9-15-2022

Pharmacists in Italy in **Grease or Grit?: International Case Studies of Occupational Licensing and Its Effects on Efficiency and Quality**

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Citation
Pagano, Eva, Mario Pagliero, Emanuele Pivetta, and Lorenzo Richiardi. 2022. "Pharmacists in Italy." In Grease or Grit?: International Case Studies of Occupational Licensing and Its Effects on Efficiency and Quality, Morris M. Kleiner and Maria Koumenta, eds. Kalamazoo, MI: W.E. Upjohn Institute for Employment Research, pp. 51-74.
https://doi.org/10.17848/9780880996877.Ch4

Grease or Grit?

International Case Studies of Occupational Licensing and Its Effects on Efficiency and Quality

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Editors

2022

W.E. Upjohn Institute for Employment Research
Kalamazoo, Michigan

Library of Congress Cataloging-in-Publication Data

Names: Kleiner, Morris M., editor. | W.E. Upjohn Institute for Employment Research.
Title: Grease or grit? : international case studies of occupational licensing and its effects on efficiency and quality / Morris M. Kleiner, Maria Koumenta, editor.
Description: Kalamazoo, Michigan : W.E. Upjohn Institute for Employment Research, 2022. | Includes bibliographical references and index. |
Summary: "The book provides a comprehensive approach to whether a dominant governmental institution in the labor market-occupational licensing-greases, which enhances, or on the other hand results in grit, which diminishes the efficient workings of labor and service markets in parts of Europe and the United States. The detailed case studies in the book indicate that an increase in the availability of service providers or enhanced competition does not have negative effects on the quality of the services provided, prices, or survey measures of consumer satisfaction" — Provided by publisher.
Identifiers: LCCN 2022026785 (print) | LCCN 2022026786 (ebook) | ISBN 9780880996860 (paperback) | ISBN 9780880996877 (ebook)
Subjects: LCSH: Occupations—Licenses—United States. | Occupations—Licenses—Europe. | Labor market—United States. | Labor market—Europe.
Classification: LCC HD3630.U6 G74 2022 (print) | LCC HD3630.U6 (ebook) | DDC 331.120973—dc23/eng/20220728
LC record available at https://lccn.loc.gov/2022026785
LC ebook record available at https://lccn.loc.gov/2022026786

W.E. Upjohn Institute for Employment Research
300 S. Westnedge Avenue
Kalamazoo, Michigan 49007-4686

Cover design by Carol A.S. Derks.
Index prepared by Diane Worden.
Printed in the United States of America.
Printed on recycled paper.

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Pharmacists in Italy

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In Italy, as well as in many other countries, the work of pharmacists and the production, trade, and distribution of drugs is heavily regulated—justifiably so, considering the dangers associated with the improper use of medicines. Most drugs must be distributed through an authorized pharmacy, the main exception being over-the-counter (OTC) drugs, which are subject to lighter regulation. Pharmacies must employ licensed pharmacists, who are subject to educational requirements. The number of pharmacies and their locations are also subject to strict regulation, and they are established through an administrative procedure that links the number of pharmacies in a given city to the size of the local population. The rules used to determine the number of pharmacies in each city are relatively stable, although significant changes occurred in 1991 and 2012, which provided for increases in pharmacies.

Since the price of most drugs sold in Italian pharmacies (with the exception of OTC drugs) is also regulated, the key factor affecting the quality of the service is product accessibility. Therefore, this chapter focuses on the impact of regulation on the availability of pharmacies and its potential effects on human health. We use health outcomes measures from hospital admission records that can capture the potential impact of access to medicines (and the other services provided in pharmacies) on the health of the population.

INSTITUTIONAL CONTEXT: THE EUROPEAN PHARMACY MARKET

The pharmacy market in Europe is characterized by significant government control on entry, scope of activities, and profit margins. After a series of reforms over the past two decades, the system began to change.

Vogler, Habimana, and Arts (2014) classify countries into two broad groups: regulated countries, such as Austria, Denmark, Finland, and Spain, and less-regulated countries, such as England, Ireland, the Netherlands, Norway, and Sweden.[1] In general, regulated countries apply demographic rules (e.g., number of potential consumers for each pharmacy) and geographic criteria (e.g., distance to existing pharmacies) to determine entry into the market. Moreover, they tend to impose restrictions on ownership of pharmacies. Less-regulated countries were subject to different types of liberalization.[2]

The authors find that after deregulation, the number of pharmacies increased and the number of inhabitants per pharmacy dropped. This phenomenon was particularly strong in Norway and Sweden. These new pharmacies tend to be established mainly in urban areas, with few new pharmacies in rural areas. There are indications of an increased workload for pharmacists in some deregulated countries. Moreover, they note that after liberalization, specific stakeholders, such as wholesalers, may gain market power and possibly limit competition (Norway), partially offsetting the increase in competition because of the larger number of pharmacies. Anell (2005) finds somewhat similar results in his study of the pharmacy market in Norway and Iceland—namely that the number of pharmacies increases (and prices tend to decrease), but also concentration seems to increase as a result of horizontal integration of formerly independent pharmacies.

Schaumans and Verboven (2008) study entry and conduct regulation of pharmacies and physicians in Belgium, where both professions have regulated fees and markups, and where there is a ban on most types of advertising. Moreover, there are significant restrictions to entry based on geography and size of the local population. The presence of these kinds of regulations is often justified to ensure a minimum availability of supply in less profitable regions without inducing excessive entry elsewhere. The authors evaluate this public interest motivation

and develop a model of entry by two types of professions: physicians and pharmacists. The results show that entry in one profession has a positive effect on the profitability of entry into the other profession, supporting the idea that these professions are strategic complements. Moreover, geographical entry restrictions substantially limit the number of firms. They conclude that the current regime of highly regulated markups and restricted entry seems to protect the private interests of existing pharmacies more than the public interests. They also suggest that it is possible to induce a large shift in rents to consumers without reducing geographic coverage by combining reductions in geographical and markup restrictions.

The Italian Pharmacy Market

Pharmacists are entitled to distribute prescription drugs to consumers. They are required to meet educational requirements and pass a licensing exam. OTC drugs can be distributed to consumers within pharmacies, supermarkets, and other shops.[3] In the latter two cases, a pharmacist must always be present during store hours.[4] There is little variability in the type of service provided by Italian pharmacies, since prices are fixed and the training and skills of pharmacists are strictly regulated. Hence, the most important aspect of quality is the accessibility of pharmacies to consumers. This is particularly relevant in smaller towns and villages, namely in rural areas, where older consumers (or those affected by chronic pathologies) might have substantial mobility problems.

There are few studies on the Italian market for pharmacies. Calzolari et al. (2013) investigate how pharmacies adjust prices based on the composition of their consumers. They empirically study the pricing strategies of Italian pharmacies in the market for diapers and some hygiene products, whose prices are not regulated. The empirical estimation strategy exploits the demographic rule that links the number of pharmacies to the population size in each city (this approach will be described in detail below). The results show that more competitive markets tend to have significantly lower prices. Mocetti (2016) provides evidence that the possibility of inheriting the ownership of a pharmacy may affect the career choices of pharmacists' children and intergenerational mobility.

The Pharmacy Market and Public Health

Many studies over the past 40 years have assessed potential health effects of pharmacist-provided direct patient care services. There is substantial evidence that pharmacist involvement in direct patient care can have beneficial effects on patient health outcomes (Chisholm-Burns et al. 2010).

Because community pharmacists are among the most accessible health care providers, the clinical services they provide can have a major impact on patient health outcomes. Their access to prescription refill information and frequent interactions with patients uniquely position them to help patients adhere to a medicine regimen. This is evidenced especially in the treatments of Type 2 diabetes (Nazar et al. 2015; Pousinho et al. 2016), cardiovascular diseases (Altowaijri, Phillips, and Fitzsimmons 2013; Koshman et al. 2008; Tsuyuki et al. 2016), and seasonal influenza (Gai and Feng 2017; Kirkdale et al. 2017). However, as evidenced by the review of Blalock et al. (2013) in the United States, the effectiveness of pharmacist-provided direct patient care services delivered in the community setting is more limited than in other settings, such as hospitals. Only 50 of the 134 outcomes (37.3 percent) examined in the 21 articles that Blalock and colleagues reviewed revealed between-group differences or changes over time that were consistent with beneficial intervention effects.

Besides positive impact on health outcomes, density of community pharmacies is also associated with an increase in drug supply (mainly OTC medicines), some of which may be abused. Cooper (2013) identifies OTC medicine abuse in many countries together with a range of other problems. The first is the direct harm caused by the pharmacological or psychological effects of drug abuse or misuse. Although there was variability across countries, five key groups emerged: codeine-based (especially compound analgesic) medicines, cough products (particularly dextromethorphan), sedative antihistamines, decongestants, and laxatives. The second is the physiological harm related to the adverse effects of a secondary active ingredient in a compound formulation, causing, for example, upper gastrointestinal bleeding. Both types of harm led to concerns about overdoses and excessive use of emergency services. Finally, the literature identified other negative effects, such as progression to abuse of other substances, economic costs, and effects on

personal and social life (Cooper 2013). To the best of our knowledge, the association between community pharmacy density and increased hospitalizations due to medicine abuse has not been systematically explored.

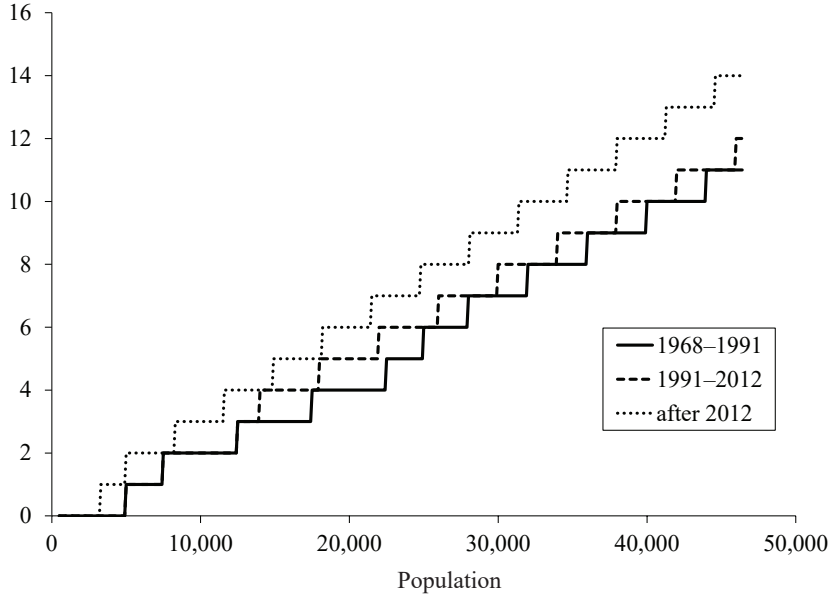
TYPE OF REGULATION

In Italy, most drugs must be distributed through an authorized pharmacy, the main exception being over the counter (OTC) drugs, which are subject to lighter regulation. The number of pharmacies and their location is subject to strict regulation determined through an administrative procedure. Each of the 20 Italian regional governments determines the number of pharmacies in each municipality and their exact location (minimum distance requirements between pharmacies also apply). The procedure is complex, and the process also involves city councils, local health services, and the professional associations of pharmacists. The size of the population living in each municipality is the main determinant of the number of pharmacies, and the function that maps the local population to the maximum number of pharmacies in each municipality is set by law. Since 1968, three such functions have been used.

The first, used between 1968 and 1991, required a maximum of one pharmacy every 5,000 inhabitants in municipalities with a population up to 25,000, and one pharmacy every 4,000 inhabitants in larger towns. In small municipalities, with populations below 25,000, if the remainder obtained dividing the population by 5,000 is larger than 2,500, it is possible to open an additional pharmacy. In larger towns, the remainder obtained after having assigned one pharmacy to every 4,000 inhabitants is ignored. This rather complex requirement generates the step function with somewhat irregular steps described in Figure 4.1.

The second function, in place between 1991 and 2012, required one pharmacy for every 5,000 inhabitants in municipalities up to 12,500, and one pharmacy for every 4,000 in larger towns. The remainder allows for the opening of a new pharmacy only if it is larger than 50 percent of the population requirement. Broadly speaking, this new function increases the number of pharmacies by decreasing the population threshold (12,500 instead of 25,000) and by not ignoring the remainders

Figure 4.1 Number of Pharmacies Allowed in Each Municipality According to the Demographic Rule

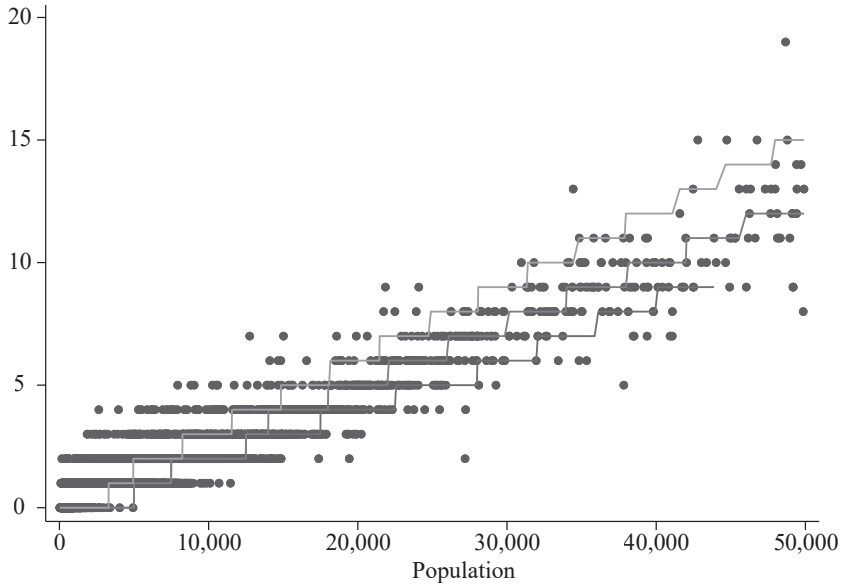


NOTE: The figure reports the number of pharmacies allowed to operate in each municipality as a function of the local population according to the demographic rule in place in three different periods.
SOURCE: Authors' calculations based on laws 475, 1968; 362, 1991; and 27, 2012.

in larger towns. Figure 4.1 compares this new step function with the one in place between 1968 and 1991.

The third function, introduced in 2012, provides for one pharmacy every 3,300 inhabitants. As before, the remainder allows for the opening of a new pharmacy only if it is larger than 50 percent of the population requirement. This change generates the third step function described in Figure 4.1. These new rules further increase the number of pharmacies. In principle, the demographic rules described in Figure 4.1 provide for a simple rule that links local population to number of pharmacies. However, a number of complications arise in the application of such rules, which make the link between number of pharmacies and population much more complex, as shown in Figure 4.2.

Figure 4.2 Number of Pharmacies and Population in Italian Municipalities



NOTE: The figure shows the number of pharmacies in each Italian municipality and the local population in 2015, with the three demographic rules used in the 1968–2016 period (see Figure 4.1).

SOURCE: Authors' calculations based on data from Istat and Italian Ministry of Health, and laws 475, 1968; 362, 1991; and 27, 2012.

The first issue relates to the municipalities with more pharmacies than the number set by the demographic rule. This may occur as a result of the status quo in 1968 or as a consequence of shrinking population in some municipalities. In absence of a clear indication of which pharmacy is supposed to close, and being generally profitable businesses, pharmacies in excess of the demographic rule are often allowed to operate. This allows for municipalities with more pharmacies than what the demographic rule would predict.

The second complication relates to small villages, which may not be entitled to a pharmacy according to the demographic rule. In rural areas, the closest pharmacy may prove to be too far away to guarantee a minimum availability of medicines. Therefore, exceptions to the rule

are possible, and additional pharmacies can be allowed in small villages (less than 12,500 inhabitants) in rural areas (but subject to minimum distance requirements from other pharmacies).

A third concern arises as a consequence of the complex procedure required to update the list of pharmacies and then to select the pharmacists in charge of each pharmacy (this requires a public competition subject to specific rules). As a result, years of delay are not uncommon. Such an inefficient administrative procedure results in municipalities with fewer pharmacies than what the demographic rule would predict. In 2016, only a few regions had completed the procedures to update the list and opened the required new pharmacies (Bocci 2016). Finally, additional pharmacies may be opened (at most 5 percent of the total) in locations with large flows of people such as train stations, airports, and large shopping centers (but subject to specific minimum distance requirements from other pharmacies).

Each change in regulation was motivated by the desire to increase the availability of pharmacies. However, as described above, the impact was delayed because of slow implementation. The reforms took place during a period in which other attempts to liberalize some professional service markets also occurred. These were typically opposed by professional associations, and their effects were significantly attenuated with respect to the initial goals. The most significant example is the so-called Bersani reform in 2006, which canceled price floors (at the time still in place for a number of professions) and lifted the ban on commercial advertising and contingent fees. The market for OTC drugs was also liberalized, allowing supermarkets to enter into a highly regulated market, in direct competition with pharmacies (see Pagliero [2015] for a description of these reforms and some evidence on their impact).

QUALITY INDICATORS

As discussed above, pharmacists are considered primary health care providers—chronically ill patients often ask their pharmacists about their pathologies, medications, and other needs. For this reason, pharmacies represent an important factor contributing to the management of chronic diseases. Based on the organization of the Ital-

ian National Health Care system and clinical characteristics, and for reasons described below, we select four health outcomes of interest: 1) influenza and influenza-associated complications, including pneumonia; 2) diabetes; 3) acute coronary syndromes, including acute myocardial infarction (AMI); and 4) upper gastrointestinal bleeding.

Influenza

Influenza is characterized by seasonal outbreaks—at least one during the cold seasons—and its incidence and mortality depend on individual-related factors (e.g., age, comorbidities, immunocompetence), environmental factors (e.g., low temperatures, time course of the outbreak) and medical factors (e.g., antiviral treatment) (Huang et al. 2015). The World Health Organization suggests annual preventive vaccination, especially for high-risk populations (such as older people, pregnant women, or immunocompromised hosts). In these subgroups of the population, the risk of hospital admissions and death for influenza itself or for some of its complications (e.g., viral pneumonia, bacterial co-infection, or respiratory failure) is higher than in the general population. We chose influenza for one of the four outcomes of interest because it is characterized by an acute seasonal outbreak, and vaccination and the availability of pharmacies can have an impact on hospital admissions and mortality.

Diabetes

The prevalence of diabetes, a chronic syndrome, is increasing among all ages. Without proper management, over time diabetes can cause cardiovascular, renal, neural, and ocular damage. For this reason, the World Health Organization suggests several preventive strategies, but if a diagnosis is confirmed, it is essential to obtain a tight control of blood sugar through diet and pharmacological approaches. The number and the density of pharmacies can influence both blood sugar level testing and adherence to therapy.

Coronary Syndromes

The coronary syndromes are chronic diseases with multiple possible acute recurrences. The definition of *coronary syndrome* is wide and

is related to all coronary heart diseases that cause frequent and lethal acute manifestations, such as myocardial infarction and heart failure. Coronary diseases have a different development than diabetes. Their first manifestation could be more frequently lethal. For this reason, the prevention of these acute events is a cornerstone of the management suggested by the World Health Organization. It is based on diet, physical activity, smoking cessation, and blood pressure control. The first three preventive actions are the goal of global public health strategies, based on awareness campaigns, but community pharmacies could contribute to the prevention and effective treatment of hypertension. Pharmacies play a role in facilitating both adherence to treatment and blood pressure monitoring. They also distribute lipid-lowering medications, for which adherence is a well-known problem.

Upper Gastrointestinal Bleeding

Nonsteroidal anti-inflammatory drugs, the most widely used painkillers, may increase the risk of upper gastrointestinal bleeding in absence of a correct preventive strategy. Access to pharmacies may affect overuse of nonsteroidal anti-inflammatory drugs, thus increasing the risk of upper gastrointestinal bleeding. On the other hand, it can also help increase adherence to therapy with proton pump inhibitors, as well as with some H2 antagonists, which treat, among other ailments, stomach ulcers and acid reflux. These drugs are some of the most used worldwide, with a long-term indication, and may prevent bleeding due to the long-term use of painkillers.

DATA SOURCES

For the analysis based on the municipality-level data (described below), we obtained the total number of admissions/hospital discharge records aggregated by sex, age class, municipality, and calendar year for selected causes of hospital admission over the period 2000–2015. Hospital discharge records contain details about the main and secondary discharge diagnoses, the implemented operations, and clinical discharge information.[5] For the analysis based on province-level data (also

described below), we obtained data from the Health for All database (HFA).[6] The HFA database, maintained by the World Health Organization, brings together selected indicators on demographics, health status, health determinants, and risk factors at the national or subnational level.[7] To obtain province-specific measures of mortality and admission rates, we averaged the yearly rates for five years (2010–2014 for mortality and 2011–2015 for admissions).[8]

This section illustrates the results of two different approaches to estimating the impact of the availability of pharmacies on health outcomes. The first uses cross-sectional data on Italian provinces to examine the demographic rule that links the number of pharmacies to the population size in each city. This variability in pharmacies per capita across provinces can be used to estimate the effect of interest. The second approach uses city-level data and the specific nature of the demographic rule, which provides for sharp steps, as illustrated in Figure 4.1.

The Number of Pharmacies in Italian Municipalities

Our data set includes the number, exact location, date of first opening, and changes of ownership of pharmacies in each municipality (the Italian government collects the data for administrative reasons).[9] The data set includes observations for 7,948 municipalities.[10] As a result of the demographic rule, the number of pharmacies is linked, although imperfectly, with the local population. This is shown clearly in Figure 4.2, which reports the number of pharmacies in each Italian municipality and the local population in 2015. Still, there are deviations from the demographic rule, which are particularly frequent in small municipalities (with less than 12,500 inhabitants). For these towns and villages in rural areas, the constraint imposed by the demographic rule is not binding, and the number of pharmacies is systematically higher than the values predicted by the demographic rule. However, in larger cities, it is not uncommon to observe fewer pharmacies than the predicted number.

Table 4.1 provides summary statistics. On average, municipalities have just 2.2 pharmacies, reflecting the small size of most Italian municipalities. Only 5 percent of municipalities have 6 or more pharmacies. About 14 percent have no pharmacies. The number of inhabitants per pharmacy varies across municipalities. The average is 2,808, but there is significant variability. About 50 percent of municipalities have fewer

Table 4.1 Summary Statistics on the Number of Pharmacies in Italian Municipalities

Variable	*N*	Mean	S.d.	p5	p10	p25	p50	p75	p90	p95
Number of pharmacies	7,948	2.22	11.78	0	0	1	1	2	4	6
Inhabitants/ number of pharmacies	6,834	2,808	1,697	569	784	1,383	2,585	3,995	5,032	5,845

NOTE: The table reports the number of observations, the mean, standard deviation (S.d.), and percentiles (5th, 10th, 25th, 50th, 75th, 90th, and 95th) of the distribution of each variable (2015).

SOURCE: Authors' calculations based on data from Istat and Italian Ministry of Health.

than 2,585 inhabitants for each pharmacy. About 25 percent have more than 4,000. This illustrates the effects of the delays in implementing the 2012 reform, which set a target of 3,300 inhabitants for each pharmacy.

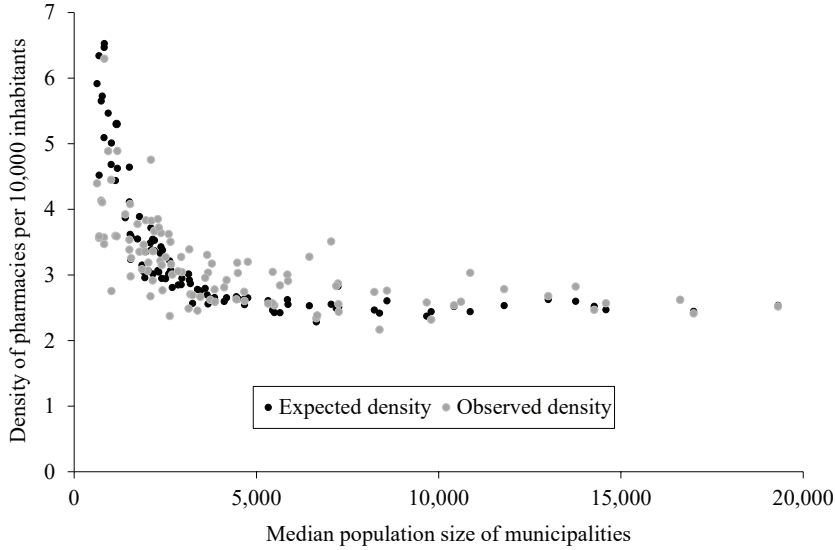
Results from Data at the Province Level

When using the 2010 population as the denominator, the mean observed density of pharmacies by province was 3.04 per 10,000 inhabitants, with a range of 2.16 and 6.30 per 10,000 inhabitants, while the mean expected density of pharmacies was 2.85 per 10,000 inhabitants with a range between 2.28 and 6.53 per 10,000 inhabitants. Thus, both densities varied widely over provinces.[11] Both the observed and the expected densities depend on the distribution of the population size of the municipalities within each province. This is depicted in Figure 4.3, in which observed and expected densities are plotted against the province-specific median population size of municipalities. The median population size explained 31 percent of the variation in expected pharmacies and 27 percent of the variation in observed pharmacies.

The age-standardized admission rates per 10,000 inhabitants for the period 2011–2015 was between 28.5 and 144.4 for influenza/pneumonia, 45.1 and 120.4 for AMI, and 5.3 and 60.5 for diabetes. Figure 4.4 shows maps with province- and gender-specific age-standardized admission rates for the three outcomes of interest.

While for influenza/pneumonia there was a clear north-south gradient, the rates for the other two outcomes did not follow straightforward geographical patterns. Table 4.2 summarizes the results of the regres-

Figure 4.3 Province-Specific Observed and Expected Densities of Pharmacies by Median Municipality Population



SOURCE: Authors' calculations based on data from Istat and Italian Ministry of Health.

sion models carried out to estimate the association between observed/expected densities of pharmacies and age-standardized admission or mortality rates of influenza/pneumonia, AMI, and diabetes.[12] Estimates reported in the table should be interpreted as the estimated increase or decrease in admission or mortality rates by a unit increase in expected or observed province density of pharmacies (i.e., an increase in 1 pharmacy per 10,000 inhabitants). For example, the coefficient of –8.7 in the upper left corner of the table implies an estimated decrease of 8.7 per 10,000 in the age-standardized rate of influenza/pneumonia admissions associated with an increase of 1 per 10,000 inhabitants in the observed number of pharmacies.

The adjusted estimates account for other determinants of the three outcomes of interest, namely urbanization level, macro geographical area (North, Central, and South Italy) and educational level. For both the observed and the expected density of pharmacies, we also conducted a sensitivity analysis, restricting the sample to provinces with less than

Figure 4.4 Gender-Specific and Age-Standardized Admission Rates (per 10,000 inhabitants) for Influenza/Pneumonia, Acute Myocardial Infarction (AMI) and Diabetes, by Italian Provinces, 2013

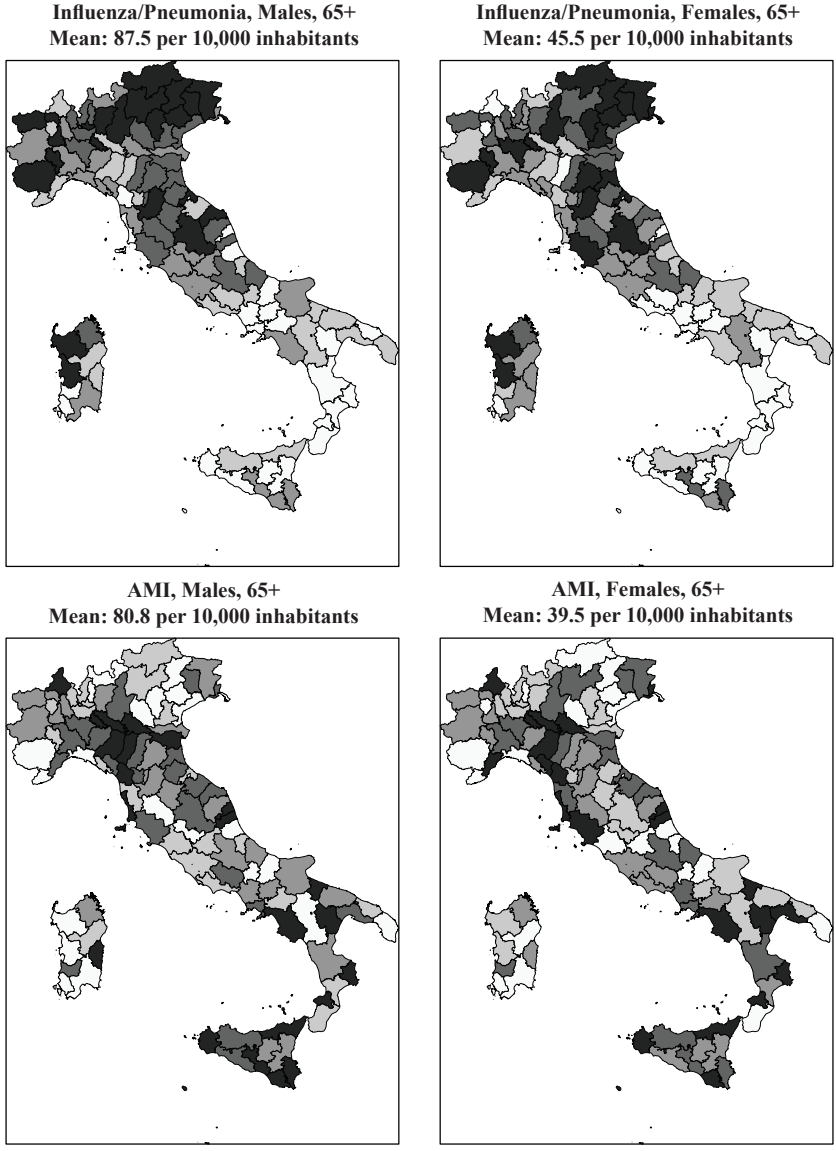
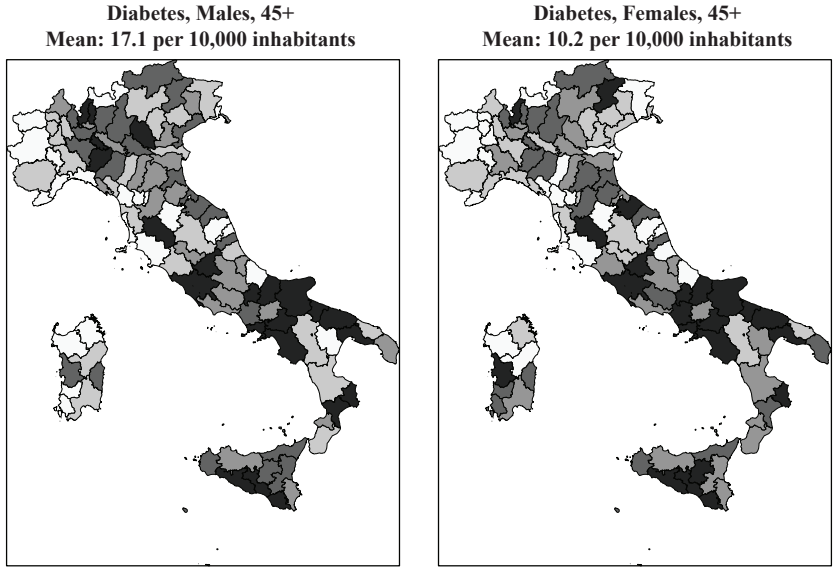


Figure 4.4 (continued)



NOTE: Shades indicate quintiles, where the darkest shade corresponds to the highest rate.
SOURCE: Health for All database.

1,000,000 inhabitants. This analysis aimed at checking that our results were not biased by the contribution of large cities in which the access to pharmacies and their density may be different compared to the rest of the country.

It should be noted that geographical patterns associated with both the density of pharmacies and the rates of hospitalization or death could hide or emphasize the estimated associations. Overall, we find no evidence of association between the observed or expected density of pharmacies and admission rates for AMI and diabetes. There is an inverse association between the observed density of pharmacies and admission rates of influenza/pneumonia, although this association was strongly attenuated in the analysis on the expected density of pharmacy. We find no evidence of association with mortality for influenza/pneumonia, AMI, or diabetes for the observed or for the expected density of pharmacies. Results from the analyses restricted to provinces with a popula-

Table 4.2 Association of Observed and Expected Densities of Pharmacies with Admission and Mortality Rates of Influenza/Pneumonia, Acute Myocardial Infarction and Diabetes

Density of pharmacies	Influenza/pneumonia		Acute myocardial infarction		Diabetes	
	Admission rates	Mortality rates	Admission rates	Mortality rates	Admission rates	Mortality rates
	Observed density of pharmacies					
Crude	−8.66***	−0.68*	−0.52	1.24	−0.12	0.14
	(2.96)	(0.38)	(1.95)	(0.98)	(0.99)	(0.77)
R^2	0.069	0.031	0.001	0.016	< 0.001	< 0.001
Adjusted coefficient[a]	−8.47***	−0.33	−0.20	1.06	−0.45	−0.33
	(2.53)	(0.24)	(2.08)	(1.01)	(0.99)	(0.39)
R^2	0.443	0.669	0.057	0.138	0.165	0.787
Adjusted and restricted coefficient[a]	−8.52***	−0.29	−0.38	1.11	−0.16	−0.23
	(2.62)	(0.26)	(2.25)	(0.93)	(1.01)	(0.40)
R^2	0.440	0.643	0.052	0.148	0.148	0.764
	Expected density of pharmacies[b]					
Crude	0.72	0.42*	−1.92	−0.84	−0.62	−1.08
	(2.02)	(0.25)	(1.26)	(0.64)	(0.65)	(0.49)
R^2	0.001	0.028	0.002	0.017	0.009	0.046
Adjusted coefficient[a]	−2.89	0.02	−1.63	−0.15	−0.31	−0.24
	(1.76)	(0.16)	(1.38)	(0.68)	(0.67)	(0.26)
R^2	0.395	0.663	0.070	0.129	0.165	0.787
Adjusted and restricted coefficient[a]	−2.72	0.02	−1.73	−0.24	−0.33	−0.29
	(1.80)	(0.17)	(1.47)	(0.62)	(−0.66)	(0.26)
R^2	0.388	0.638	0.070	0.136	0.150	0.766

[a] Adjusted for proportion of population living in areas with low urbanization, macro geographical area, proportion of the population with high educational level; restricted to provinces with less than 1,000,000 inhabitants.

[b] Based on the 1991 legislation.

NOTE: *significant at the 0.10 level; **significant at the 0.05 level; ***significant at the 0.01 level. Based on 102 provinces; 92 provinces in the restricted analyses.

SOURCE: Authors' calculations based on data from Istat, Health for All, and Italian Ministry of Health.

tion size lower than 1,000,000 are consistent with the results carried out on all provinces, with no evidence of bias introduced by large cities.

Results from Data at Municipality Level

Data at the municipality level were used to exploit the arbitrary values taken by a specific step of the demographic rule described in Figure 4.1. We focus on one specific step in the demographic rule (at 7,500 inhabitants) for the 2005–2011 period. This choice is motivated by the fact that the step has not changed since the introduction of this type of regulation in the 1960s, which allows us to explore the long-run effects of the regulation. Moreover, most Italian municipalities are small, which implies that there are many observations around the threshold. We select 1,214 municipalities with populations between 5,000 and 10,000, creating a symmetric window (±2,500) around the step and merge data on the number and location of each pharmacy in each municipality with data from hospital discharges.[13] This is a relatively homogeneous sample of small towns and villages. On average, municipalities in this sample have 1.7 pharmacies. Hence, the opening of one pharmacy can potentially make a difference for consumers.

Table 4.3 reports the average number of admissions and the average number of pharmacies in the sample. Figure 4.5 reports the average

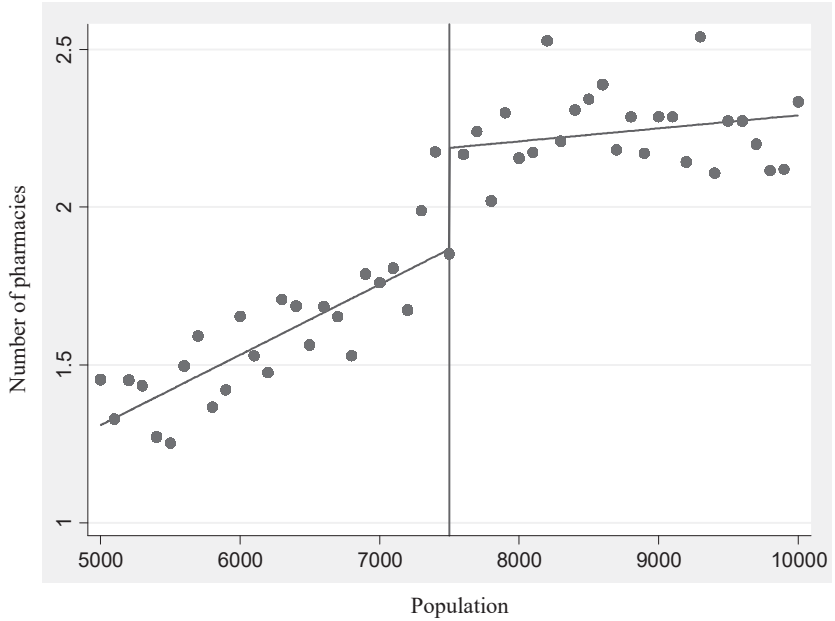
Table 4.3 Summary Statistics for Number of Yearly Admissions for the Selected Health Outcomes and Number of Pharmacies

Variable	Mean	S.d.	Min	Max
Upper gastrointestinal bleeding	3.52	2.46	0	26
Coronary diseases	21.28	10.02	0	80
Diabetes	0.49	1.16	0	45
Influenza	15.29	9.43	0	77
Number of pharmacies	1.78	0.67	0	5
Number of pharmacies according to the demographic rule	1.35	0.47	1	2
Observations		8,498		

NOTE: Each observation corresponds to one city in one municipality in one year in the 2005–2011 period.

SOURCE: Authors' calculations based on data from Istat, Health for All, and Italian Ministry of Health.

Figure 4.5 Average Number of Pharmacies and Population

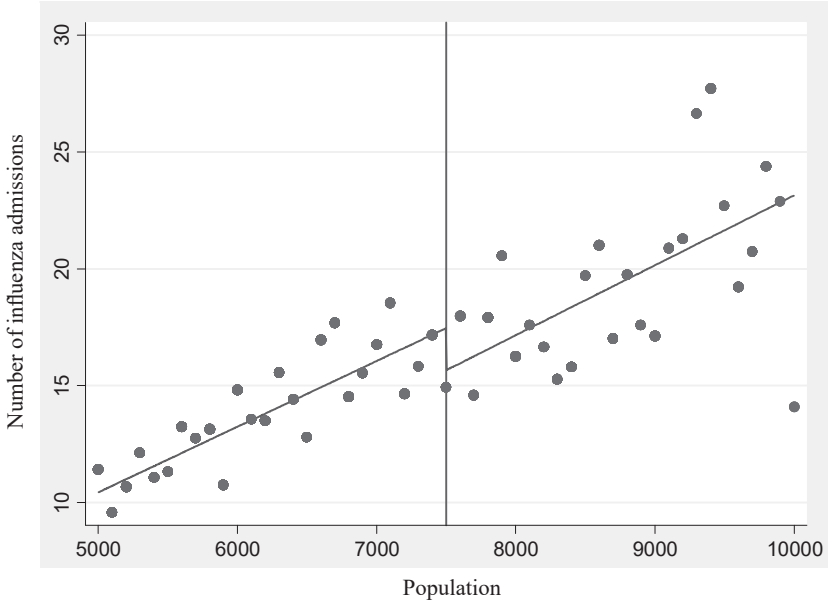


NOTE: The figure reports the average number of pharmacies in municipalities of different size according to historical population (intervals of 100 inhabitants). The lines are the fitted values of a linear regression of number of pharmacies on population on each sides of the 7,500 threshold, which corresponds to an increase from one to two pharmacies according to the demographic rule in place until 2011.

SOURCE: Authors' calculations based on data from Istat, Health for All, and Italian Ministry of Health.

number of pharmacies for municipalities of different size. Each dot in the figure corresponds to the average number of pharmacies in a specific interval of 100 between 5,000 and 10,000 inhabitants. The lines on both sides of the vertical line are the fitted values of a linear regression on each side of the 7,500 threshold (vertical line), which corresponds to an increase from one to two pharmacies according to the demographic rule. The discontinuity at the threshold corresponds to a 0.28 increase in the number of pharmacies.[14] This is in line with the fact that regulation induces an increase in the number of pharmacies at the threshold, although other variables may also influence the observed number of pharmacies.

Figure 4.6 Average Number of Influenza Admissions and Population



NOTE: The figure reports the average number of influenza admissions in municipalities of different size according to historical population (intervals of 100 inhabitants). The lines are the fitted values of a linear regression of number of admissions on population on each sides of the 7,500 thresholds, which corresponds to an increase from one to two pharmacies according to the demographic rule in place until 2011.

SOURCE: Authors' calculations based on data from Istat, Health for All, and Italian Ministry of Health.

Figure 4.6 shows the corresponding results for the average number of influenza admissions. In this case, there is a negative jump at the threshold of 2.1 cases (statistically significant at 5 percent confidence level). Hence, Figures 4.5 and 4.6 suggest that the increase in the number of pharmacies caused by the threshold is associated with a significant decrease in the number of influenza admissions. The magnitude of the effect is sizable. An increase in the average number of pharmacies of 0.28 (as in Figure 4.5) corresponds to a drop of about 2.1 in the average number of hospital admissions. Hence, a 16 percent increase in the number of pharmacies corresponds to a 13 percent reduction in

the average number of influenza related admissions. We find no similar effects for the other health outcomes.

In conclusion, this approach focuses on a subsample of small municipalities in which about half are above and below the threshold. The threshold remained in place for a long time and provides for a relatively large increase in the availability of pharmacies. Hence, the results suggest the existence of a negative long-run effect of the availability of pharmacies on the number of hospital admissions related to influenza.

CONCLUDING REMARKS AND IMPLICATIONS FOR POLICY

This case study examined the impact of regulation on the number and location of pharmacies in Italy and its potential effects on human health. We used health outcomes measures from hospital admission records that can potentially capture the impact of access to medicines (and the other services provided in pharmacies) on the health of the population.

The results from the analysis at the province level support the hypothesis of an inverse association between density of pharmacies and admission rates of influenza. Results using municipality-level data provide complementary and potentially more valid evidence, as they are biased to a lesser extent by geographical confounding. These results are consistent with the results obtained from the analysis of the data at the province level and suggest a long-run effect of pharmacy availability on consumer health. In either analytical approach we find no evidence of association between the density of pharmacies and admission rates for AMI and diabetes or upper gastrointestinal bleeding as a marker of potential negative effects of an increased number of pharmacies.

Overall, the results provide the first evidence on how regulation of the market for pharmacies might affect service availability (a crucial determinant of quality in this market) and consumer health. While these are promising results, they should be interpreted with care. Longer time series could be used in future research to detect the dynamic effects of the availability of pharmacies. Regression discontinuity designs can capture the long-run effects, but they provide results that are difficult

to extrapolate out of the sample, as these techniques focus on a very specific sample.

From a policy perspective, our results suggest that restrictions to the number of pharmacies might negatively affect health outcomes of the population. Increasing availability of pharmacies may not only have positive economic effects (e.g., lower prices for unregulated products) but also positive health effects. Guaranteeing a sufficient availability of pharmacies in rural areas may be difficult due to the low profitability of these markets. However, direct subsidies to rural pharmacies seem to be a better policy option than entry restrictions over the entire range of market size. Although strict regulation of the pharmacy market can be justified by the possible dangers associated with the improper use of medicine, it is important to consider the specific effects of entry regulation separately from the regulation of the use and prescription of drugs. We did not find an association between increased competition in the pharmacy market and decreased safety standards, at least in terms of the measured side effects of drugs. To the contrary, the availability of pharmacies and competent pharmacists might have positive effects on health.

Notes

1. Unfortunately, Italy is among the countries not included in the analysis.
2. In 2005, England revised its "control of entry test" system. In 2002, Ireland revoked the rules for the opening of new pharmacies, and in 1998, the Netherlands abolished restrictions on the establishment of new pharmacies. Norway deregulated in 2001, and Sweden, in 2009, ended the monopoly of the state-owned pharmacy company, owner of all pharmacies.
3. The market was subject to a modest liberalization in 2006, when para-pharmacies and supermarkets were allowed to enter the market and sell OTC drugs. The new regulations were introduced by decree-law at the end of June 2006 and converted into law by the Italian parliament at the beginning of August.
4. Attending physicians are not allowed to distribute drugs.
5. The Italian health care system is a regionally based national health service that provides free universal coverage at the point of service. Providers are paid for their activities by means of a prospective payment system based on diagnosis related groups. In order to allocate each patient to a specific diagnosis related group, the Italian Ministry of Health has implemented the hospital discharge records (HDRs) system at a national scale (Ferrè et al. 2014). Hospital discharge records are used to collect information about individual patients such as inpatient data, details of implemented therapies/operations, and clinical discharge information. Hospital

discharge record collection is mandatory, and includes both ordinary and outpatient admissions (day hospital). The records are first collected at the regional level and then forwarded to the Italian Ministry of Health.

6. The HFA database is accessible through the website of the National Institute of Statistics (ISTAT) at the following address: https://www.istat.it/it/archivio/14562 (accessed June 22, 2022).
7. Specifically, the data on hospital admissions is provided by ISTAT based on HDR data. ISTAT is also responsible for the collection and coding of mortality data at the national level.
8. The analysis was limited to a five-year period because the boundaries and number of Italian provinces have changed over time, and a longer period time would have implied a restriction to a smaller number of provinces. In our analysis, we excluded only data for the Sardinia region, which includes a small proportion of the Italian population (less than 3 percent).
9. Italian Ministry of Health, http://www.dati.salute.gov.it (accessed December 13, 2021).
10. We exclude a few municipalities that were created after 2006 or changed name during the same period. We also exclude temporary points of sale (e.g., open only in summer in tourist areas) or smaller branches of authorized pharmacies (e.g., open in tourist areas and/or in specific periods), which are not subject to the demographic rule.
11. The correlation coefficient between observed and expected densities is 0.71.
12. The table reports the estimated regression coefficient of pharmacy density, its standard error, and the regression R^2.
13. In the regression discontinuity analysis, we use the maximum historical population method proposed by Calzolari et al. (2013). In practice, the discontinuity is based on the maximum population in the 1971–2001 period instead of current population to account for the fact that the number of pharmacies does not adjust downward when the population shrinks. See Calzolari et al. (2013) for a detailed discussion of this method.
14. Statistically significant at the 5 percent confidence level.

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