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The pharmaceutical care and the rejected constitutional reform: what might have been and what is

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Summary. This study analyzes the current state of legislation pertaining to pharmaceutical/health care in a period of normative ferment characterized by continuous changes, after countless discussions that have been held on a proposed constitutional reform (rejected by the will of the people at the end of 2016). After a general reflection on the division of legislative powers between the State and its Regions, in the light of attempts to bring about a reform, we will analyse specific problems: from the recent, but in some ways already defined as historic, approval of the new Essential Levels of Care (LEC), the approval of the 2017 Budget Law (concerning important items such as the purchase of drugs), until we reach the Draft Law on competition which is in the process of being approved. All this is taking place in the context of loyal, unavoidable cooperation between State, Regions and local institutions, in the spirit of the ascendancy of the right to health over economic/financial interests in the country. (www.actabiomedica.it)

Key words: right to health, pharmaceutical care, State and Regional powers, purchase of drugs

It is best to fidget in doubt,
that be still in error.
(A. Manzoni)

Introduction: healthcare, sub specie pharmaceutical, after the rejection of the proposed constitutional reform

On December 4, 2016, the Italian people voted against the proposed constitutional reform adopted by Parliament on April 12, 2016.

This paper presents an analysis of some profiles within the pharmaceutical system which are functionally connected to the health service in order to understand how the latter might have been affected by the proposed reform, in this manner bringing about the current state of affairs. The pharmaceutical service is obviously relevant to public service, being responsible for implementing the fundamental right to health as set out in art. 32 of the Italian Constitution. In specie, the right of access to medication, free from limitations imposed by income and place of residence, is an expression of the sacrosanct right of every citizen to lead a dignified life.

Art. 32 Const. is clear on this point: it is the duty of the State to protect health both as an individual right and a collective interest. The right to health therefore has a composite nature, as it is a right and also the freedom to cure oneself, but in one's endeavours to do so also encompasses the right to expect to be assisted by the State. It is no coincidence that, in accordance with art. 3 Const., it is the duty of the State to remove all economic and social barriers that hinder, in breach of citizens' equality, the full development of the human being. Therefore, there is no doubt that pharmaceutical care, just as healthcare in general, is a public service of general interest. In fact, the State has created the National Health Service (NHS), a vehicle which provides pharmaceutical care under the supervision of the

Regions (which is also healthcare thanks to the advent of multi-service pharmacies), functioning throughout the nation by means of public and private pharmacies.

The regionalization of pharmaceutical care (and healthcare in general) started in the 90s with the so-called Bassanini reform (1). The idea was to progressively bring legislation and administrational practices towards the requirements of local communities. This process of decentralization is known to have reached its peak with the full adoption of the principle of subsidiarity (2), as regulated in the Constitution (art. 118 Const.), though European inputs (first acknowledged in the Maastricht Treaty) must not be forgotten. The State's exclusive right to exercise sovereign authority has not historically been very fruitful and, moreover, has never been appreciated by the community, which has often felt neglected, and even abandoned, by the very State. With the adoption of Constitutional Law no. 3, October 18, 2001, the federalist reform of the order was carried out; this reform can mostly be noted in the revision of Title V of the Constitution, which deals with the division of powers between the State and Regions.

The division of power between the State and Regions: the current situation

It is known that it is the State's exclusive responsibility to determine the "essential levels of performances concerning civil and social rights", in order to ensure their even application throughout the country. The Regions and the autonomous Provinces of Trento and Bolzano, on the other hand, are responsible for the "protection of health" on matters covered by concurrent legislation.

Regarding pharmaceutical care and its peculiar "two-faced", legal nature, being both a general public service and a business and commercial enterprise, other aspects can be noted: "protection against unfair competition", which is exclusively the responsibility of the State and "trade" which, in the absence of detailed specifications, is attributable on a residual basis to regional powers (3).

If the analysis then focuses on two specific elements of pharmaceutical care, such as the management of public pharmacies and the distribution of medicinal products, we note that "local finance" also assumes a certain importance. This, again on a residual basis, is attributable to the exclusive power of the Regions and the autonomous Provinces of Trento and Bolzano. In this last respect, art. 119 Const. declares the financial autonomy of local authorities in terms of revenue and expenditure, to enable them to fund the public functions attributed to them.

In this way, legislative jurisdiction is split between the State and Regions, implying as anticipated the existence of a "waterfall" or "drop down" system. This includes administrative functions, which are exercised in accordance with the principles of subsidiarity, differentiation and adequacy as set out in art. 118 Const.

Thus, State and Regions (along with the provinces, municipalities and metropolitan cities) are on an equal footing (art. 114 Const.), being equally necessary to the existence and continuity of the legal system. Therefore, their legal relationship must follow protocols based on the principle of loyal cooperation and respect for the areas in which they possess legislative and organizational autonomy.

Finally, it should be noted that art. 120 Const. provides for the Government to take the place of local authorities in order to ensure legal and economic unity and guarantee the aforementioned civil and social rights.

In the case of the latter parameter, even the government's power to act in place of a local authority (governed by Law June 5, 2003, no. 131, and in truth rarely applied) guarantees the fluidity of the distribution of power.

In particular, if the "essential levels of performance" is a mobile parameter that regulates the responsibility attributed to certain powers (and not only this, as we will see shortly), the power of substitution does not affect institutional titles, but only the concrete exercise of the powers that are and remain the responsibility of local authorities (in fact, the implementing legislation mentioned above provides for local authorities to compensate for their inertia by initiating the process of substitution). In fact, both parameters, in opening and closing the system dividing power between the State and Regions, have shown themselves to be mechanisms aimed at achieving a similarity rath-

er than an absolute conformity of services (for purposes of the present study, in the field of healthcare).

The proposals of the rejected constitutional reform

The proposed reform aimed to make changes to all of the parts of the constitution cited above in a "state-centric"sense (4). In fact, the reform would have brought many powers that are currently shared between State the Regions under exclusive power of the State, effectively eliminating art. 117 Const. which is responsible for separating these powers. The reform therefore listed the matters that fell within the exclusive power of the State and those that came within the exclusive power of the Regions.

It is noticeable that the State has tried to include, as well as the power to determine, "essential levels of care", "the general and common principles for the protection of health, social policies and food security" in its exclusive competence; while "planning and organization of health and social services" was given to the Regions. Likewise, the State would have kept an exclusive competence in the field of competition, while giving a broader meaning to the term as it is currently used: if the referendum had passed, the State would have been responsible for issues relating to the"protection" and "promotion" of competition.

The reform did not, however, go into detail on this matter, except for including a residual clause stating that any matters not falling under the competence of the State was to be included in Regional competences: trade and local finance remained in the competence of the Regions.

Clarification is urgently needed on both matters.

Regarding trade, the reform specifically provided that, in compliance with art. 117 Const., "local economic development" fell under the exclusive competence of the Regions and this point clashed with the provisions on competition.

However, when it came to local finance, a provision giving "upstream" control to the State had been added to art. 119 Const. (this provision is a symbol of the autonomy given to local authorities): according to the reform, reference indicators of costs and requirements had to be defined by State law, in order to permit the local authority to carry out its financial functions efficiently.

An addition which was certainly dictated by the need to contain public spending, an issue which has never been concealed by any reformist legislator (even when it comes to protecting the right to health), with the aim of putting brakes on the Regions' excessive spending habits, especially when it comes to healthcare.

Furthermore, in terms of competences art. 117 Const. provides for an equality of functions: regulatory functions would be exercised in accordance with respective legislative powers.

Certainly, it appears contradictory that the reform did not set out a more effective amendment to art. 118 Const.: in fact, irrespective of a few additions, this ar-

Table 1. Conventional pharmaceutical spending. Trends observed from 2010-2016 (5)

Year	no. prescriptions (in millions)	Prescriptions/ citizen (average no.)	no. packages of medicines	Packages/citizen withdrawn from pharmacy (average no.)	Net pharmaceutical expenditure charged by SSN (National Health Service)	National Health Service: net contracted pharmaceutical expenditure (trend% compared to the previous year)
2016	~587	9.7	~1.12 billion	18.5	8.445.620.272	-1.3
2015	~596	9.8	~850 million	14	8.655.142.395	-1.4
2014	~609	10	~1.121 billion	18.4	8.774.668.314	-3.1
2013	~607	10.19	~1.118 billion	18.7	9.058.020.186	-2.5
2012	~591	~10	~1.88 billion	18	9.290.529.550	-9.1
2011	~590	~10	~1.80 billion	18	10.217.246.769	-8.6
2010	~587	9.84	~1.73 billion	18	11.174.399.155	-0.7

ticle had kept its reference to the principle of subsidiarity, differentiation and adequacy that was actually in disagreement with the reform's "state-centric" intent. Presumably, the constitutional legislator could not have done otherwise, given existent Community obligations in this matter (3), and the self-imposed limit in the reform's attempt to make changes to articles 116 and 117 Const. seems to agree with this reasoning.

Reference is made to the provision set out in art. 117 Const., according to which the State's power to delegate the exercise of regulatory functions in matters which are under its exclusive competence to the Regions was maintained. Rather, the reformed art. 116 Const. made it possible for the Regions, provided their budgets were balanced (reaffirming the need to the contain public spending), after consulting the local authorities in accordance with a State law, to apply for legislative powers in specific fields, including the field relating to "general and common provisions for social policies", to be given to them.

Finally, a safeguard clause could be found within art. 117 Const., according to which the State could "intervene" in matters which did not come under their exclusive legislative competence, whenever the Republic's economic or legal integrity called for it, or when it was in the National interest to do so. However, as the reference to the substitutional power addressed in art. 120 Const. (which proposed the possibility of requesting a reply from the Senate within a specific period of time, after which the government could still exercise its substitutional power) had not been deleted, it is not clear what this power of intervention would have consisted of (would it have subtracted entitlement or merely the practical use of power?), although the fact that a statutory reserve remains is a small comfort.

Given the above, it is reasonable to wonder if this kind of reform would have brought about hoped-for savings and a reduction in conflicts of legal competence at least in the field of healthcare.

Achieving uniform healthcare in the country is certainly desirable, and also helps combat the distressing practice of "health tourism", which arises from existing differences between the Regions, created by years of confused federalism.

However, it is hard to understand how the reform proposes to differentiate between the determination of "general and common provisions" by the State and the "programming" (in particular) and "organization" of health and social services on the part of the Regions.

After all, is the need for national uniformity not already guaranteed by the power of the State to determine basic levels pertaining to civil and social rights, which undoubtedly reflect on the right to health, as well as the government's substitutional power which is provided for in art. 120 Const.?

Perhaps the problem is to guarantee the success, meaning the application, of this principle?

On the matter of healthcare, the State must define everything that is fundamental (eg: the therapeutic purpose of a practice or a medicine), using scientific, not political, criteria (in the hopes that it uses competent authorities for this purpose).

On the other hand, everything that of an organizational or technical nature (eg: the identification of bodies and procedures) should be defined by the Regions, which can meet the needs of local communities more realistically. Perhaps the same doubt had also risen in the mind of the legislative reformer, who had foreseen the possibility for Regions to be given legislative powers (though these were limited to the "general and common rules" of social policies) as well as the ability to delegate regulatory powers in all matters which were under the competence of the State.

Perhaps these were to be considered the new safeguard clauses of a basically "state-centric" system and not so much the "new" powers of State intervention.

However you want to interpret it, this reform would have undermined the principle of subsidiarity, and it is not unlikely that this could have resulted in the proliferation of appeals at national (because the Constitution would continue to support the principle of subsidiarity) and EU level.

To this picture we must add what appeared to be mere declarations of intent, or broad guidelines, on the new role of the Senate: yes, it should represent the interests of local institutions, but, in the absence of a law on how its members would be appointed and the kind of power that it would wield, every attempt to interpretet it is purely a useless, dogmatic risk. The legislator would still have had to take this innovation into consideration, as the reform intended for the "new" Senate to become a place in which local interests were combined.

Legislative reactions after the rejection of the reform. Conclusions

For the purposes of this study, it seems that the proposed reform intended to: reduce spending; guarantee the homogeneity of the right to health on a national level (by overcoming differences between Regions and local health agencies thereby dissuading the practice of "health tourism"); reduce existing conflicts of competence between the State and Regions; achieve the more efficient and legitimate representation of local needs in the new Senate.

However, our analysis shows that the proposed reform, might not have been effective, due to the nature of the legal instruments utilized; this could have provoked an unnecessary legislative activity (particularly in the field of healthcare). There is no doubt, however, that had it been approved, the reform would have been yet another legislative proposal devoid of consistency and coherence. In truth, the legal system pertaining to healthcare/pharmaceutical care is currently undergoing a profound transformation, which is being achieved through other laws that, prior to the referendum, legislators were trying, with great difficulty, to make compatible with the reform itself.

Before the reform was rejected by popular vote, the possibility of finding the funding needed for the final approval, after 15 years, of the essential levels of care (LEC) (6) was being discussed. The Ministerial Decree relating to pharmaceutical care issued on January 12, 2017, introduces some new features (compared to the now obsolete LEC which were in force until today): the variety of distribution channels (via affiliated pharmacies, direct distribution and on account of public or private pharmacies) and the aforementioned multi-service pharmacy (7). For years, these have been a significant innovation, that has not yet come into full effect: the pharmacy is a primary point of reference for the protection of the patient's right to health by ensuring not only rights of access to the drug, but a broader right of access to care, placing itself as an intermediary between State and patient. As mentioned in the Introduction, this type of pharmacy would not be limited to pharmaceutical care, but its role would include all aspects of healthcare, in the same way as other healthcare facilities. In this decree, the introduction of a specific National Commission for guaranteeing LEC is of great importance. This will be responsible, for updating the essential levels of assistance each year; equally important is the creation of a task force composed of various organs (Ministry of Health, Institute of Higher Health, Italian Medicines Agency AIFA, National Agency for Regional Health Services and NAS) with the task of monitoring the implementation of LEC at Regional level, with the Regions having to submit a quarterly report to the Ministry of Health. All this seems, of course, aimed at guaranteeing that the LEC will be applied consistently in different Regions, avoiding unacceptable differences (might it be that the rejection of the reform has influenced this choice?). However, the Regions are not totally convinced that all the services that they will have to provide come under the estimated financial budget. This matter is currently undergoing change.

In fact, the LEC must be interpreted by taking another important law, passed at the start of the year, into consideration: the 2017 Budget Law. The right to health, has always been considered against other interests, particularly of an economic and financial nature.

In this law, the State has lumped everything together and inserted hospital spending (both direct spending and public and private expenditure carried out by pharmacies) under "pharmaceutical expenditure - direct purchases".

In addition, the ceiling on expenditure has been fixed at a lower level than conventional pharmaceutical expenditure (which, in the estimated budget law, only includes distribution by way of public and private pharmacies). It is the Regions themselves that have questioned this mechanism (one doubt was expressed together with the Italian Society of Hospital Pharmacists, SIFO), wondering whether it won't actually lead them to spend more, even only because they will exceed the spending limit imposed on direct purchases, forcing them to go through standard healthcare procedures which are more costly. It should also be considered that spending on cancer drugs and innovative drugs that are not included in the funding that has been specifically allocated for them is also included in the ceiling for direct purchases. Even these profiles, however, are constantly changing, since the Budget Law makes a reference to a future Ministerial Decree

and a future determination by AIFA, concerning the allocation of the resources mentioned (to date, two funds have been established for innovative cancer drugs and innovative drugs) and for determining the criteria for classifying a drug as innovative respectively, the Italian Medicines Agency (AIFA) is the national authority responsible for the regulation of drugs in Italy. It is a public body operating autonomously, transparently and in a cost-effective manner, under the direction of the Ministry of Health and the vigilance of the Ministry of Health and the Ministry of Economy. It cooperates with the Regional Authorities, the National Institute of Health, Research Institutes, Patients' Associations, Health Professionals, Scientific Associations, the Pharmaceutical Industry, producers and distributors.

But that is not all. After the constitutional reform was rejected, at the end of the year, at the same time as the latest discussions on the Budget Law were being held, AIFA lifted one of its own determinations, no. 458 of 2016, which defined the criteria for therapeutic equivalence evaluations. This determination had facilitated Regional centralized purchasing of drugs which were therapeutically equivalent but had different active ingredients. These procedures had long been criticized by Farmindustria (which felt this debased the hardships and costs associated with research), by doctors' associations (who complained of having to limit issuing prescriptions) and by the patients themselves (who worried, especially when affected by chronic diseases, about the continuity of their care). Obviously, this regional practice appeared to be aimed exclusively at curbing costs. Recently, a ruling of the Piedmontese Regional Administrative Court (published 16 March 2017) (8) rejected a law issued by the Region of Piedmont which encouraged the purchase of medicines with broad therapeutic equivalence, recognizing that the power to define the criteria for determining equivalency belongs exclusively to AIFA and that, in any case, doctors' freedom to write prescriptions and the patients' right to health cannot be limited.

In revoking the aforementioned determination, AIFA expressed a wish for objective procedures, made between the State (Ministry and AIFA) and Regions, to be adopted swiftly. A wish that uniform legislation be guaranteed at national level and, so far, apparently a victory in the need to balance the right to health with economic interests.

There are issues of agreement between the State and Regions when it comes to the purchase of drugs, too. These are caused by the division of legislative powers in the health sector that the rejected constitutional reform aimed to solve. Purchasing suffers from excessive fragmentation of demand (lots of medicines purchased by individual Regions, individual local health agencies or even individual health centres or hospitals), and it is also affected by differences in terms of the financial resources available to the buying public. This therefore creates additional differences between the Regions and even between individual hospitals in the same Region, which also have a negative impact on the distribution of medicines (for example, even the supply of products to pharmacies that operate on behalf of the local health authority depends on these public tenders).

Indeed, in 2014 there was a first national attempt at centralizating purchasing, by including medicines in the list of products for which centralized purchasing needs to be guaranteed by CONSIP, a public stock company owned by the Italian Ministry of Economy and Financ, (its procedures are specifically aimed at guaranteeing that the conditions set out in the offers were equal). CONSIP's operations clearly suffer from a lack of surveillance: after recent serious legal proceedings, its reliability in society and among local authorities has practically vanished (9). In fact, it recently raised the alarm (10) about public tenders which had no participants, when they were held for individual hospitals, specifically for the direct distribution of drugs. In these cases, the problem of having to apply the lowest price is evident, and is repeatedly challenged by pharmaceutical companies that consider it to go against practices of fair competition. They would like to replace it with the most economically advantageous offer. In actual fact, the 2016 Public Procurement Code cites this as being the basis of all public tenders, reserving the lowest price to exceptional situations. These are, nonetheless, precisely set out in the "standardized purchasing or special market situations" and it seems complicated not to include the purchase of some, if not all pharmaceutical products in this statement. Finally, it should be noted that innovations to competition in the pharmaceutical sector are not

a being fought over by State and Regional powers. It seems the innovations will come into being very soon thanks to the much-discussed decree on competition (the approval of which was postponed because of the referendum).

This will affect the legal standing of private pharmacies with the introduction of capital, namely that a limited company can have members who are not necessarily pharmacists (the battleground refers to the limits that must be imposed, probably by identifying the highest number of pharmacies that can be managed by a limited company on a regional or national territory). The pinnacle of competitiveness applied, however, to pharmaceutical products which are not simply merchandise but part of healthcare. And though the constitutional reform, which added "promotion" as well as the "protection" of competition to State competence, was rejected, it appears that it has nonetheless not been ignored by the State and the Regions, whose local authorities, have sold their shares in public pharmacies in favour of private pharmacies, finding in this way a very profitable way to raise funds.

In conclusion, based on what has been said, at least two profiles emerge: the protection of the right to health and the division of powers between the State and Regions.

Too often, the right to health, and especially the right to health and pharmaceutical care, suffers from interests that are purely financial. As pharmacies become sales outlets, like shops, their potential to become the first place to which the patient turns (something which has partly been achieved thanks to their millennial tradition) is denied. The patient should not be seen as a customer (and he should not feel like one) but should feel he can go to the pharmacy before having to consult hospitals, healthcare services, etc. So, fixing our attention on the problem of distributing drugs, for example, for some of them, one of two things can be chosen: either by making it easier for the patient to get medicine from the hospital or through pharmacies that sell pharmaceutical products on behalf of the health authority (a process that is currently divided into many, complicated steps), or making medications directly available to the pharmacy, by giving the right of access to the patient's medication precedence over everything else.

And finally, the issue of State and Regional competences that intertwine and overlap: this probably does not depend exclusively on the powers they currently share in the healthcare sector but actually depends on the horizontal nature of the sector itself. Had the constitutional reform been approved, nothing would have changed: eliminating concurrent competences while leaving "the general and common provisions for the protection of health" to the State and the "planning and organization of health services" to the Regions does not appear to be the most effective means to counter a problem that arises from the horizontal nature of the matter (that and would have remained so).

In a recent landmark ruling (11), the Constitutional Court, declared the unconstitutionality of the founding principles of the enabling law on the reform of public administration, citing the argument based on the constitutional principle of loyal cooperation (12) between the central State and decentralized institutions (intimately connected to the principle of subsidiarity), on the basis of which, in order to make changes to this matter, the State would have to involve the Regions by asking for their agreement rather than the weaker method that is actually used: asking for their opinion.

Perhaps that legal argument might be seen as an admonition for equality and unity? (13).

References

1. Actually, four laws, no. 59 of 1997 (Bassanini), no. 127 of 1997 (Bassanini), no. 191 of 1998 (Bassanini), no. 50 of 1999 (Bassanini).
2. Vecchio F. Declinations, constitutional principle of subsidiarity, http://www.forumcostituzionale.it/wordpress/images/stories/pdf/nuovi%20pdf/Paper/0033_vecchio.pdf.
3. In general, Toriello F. The general principles of Community law, 2000: 1-542, in particular on the principle of subsidiarity De Pasquale P. The principle of subsidiarity in the European Community. 2000: 1-1160.
4. Signorelli C, Odone A, Gozzini A, Petrelli F, Tirani M, Zangrandi A, Zoni R, Florindo N. La riforma costituzionale mancata e i possibili riflessi sulla sostenibilità del Servizio Sanitario Nazionale. Acta Biom 2017; 88(1): 91-94.
5. https://www.federfarma.it/Spesa-e-consumi-farmaceutici-SSN/La-spesa-farmaceutica-nel-2010.aspx
6. http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=2842.

7. For further information: http://www.fofi.it/ordinebs/pagina.php?pagina_id=3922&tipo=news; https://www.federfarma.it/Edicola/Ultime-notizie/24-11-2016-00-20-07.aspx.; http://www.sanita24.ilsole24ore.com/art/imprese-e-mercato/2016-02-23/la-distribuzione-diretta-farmaci-ospedale-fa-risparmiare-ma-puo-coesistere-quella-nome-e-conto-130103.php?uuid=ACHxkMaC.
8. https://www.giustiziaamministrativa.it/cdsintra/cdsintra/AmministrazionePortale/DocumentViewer/index.html?ddocname=UQ52IUWUHVWABNBACZ37PEC3IY&q=.
9. http://www.ansa.it/sito/notizie/cronaca/2017/03/01/consip-arrestato-per-corruzione-alfredo-romeo_80adbeaf-cb97-4f9a-8f09-a379bc38d266.html.
10. http://www.anticorruzione.it/portal/public/classic/AttivitaAutorita/Pubblicazioni/RapportiStudi/_RelazioneFarmaci/.
11. Court Const., November, 25, 2016, n. 251, www.cortecostituzionale.it.
12. AA.VV. Cooperative Principle and system of autonomies: regulations and organic relations activities, http://www.federalismi.it/document/04052006024747.pdf.
13. For a thorough analysis of the reform: Signorelli C, Fara GM, Odone A, Zangrandi A. The reform of the Italian Constitution and its possible impact on public health and the National health service. Health Policy 2017; 121 (1): 90-91. doi.org/10.1016/j.healthpol.2016.10.008

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