PIL (Table 4), 172 (69.6%) reported that they

read the whole PIL, and the remaining respondents mainly read the indications [43 (17.4%)], dose and instructions [42 (17.0%)] and adverse reactions [41 (16.6%)]. Among those who sometimes read the PIL, the most consulted sections were the dose and instructions [14 (27.5%)] and, with the same frequency [8 (15.7%)], the adverse reactions and the indications.

The level of understanding of the PIL seemed to be related to age and level of education (Table 3). Among the respondents aged between 18-45 years, only 10 (6.1%) claimed to have difficulties understanding PIL, versus 17 (25.4%) in the group aged 65 years or older. Furthermore, only 9 (7%) of the respondents with higher education, versus 3 (15.8%) of respondents with no education, reported difficulties in understanding the PIL.

3.4. Perception of drug safety

To the question: "In your opinion, what type of medicine is safer?" (Table 5), 279 (69.4%) responded that prescribed medicines are safer, and 70 (17.4%) replied that both prescribed and non-prescribed medicines are equally safe. The perception of drug safety seems to differ depending on the age group. In the opinion of 100 (60.6%) of the respondents aged between 18-45 years versus 60 (89.6%) of the respondents aged 65 years or older ($p < 0.01$), prescribed medicines are safer. On the other hand, 294 (73.1%) reported not knowing who regulates medicines in Spain.

In relation to the use of the internet, 166 (41.3%) of the respondents reported that they always used it, 140 (34.8%) reported using it sometimes, and 83 (20.6%) reported that they never used it. The level of internet use was clearly dependent on the age group analysed ($p < 0.01$), being higher in younger interviewees, and increasing proportionally with the level of education ($p < 0.01$). It is important to highlight that in the group aged 65 years or more, 45 (67.2%) of the respondents reported that they never used the internet.

A high percentage [333 (82.8%)] of respondents claimed not to be aware of consumer reporting of suspected ADR, and 346 (86.1%) stated their agreement with this option. The responses in this last section were also in relation to age and level of studies; 145 (87.8%) of respondents in the 18-45 years group agreed versus 47 (70.1%)

in the 65 or over group. In addition, 122 (94.6%) of the respondents with higher education were in favour of this new option versus 12 (63.1%) of the respondents with no education. In the opinion of the majority of the surveyed population [368 (91.6%)], consumers should receive more information about this possibility.

4. Discussion

Our study presents some aspects of consumers' viewpoints on medicine consumption, the use of PIL as a source of information about medications and the awareness level of the population concerning consumer reporting of suspected ADR.

The study covers the views of consumers of different ages and levels of education but does not analyse the views of patients or people affected by severe diseases. In our observations, people in general show great interest in any information about medicines, and therefore collecting and ascertaining their observations in relation to ADR or other medication-related problems could be an interesting area for future research. The limitations of the study include potential bias in the collection of the responses in the street interviews or lack of information in the self-completed surveys.

In our results, the declared medicine consumption in the previous three months was higher than that found by Krska et al[17] in a similar survey performed in the U.K., although according to the 2014 Eurostat Report on Medicine Use Statistics[20], the rates of prescribed/non-prescribed medicine use were 53.1%/21.9% in the Spanish population and 53.0%/43.3% in the U.K. population. On the other hand, nearly 20% of our respondents reported that they had been consuming some type of medicine without a prescription, and this figure was greater in the younger group and in the group with a higher level of education. These observations are in agreement with other studies performed in Spain; Jimenez-Rubio et al[21], in a study on self-medication in the previous two weeks, found that 14% of individuals consumed some medicines without a medical prescription, and this was also more common in the younger population. In contrast, we observed that only a small proportion of consumption of medicines without a prescription was based on pharmacist advice, with self-medication being the more common scenario. It is important to underline that

according to the Centro de Investigaciones Sociológicas[22] in Spain, 15.1% of the population admits to keeping spare packs of medicines at home. The use of these stored medicines plus the purchase of some medicines without a medical prescription could be the basis of the self-medication detected in our study.

A large part of the population surveyed in our study knew the reason why they were taking some drug(s), and this knowledge was more common in the older people surveyed. In our opinion, this high level of knowledge could be related to pharmacological prescriptions for the treatment of chronic diseases, such as ischaemic cardiopathy, diabetes and osteoarthritis that are common in this age group[23]. However, more widespread knowledge of other points related to the management of pharmacological treatments, such as the duration of these treatments, seem to require an improvement in the information provided to patients by health professionals. Competent authorities for the regulation of medicines in several European countries have recently reviewed their practices regarding communication about the safety of medicines[24].

With regard to the PIL as a drug information source, the majority of the surveyed population claimed to always or sometimes read the PIL, which is in agreement with previous reports from Spain[25] and other countries[26-27]. The level of comprehension of the PIL in our observations was high, although older people and people with a lower level of education present more difficulties in the comprehension of the PIL. To improve the understanding of the PIL and to promote their use, several measures, such as the inclusion of short, structured and visual/text explanations, have been proposed[28-30].

Some previous studies[28,31,32] have indicated that information on drug safety is the most-read part of the PIL. However, in our study, only the surveyed population that occasionally read the PIL reported this preference. Globally considered, the population we surveyed did not show a preference for reading the information on drug safety in the PIL compared to the indications and dose or duration of treatments, underlining the interest of consumers in all aspects of drug use.

In general terms, we observed in consumers a low awareness of drug safety, who regulates medicines in Spain and the new option for consumers to directly report

ADR. The awareness of these issues found in our study was slightly lower than that found in Portugal[33] but similar to that observed in the UK[17]. Moreover, the majority of our surveyed population showed a positive attitude after being informed of consumer reporting of ADR, in agreement with previous observations[34-37]. To facilitate consumer reporting of ADR, drug regulatory agencies and pharmacovigilance centres have developed websites for online reporting[38-39]. In this sense, it is important to emphasize that, according to a recent national survey conducted in Spain[22], 18.1% of the Spanish population regards it as "not necessary" to have internet access at home, a similar percentage to that found in our survey. This suggests the importance of developing complementary systems of reporting, such as telephone lines or paper formats that can facilitate the collaboration of this population group.

5. Conclusion

Consumers have great interest in useful information about all aspects of the use of medicines: efficacy, safety, indications and duration of treatments. In relation to drug safety, consumer reporting of suspected ADR is not sufficiently well known but is greatly appreciated, especially by people with a high level of education and young people.

6. Declarations

Conflict of interest

The author(s) declare that they have no conflict of interest to disclose.

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Table 1. Demographic details of the surveyed population versus the Spanish census data

Characteristic		Surveyed population, n (%)	Spanish census data, 2011 (%)
Gender			
	Male	145 (36.1)	49.4
	Female	257 (63.9)	50.6
Age (years)			
	18 – 45	165 (41.0)	40.7
	46 – 65	164 (40.8)	25.1
	> 65	67 (16.7)	16.4
	Unknown or not applicable	6 (1.5)	17.8
Education			
	Higher	129 (32.1)	21.5
	Upper secondary	94 (23.4)	16.6
	Primary or compulsory secondary	151 (37.6)	36.5
	No education	19 (4.7)	9.4
	Unknown or not applicable	9 (2.2)	16.0

Table 2. Use of medicines

		Age (years)					Sex			Level of education						Total
		18-45	46-65	>65	Unk	X^2	Female	Male	X^2	Higher	Upper Secondary	Primary or compulsory secondary	No studies	Unk	X^2	
		n (%)	n (%)	n (%)	n (%)	P value	n (%)	n (%)	P value	n (%)	n (%)	n (%)	n (%)	n (%)	P value	n (%)
1. In the previous three months, have you taken any drug?						< 0.01			0.06						0.80	
	Yes	125 (75.8)	139 (84.7)	64 (95.5)	3 (50)		220 (85.6)	111 (76.5)		102 (79.0)	77 (81.9)	127 (84.1)	17 (89.5)	8 (88.9)		331 (82.3)
	No	38 (23.0)	24 (14.6)	3 (4.5)	3 (50)		36 (14)	32 (22.1)		27 (21.0)	16 (17.0)	22 (14.6)	2 (10.5)	1 (11.1)		68 (16.9)
	DK-NR	2 (1.2)	1 (0.7)	0 (0)	0 (0)		1 (0.4)	2 (1.4)		0 (0)	1 (1.1)	2 (1.3)	0 (0)	0 (0)		3 (0.8)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)
2. In the previous three months, have you taken any drug by medical prescription?						< 0.01			< 0.05						< 0.01	
	Yes	75 (45.5)	109 (66.5)	64 (95.5)	3 (50)		171 (66.5)	80 (55.2)		60 (46.5)	62 (66.0)	105 (69.5)	17 (89.5)	7 (77.8)		251 (62.4)
	No	48 (29.1)	30 (18.3)	0 (0)	0 (0)		49 (19.1)	29 (20)		41 (31.8)	14 (14.9)	22 (14.6)	0 (0)	1 (11.1)		78 (19.4)
	DK-NR	42 (25.4)	25 (15.2)	3 (4.5)	3 (50)		37 (14.4)	36 (24.8)		28 (21.7)	18 (19.1)	24 (15.9)	2 (10.5)	1 (11.1)		73 (18.2)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)
3. If it was not taken by medical prescription, who recommended it?						< 0.05			0.55						0.10	
	Pharmacist	10 (6.1)	8 (4.9)	0 (0)	0 (0)		11 (4.3)	7 (4.8)		11 (8.5)	2 (2.1)	5 (3.3)	0 (0)	0 (0)		18 (4.5)
	Other HP	3 (1.8)	2 (1.2)	1 (1.5)	0 (0)		5 (1.9)	1 (0.7)		2 (1.5)	0 (0)	4 (2.7)	0 (0)	0 (0)		6 (1.5)
	Other, no HP	4 (2.4)	2 (1.2)	0 (0)	0 (0)		2 (0.8)	4 (2.8)		2 (1.5)	3 (3.2)	0 (0)	0 (0)	1 (11.1)		6 (1.5)
	Myself	30 (18.2)	18 (11.0)	0 (0)	0 (0)		32 (12.5)	16 (11.0)		25 (19.5)	8 (8.5)	15 (9.9)	0 (0)	0 (0)		48 (11.9)
	DK-NR-NA	118 (71.5)	134 (81.7)	66 (98.5)	6(100)		207 (80.5)	117 (80.7)		89 (69.0)	81 (86.2)	127 (84.1)	19 (100)	8 (88.9)		324 (80.6)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)
4. When you have to take a drug, do you know what is it for?						0.30			0.45						0.20	
	Yes	142 (86.1)	151 (92.1)	66 (98.5)	6 (100)		233 (90.7)	132 (91.0)		118 (91.5)	83 (88.3)	137 (90.7)	19 (100)	8 (88.9)		365 (90.8)
	No	2 (1.2)	3 (1.8)	0 (0)	0 (0)		2 (0.8)	3 (2.1)		2 (1.5)	1 (1.1)	2 (1.3)	0 (0)	0 (0)		5 (1.2)
	Sometimes	19 (11.5)	8 (4.9)	1 (1.5)	0 (0)		20 (7.7)	8 (5.5)		9 (7.0)	8 (8.5)	11 (7.3)	0 (0)	0 (0)		28 (7.0)
	DK-NR-NA	2 (1.2)	2 (1.2)	0 (0)	0 (0)		2 (0.8)	2 (1.4)		0 (0)	2 (2.1)	1 (0.7)	0 (0)	1 (11.1)		4 (1.0)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)
5. Do you know when and with what frequency you have to take it?						0.22			0.19						0.30	
	Yes	143 (86.7)	153 (93.3)	65 (97.0)	6 (100)		234 (91.1)	133 (91.7)		118 (91.5)	84 (89.4)	139 (92.0)	19 (100)	7 (77.8)		367 (91.3)
	No	5 (3.0)	4 (2.4)	1 (1.5)	0 (0)		4 (1.6)	6 (4.1)		5 (3.9)	2 (2.1)	3 (2.0)	0 (0)	0 (0)		10 (2.5)
	Sometimes	15 (9.1)	5 (3.1)	0 (0)	0 (0)		16 (6.2)	4 (2.8)		6 (4.6)	6 (6.4)	7 (4.6)	0 (0)	1 (11.1)		20 (5.0)
	DK-NR	2 (1.2)	2 (1.2)	1 (1.5)	0 (0)		3 (1.2)	2 (1.4)		0 (0)	2 (2.1)	2 (1.4)	0 (0)	1 (11.1)		5 (1.2)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)
6. Do you know how long you have to take it for?						< 0.01			0.20						0.20	

	Yes	121 (73.3)	145 (88.4)	64 (95.5)	6 (100)		215 (83.7)	121 (83.4)		108 (83.7)	73 (77.6)	129 (85.4)	19 (100)	7 (77.8)		336 (86.6)
	No	12 (7.3)	11 (6.7)	0 (0)	0 (0)		11 (4.3)	12 (8.3)		6 (4.7)	6 (6.4)	11 (7.3)	0 (0)	0 (0)		23 (5.7)
	Sometimes	28 (17.0)	8 (3.7)	2 (3.0)	0 (0)		27 (10.5)	9 (6.2)		14 (10.8)	13 (13.8)	8 (5.3)	0 (0)	1 (11.1)		36 (9.0)
	DK-NR	4 (2.4)	2 (1.2)	1 (1.5)	0 (0)		4 (1.6)	3 (2.1)		1 (0.8)	2 (2.2)	3 (2.0)	0 (0)	1 (11.1)		7 (1.7)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)

DK: do not know, NR: no reply, NA: not appropriate, Unk: unknown, HP: Health Professionals

Table 3. Reading and understanding the patient information leaflet (PIL)

		Age (years)					Sex			Level of education						Total
		18-45	46-65	>65	Unk	X^2	Female	Male	X^2	Higher	Upper Secondary	Primary or compulsory secondary	No studies	Unk	X^2	
		n (%)	n (%)	n (%)	n (%)	P value	n (%)	n (%)	P value	n (%)	n (%)	n (%)	n (%)	n (%)	P value	n (%)
1. Do you read the PIL for medicines?						0.05			0.40						0.07	
	Always	104 (63.0)	101 (61.6)	39 (58.2)	3 (50)		158 (61.5)	89 (61.4)		87 (67.4)	57 (60.6)	87 (57.6)	10 (52.6)	6 (66.7)		247 (61.4)
	Sometimes	24 (14.6)	10 (6.1)	15 (22.4)	2 (33.33)		31 (12.0)	20 (13.8)		13 (10.1)	9 (9.6)	23 (15.2)	5 (26.3)	1 (11.1)		51 (12.7)
	Never	35 (21.2)	51 (31.1)	13 (19.4)	1 (16.7)		67 (26.1)	33 (22.7)		29 (22.5)	26 (27.7)	40 (26.5)	4 (21.1)	1 (11.1)		100 (24.9)
	NR-NA	2 (1.2)	2 (1.2)	0 (0)	0 (0)		1 (0.4)	3 (2.1)		0 (0)	2 (2.1)	1 (0.7)	0 (0)	1 (11.1)		4 (1.0)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)
2. Do you find the PIL difficult to understand?						< 0.01			< 0.05						< 0.05	
	Yes	10 (6.1)	15 (9.1)	17 (25.4)	0 (0)		29 (11.3)	13 (9.0)		9 (7)	6 (6.4)	23 (15.2)	3 (15.8)	1 (11.1)		42 (10.4)
	Sometimes	72 (43.6)	83 (50.6)	29 (43.3)	3 (50)		110 (42.8)	77 (53.1)		55 (42.6)	32 (34.0)	51 (33.8)	3 (15.8)	4 (44.5)		187 (46.5)
	No	71 (43.0)	60 (36.6)	12 (17.9)	2 (33.3)		104 (40.5)	41 (28.3)		61 (47.3)	49 (52.1)	66 (43.7)	8 (42.1)	3 (33.3)		145 (36.1)
	DK-NR	12 (7.3)	6 (3.7)	9 (13.4)	1 (16.7)		14 (5.4)	14 (9.6)		4 (3.1)	7 (7.5)	11 (7.3)	5 (26.3)	1 (11.1)		28 (7.0)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)

DK: do not know, NR: no reply, NA: not appropriate, Unk: unknown

Table 4. Reading of the different sections of the patient information leaflet (PIL)

What part of the PIL do you read?	Reading of the PIL (Question 1, Table 2), n (%)		
	Always	*Sometimes*	*Always or sometimes*
All	172 (69.6)	2 (3.9)	174 (58.4)
What you should take it for (indications)	43 (17.4)	8 (15.7)	51 (17.1)
How to take it (dose and instructions)	42 (17.0)	14 (27.5)	56 (18.8)
Secondary effects (adverse reactions)	41 (16.6)	8 (15.7)	49 (16.4)
Others	2 (0.8)	1 (2.0)	3 (1.0)
DK-NR-NA-NL	2 (0.8)	30 (58.8)	32 (10.7)
Total	247 (100)	51 (100)	298 (100)

DK: do not know, NR: no reply, NA: not appropriate, NL: null

Table 5. Perception of drug safety

		Age (years)					Sex			Level of education						Total
		18-45	46-65	>65	Unk	X^2	Female	Male	X^2	Higher	Upper Secondary	Primary or compulsory secondary	No studies	Unk	X^2	
		n (%)	n (%)	n (%)	n (%)	P value	n (%)	n (%)	P value	n (%)	n (%)	n (%)	n (%)	n (%)	P value	n (%)
1. In your opinion, what type of medicine is safer?						< 0.01			0.80						0.29	
	Prescribed	100 (60.6)	116 (70.7)	60 (89.6)	3 (50)		178 (69.2)	101 (69.7)		78 (60.5)	65 (69.1)	115 (76.2)	14 (73.6)	7 (77.8)		279 (69.4)
	Non-prescribed	3 (1.8)	0 (0)	2 (3.0)	0 (0)		2 (0.8)	3 (2.1)		2 (1.5)	1 (1.1)	1 (0.7)	1 (5.3)	0 (0)		5 (1.2)
	Both	40 (24.2)	26 (15.9)	4 (6.0)	0 (0)		45 (17.5)	25 (17.2)		29 (22.5)	15 (16.0)	24 (15.9)	1 (5.3)	1 (11.1)		70 (17.4)
	None	16 (9.7)	12 (7.3)	0 (0)	2 (33.3)		19 (7.4)	11 (7.6)		15 (11.6)	8 (8.5)	4 (2.6)	2 (10.5)	1 (11.1)		30 (7.5)
	DK-NR	6 (3.7)	10 (6.1)	1 (1.4)	1 (16.7)		13 (5.1)	5 (3.4)		5 (3.9)	5 (5.3)	7 (4.6)	1 (5.3)	0 (0)		18 (4.5)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)
2. Do you know who regulates medicines in Spain?						< 0.05			0.08						< 0.01	
	Yes	24 (14.5)	46 (28.0)	14 (20.9)	3 (50)		49 (19.1)	38 (26.2)		35 (27.1)	21 (22.3)	26 (17.2)	3 (15.8)	2 (22.2)		87 (21.7)
	No	133 (80.6)	111 (67.7)	47 (70.1)	3 (50)		191 (74.3)	103 (71.0)		89 (69.0)	67 (71.3)	119 (78.8)	15 (78.9)	4 (44.5)		294 (73.1)
	DK-NR	8 (4.9)	7 (4.3)	6 (9.0)	0 (0)		17 (6.6)	4 (2.8)		5 (3.9)	6 (6.4)	6 (4.0)	1 (5.3)	3 (33.3)		21 (5.2)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)
3. Do you use the internet?						< 0.01			0.10						< 0.01	
	Always	99 (60)	57 (34.8)	9 (13.4)	1 (16.7)		97 (37.7)	69 (47.6)		78 (60.5)	41 (43.6)	46 (30.5)	0 (0)	1 (11.1)		166 (41.3)
	Sometimes	58 (35.2)	70 (42.7)	9 (13.4)	3 (49.9)		96 (36.6)	46 (31.7)		43 (33.3)	38 (40.4)	52 (34.4)	3 (15.8)	4 (44.5)		140 (34.8)
	Never	2 (1.2)	35 (21.3)	45 (67.2)	1 (16.7)		55 (21.4)	28 (19.3)		4 (3.1)	12 (12.8)	49 (32.5)	15 (78.9)	3 (33.3)		83 (20.6)
	DK-NR	6 (3.6)	2 81.2)	4 (6.0)	1 (16.7)		11 (4.3)	2 (1.4)		4 (3.1)	3 (3.2)	4 (2.6)	1 (5.3)	1 (11.1)		13 (3.2)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)
4. Do you know that consumers can directly report suspected ADR?						0.60			0.60						< 0.01	
	Yes	22 (13.3)	23 (14.0)	11 (16.4)	0 (0)		36 (13.6)	21 (14.5)		10 (7.8)	12 (12.8)	19 (19.2)	5 (26.3)	0 (0)		56 (13.9)
	No	137 (83.0)	138 (84.2)	52 (77.6)	6 (100)		212 (82.5)	121 (83.4)		116 (89.9)	79 (84.0)	117 (77.5)	14 (73.7)	7 (77.8)		333 (82.8)
	DK-NR	6 (3.7)	3 (1.8)	4 (6.0)	0 (0)		10 (3.9)	3 (2.1)		3 (2.3)	3 (3.2)	5 (3.3)	0 (0)	2 (22.2)		1 (3.3)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)
5. Do you agree that this option should be available?						< 0.01			0.60						< 0.01	
	Yes	145 (87.8)	148 (90.2)	47 (70.1)	6 (100)		218 (84.8)	128 (88.3)		122 (94.6)	82 (87.3)	125 (82.8)	12 (63.1)	5 (55.6)		346 (86.1)
	No	10 (6.1)	13 (7.9)	11 (16.4)	0 (0)		23 (8.9)	11 (7.6)		1 (0.8)	8 (8.5)	19 (12.6)	4 (21.1)	2 (22.2)		34 (8.5)
	DK-NR-NA	10 (6.1)	3 (1.9)	9 (13.5)	0 (0)		16 (6.2)	6 (4.1)		6 (4.6)	4 (4.2)	7 (4.6)	3 (15.8)	2 (22.2)		22 (5.4)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)
6. In your opinion, should consumers receive more information about this option?						< 0.01			0.30						0.10	
	Yes	152 (92.1)	158 (96.3)	53 (79.1)	5 (83.3)		239 (93.0)	129 (89.0)		122 (94.6)	87 (92.6)	137 (90.7)	15 (78.8)	7 (77.8)		368 (91.6)

	No	2 (1.2)	1 (0.6)	2 (3.0)	0 (0)		2 (0.8)	3 (2.0)		0 (0)	2 (2.1)	3 (2)	0 (0)	0 (0)		5 (1.2)
	DK-NR-NA	11 (6.7)	5 (3.1)	12 (17.9)	1 (16.7)		16 (6.2)	13 (9.0)		7 (5.4)	5 (5.3)	11 (7.3)	4 (21.1)	2 (22.2)		29 (7.2)
	Total	165 (100)	164 (100)	67 (100)	6 (100)		257 (100)	145 (100)		129 (100)	94 (100)	151 (100)	19 (100)	9 (100)		402 (100)

DK: do not know, NR: no reply, NA: not appropriate, Unk: unknown, ADR: adverse drug reactions