

The pharmacist's role in health information, vaccination and health promotion

F. Petrelli¹, F. Tiffi¹, S. Scuri¹, C.T.T. Nguyen², I. Grappasonni¹

Key words: Vaccination, Vaccine hesitancy, Pharmacists, Law no. 119/2017, Public Health

Parole chiave: Vaccinazioni, Esitazione vaccinale, Farmacisti, Legge n. 119/2017, Sanità Pubblica

Abstract

On the subject of vaccination, owing to complex issues connected to vaccine refusal and vaccine hesitancy, the pharmacist is seen as a professional figure in the health sector who is qualified to improve social accountability with the aim of increasing the consent. In order to provide accurate information, Law no. 119/2007 has confirmed the central role of the pharmacist in the promotion of prophylactic vaccination, explicitly stating under art. 2 that the Ministry will be able to count on the collaboration of pharmacists as well as general practitioners and paediatricians. Pharmacists are pinpointed as new professional figures who could assist the national health service in its vaccine awareness and administration campaigns. Art. 5 comma 1 of Law no.119/2017 states that to meet vaccine goals, each Region will be able to allow vaccines to be booked through the Italian booking system (CUP) and administered free-of-charge in authorized pharmacies.

Introduction

A heated debate continues between supporters of vaccination and those who, for ethical and indeed even ideological reasons, support anti-vaccine movements. Though a number, albeit very small, of the population firmly refuse vaccination for themselves and/or their offspring, there is another larger group which approaches vaccination with variable degrees of hesitation (1, 2).

A pertinent aspect of the relationship between healthcare professionals and their customers can be observed in a physician's communication skills, as well as in his knowledge and skill in the field of vaccination. Indeed, it could be said

that healthcare workers' approach and communication strategies could probably be reviewed and improved. To this effect, the results of a study carried out in the USA (3) are telling. The study tested the efficacy of messages meant to reduce insecurity and increase acceptance of the MMR vaccine in the general population.

None of these messages actually increased parental willingness to vaccinate their offspring. Communication techniques promoting immunization were found to have been ineffective, and in some cases increased hesitancy and reduced the intent to vaccinate. Consequently, the need to investigate the reasons which have influenced opinions on immunization and better understand the

¹ School of Medicinal and Health Products Sciences, University of Camerino, Italy

² Department of Pharmaceutical Administration and Economics, Hanoi University of Pharmacy, Hanoi, Vietnam

complex social issues that surround vaccine hesitancy, a complex yet considerable phenomenon (4-7), has become evident.

Just as for any other medical intervention, vaccines carry health risks for individuals and the community and as is the case for all prescribed drugs, must be duly studied and assessed (8, 9). This issue has become even more intense after the adoption of Law no. 119/2017 (10, 11) which introduced another six mandatory vaccinations to the existing four required for school-entry.

The new regulations have created dissent in terms of strategic choices, a situation which has also been observed in the scientific world, but at the same provided various topics for debate. According to WHO data, immunization responses have been responsible for saving at least 10 million human lives from 2010 to 2015 (12, 13) and are an effective tool in the prevention of illness from a health, social and ethical perspective.

In this spirit, in order to minimize health risks in children, it is essential that the parents have an appropriate knowledge of medical terminology, especially when it comes to the correct use of medicines (14-17) and treatments (18-25). In Italy, as the start of the 2018/19 school year approached, the Government had to take steps to correct a situation that was partly due to its National Vaccine Register not having been completed in time. It did this by amending Decree no. 108/2018 (26), following the conversion of Decree no. 108/2018 (26), converted into Law no. 108/2018, which upheld mandatory vaccines for school entry as required by the so-called “Lorenzin” Law (from the name of the Minister of Health), but extended the deadline for delivering up-to-date vaccine records until March 2019 (27).

The provisions contained in Decree law no.73/2017 have nevertheless focused attention on areas of possible conflict between individual and community rights to health relating to mandatory vaccinations.

Petitioned by the Veneto Region on whether the rule stating that failure to present vaccine records would result in children being banned from attending nursery school should also be extended for the 2017/2018 school year, the Special Committee of the State Council answered in the affirmative, stressing the value of solidarity in the right to health, in accordance with art. 32 of the Italian Constitution and the precautionary principle (28).

By analysing the case-law of the Constitutional Court (more specifically: sentence no. 307 of 1990, no. 258 of 1994, no. 118 of 1996), the Special Committee of the State Council maintains that, contrary to the view held by supporters of some reductionist interpretations of the right to health, the Constitution does not actually recognize the unconditional, absolute freedom to refuse treatment or be obliged to undergo any health treatment for the simple reason that choosing the wrong sort of treatment or making a personal decision to refuse treatment, especially when dealing with diffuse disease, can have negative consequences on the health of many, in particular those who are classed as weak or are already ill.

The law has also been criticized (29) for reintroducing ten compulsory vaccinations, prescribing fines for failure to comply with its provisions, and refusing nursery and primary school entry for unvaccinated children aged 0 to 6 without having provided services to provide

needed information. Law no. 119/2017 places particular emphasis on the fact that the right to choose medical treatment and the community’s right to health should co-exist. The need to guarantee accurate information on the risks and benefits of vaccination is fundamental, even when compulsory health treatments are involved, and helps put into perspective the perception of risk which can lead to an unjustified rejection of vaccination, above all for children.

It is clear that, beyond legal and political debates on the responsibility of the State and its Regions, immunization involves key issues such as legal assistance and the guardianship of minors, since modern techniques of procreation and parenting styles have gone beyond traditional familial models and opened up new vistas. And if the right to be heard can be accepted as an adequate solution for minors who are capable of forming their own views, the need to accurately establish a public body which can guarantee the rights of the minor are upheld and compensate or integrate the will of the parents in the case of younger children and infants cannot be ignored. After appropriate changes have been introduced, an existing body which might carry out this task is the Ombudsman for Childhood and Adolescence, introduced by Law no. 112/2011 and Regional laws (30).

In light of the above, it is essential to re-establish a relationship of trust between citizens and influential figures in healthcare; workers in this field shall have to offer credible information and work towards social empowerment to seek consent. To this end, it is fundamental to include the pharmacist as well: a professional figure who, in a given geographical area, is highly appreciated by the community and whose pharmacy is regarded as a point of reference for health issues.

The pharmacist and vaccination

In view of the fact that the pharmacist can and is expected to take an active role in preventing infectious diseases, in the context of vaccination, Law no. 119/2017 has accorded a central role to this professional figure, who is expected to cooperate with primary care paediatricians and general practitioners with the aim of giving appropriate advice to anyone who might be vaccine hesitant or intends to refuse vaccination.

The new decree has emphasized the participative, informative and personal phase healthcare workers take on when they deal with families who view the coercive nature of mandatory vaccination in a bad light. In the debate on vaccination, pharmacists are often indicated as new professional figures who could assist the National Health Service in its vaccine awareness and administration campaign. The President of SUNIFAR (Unified Trade Union of Rural Pharmacists) has said that *«In the context of prevention, providing information could be one of our responsibilities...»* (31). But even though a pharmacist, having sat specific exams, is well trained on the subject, the President feels training needs to be improved: *«the focus should be on informing and training, with CME (continual medical education) courses on the correct administration of vaccines and vaccine campaigns, as if we had 18 thousand transmitters throughout the country. Something that would probably make a real difference. At the moment, though, we aren't getting the same answers from our colleagues, because no-one has thought of involving pharmacists for this purpose. In short, we need to regain control of pharmacovigilance and prevention ...»*.

On the other hand, the President is not so sure about the likelihood of pharmacists administering the actual vaccinations. *«But I do not wish, in this way, to start competing with the medical doctors whose job it is to deal with this issue. I do, however, insist on the role of the pharmacist in vaccine storage, as we know this aspect is not always followed correctly, and in some situations the cold chain is not adequately maintained. Italian pharmacies have logistics and control systems which would allow vaccines to be stored properly...»* (31).

The pharmacist is still seen as representative, playing a key role in monitoring, controlling and preventing the spread of infectious and widespread diseases

through mandatory vaccination which is proposed or strongly recommended in Italy (32, 33). This role was reiterated in the Prime Ministerial Decree adopted on January 12, 2017 and published in Gazzetta Ufficiale (the

Togliere lo spazio: no.65

the Italian Government) no. 65, 18 March 2017 with the title: “New LEAs” (New standards of minimum healthcare provision). The new standards mention the need to provide appropriate information on compulsory vaccines, recommended vaccines for members of society who are at risk, and the observation and appraisal of any adverse reactions.

These practices had already been properly identified and included in the Legislative Decree no. 153, 3 October 2009, pursuant to (in accordance with) article 11 of Law no.69, 18 June 2009, which calls for pharmacies to participate in specific practices of pharmacovigilance services (in this particular case, the surveillance of adverse events following immunization) and the provision of frontline healthcare services. Pharmacies play an active role in the realization of health education programmes and disease prevention schemes, tailoring information to each individual structure and, where necessary, providing special training to all pharmacists involved.

As noted in comma 5, art. 1 of the above-mentioned Decree, it is the job of the National Health Service (NHS) to promote cooperation between private and state-owned pharmacies operating in agreement with the Italian NHS, GPs and paediatricians in all activities which are part of these “new services”. The pharmacist can and should promote the diffusion of scientific culture, substantiating the validity of the risk-benefit ratio for vaccination.

Law no.119/2017 has confirmed the positive role of the pharmacist in prophylactic vaccination, expressly setting out in art. 2 that, in order to provide information and educate people on the aims of the decree, the Ministry of Health shall be able to count

on the collaboration of local pharmacists and their pharmacies, as well as GPs and paediatricians. Furthermore, to meet vaccine goals, art. 5 comma 1 of Law 118/2009 states that each Region can allow people to book an appointment free of charge in authorized pharmacies which are open to the public through the Italian booking system, CUP.

In the field of prevention, the role of the pharmacist is more important than ever, even more so after the controversies which have tarnished vaccine campaigns following the recent adoption of the new norms, alongside an increase in vaccine refusal rates. The pharmacist could play a decisive role in providing information, aiming to change “dissent” to “informed consent”, educating people on the benefits associated with immunization, risks and common vaccine side-effects, making sure immunization schedules are met, promoting seasonal vaccination campaigns, monitoring and reporting adverse reactions.

It should also be noted that pharmacists are obliged to follow their Code of Ethics, a document which protects their dignity and the ethical values associated with their profession. The Code contains provisions which guarantee the health of individuals and the community and states that the pharmacist must play an active role in health education programmes and disease prevention campaigns aimed at the general population and at-risk groups at both national and regional level and must select the appropriate means of doing so.

In fact, The Code of Ethics establishes that *« in his capacity as health-worker, the pharmacist shall collaborate with the authorities and assist them in the attainment of their objectives»*, that is to say the goals that are set out in the National Vaccine Prevention Plan 2017/2019. Additionally: *«The pharmacist participates in awareness campaigns aimed at prevention and health education, promoted or organized by the competent authorities working together with*

the Italian National or Provincial Order of Pharmacists».

Article 8 of the Code establishes that: *«The pharmacist contributes to the protection of public health in compliance with pharmacovigilance»*, including adverse reactions which will be registered on a form provided by the Ministry of Health (34, 35). Again, art. 12 states that *«In their advisory role, pharmacists guarantee information that is clear, complete and correct, with special attention to the appropriate use of medicines, their contraindications, side-effects and their storage»*.

And finally, art. 13, comma 2 of the Code of Ethics states that: *«The pharmacist should maintain relationships with members of other health-related professions and should comply with the principle of respect when dealing with health-care workers, enabling cooperation also with a view to exchanging knowledge and must abstain from publicly criticizing their actions»*, even though, in the specific case of immunization, it is possible for a pharmacist to legitimately express opinions which are in disagreement with the doctor who is against treatment.

Finally, on the subject of vaccination policies, the position taken by the Italian Federation of Pharmacists (FEDERFARMA) must be mentioned. With regard to raising citizens' awareness in connection with the increase in vaccine hesitancy, it has declared that pharmacies can be employed as the Ministry of Health and Regions see fit in order to aid in national vaccine campaigns and vaccine distribution, as well as promoting vaccination and guaranteeing adequate information on correct lifestyle choices to prevent disease and reduce the spread of disease (34-36).

Conclusions

Parties involved in the issues connected with paediatric immunization programmes

are therefore the parents, doctors, pharmacists and minors. Since the adoption of Law no. 119/2007, vaccine coverage rates have actually increased in spite of criticism for the failure to implement a national vaccine register which would record data on vaccination schedules and include information on people who are: up to date or not; have natural immunity; who should not be vaccinated; and finally, doses and schedules.

We can only wait to see what the new Government will decide for the future. The longstanding lack of confidence in politics has fuelled prejudicial attitudes and made it easy to have misgivings about institutional decisions. It is essential to go against this trend: health workers can concentrate their efforts on those who are uncertain, providing them with scientific and legal tools which are often overlooked and/or underestimated.

Riassunto

Il ruolo del farmacista nell'informazione sanitaria, nella profilassi vaccinale e nella promozione della salute

In materia di vaccinazioni, viste le problematiche legate al rifiuto e all'esitazione vaccinale, il ruolo sanitario del farmacista rappresenta una figura professionale che potrebbe svolgere un'opera di responsabilizzazione sociale per la ricerca del consenso. Al fine di fornire un'adeguata informazione la legge n.119/2017 ha confermato il ruolo importante del farmacista riguardo la vaccinoprofilassi prevedendo espressamente all'art. 2 che il Ministero si avvarrà della collaborazione, oltretutto dei medici di medicina generale e dei pediatri di libera scelta, anche dei farmacisti delle farmacie territoriali. I farmacisti vengono indicati come le nuove figure che potrebbero aiutare il SSN nella campagna di sensibilizzazione e somministrazione dei vaccini. L'art. 5 comma 1 Legge n.119/2017, ha previsto che per agevolare gli adempimenti vaccinali le Regioni potranno prevedere che la prenotazione gratuita potrà avvenire presso le farmacie convenzionate aperte al pubblico attraverso il Centro Unificato di Prenotazione (CUP).

References

- Petrelli F, Contratti CM, Tanzi E, Grappasonni I. Vaccine hesitancy, a public health problem. *Ann Ig* 2018; **30**(2): 86-103. doi: 10.7416/ai.2018.2200.
- We are referring to vaccine hesitancy. Available on: www.salute.gov.it [Last accessed: 2019, Apr 23].
- Nyhan B, Reifler J, Richey S, Freed GL. Effective messages in vaccine promotion: a randomized trial. *Pediatrics* 2014; **133**(4): e835-42. doi: 10.1542/peds.2013-2365.
- Vaccine hesitancy in Italy, an overview of the situation in our country. Available on: www.vaccinarsi.org/notizie/2018/01/29/esitazione-vaccinale-italia-vaccine [Last accessed: 2019, Apr 23].
- Vaccines and vaccination, tools. Available on: <http://www.immunize.org/clinic/vaccine-recommendations.asp> **Errore. Riferimento a collegamento ipertestuale non valido.** [Last accessed: 2019, Apr 23].
- Biasio LR, Corsello G, Costantino C, et al. Communication about vaccination. A shared responsibility. *Hum Vaccin Immunother* 2016; **12**(11): 2984-7. doi: 10.1080/21645515.2016.1198456.
- Biasio LR, Carducci A, Fara GM, et al. Health Literacy, Emotionality, Scientific Evidence: Elements of an Effective Communication in Public Health. *Hum Vacc Immunother* 2018; **14**(6): 1515-6. doi: 1080/21645515.2018.1434382.
- Real risks connected to vaccination. Available on: <https://www.vaccinarsi.org/scienza-conoscenza/vantaggi-rischi-vaccinazioni/rischi/rischi-reali-connessi-alle-vaccinazioni> [Last accessed: 2019, Mar 25].
- Mantovani A. Immunità e Vaccini. Segrate, Milano: Mondadori, 2016, pag. 62.
- Law no. 119, 31 July 2017 Converted into law with amendments introduced by decree law no. 73 of 7 June 2017, containing extension of terms set by legal provisions (GU General Series no.182, 05-08-2017).
- Siracusa M, Grappasonni I, Petrelli F. The pharmaceutical care and the rejected constitutional reform: what might have been and what is. *Acta Biomed* 2017; **88**(3): 352-9. doi: 10.23750/abm.v%vi%i.6376
- World Health Organization (WHO). The power of vaccines: still not fully utilized. Available on: <https://www.who.int/publications/10-year-review/vaccines/en/> [Last accessed: 2019, Apr 23].
- Signorelli C, Odone A, Gozzini A, et al. The missed Constitutional Reform and its possible impact on the sustainability of the Italian National Health Service. *Acta Biomed* 2017; **88**(1): 91-4. doi: 10.23750/abm.v88i1.6408.
- Grappasonni I, Petrelli F, Klusonová H, Kracmarová L. Level of understanding of medical terms among Italian students. *CeskaSlov Farm* 2016; **65**(6): 216-20.
- Spacilova L, Klusonova H, Petrelli F, Signorelli C, Visnovsky P, Grappasonni I. Substance use and knowledge among Italian high school students. *Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub* 2009; **153**(2): 163-8.
- Grappasonni I, Scuri S, Tanzi E, Kracmarova L, Petrelli F. The economic crisis and lifestyle changes: a survey on frequency of use of medications and of preventive and specialistic medical care, in the Marche Region (Italy). *Acta Biomed* 2018; **89**(1): 87-92. doi: 10.23750/abm.v89i1.7068
- Cioffi P, Laudadio L, Nuzzo A, Belfiglio M, Petrelli F, Grappasonni I. Gemcitabine-induced posterior reversible encephalopathy syndrome: a case report. *J Oncol Pharm Pract* 2012; **18**(2): 299-302. doi: 10.1177/1078155211424628.
- Grappasonni I, Petrelli F, Scuri S, Mahdi SS, Sibilio F, Amenta F. Knowledge and Attitudes on Food Hygiene among Food Services Staff on Board Ships. *Ann Ig* 2018; **30**(2): 162-72. doi: 10.7416/ai.2018.2207.
- Scuri S, Tesaro M, Petrelli F, Peroni A, Kracmarova L, Grappasonni I. Implications of modified food choices and food-related lifestyles following the economic crisis in the Marche Region of Italy. *Ann Ig* 2018; **30**(2): 173-9. doi: 10.7416/ai.2018.2208.
- Grappasonni I, Marconi D, Mazzucchi F, Petrelli F, Scuri S, Amenta F. Survey on food hygiene knowledge on board ships. *Int Marit Health* 2013; **64**(3): 160-7.
- Siracusa M, Petrelli F. Trade of food supplement: food or drug supplement? *Recenti Prog Med* 2016; **107**(9): 465-71. doi: 10.1701/2354.25224.
- Grappasonni I, Paci P, Mazzucchi F, De Longis S, Amenta F. Awareness of health risks at the workplace and of risks of contracting communicable diseases including those related to food hygiene among seafarers. *Int Marit Health* 2012; **63**(1): 24-31.

23. Cioffi P, Marotta V, Fanizza C, et al. Effectiveness and response predictive factors of erlotinib in a non-small cell lung cancer unselected European population previously treated: a retrospective, observational, multicentric study. *J Oncol Pharm Pract* 2013; **19**(3): 246-53. doi: 10.1177/1078155212465994
24. Petrelli F, Grappasonni I, Kracmarová L, Cioffi P, Tayebati SK, Esposito L. Rare diseases in Italy: analysis of the costs and pharmacotherapy. *Ceska Slov Farm* 2013; **62**(4): 159-62.
25. Grappasonni I, Petrelli F, Amenta F. Deaths on board ships assisted by the Centro Internazionale Radio Medico in the last 25 years. *Travel Med Infect Dis* 2012; **10**(4): 186-91. doi: 10.1016/j.tmaid.2012.06.006.
26. Interministerial circular no. 20546, 6 July 2018. Operational instructions on vaccine policies for school year 2018-19. **Errore. Riferimento a collegamento ipertestuale non valido.** Available on: http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=3417 [Last accessed: 2019, Apr 23].
27. Law 21 September 2018, no. 108 Converted into law with amendments introduced by decree law no.91 of 25 July 2018, containing extension of terms set by legal provisions (GU General Series no. 220, 21-09-2018).
28. State Council, Meeting of the Special Commission dated 20 September 2017. Available on: <http://www.camera.it/temi/ap/2017/09/28/OCD177-3067.pdf> [Last accessed: 2019, Apr 23].
29. Constitutional Court, Sentence no. 5/2018 Ruling on the constitutional legitimacy, President Grossi - Author Cartabia Public hearing of 21/11/2017 Decision of 22/11/2017 Deposited 18/01/2018 and published in the GU General Series no 4, 24-01-2018. Available on: <https://www.cortecostituzionale.it/actionSchedaPro-nuncia.do?anno=2018&numero=5> [Last accessed: 2019, Apr 23].
30. Law 12 July 2011, no. 112. Establishment of the Ombudsman for Childhood and Adolescence. (GU General Series no.166 of 19-07-2011).
31. Pagliacci S. (Sunifar): Vaccini, Pagliacci (Sunifar): farmacia presidio per vigilanza e prevenzione. Available on: <http://www.farmacista33.it/vaccini-pagliacci-sunifar-farmacia-presidio-per-vigilanza-e-prevenzione/politica-e-sanita/news--40475.html> [Last accessed: 2019, Apr 23].
32. Siracusa M, Grappasonni I, Petrelli F. The criminal liability of the hospital pharmacist vs the liability of the hospital. *Recenti Prog Med* 2016; **107**(1): 19-24. doi: 10.1701/2132.23100.
33. Mignini F, Sabbatini M, Pascucci C, Petrelli F, Grappasonni I, Vanacore N. Pharmacoepidemiological description of the population of the Marche Region (central Italy) treated with the antipsychotic drug olanzapine. *Ann Ist Super Sanita* 2013; **49**(1): 42-9. doi: 10.4415/ANN_13_01_08.
34. Petrelli F, Grappasonni I, Peroni A, Kracmarova L, Scuri S. Survey about the potential effects of economic downturn on alcohol consumption, smoking and quality of life in a sample of Central Italy population. *Acta Biomed* 2018; **89**(1): 93-8. doi: 10.23750/abm.v89i1.7059.
35. Kracmarová L, Klusonová H, Petrelli F, Grappasonni I. Tobacco, alcohol and illegal substances: experiences and attitudes among Italian university students. *Rev Assoc Med Bras* (1992) 2011; **57**(5): 523-8.
36. Scuri S, Petrelli F, Tesauo M, Carrozzo F, Kracmarova L, Grappasonni I. Energy drink consumption: a survey in high school students and associated psychological effects. *J Prev Med Hyg* 2018; **59**(1): E75-E79. doi: 10.15167/2421-4248/jpmh2018.59.1.898.