



A preliminary feasibility study for the trial of anti-cocaine vaccine

Bertoncelli Sara



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General aim of the study

Preliminary processing of the data collected through self-administrated questionnaires aimed at investigating:

1. acceptability
2. reasons
3. doubts

about anti-cocaine vaccine trial.



Specific objectives

1. Investigate the perception of efficacy of the anti-cocaine vaccine by professionals and cocaine users
2. Investigate trial acceptability
3. Investigate reasons and doubts about joining the trial
4. Evaluate the warranties that both the targets consider necessary in order to join the trial
5. Identify the information that professionals and cocaine users think are necessary before joining the trial
6. Compare the opinions of the two targets about same areas of investigation



Target

1. Drug abuse professionals:

- Physician
- Psychologist
- Psychiatrist
- Nurse
- Social worker
- Educator
- Researcher
- Sociologist

2. Cocaine users



Methodology

Self-administration of questionnaires at the two target populations (drug abuse professionals and cocaine users) afferent the following services in Italy:

1. Drug abuse services
2. Therapeutical communities
3. Social cooperatives
4. Narcotics Anonymus (Self-help Association)



Enti coinvolti

- ASL N. 1 Benevento - U.O.S. Dipendenze patologiche Telesse Terme
- AS N. 4 - U.O.C. SerT Cosenza
- ASL NA 4 - U.O. Complessa SerT di Nola distretto 73
- ASL N. 5 - SerT di Rivoli - Dipartimento Patologia delle Dipendenze Collegno TO
- ASL N. 5 - Comunità Terapeutica Lucignolo & Co Rivoli
- AS N. 7 - SerT Catanzaro
- AUSL N. 8 Dipartimento delle Dipendenze di Siracusa
- AST N. 11 - Dipartimento delle Dipendenze Reggio Calabria
- ULSS N. 20 Dipartimento delle Dipendenze di Verona (SerT1; SerT2; SerT3)
- ASL Bergamo - SerT Bergamo 2 Martinengo
- ASL Brescia - SerT Brescia
- ASL Como - SerT Appiano Gentile
- ASL Cremona - SerD Crema
- AUSL FG2 - SerT di Cerignola - Dipartimento Dipendenze Patologiche
- USL Modena - SerT di Mirandola (Dipartimento di Salute Mentale - Settore Dipendenze Patologiche)
- AUSL Parma - SerT di Parma
- ASL Varese - Dipartimento delle Dipendenze
- ASUR zona 3 - SerT di Campobasso
- Narcotici Anonimi - Associazione di auto-mutuo aiuto



Areas of the questionnaire

1. Perception of efficacy of the anti-cocaine vaccine
2. Importance assigned to psychological support
3. Importance assigned to privacy and anonymity
4. Perceived risk of the temptation of overcoming the anti-cocaine vaccine barrier
5. Perceived efficacy of a possible preventive vaccine
6. Perceived problems of the controls respect
7. Perception of a possible social discrimination (having to go to the drug abuse service, positivity to anti-cocaine antibodies)
8. Acceptability of the trial
9. Reasons in favour of joining the trial
10. Doubts about joining the trial
11. Perception of efficacy of pharmacological therapies in the treatment of drug abuse
12. Warranties necessary to take part in the trial
13. Necessity of more information on anti-cocaine vaccine



Results: subjects interviewed

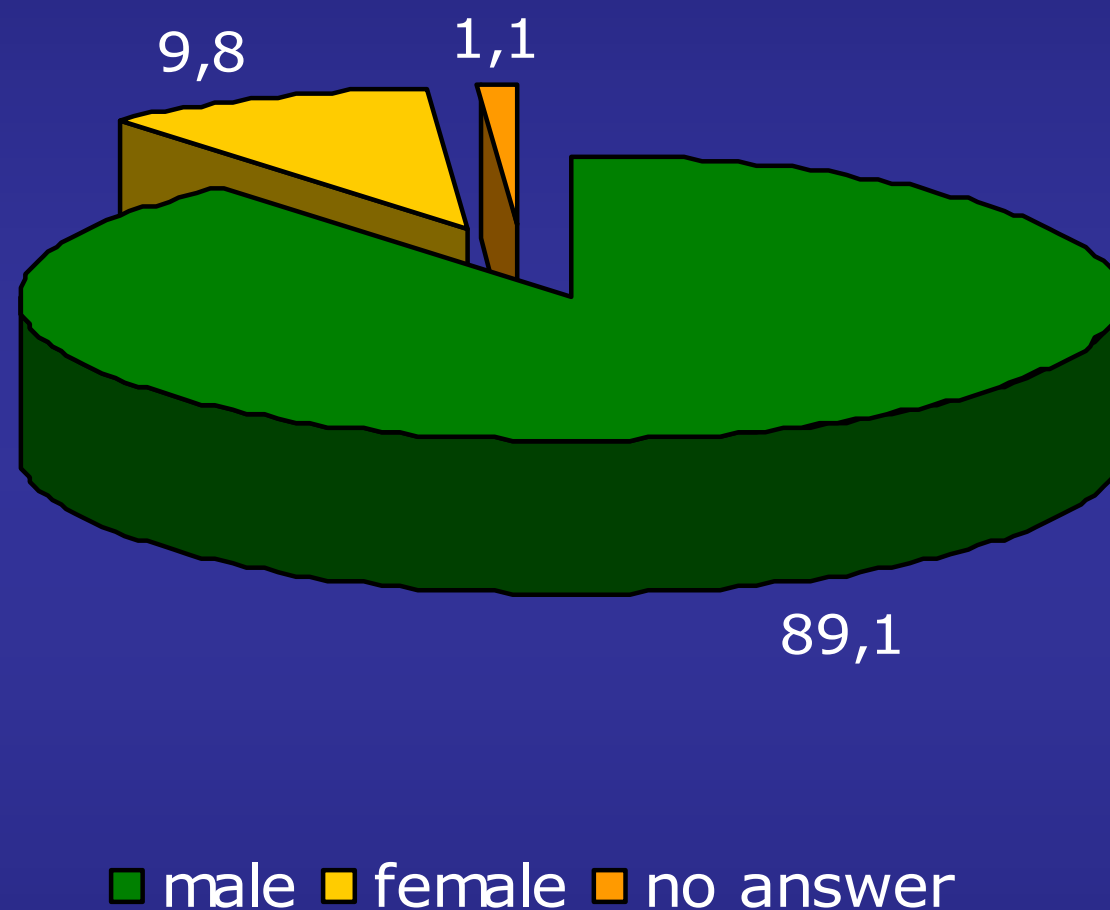
A total number of 344 subjects replied to the questionnaires, amongst whom:

- **170** drug abuse professionals
- **174** cocaine users



Cocaine users' features

Gender distribution (%)

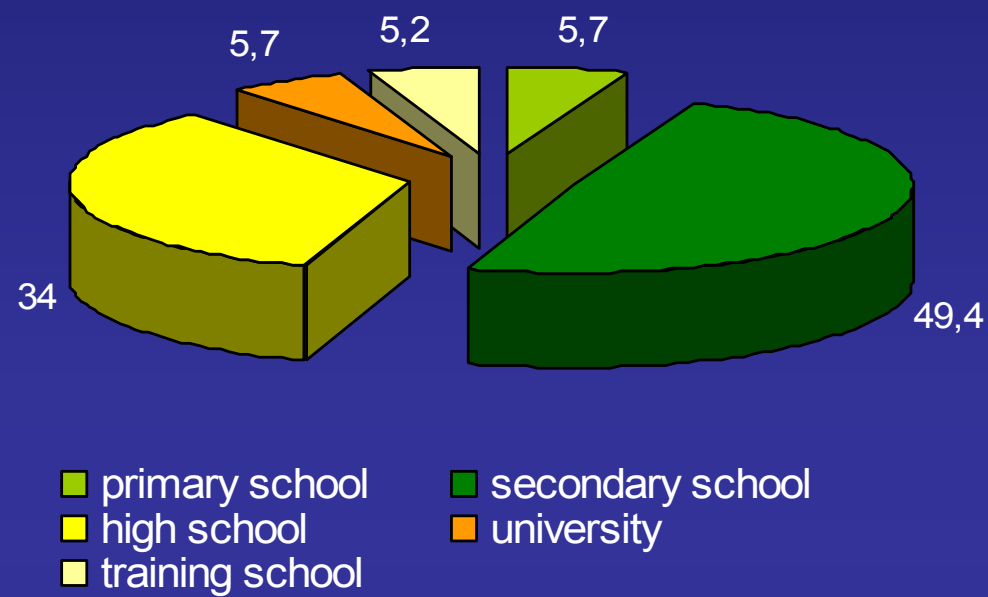


Cocaine consumers are mainly male (89,1%) and the mean age of the group is 33 years. The mean age of the first use of cocaine is 18 years.

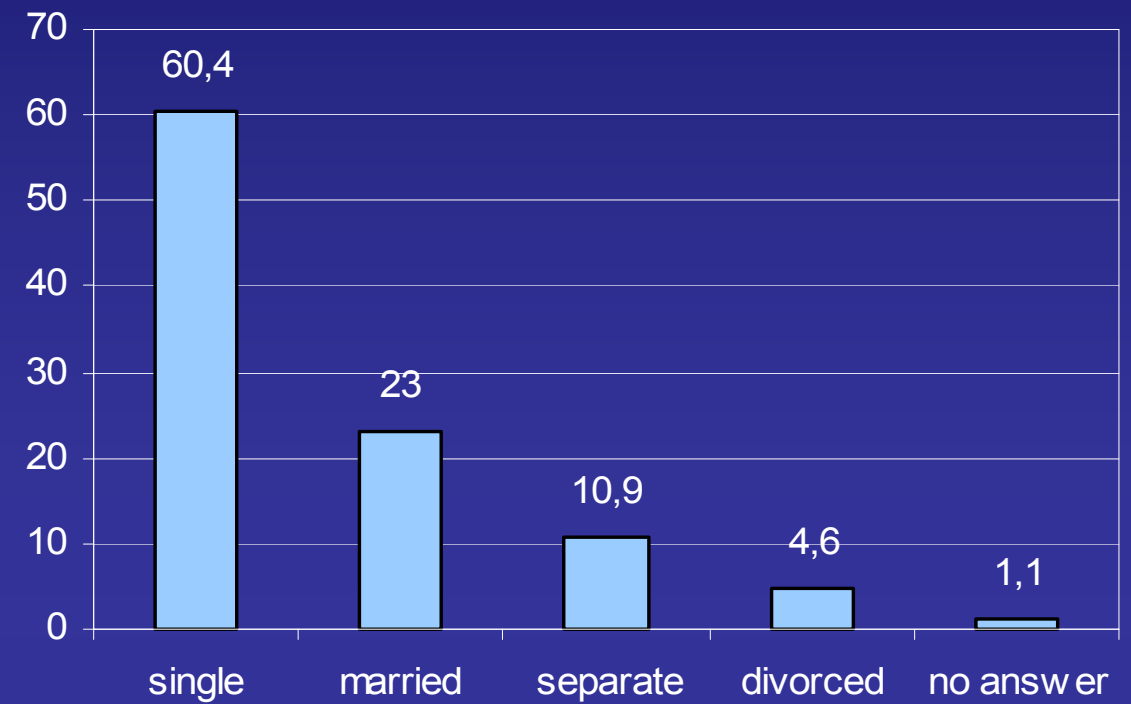


Cocaine users' features

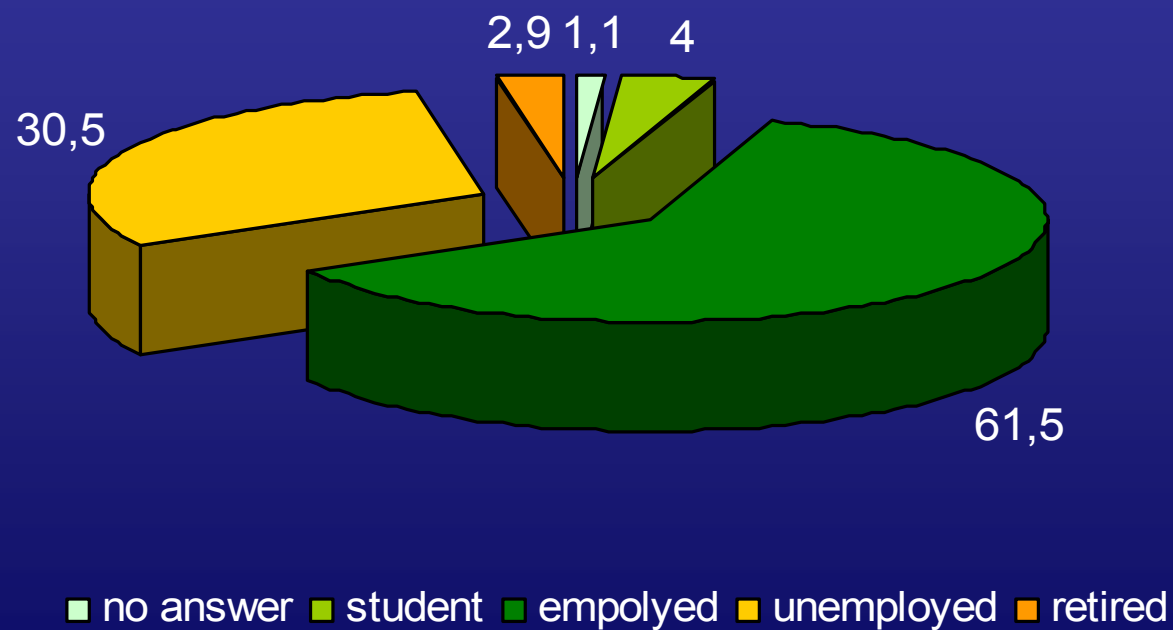
Education (%)



Marital status (%)



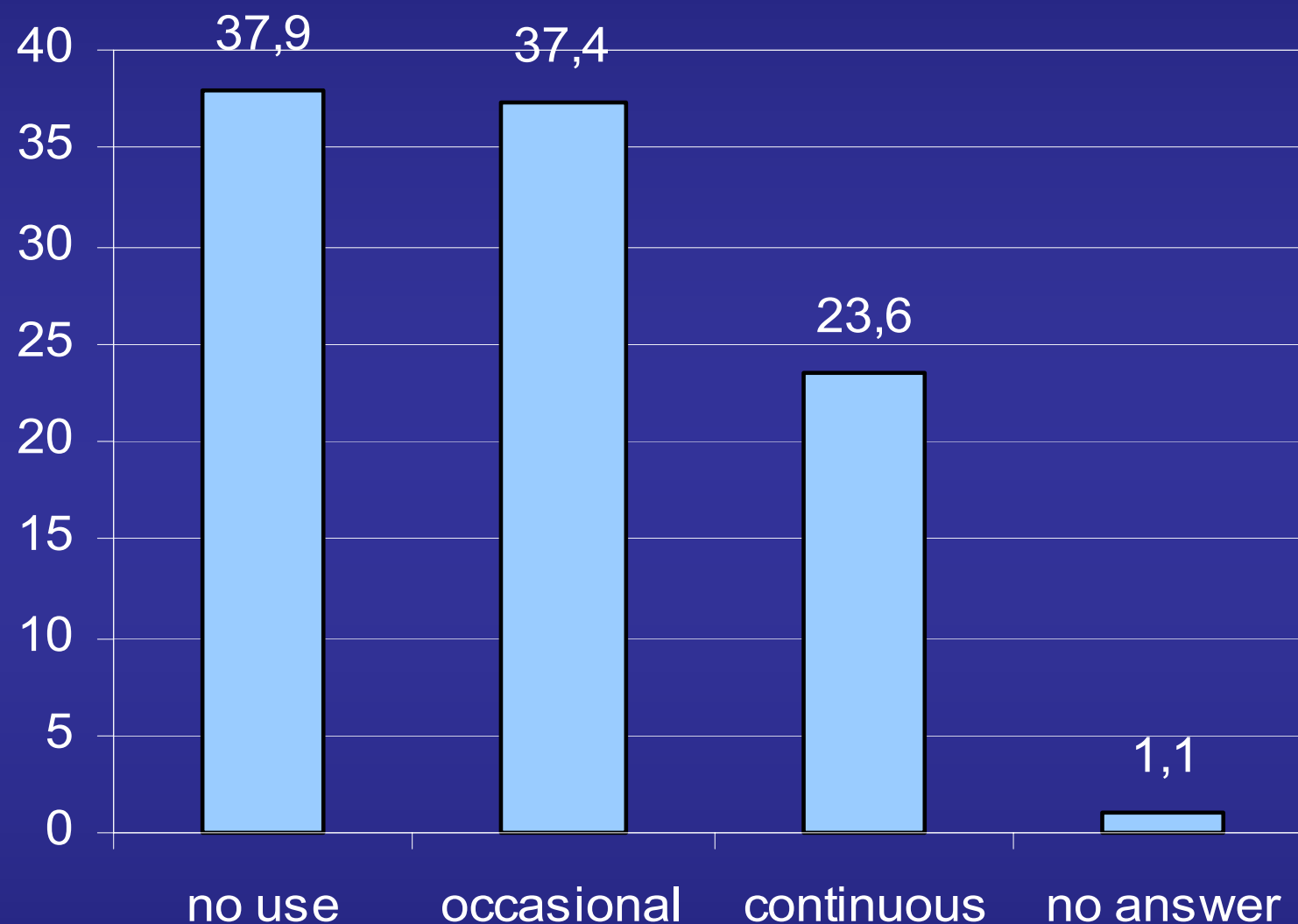
Employment (%)





Cocaine users' features

Current cocaine use (%)

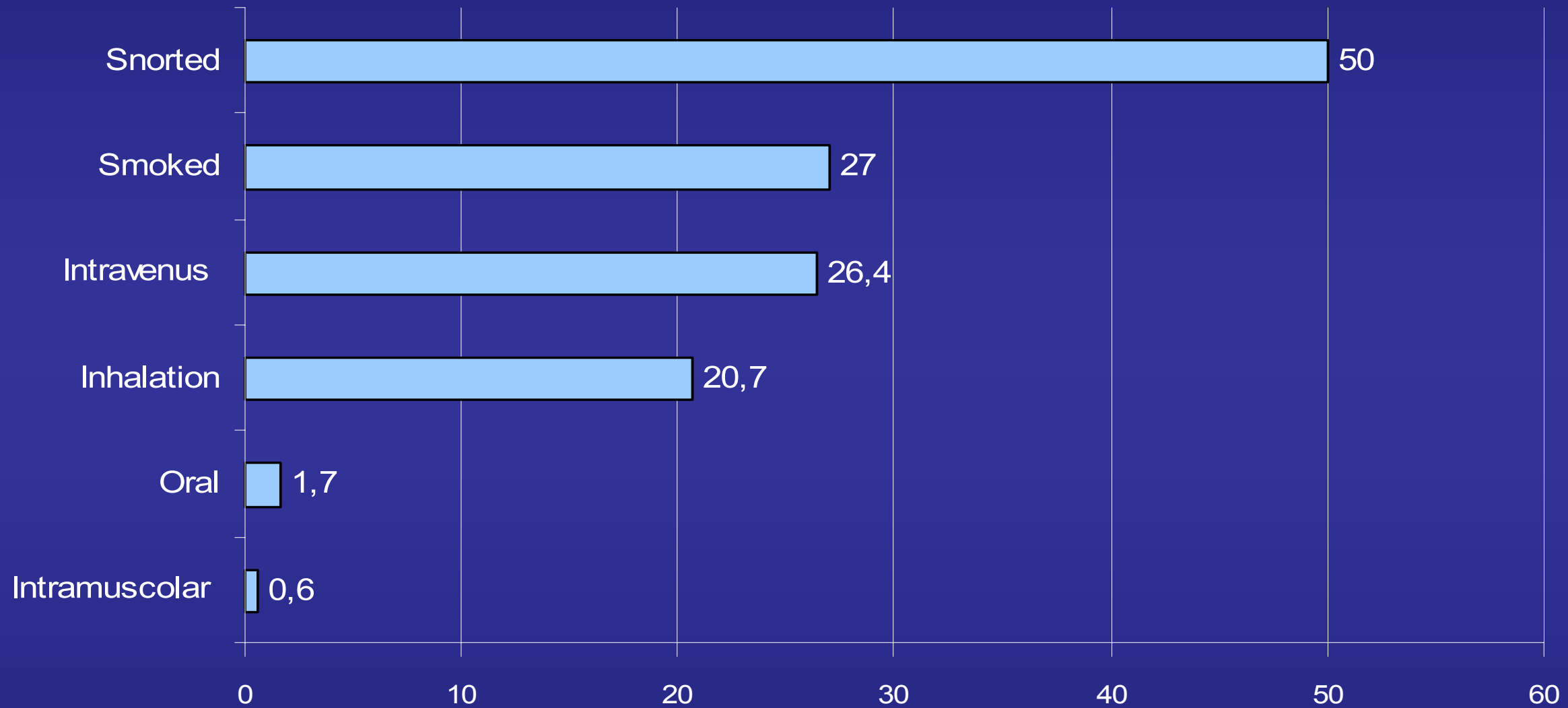


At present Cocaine consumers mainly don't use cocaine or use it occasionally (75,3%)



Cocaine users' features

Current way of cocaine taking (%)

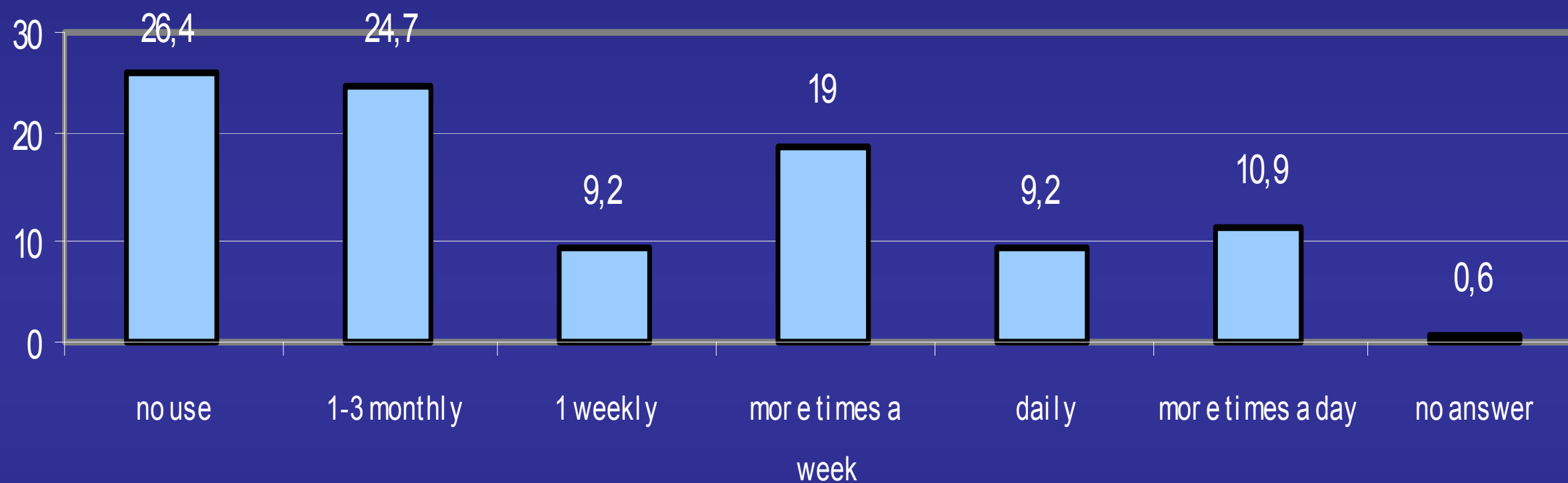


Amongst cocaine consumers currently using cocaine, 50% refer snort as main way of taking it. To be pointed out that in these percentages are counted people using more than one way of taking, too.



Cocaine users' features

Frequency of cocaine use in the last 30 days (%)

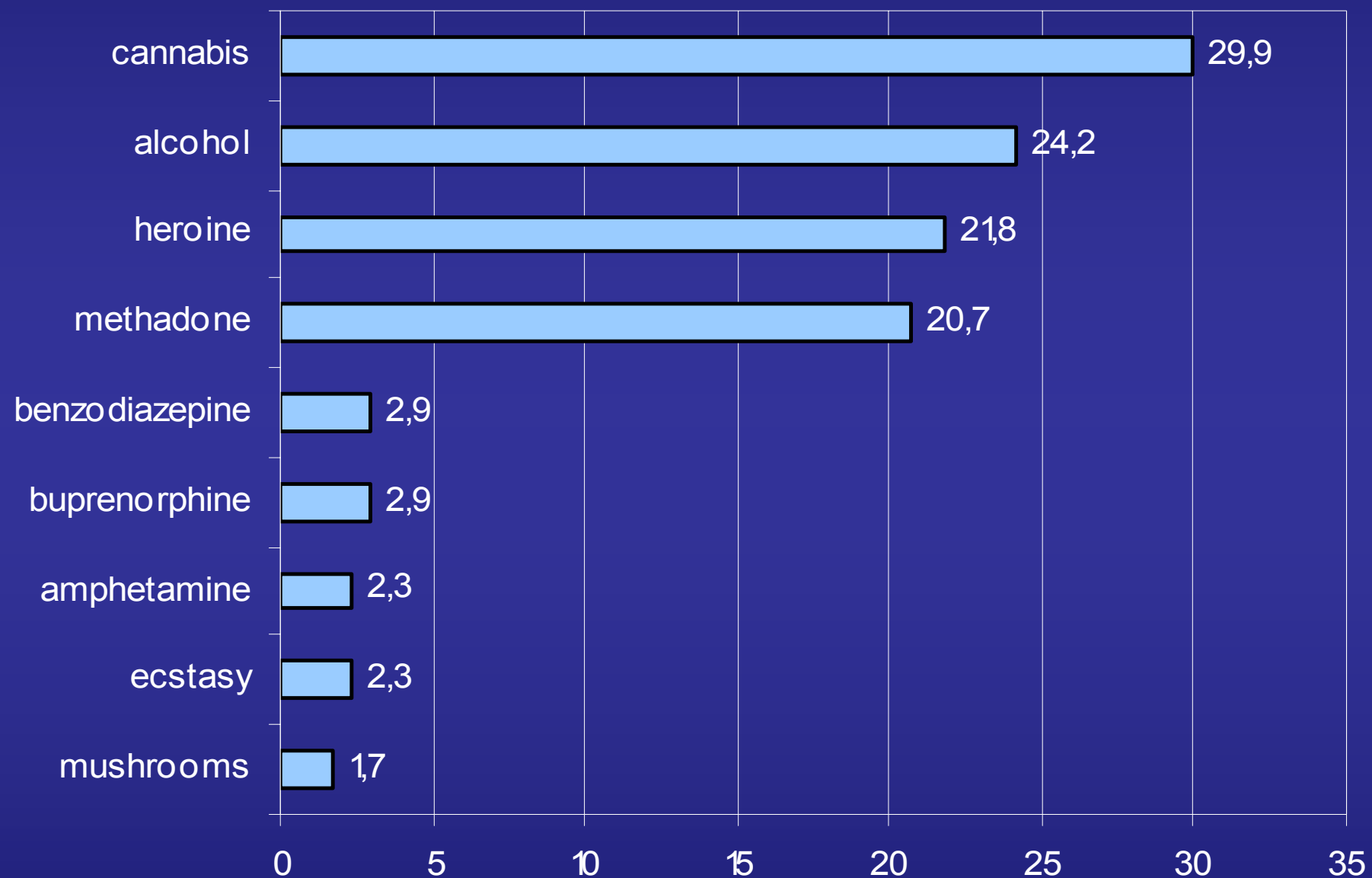


26,4% of cocaine consumers refer having not use cocaine in the last 30 days



Cocaine users' features

Use of other substances in the last 30 days (%)

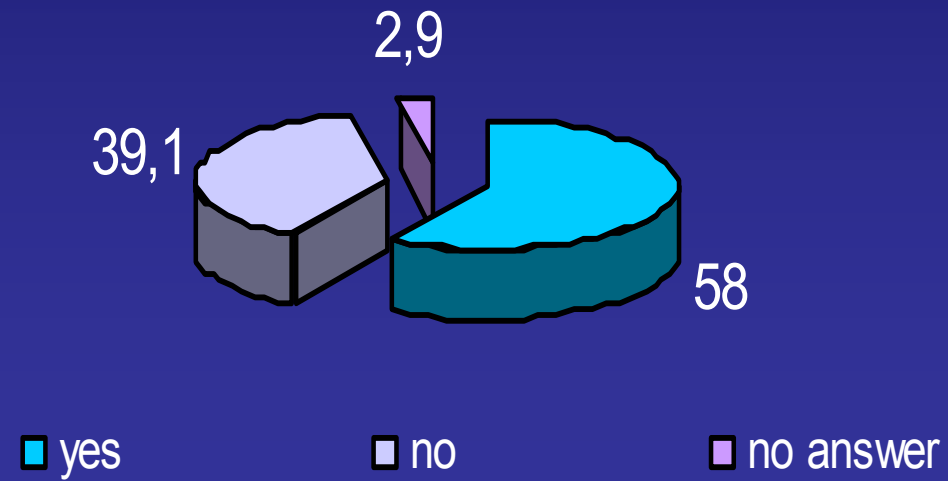


The more frequently substances used in the last 30 days are cannabis (29,9%) and alcohol (24,2%). To be noted that in these percentages are counted people using more than one substance, too. 29,9% of the sample refers not having used other substances.

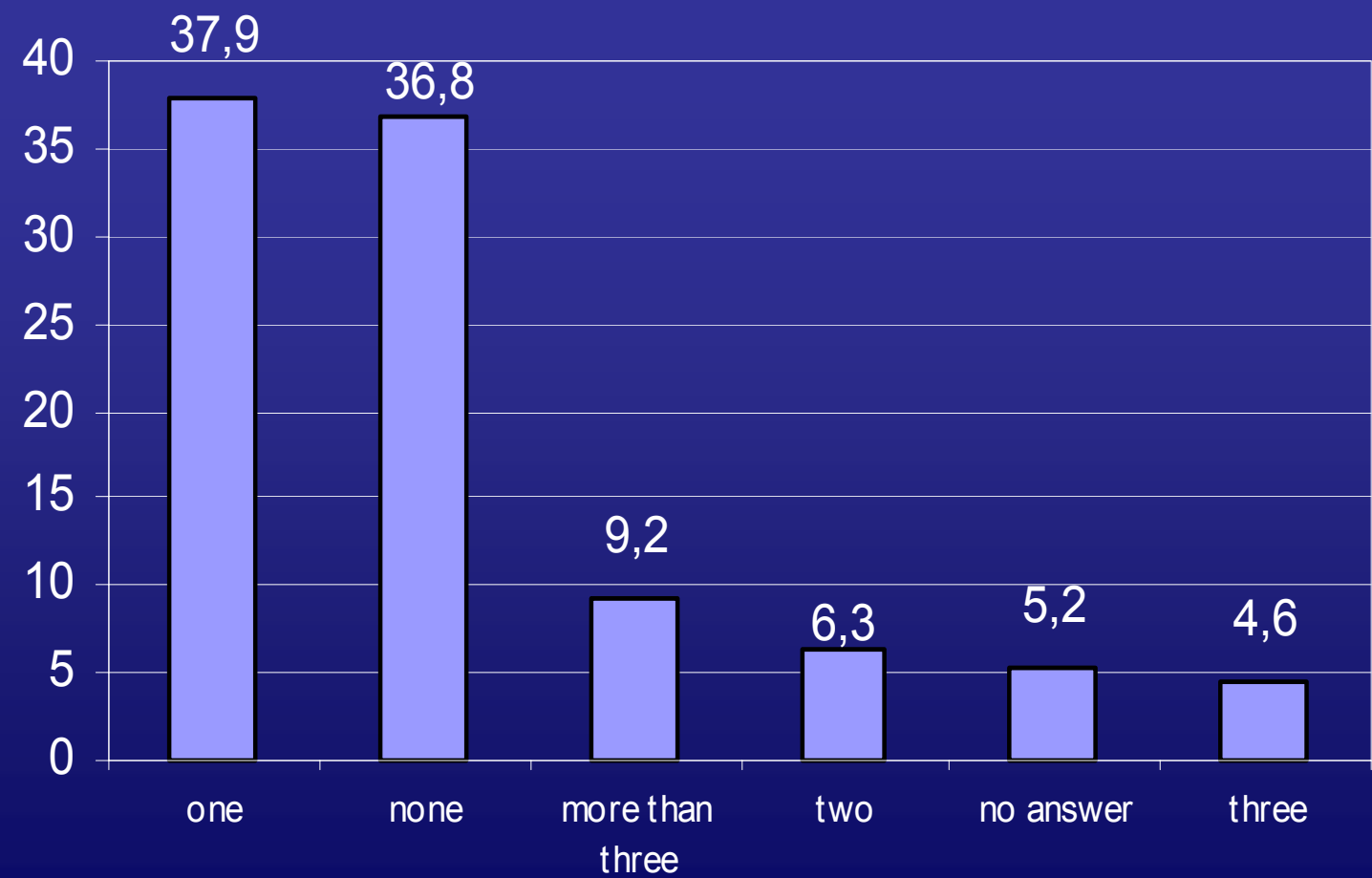


Cocaine users' features

Treatments in the past (%)



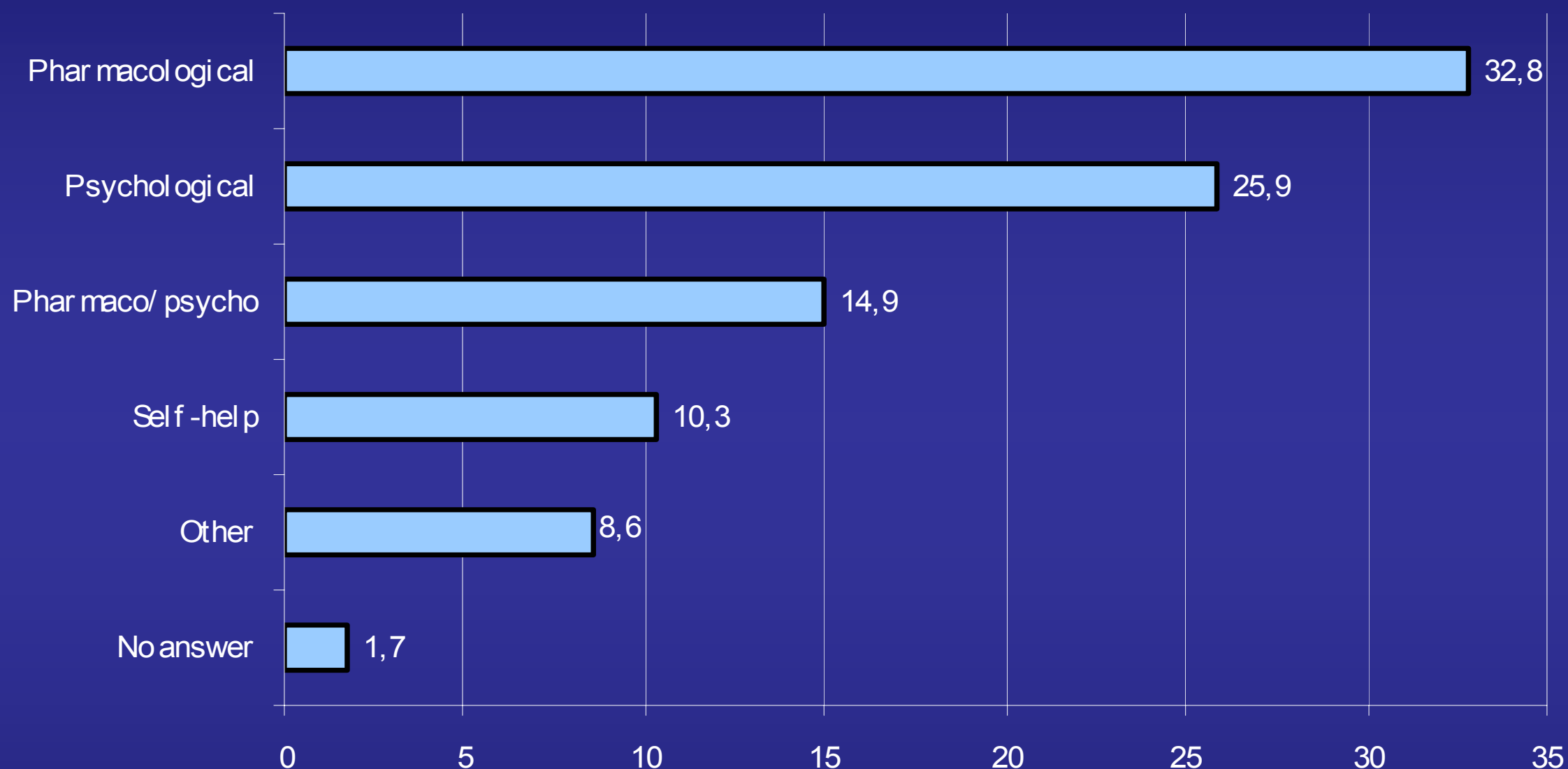
Treatments in the past 12 months (%)





Cocaine users' features

Type of treatment in the last 12 months (%)

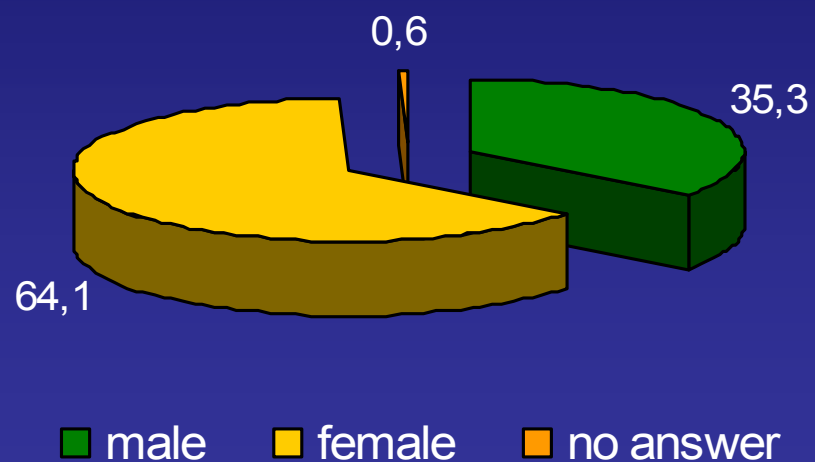


The therapy most frequently referred in the last year is the pharmacological treatment (32,8%), followed by the psychological one (25,9%). People who have referred more than one treatment are also included in the calculation of the percentages. 36,8% have not been submitted to treatment in the previous 12 months.

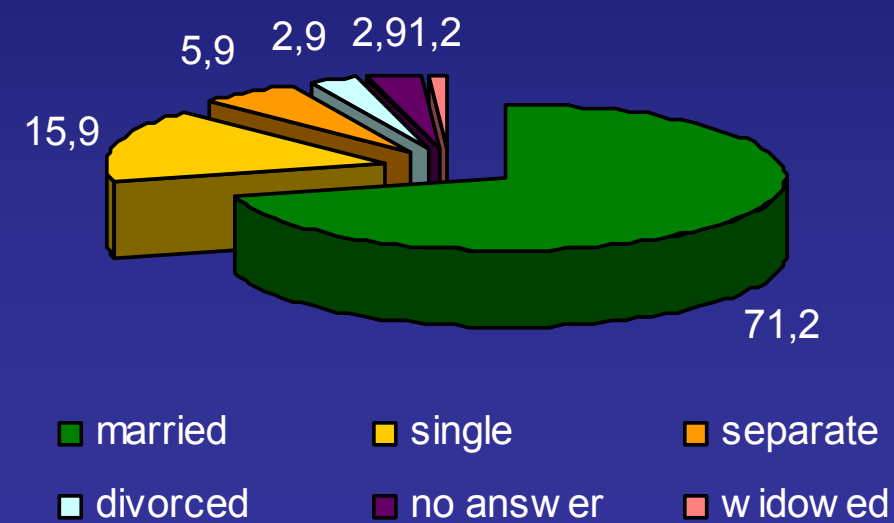


Professionals' features

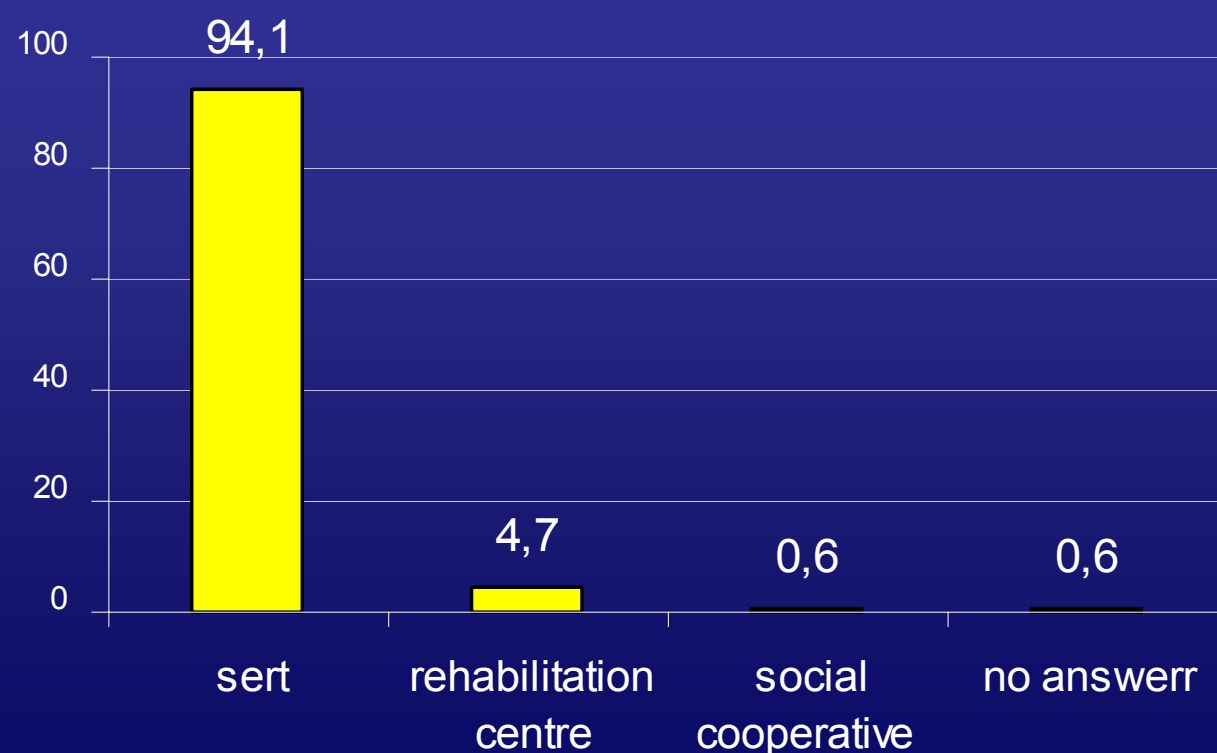
Gender distribution (%)



Marital Status (%)



Working agency (%)

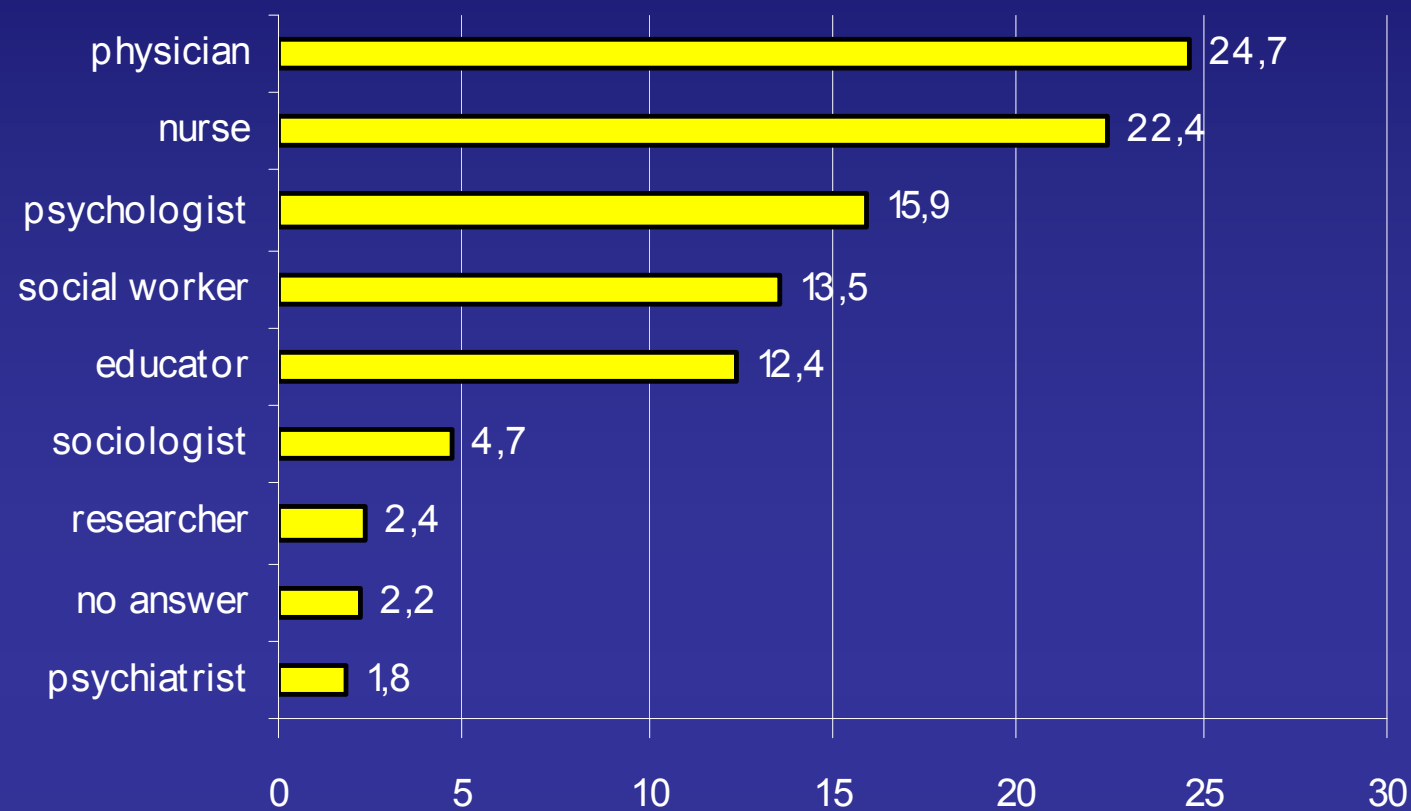


Professionals' mean age is 45 years

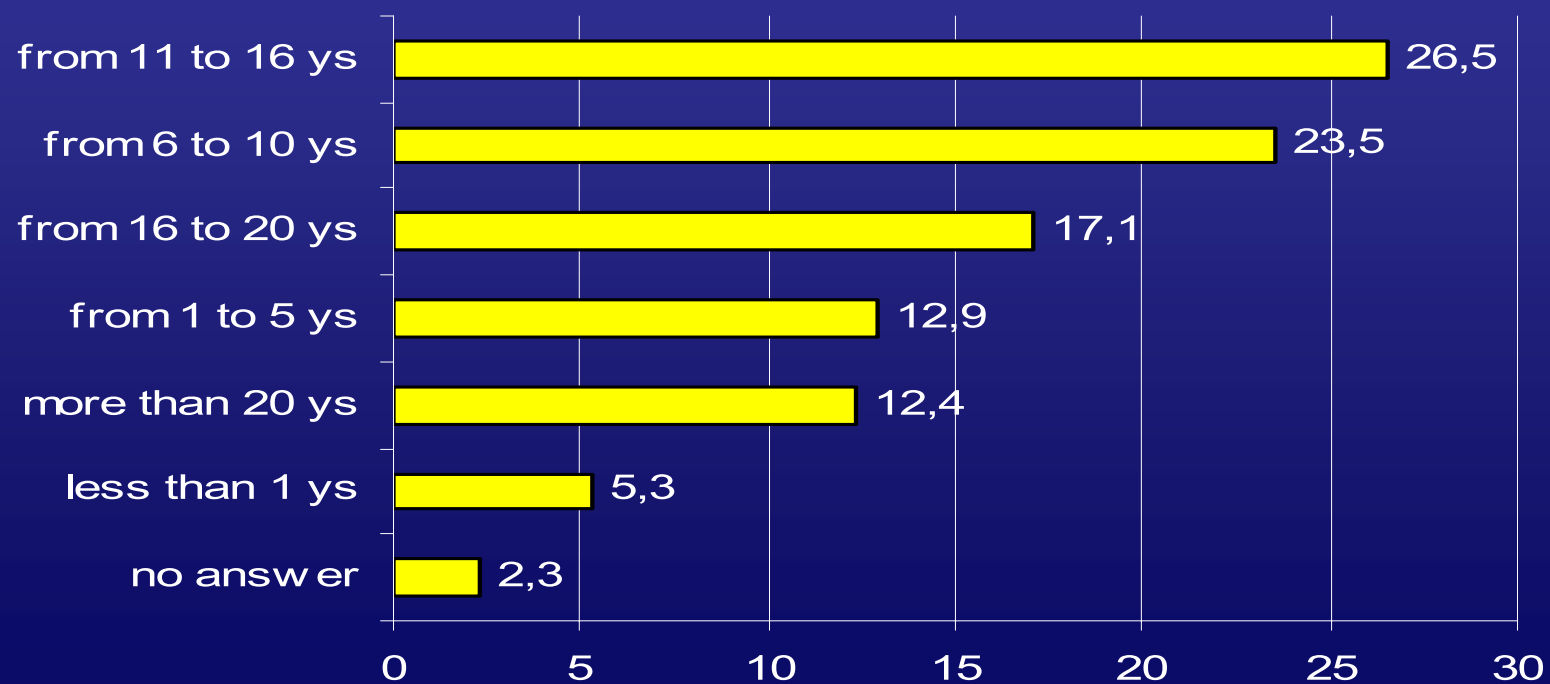


Professionals' features

Profession (%)

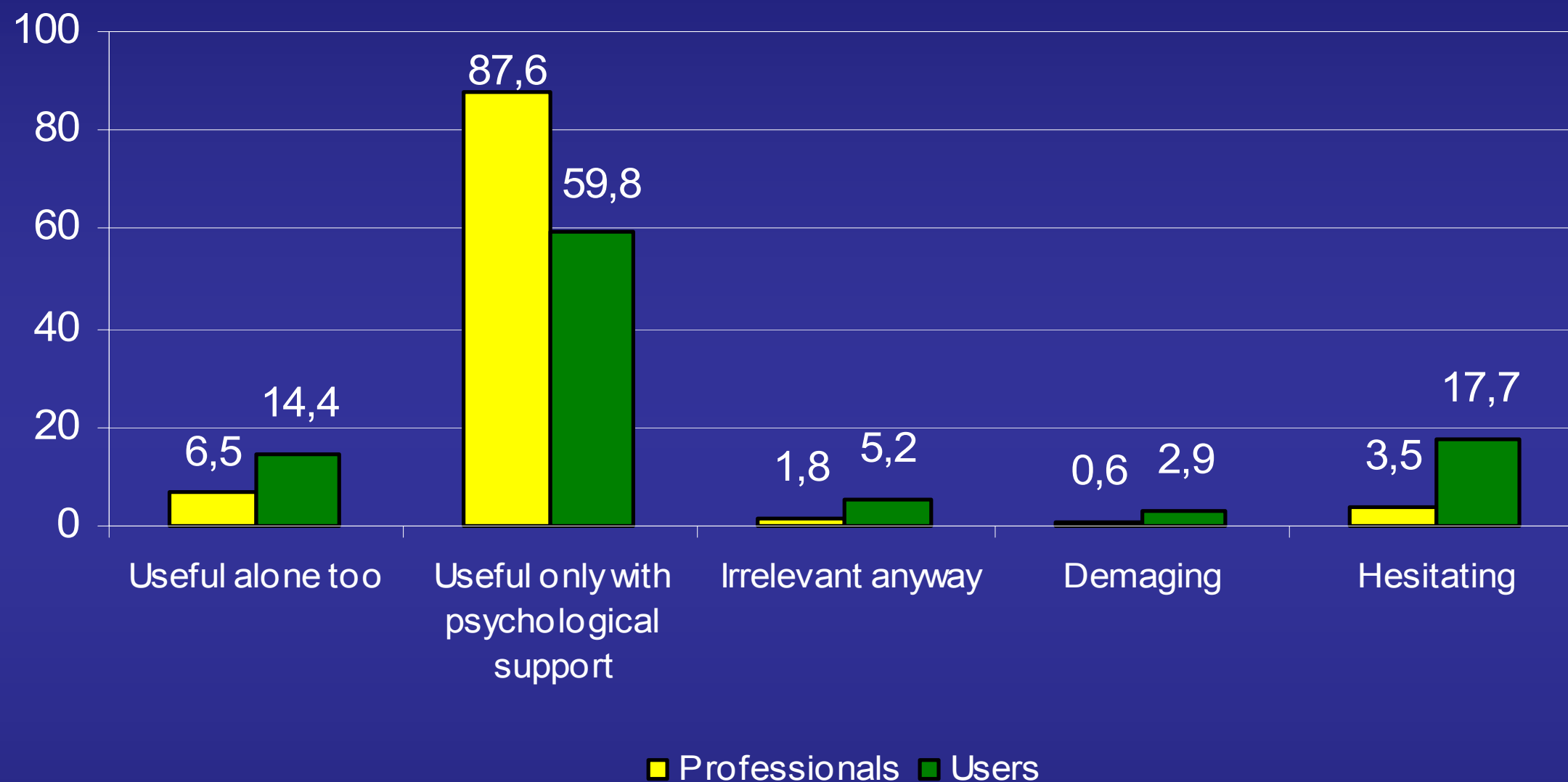


Years of Operativeness (%)





Perception of efficacy (%)

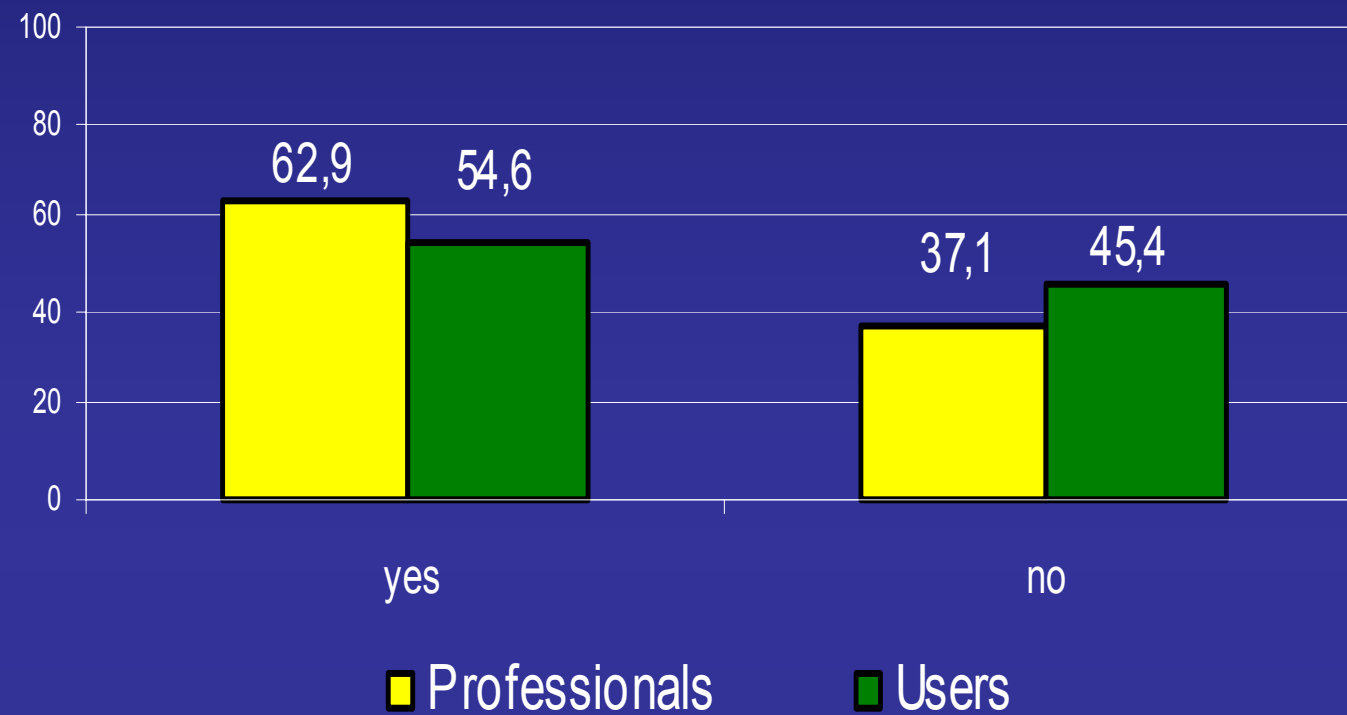


According to most consumers and professionals (59,8% and 87% respectively) the anti-cocaine vaccine for the cocaine addiction treatment can be useful only if associated with psychological support.

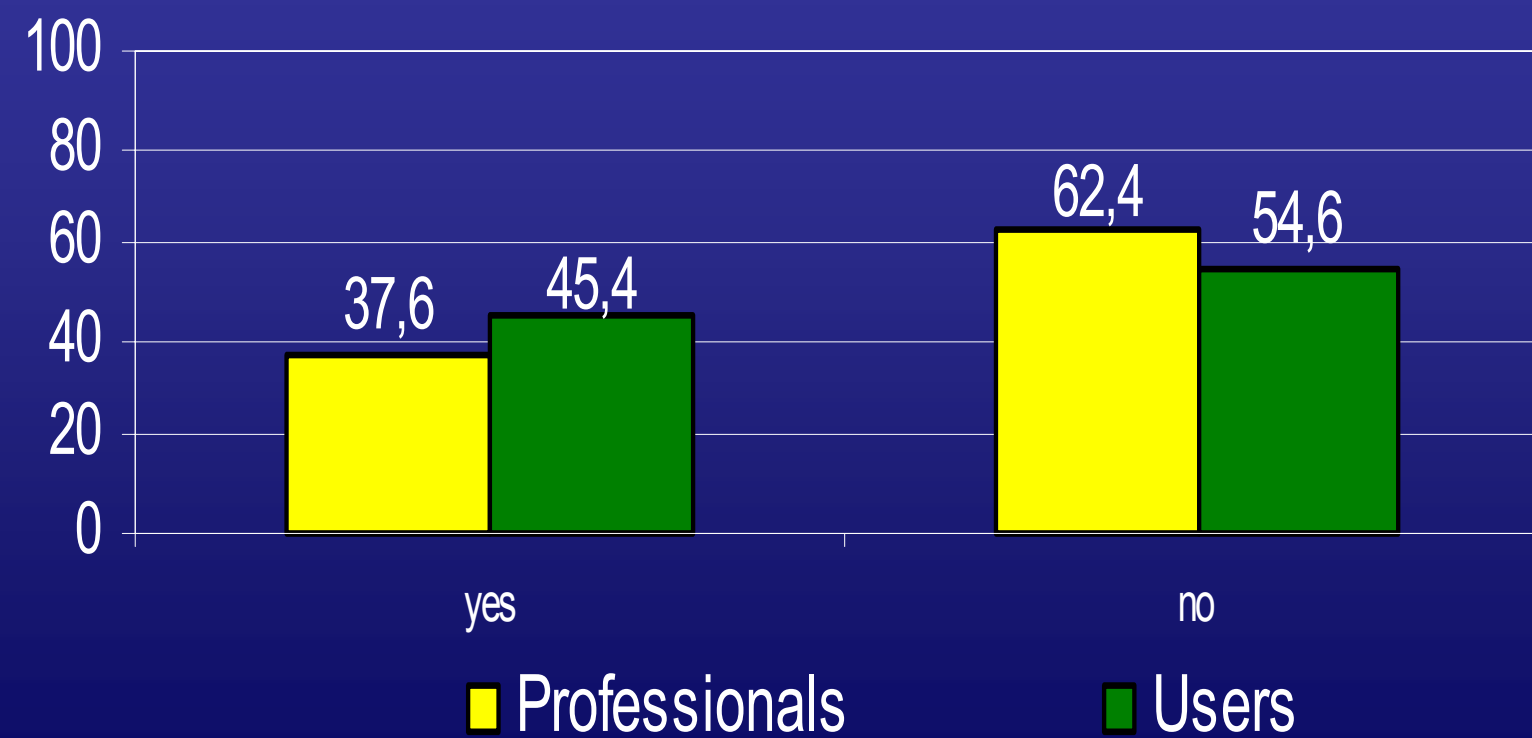


Perception of vaccine benefit (1)

Overcoming drug-abuse (%)



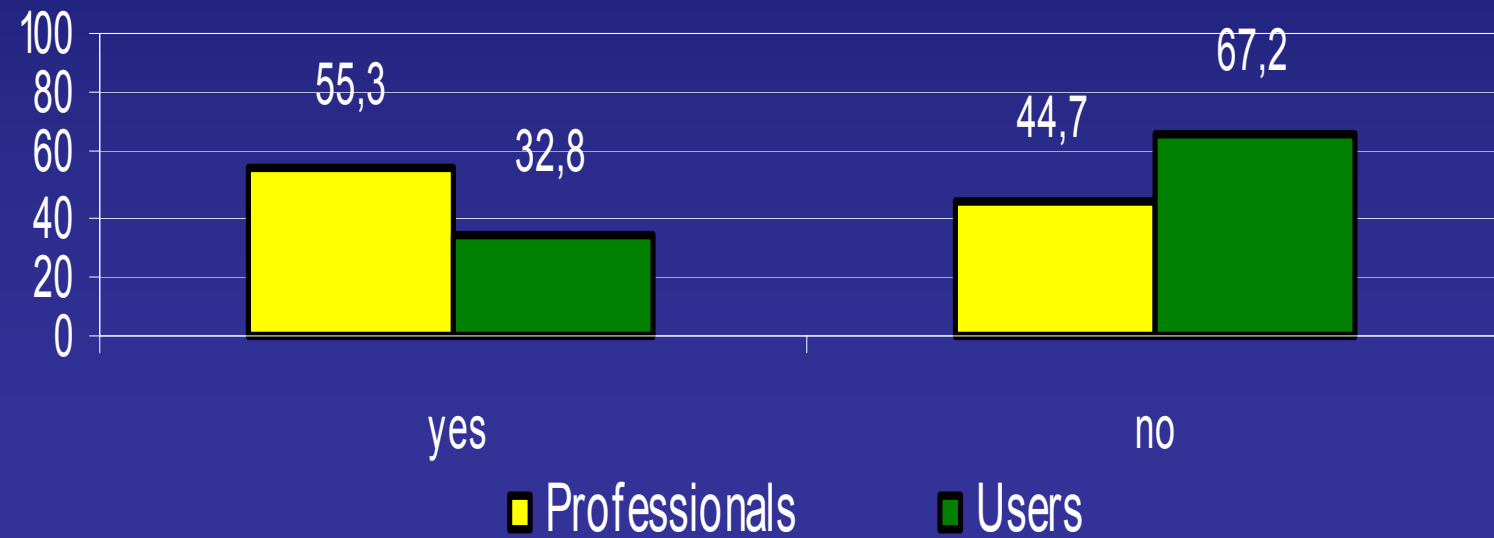
Reducing craving (%)



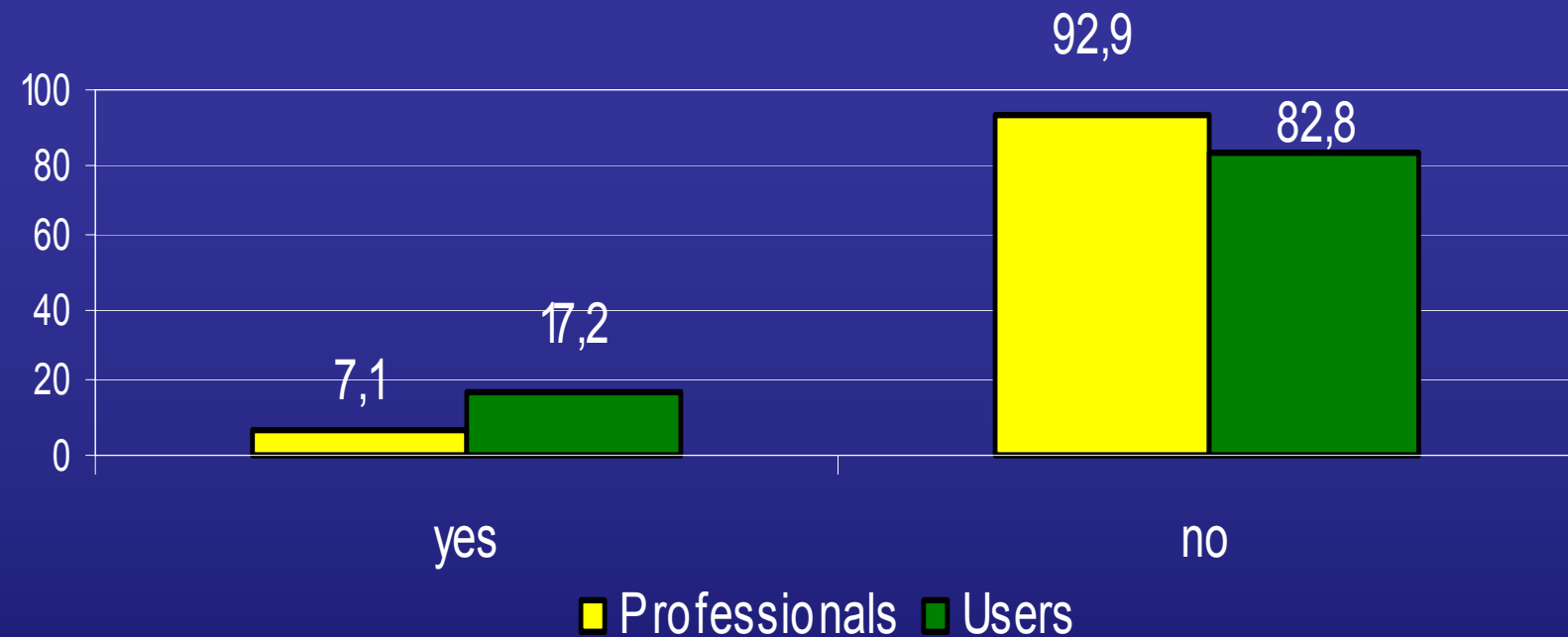


Perception of vaccine benefit (2)

Preventing relapse (%)



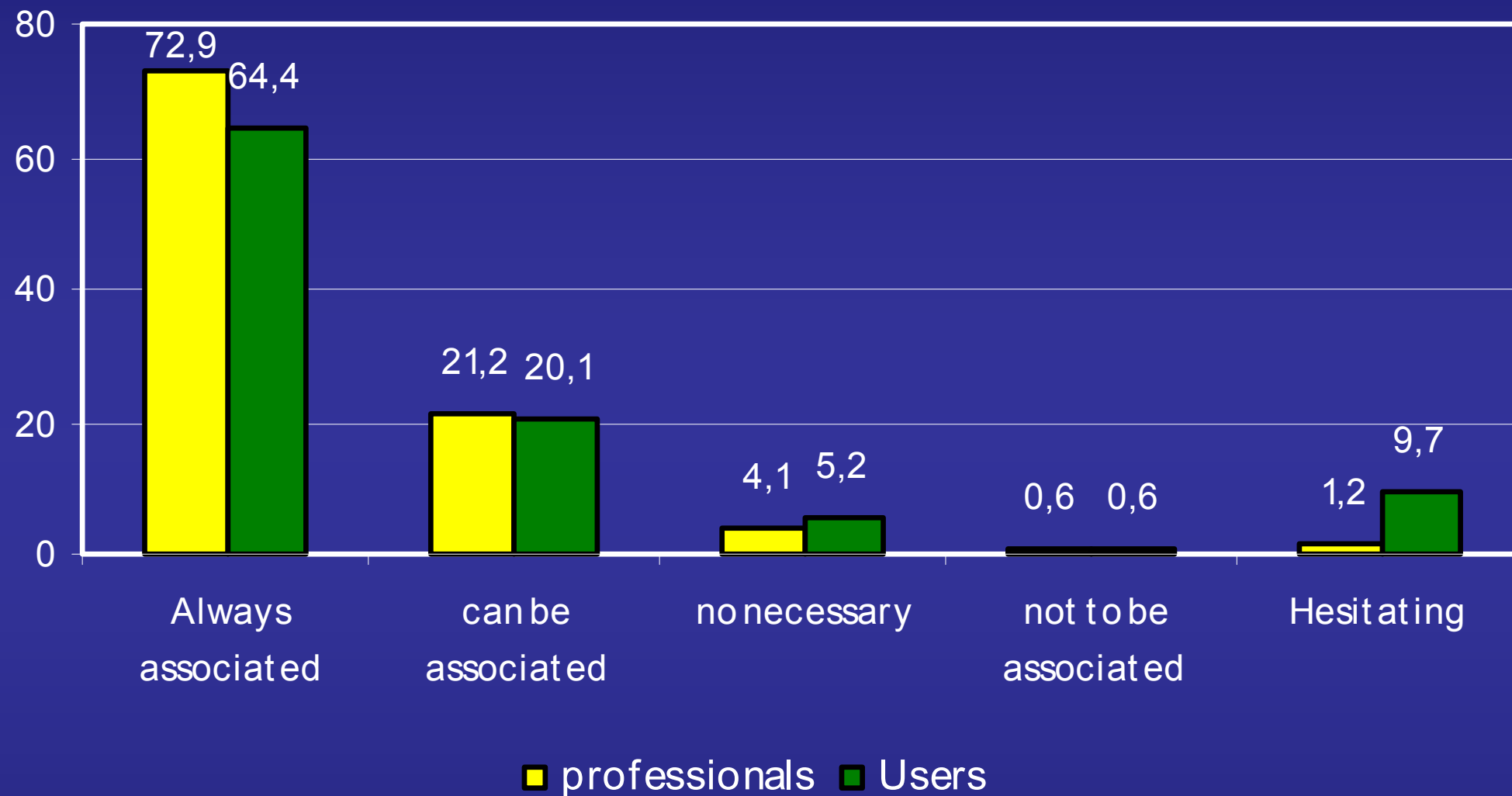
Preventing overdose (%)



The question included the possibility to provide more replies on the vaccine utility. 3,5% of professionals and 12,6% of users replied "I don't know".



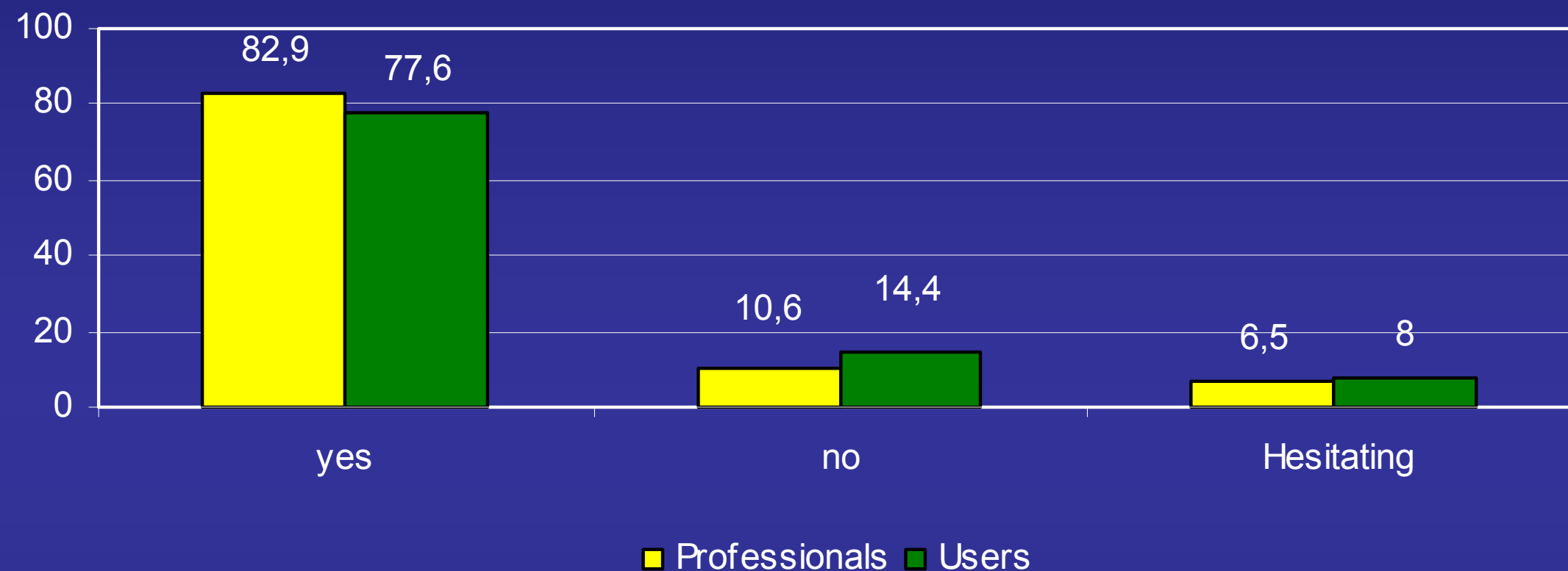
Association of the vaccine with psychological support (%)



Users and professionals confirm the necessity to associate the vaccine with psychological support in order to make it effective.



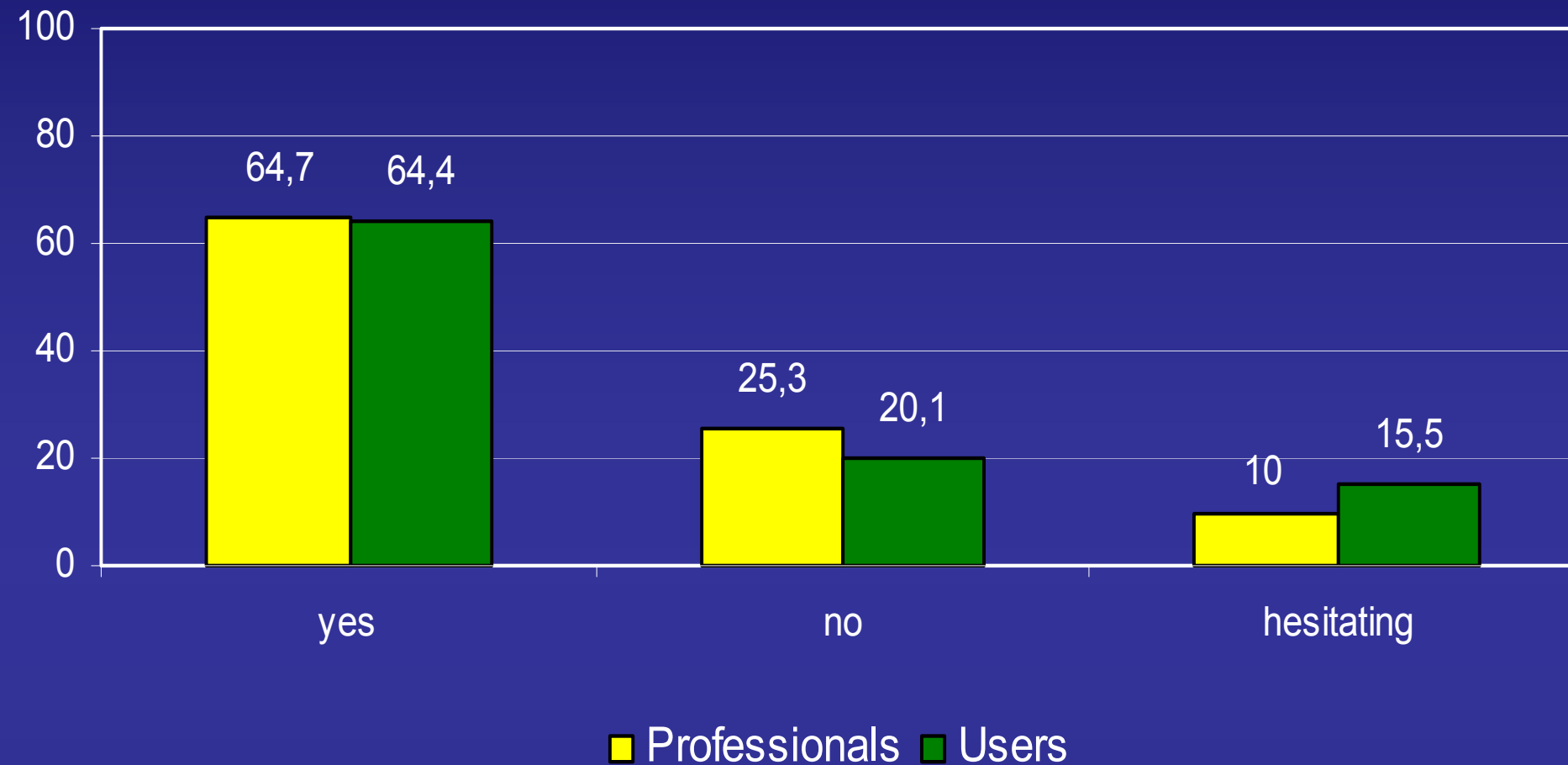
Necessity of complete anonymity (%)



According to users and professionals it is necessary to guarantee the anonymity during the trial.



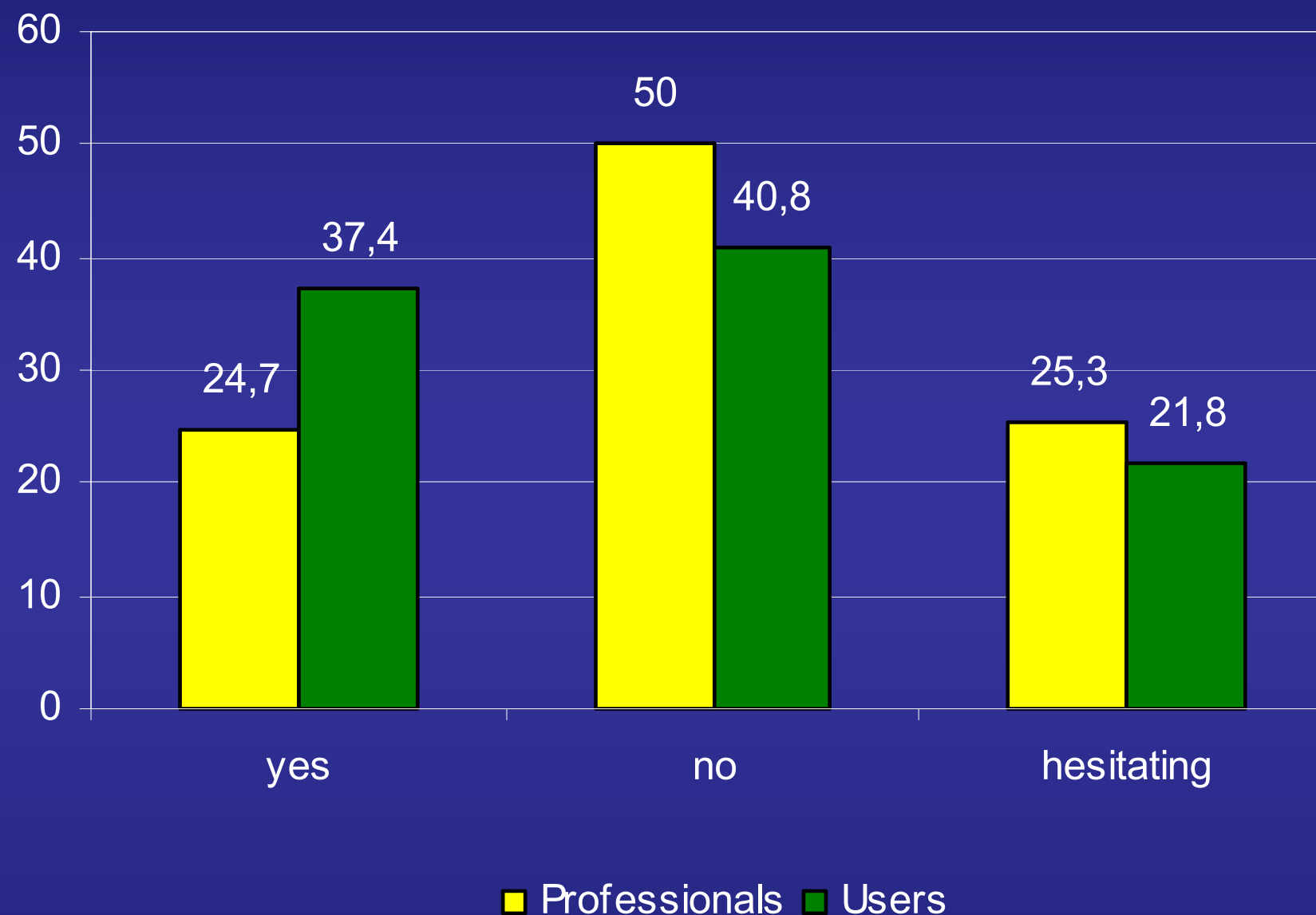
Risk of overcoming the vaccine barrier (%)



According to most users and professionals, many would try to overcome the barrier of the blocking effect of the vaccine by taking higher doses of cocaine.



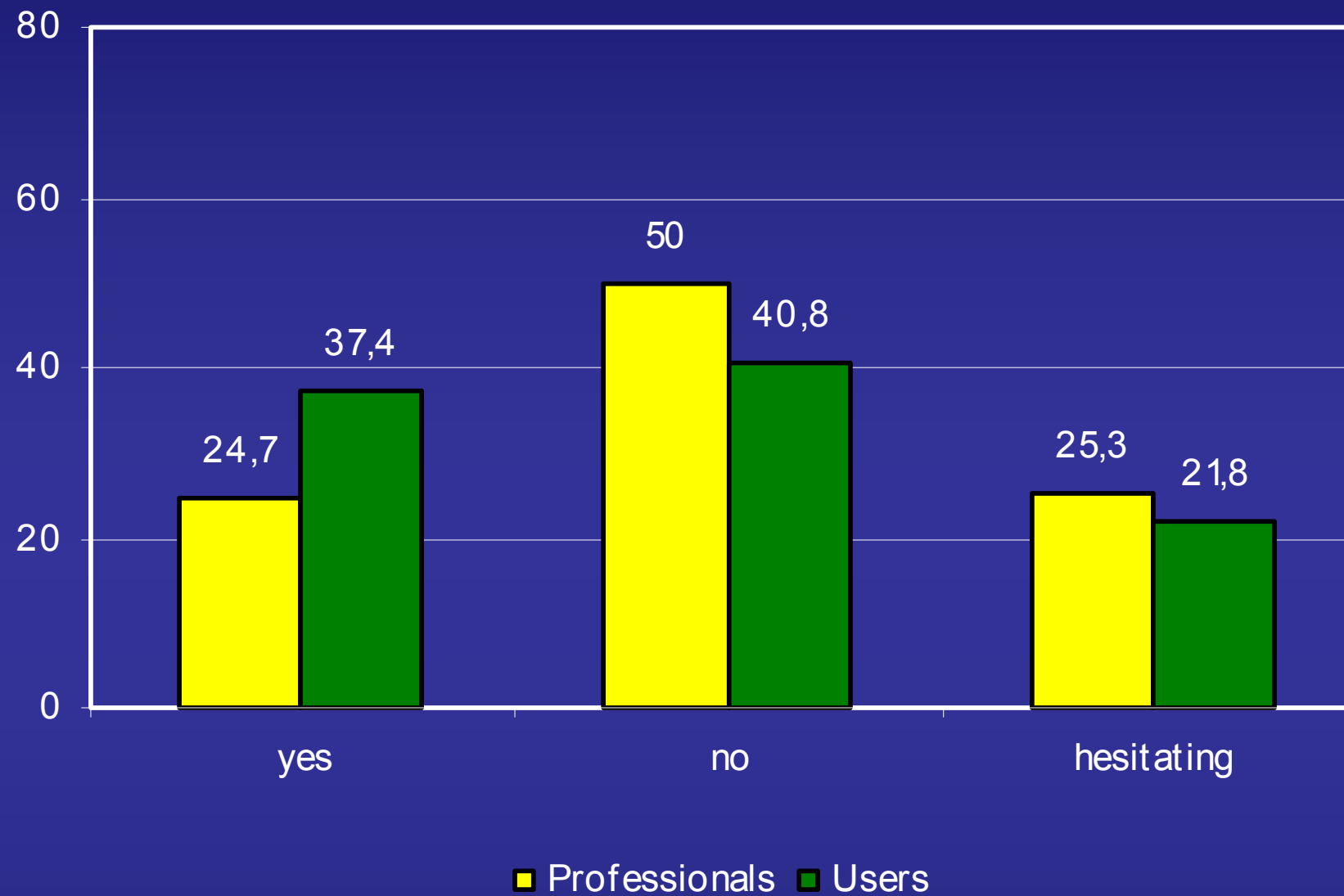
Perception of the efficacy of a possible preventive vaccine (%)



The majority of both the groups think that vaccinating people at risk who have never used cocaine is ineffective in order to avoid the use in the future. Yet, it must be pointed out that a high percentage is not sure and that users are in favour of the preventive vaccine (37,4%).



Controls too demanding? (%)

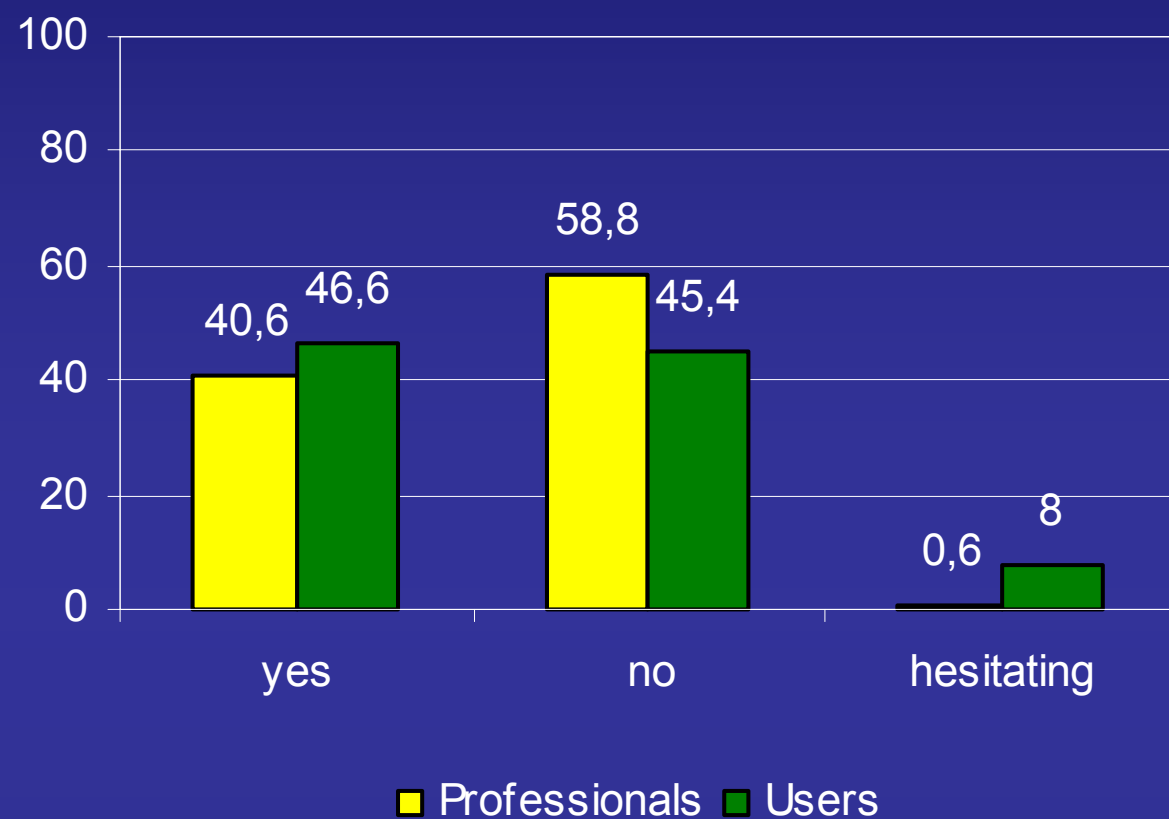


Both the groups think that being submitted to weekly periodical controls during the trial isn't too demanding for the patients.

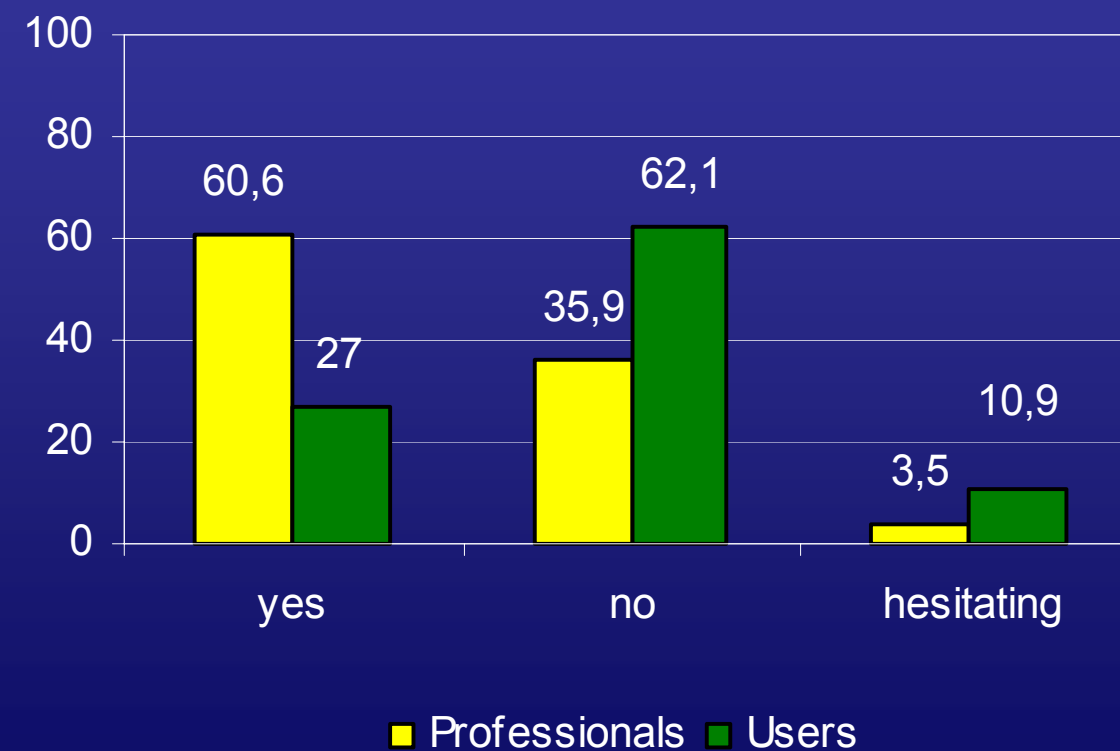


Risk of social discrimination? (%)

Possible risk of social discrimination (%)



Fear of discrimination as obstacle to participation (%)

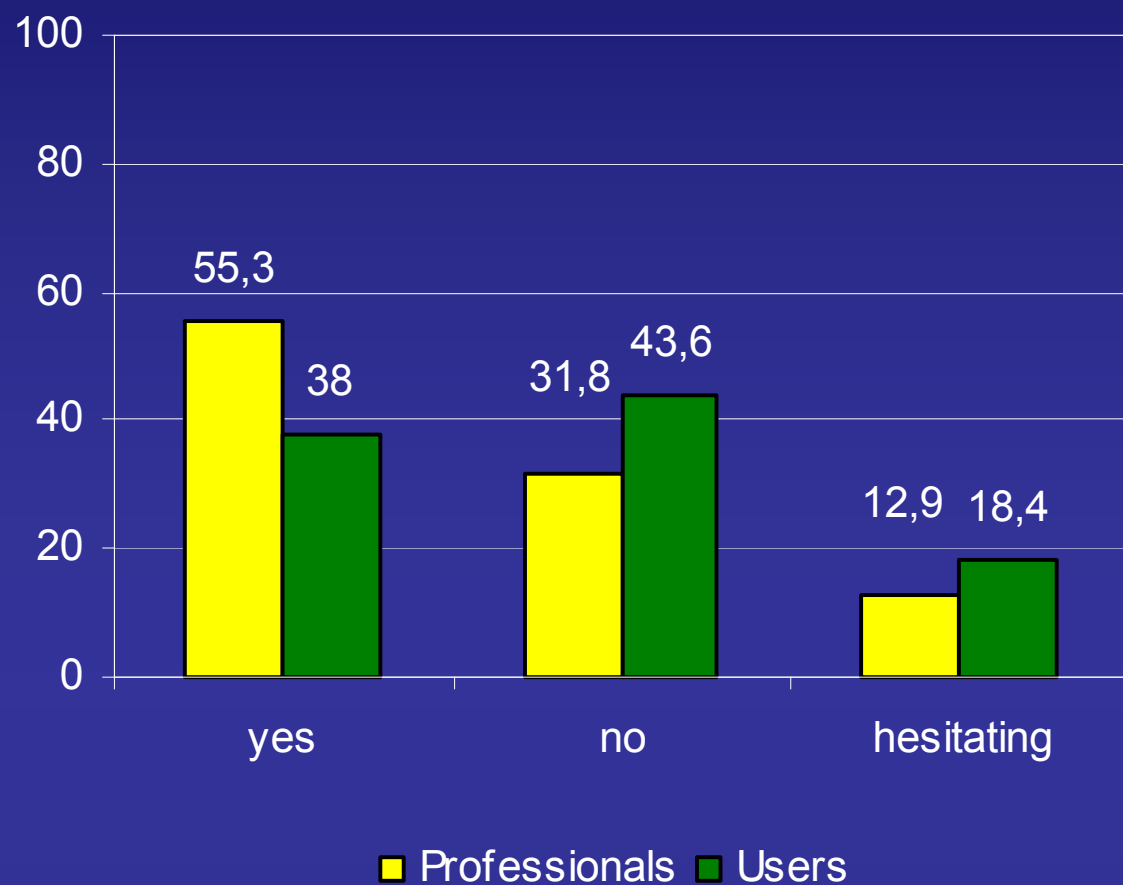




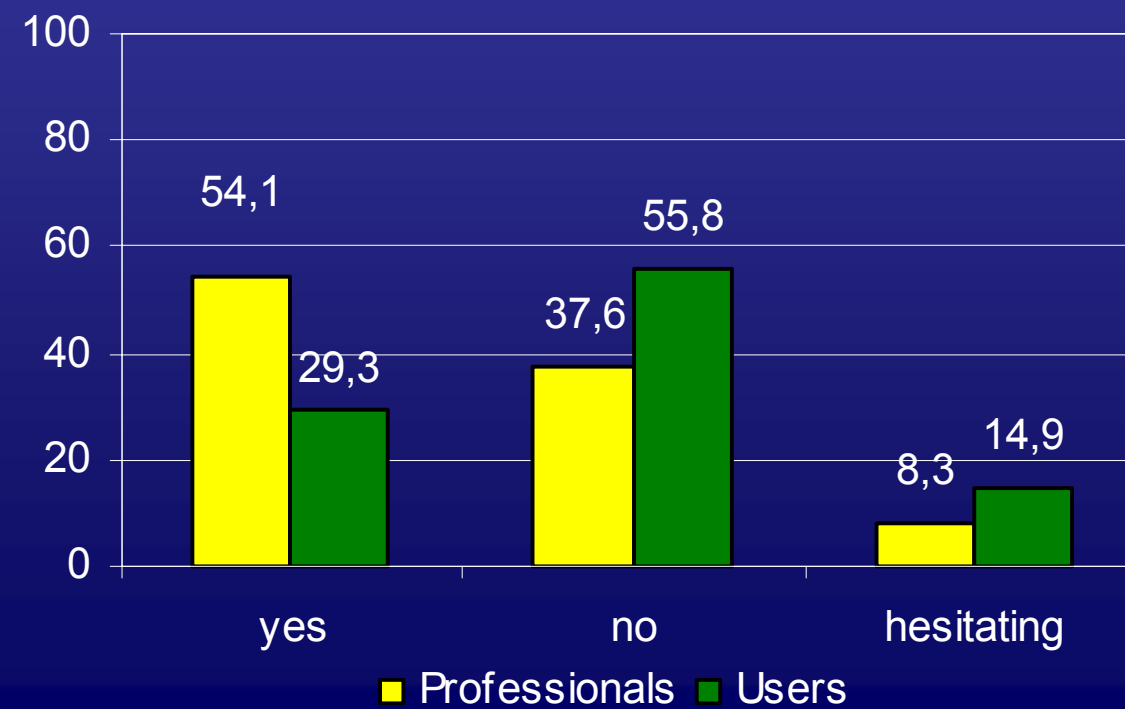
Anti-cocaine antibodies positivity as a problem? (%)



Anti-cocaine antibodies positivity as a problem (%)

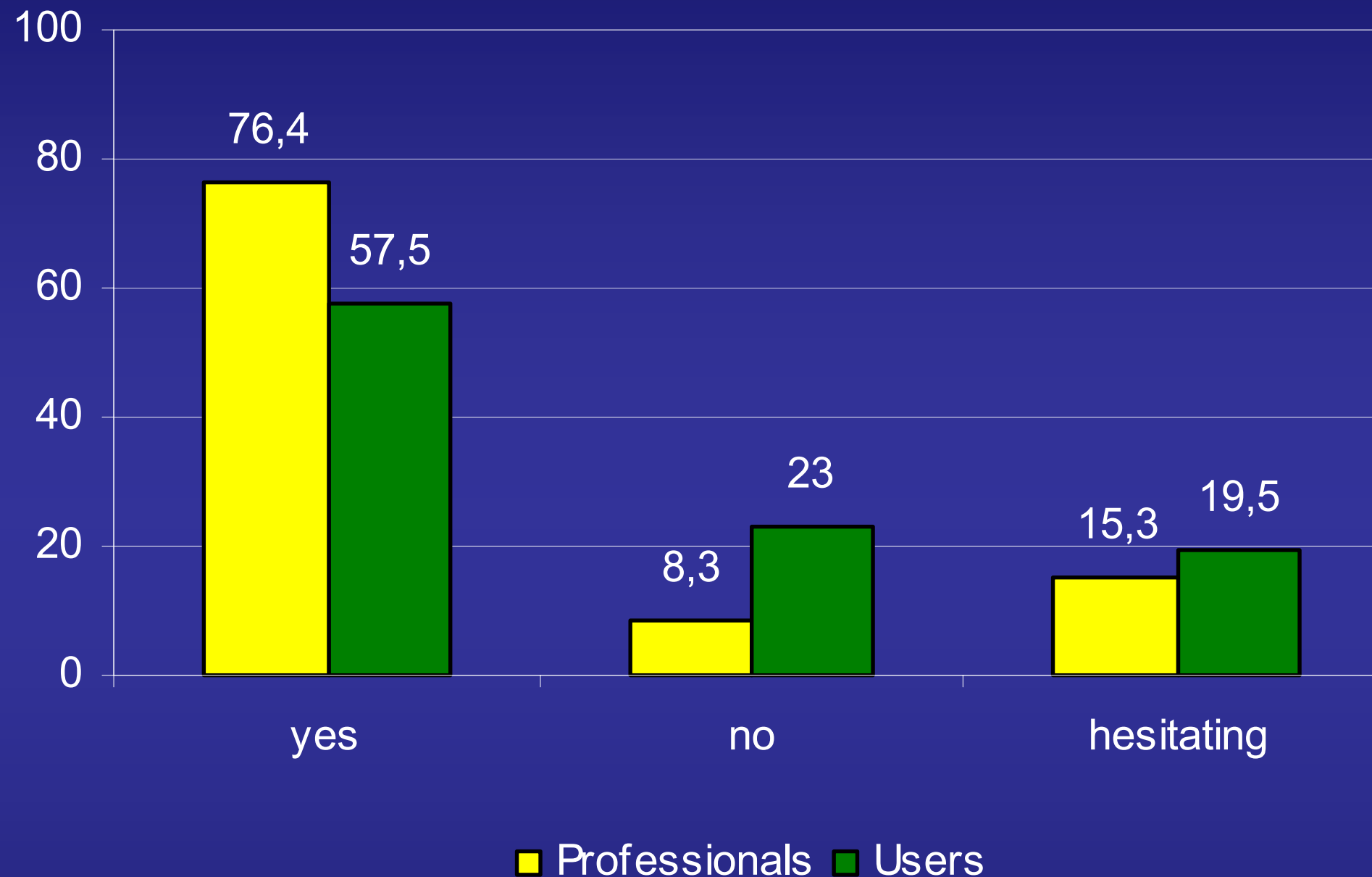


Anti-cocaine antibodies positivity as obstacle to participation (%)





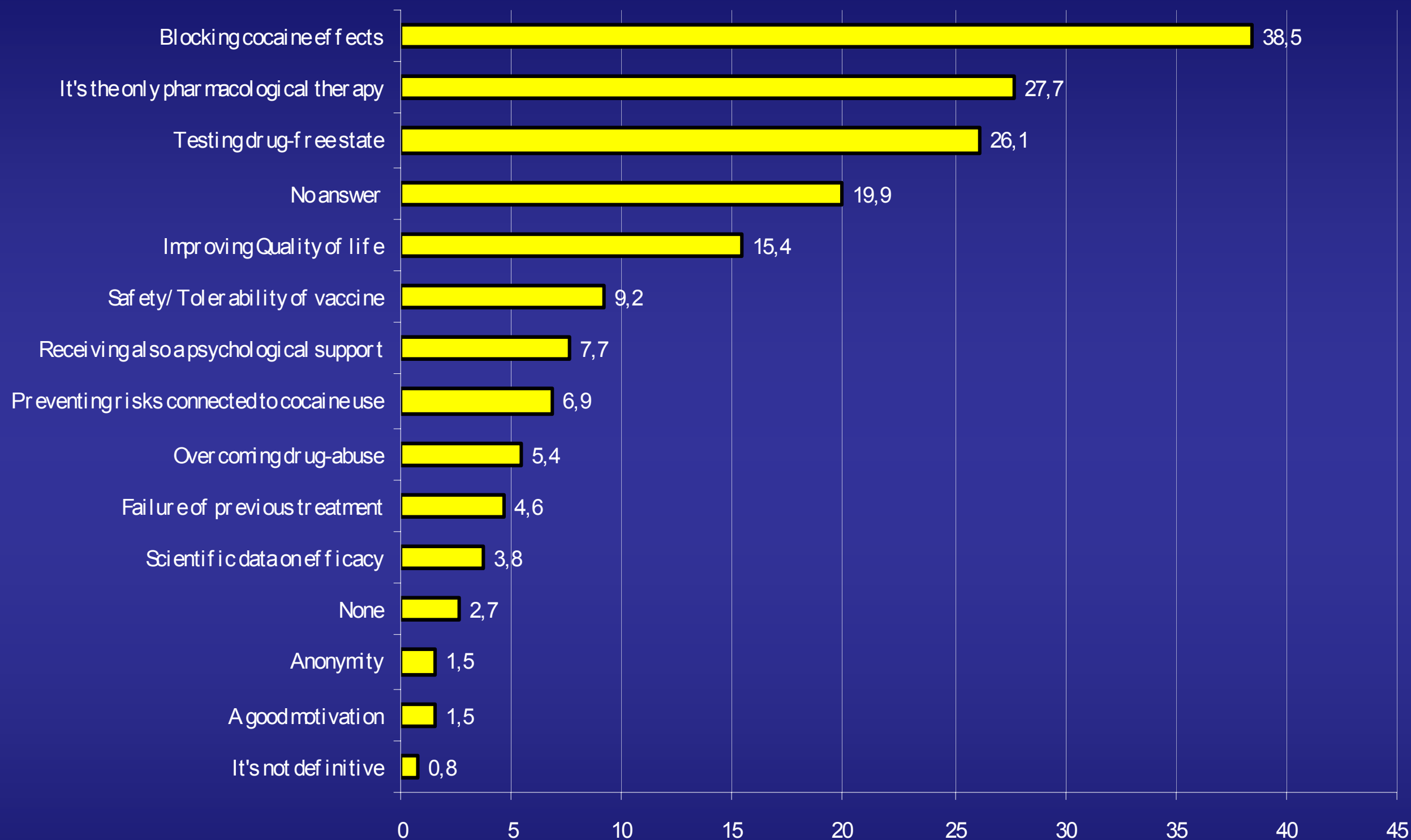
Acceptability of the trial (%)



76,4% of the professionals would suggest to a close person the participation in the cocaine vaccine trials. 57,5% of the users would be willing to be enrolled. To be pointed out the high percentage of hesitation amongst users (19,5%).



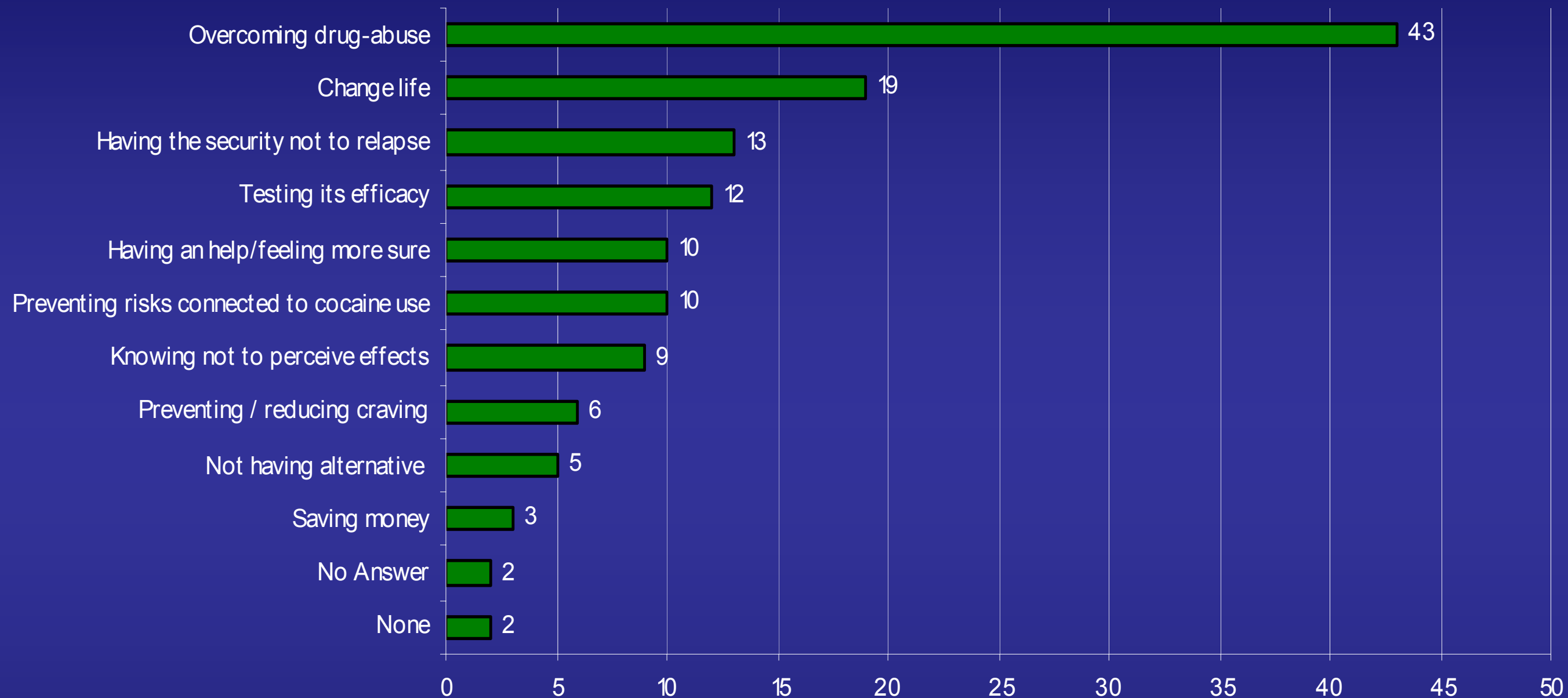
Reasons pro-trial by professionals (%)



Amongst professionals who have expressed a positive opinion towards trials, the three most frequent reasons are: the action of the vaccine which contrasts the effects of the cocaine, reinforcing the reason for not using it (38,5%); the fact that is the only therapy available for the treatment of cocaine dependence and that could be effective; at last the possibility of reaching a drug free state. Each professional can have expressed more favourable reasons.



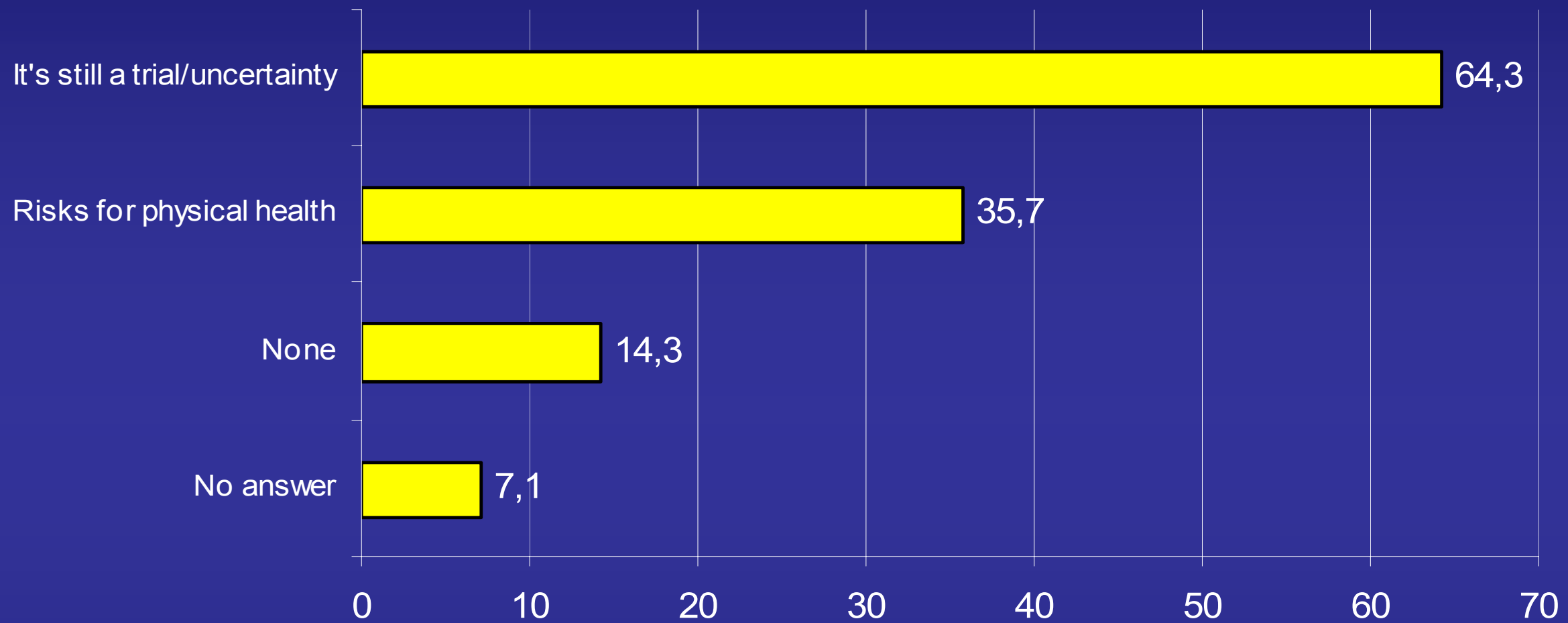
Reasons pro-trial by consumers (%)



Amongst users who have expressed a positive opinion towards the trials, the most frequent reason is to be able to overcome drug dependence (43%), followed by the hope to change life and recover the important relations (19%). Each user can have expressed more reasons pro-trial.



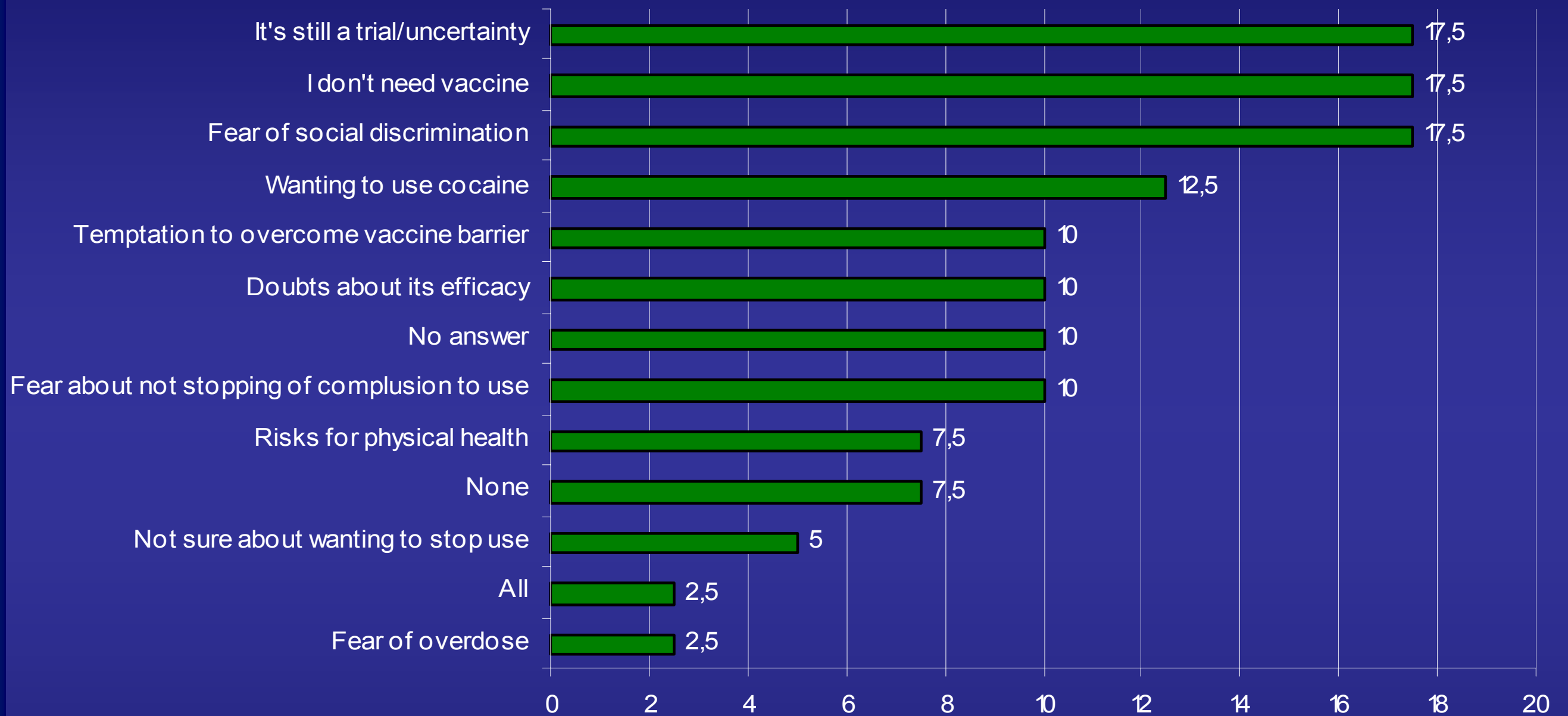
Doubts of the professionals on the participation to trial (%)



Amongst professionals who have expressed a negative opinion towards the trial the most frequent doubt is the uncertainty of the experimental phase (64,3%), followed by the fear for the health risks (35,7%).



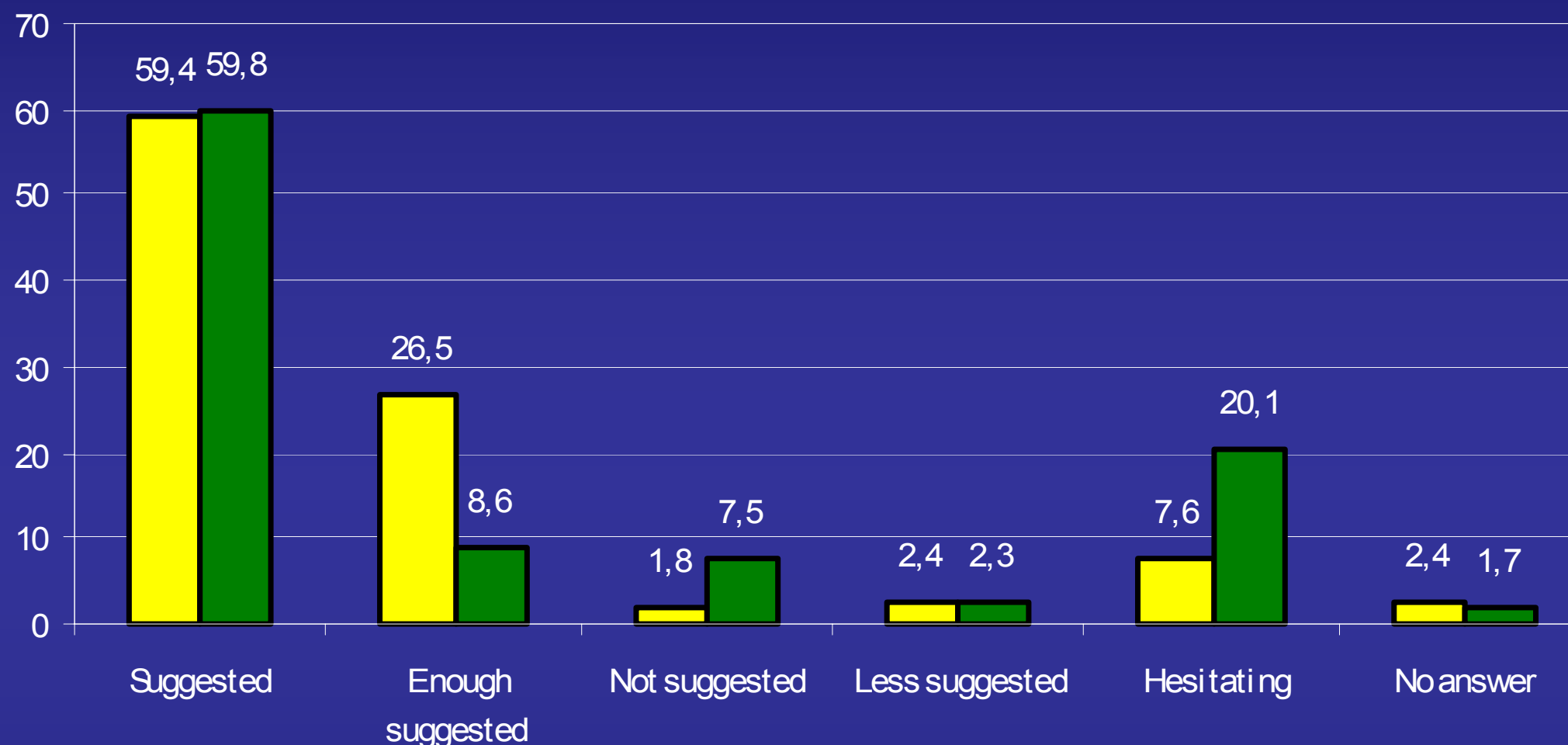
Doubts of the consumers on the participation to trial (%)



Amongst users who have expressed a negative opinion towards the trial, the most frequent doubts are (17,5%): the uncertainty associated with the trial phase; the perception of being able to manage without the vaccine and the fear of being discovered, discriminated and of having legal problems for the positivity at anti-cocaine antibodies.



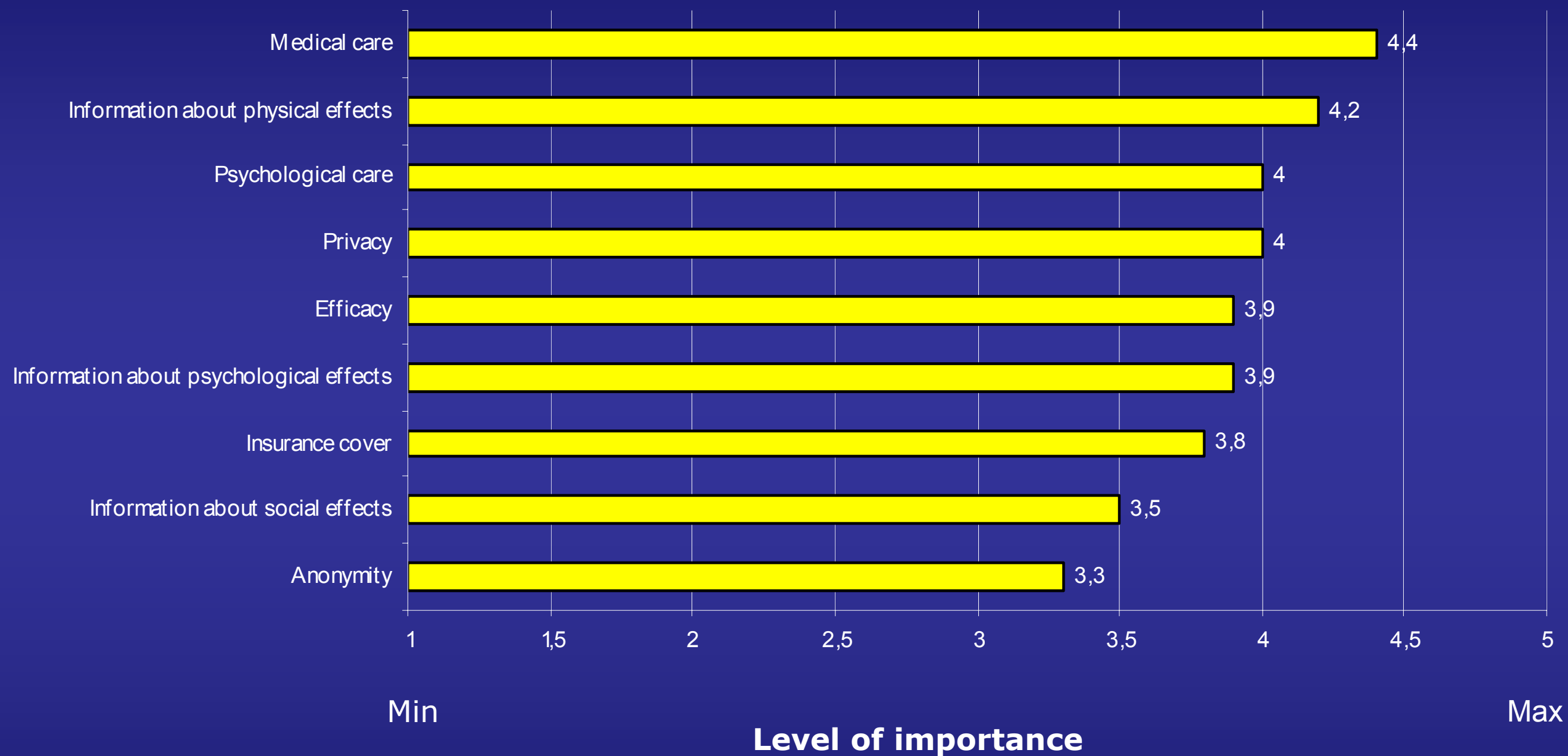
Suggestion of pharmacological therapies for drug abuse



The use of pharmacological therapies is suggested for the treatment of drug abuse both by most of professionals (59,4%) and users (59,8%).



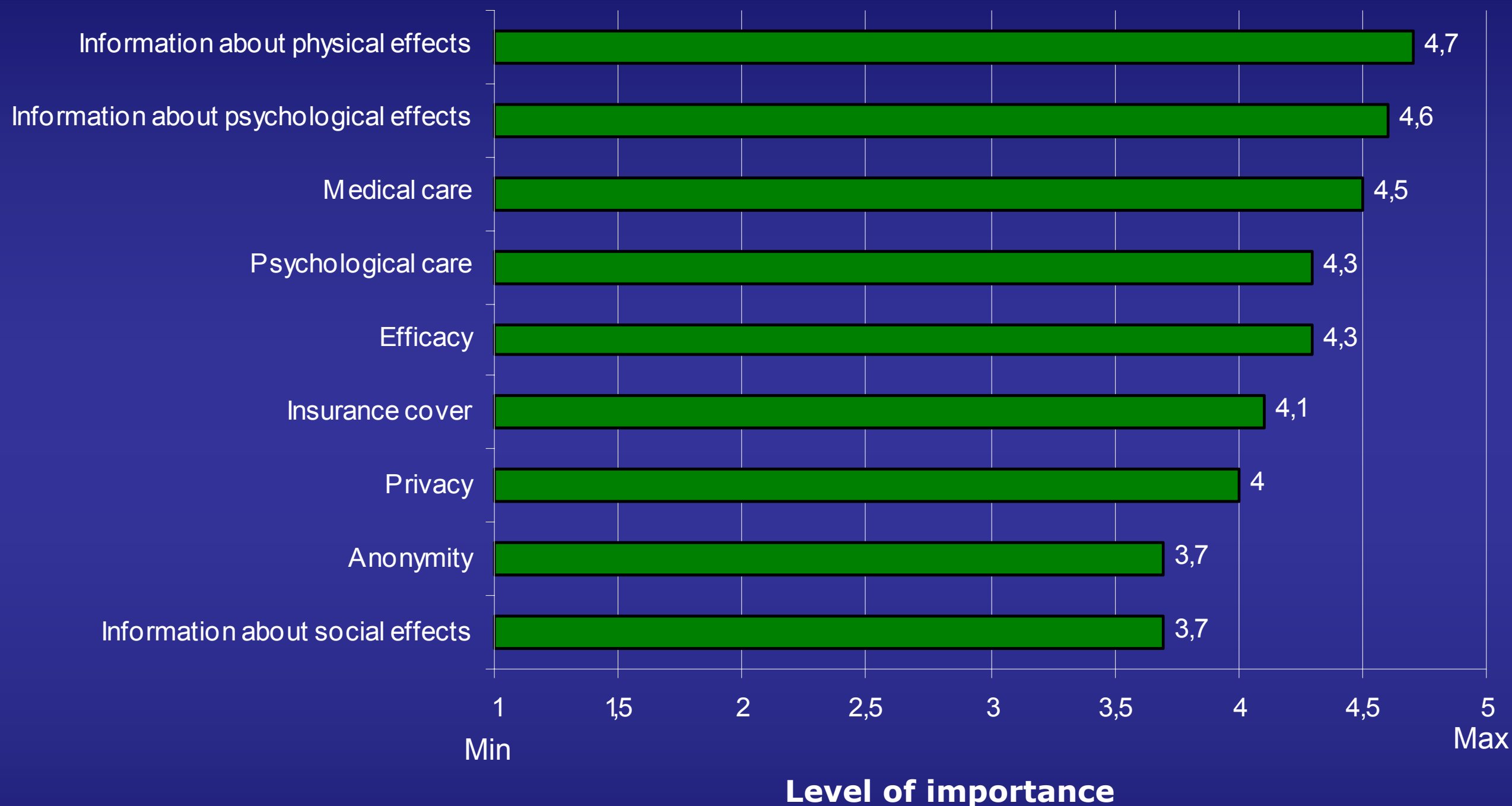
Warrenties necessary to take part in the trial by professionals (mean value)



Professionals retain necessary warrenties to take part in the trial giving patients medical and psychological care and clear information about physical health.



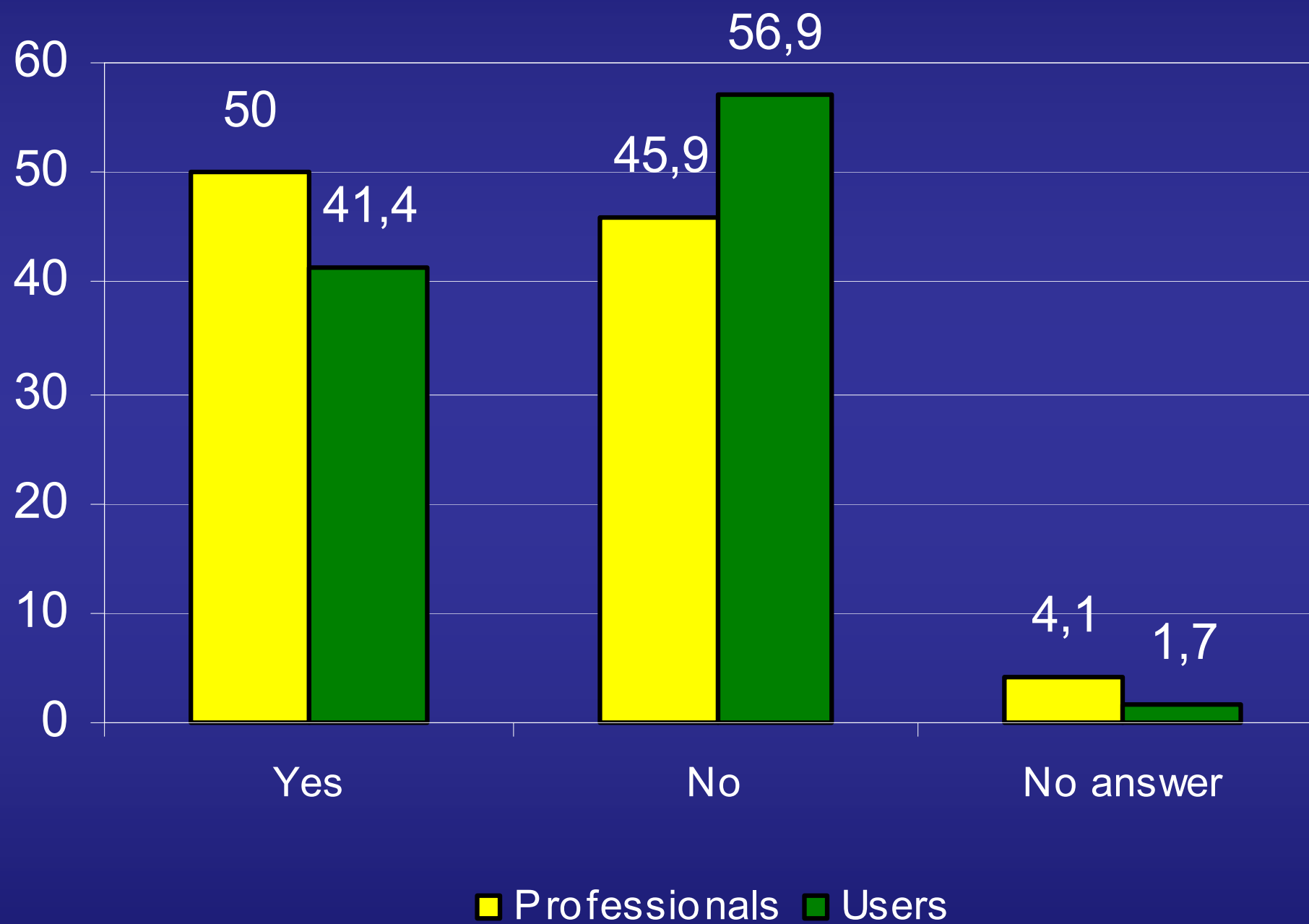
Warrenties necessary to take part in the trial by users (mean value)



Users retain necessary warrenties to take part in the trial receiving clear information about physical and psychological health and having a medical and psychological care.

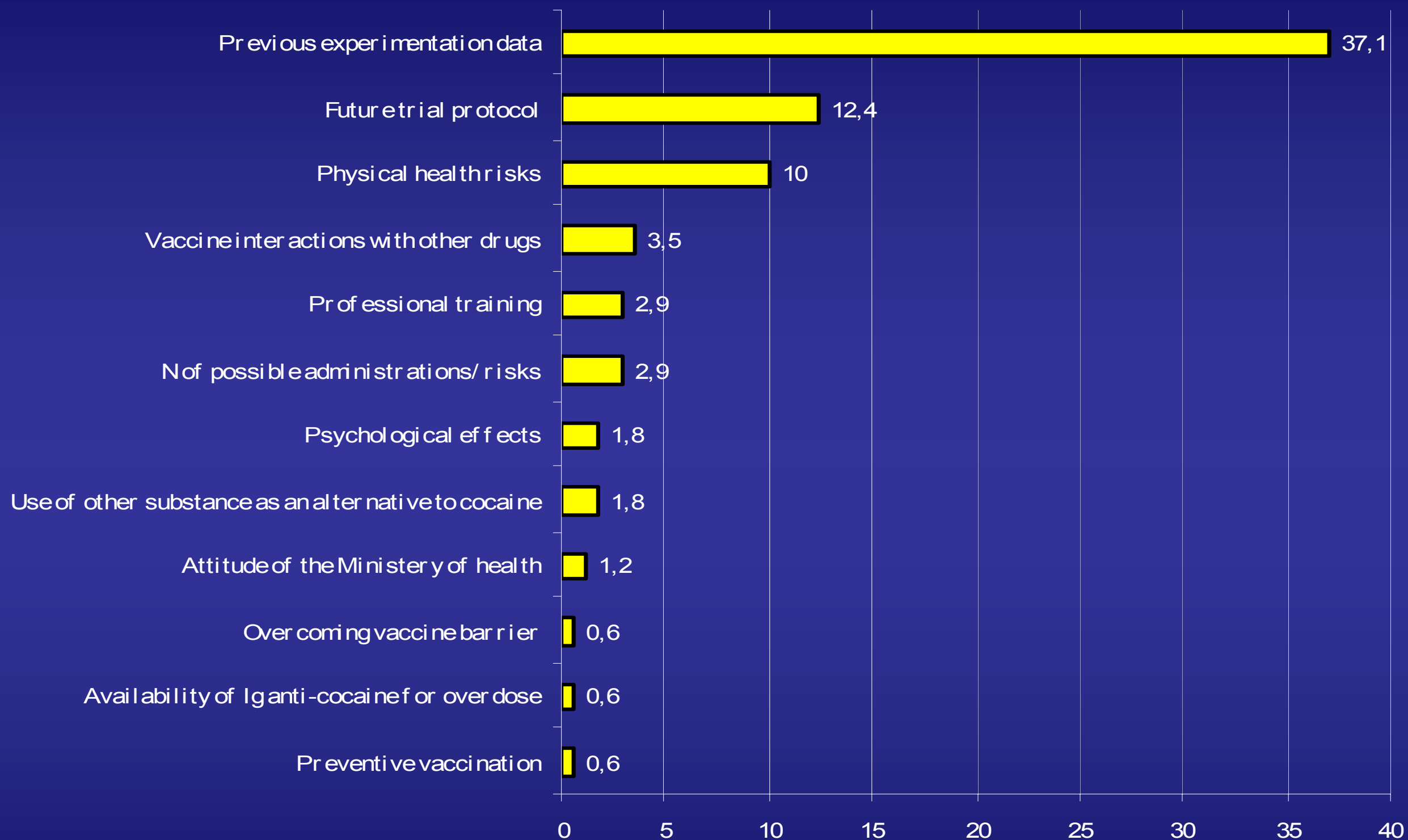


Necessity of other information (%)





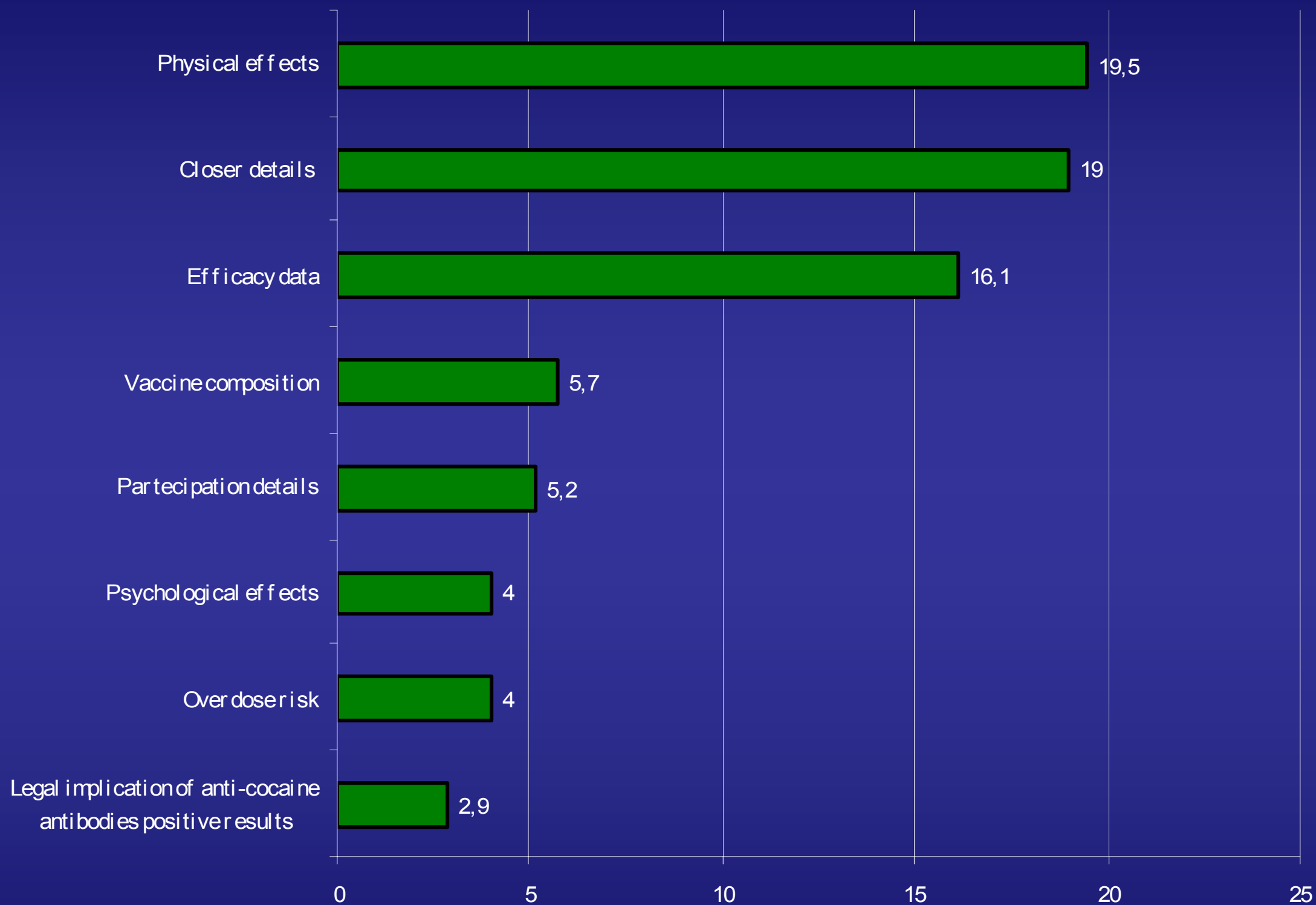
Professionals: necessary information



Amongst the information that the professionals consider missing and necessary, at first place there are the scientific data on previous trials, followed by more details on future trial protocol and on the health risks.



Consumers: necessary information



Users think it is necessary to receive more information on health risks, a general deepening, more data on previous trials and on direct experiences of the vaccine efficacy.



Conclusions (1)

1. The acceptability of the anti-cocaine vaccine trial is high both by professionals and cocaine users. The three most frequent reasons proffered by professionals are: the action of the vaccine which contrasts the effects of the cocaine, reinforcing the reason for not using it; the fact that it is the only therapy available for the treatment of cocaine dependence and that could be effective; at last the possibility of reaching a drug free state. Amongst users who have expressed a positive opinion towards the trial, the most frequent reasons are: being able to overcome drug dependence, followed by the hope to change life and recover important relationships. Both refer as main reason for not acceptability of the trial the uncertainty connected to the experimental phase of the vaccine;
2. The utility of the anti-cocaine vaccine is referred to by both the targets in reaching and maintaining a drug-free state (overcoming dependence) and preventing relapse;
3. According to most consumers and professionals the anti-cocaine vaccine, for the cocaine addiction treatment, can be useful and effective only if associated with psychological support which remain indispensable;



Conclusions (2)

4. The questionnaire has also permitted to identify doubts and fears about the trial, in order to give clearer and specific information in the future, making easier the process of decision making;
5. In detail, professionals and cocaine users think it is necessary to receive more data on previous experimentations (efficacy, safety, tolerability, number of subjects involved, risk of overcoming the vaccine barrier, interactions with other drugs, use of other substances in alternative of cocaine, etc) and on the future trial protocol (admission criteria, duration, place of trial, etc);
6. Fear of social discrimination by cocaine users is one of the main reason for the unacceptability of the trial (for example: going to a drug abuse service for the administration of the vaccine; legal implications for the positivity at anti-cocaine antibodies), thus is to be considered with great attention;
7. Finally, it is necessary to give a clear information about the anti-cocaine vaccine mechanism of action, in order to improve its efficacy and to reduce unreal expectations on "magic" solution of the dependence only thanks to having been vaccinated.



***THANKS
FOR YOUR ATTENTION***