



THE CASE OF THE ITALIAN PHARMACIES AND PARAPHARMACIES OF SERVICES FROM THE ITALIAN LAW 502/92 UP TO COVID AND THE SUPREME COURT OF CASSATION SENTENCE 2022: FROM "DISTRIBUTORS" TO REAL HEALTH FACILITIES FOR THE ELDERLY POPULATION

Michelina Barbieri¹, Andreina Maisto², Raimondo Coccozza³ and Luigi Di Lorenzo⁴

¹UOC Pharmacy A.O.San Pio Benevento

²Psychologist Orientacampue/ e-campus University Italy

^{3,4}UO Rehabilitation A.O.San Pio Benevento

ARTICLE INFO

Article History:

Received 13th April, 2022

Received in revised form 11th May, 2022

Accepted 8th June, 2022

Published online 28th July, 2022

Key words:

Ital pharmacy rules, pharmacy laws, italian parapharmacy, parafarmacie italiane

ABSTRACT

With the transformation of the SSN and following the legislative decrees 502/517 and 229/98 (Bindi reform) as well as with the subsequent regional regulations, the functional profile of the territorial pharmacies was that of the resale of pharmaceutical and non-pharmaceutical products and the pharmacist assumes the role of commercial entrepreneur. After this epochal turning point, the situation has changed even more positively as a result of law 69/209 and legislative decree 153/2000 which precisely define the functional and operational characteristics of the service pharmacies: phytotherapy, telecardiology, telespirometers, etc. The pharmacy of services is therefore an optimal response to the crisis of many suburban pharmacies that were suffering due to the reduction of the population. Conclusions: Pandemic has in any case accelerated that process of transformation of Pharmacies from commercial establishments to territorial health centers, demonstrating in the field the enormous value of well-organized pharmacies providing support and care services for many chronic patients and the elderly that the pharmacy, on the basis of qualified pathways, is no longer to be considered a marginal entity but a new capillary response to increasing services for the benefit of disadvantaged citizens (elderly de decentralized in particular) in which pharmacists can buffer the effects of the crisis by relaunching the their role as health workers

Copyright © 2022 *Michelina Barbieri et al.* This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

INTRODUCTION

With the transformation of the SSN and following the legislative decrees 502/517 and 229/98 (Bindi reform) as well as with the subsequent regional regulations, the functional profile of the territorial pharmacies was that of the resale of pharmaceutical and non-pharmaceutical products and the pharmacist assumes the role of commercial entrepreneur

(1). In the Bindi reform, on the other hand, the pharmacy begins to take on the role of a real territorial health unit, widespread (2). The pharmacist in turn is called upon to perform tasks that are more typical of a health care worker. In fact, the law provides that the pharmacy is no longer just a supplier of goods but also of services. (3)

After this epochal turning point, the situation has changed even more positively as a result of law 69/209 and legislative decree 153/2000 which precisely define the functional and operational characteristics of the service pharmacies: phytotherapy, telecardiology, telespirometers, etc. (1.3). The pharmacy de services is therefore an optimal response to the crisis of many suburban pharmacies that were suffering due to the reduction of the population. Things expand even more following

Legislative Decree 153/2010 and in particular with art. 7 which correlates the pharmacy as a service provider to the territorial therapeutic diagnostic paths envisaged for many chronic diseases. Pharmacies thus begin to intercept elderly patients and patients suffering from chronic disabling diseases, taken up and described slavishly by the dpcm 2017 (new LEA and chronic diseases) (3). The promotion of the service pharmacy fully becomes a territorial health center in the last five years and on the basis of certain paths it will no longer be a "shop" but a widespread and concrete response to growing and real health needs with enormous benefits for disadvantaged citizens, the elderly and those suffering from chronic diseases. For the health system in the last decade, the service pharmacy therefore becomes an alternative to reduce the growing inconvenience caused by the scarcity of many local services liberalization package launched by Minister Bersani. The Bersani decree (Law Decree 223/2006, definitively converted with Law no.248 of August 4, 2006), (4) Thus, with the first shock to the monopoly of drug distribution with the birth of parapharmacies, which took place with the Bersani decree passed in 2006, the green light is given to the sale of SOP and OTC drugs, in any point of sale where there is a pharmacist

*Corresponding author: **Michelina Barbieri**

UOC Pharmacy A.O.San Pio Benevento

The Pandemic and the new roles of pharmacies, pharmacists and parapharmacies.

In 2020, the Pandemic disrupts the world and with it the global health system. Among the many decrees, Article 20 of Legislative Decree 41 of 22 March 2021 also involves pharmacies and some professionals in the administration of vaccines and tampons. Pharmacists must be specifically trained and they are also responsible for acquiring the patient's informed consent. In addition, the minimum requirements necessary to adequately set up the premises for swabs and vaccinations will be established with a specific provision.

With the liberalization of tampons and the spread of tampons, pharmacies become and still are a place of reference for carrying out antigen tests for covid-19. As widely discussed, the first different interpretations arise on the possibility that tampons are made by qualified professionals (pharmacists also at parapharmacies). The cases of the Marche Region are well known and in particular the case of the Pharmacy of Alife (CE9 taken to the headlines for having undergone seizure of the activity and then, after a judicial appeal, having publicized a sentence in favor of release from seizure and pronounced to protect the professionalism of the Pharmacist owner of the pharmacy. National press organs reported the news of the victory at the beginning of 2022. In particular, the press release reported (citing the 2022 sentence of the SMCV Court) that the court had rightly excluded the crime of abusive exercise of the profession for the pharmacist graduate who performed swabs in parapharmacy (Covid antigen tests). Sentence then resumed by the Tar Marche for similar situations. The initial discussion was based on the alleged contrast with the law 178/2020 and the sentence was interpreted by many press organs as a relevant precedent juridical for many pharmacists (Supreme Court Judgment di Cassation VI Criminal Section 569 against the order of 21/01/2022 of the SMCV RG 13137/2022 Tribunal published on Facebook by the owner of the applicant pharmacy).

DISCUSSION

In the light of the first reading of the sentence, it simply appeared that "the pharmacist who makes rapid antigenic swabs in a parapharmacy does not commit an abusive exercise of the profession, a" crime "punishable by Article 348 of the Criminal Code. In fact, this is what is stated in a sentence of the Court of Cassation published on 25 May last (5) and resumed after a few days by an article by Norme & Tributi Plus, one of the collateral publications of the Sole 24 Ore. The news was then immediately picked up by various trade newspapers and it certainly has and will certainly cause discussion, because it touches on a topic - that of the dispensing of tests and swabs in parapharmacy - which in the Marche is already at the center of a long dispute. However, the interpretations were not univocal and in agreement, so much so that an online newspaper (6), commenting, asserts that "in reality, however, a careful examination of the sentence reveals that the case handled by the Supreme Court has very little connection with that of the Marche region and, therefore, the debate that will follow will have to be careful to avoid references that are not there. In summary: the matter dealt with by the Court of Cassation concerns the decision by which the Court of S. Maria Capua in Vetere had validated the seizure of antigenic tampons and accessory material to the owner of a parapharmacy that carried out rapid tests within its exercise. (6)

For the judges, the pharmacist had committed the crime of abusive exercise of the profession, and in support they had cited article 1, paragraphs 418 and 419 of law 178/2020, which authorizes pharmacies to provide rapid tests for the screening of covid-19. Ultimately, the sentence of the Supreme Court only seems to correct the Court and revoke the seizure: "The abusiveness of the exercise of the profession" write the judges "is related to activities that are considered to be the exclusive responsibility of those who have the relevant qualification" and in the in the case of antigenic tests "it is envisaged by the legislator that they can be carried out by health professionals or by other subjects deemed suitable by the Ministry of Health". Consequently, "it must be considered that the activity not only cannot be said to be precluded to pharmacists but is also specifically referable to them" (6). The provision dictated by law 178/2020 in paragraphs 418-419 of law 178/2020, continues the Court, "does not introduce a limitation inherent in the performance of the profession itself, but contemplates a discipline that has a dual purpose, that is, on the one hand ensure the best conditions of security and confidentiality from the point of view of the operational context and, on the other hand, guarantee certain economic balances, with regard to the disbursements requested from the audience of users ". (6). It is therefore clear, the newspaper concludes and it seems a shared interpretation (editor's note) that the sentence of the Court of Cassation does not open the door to the provision of rapid tests in parapharmacies, nor does it contest the 178/2020 system where it entrusts the screening service to local pharmacies. He only observes that the pharmacist who carries out rapid antigenics in the parapharmacy does not commit abusive exercise of the profession, because he is regularly registered in the register. This means, the judges continue, "that the actual violation attributable" to the owner does not concern the crime referred to in Article 348 of the Criminal Code, but is in any case "potentially relevant to other purposes and, if necessary, suitable for configuring profiles of responsibility connected to unintended consequences of the test performed ". On the other hand, the position of the Parapharmacy is different, which in defense of the owner Pharmacist underlines how the Supreme Court in Rome has definitively created a juridical precedent of the highest importance that will have developments for all pharmacists who will be able to appeal to this historic sentence (source: recurring press release of 21 June 2022).

CONCLUSIONS

That the sentence should be read within the perimeter of the story to which it refers is also confirmed by the rejection by the Supreme Court of the request made by the pharmacist to refer the question of legitimacy of 178/2020 to the Constitutional Court as they exclude the possibility of carrying out antigen tests in parapharmacies. despite the presence of pharmacists. Beyond the different positions and interpretations, the Pandemic has in any case accelerated that process of transformation of Pharmacies from commercial establishments to territorial health centers, demonstrating in the field the enormous value of well-organized pharmacies providing support and care services for many chronic patients and the elderly that the pharmacy, on the basis of qualified pathways, is no longer to be considered a marginal entity but a new capillary response to increasing services for the benefit of disadvantaged citizens (elderly de decentralized in particular) in which pharmacists can buffer the effects of the crisis by relaunching the their role as health workers as amply demonstrated during the second farces and these last months of

the Pandemic Covid 19 crisis. Pharmacies can ultimately improve the quality of "taking charge" paths in favor of the elderly population and the health system exploiting the pharmacy of services as an alternative for reduce the growing inconvenience caused by the elimination or scarcity of peripheral territorial services (1).

Bibliography

1. Altini M, Leaflet F, Prati E. Chapter 8, paragraph 8.10 Pharmaceutical assistance. In management in Health 2022 Maggioli Editore
2. Ter reform of the SSN: 229/99
3. Hospital Health. Ferrante M N V, 2021. Edition Rotari BN 2021. The Pharmaceutical Service.
4. FPress ON Line 10 June 2022 free retrieved on ine at
5. The legislation on parapharmacies and the liberalization of SOP and OTC drugs, Bersani decree (Law Decree 223/2006, <https://www.fpress.it/professione/test-rapidi-in-parafarmacia-quello-che-dice-really-the-sentence-of-the-cassation/>)
6. Supreme Court of Cassation Rome Criminal Section Sentence n. Section 569, 22434-22 of 22 May 2022. Source Facebook Recurring page (free retrieved on line on 21st June 2022 on Facebook)

How to cite this article:

Michelina Barbieri *et al* (2022) 'The Case of The Italian Pharmacies And Parapharmacies of Services From The Italian Law 502/92 Up To Covid And The Supreme Court of Cassation Sentence 2022: From "Distributors" To Real Health Facilities For The Elderly Population', *International Journal of Current Medical and Pharmaceutical Research*, 08(07), pp 343-345.
