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Italy

1. Introduction

1. The Italian Competition Authority (“the Authority” or “the AGCM”) welcomes this opportunity to share its experience and discuss the pros and cons of the various publicly-funded health systems around the world. After an overview of the Italian National Health System (NHS), highlighting the major changes and issues raised by the implementation, this contribution summarizes the areas of advocacy intervention of the Authority.
2. More specifically, this contribution focuses on competition concerns raised by the governance structure of the NHS in terms of integration of the purchasing and provision functions within the same body, the entry requirements for private operators in the market for the supply of health services, the budget allocation mechanisms and remuneration formula for the health services.

2. Organization and regulation of the Italian NHS and its evolution

2.1. The set-up of the Italian NHS

3. The Italian National Health System was created in 1978, and underwent major reforms in 1992, 1999, 2001 and 2012¹.
4. Law No. 833/1978 introduced a health system with **public funding and provision** of health services and **universal health-care coverage** for all residents based in Italy, replacing a system based on multiple social health insurance funds. The main purposes of the reform were to guarantee everyone equal access to uniform levels of care, regardless of income, with a financing scheme based on general taxation.
5. The new health-care system was partly decentralized, with three tiers: national, regional and local administration levels. The central government was responsible for financing, namely defining the criteria for the distribution of funds to the regions, attempting to progressively reduce regional imbalances and distributing funds. Regional health authorities were responsible for local planning according to health objectives specified at the national level, for organizing and managing health-care services and for allocating resources to the third tier of the system, then known as ‘local health units’ (*Unità Sanitarie Locali* – USLs). The USLs were operational agencies responsible for providing services through their own facilities or through contracts with private providers. They were run by management committees elected by assemblies of representatives from local governments. Therefore, the health system introduced by the 1978 reform envisaged an **integrated model**, in which the *function of purchasing health services (demand side) and that one of provision/supply are combined*.

¹ This section is based on the studies published by the European Observatory on Health Systems and Policies. In particular: Ferré F., de Belvis A.G., Valerio L., Longhi S., Lazzari A., Fattore G., Ricciardi W., Maresso A. *Italy: Health System Review. Health Systems in Transition*, 2014, 16(4):1–168, available on (goo.gl/XzhtL8).

6. In terms of **funding**, public hospitals, being fully integrated into the administrative structure of local health units, were financed from the budget given to the local health units by the regional authorities; all hospitals independent from the local health unit but with public status were financed on a fixed budget basis, with the annual budget determined by historical expenditure (while private hospitals were to be financed on a bed-day rate). Health structures received funding equal to the total expenses incurred, without any specific reference to the expenditure induced by the individual items of the financial statements.

7. During the 1980s, the **implementation of the reform** unveiled several issues including jurisdictional conflicts between the different levels of authority, resulting in inconsistent planning, growing accumulation of deficits by the regional governments and insufficient expertise of the health care management. Faced with these problems, the government set out new reforms to the healthcare system with Decrees No. 502/1992 and 517/1993, that combined universal coverage with the addition of new financing mechanisms (e.g., user copayments, payroll taxes).

2.2. The 1992 reform: introduction of patient choice and competition between public and private providers

8. The reform introduced managerial principles, regionalism and a limited scope for competition. First, the 1992 reform introduced **managerial principles** into the NHS. The USLs were thus converted into legal corporations, the Local Health Agencies (“*aziende sanitarie locali*” or ASLs), with more financial and managerial responsibility; major hospitals were assigned the status of public firms (“*aziende ospedaliere*” or AOs); and both ASLs and AOs were directly accountable to their Regions.

9. Second, the 1992 reform **regionalized the NHS**, with the elimination of the role of municipalities and the devolution of powers from the national tier in favour of the regional governments. The latter became responsible for ensuring the “basic benefit package” defined at national level and were given more fiscal and organizational autonomy, although they would have to use their own resources if they were unable to do so due to inefficiencies or if they wanted to provide additional services beyond those specified in the national basic package. The regionalization of the NHS was further promoted by the 2001 constitutional reform that distributed powers to Regions.

10. Third, the 1992 reform also envisaged a **quasi-market model** by introducing two elements, freedom of choice for patients and a degree of competition between providers accredited by the NHS through the entry of private operators, in order to improve efficiency, increase quality of service provided and promote innovation while containing public expenditure. However, the choice of the patients would be still limited to providers accredited with the NHS, offering their services free of charge on the basis of universal coverage and financed through social security contributions and other State resources, in a context of programming and expenditure control exercised by the health authorities.

11. The introduction of a degree of competition and patient choice allowed regional governments to experiment various institutional settings, including a model with the functions of funding, provision and planning were clearly separated like that one implemented in Lombardy Region². Most Regions implemented an integrated *models in*

² Lombardy was the only Region that carried out a complete separated model. Most hospitals were taken out of ASL control and established as independent entities. ASLs purchase services from public and private providers, while the Region has a regulatory role.

which the purchaser-provider split is not clear cut and the regulatory/planning function of the health unit might raise conflict of interests at institutional level.

12. The 1992 reform allowed the entry of private operators in the provision of health services by introducing **entry requirements** which are still in place. First, private operators must seek an *authorization* to the Region where they operate: it is a basic requirement for the exercise of health activities consisting of the possession of the minimum structural, technological and organizational standards established by national legislation. Authorization is required even for activities outside the NHS. Secondly, to be able to provide health care on behalf of the NHS, private operators shall request the *accreditation*, which is a form of public licensing necessary for providing health services on behalf of the NHS. Lastly, Regions and private operators need to make *contracts* specifying types of services, tariff levels, payment methods, quality levels, controls and penalties (*contractual arrangements*). Only in this way private operators become NHS providers and can operate on behalf of the Italian NHS, as authorization and accreditation alone are not enough for that purpose.

13. In terms of **payment systems**, the 1992 reform brought an important innovation, switching from cost-reimbursement mechanisms (bed-day rates and ex-post payments) in the financing of hospital care to prospective payment systems for both inpatient and outpatient procedures. From January 1995, hospitals and outpatient specialist providers were to be reimbursed for services rendered according to nationally predetermined rates³. Regions are free to redefine the rates according to their own standards but must take the national rate as the maximum level.

2.3. The 1999 reform: softening the quasi-market model

14. There were several deviations from the quasi-market market envisaged by the 1992 reform and some Regions made almost no progress during the 1990s in implementing them. To address this and other problems emerged during the 1990s, the government reformed the NHS again in 1999 with the Decree No. 229/1999. Regions became responsible for formulating proposals for the National Health Plan elaborated every three years, which should define the basic benefit package guaranteed to every citizen and outline the main health targets to be pursued during the Plan's time frame. The reform also softened the previous shift to quasi-market model based on competition.

15. Legislative Decree No. 229/1999 introduced **significant changes to the authorization, accreditation and contract procedures**. In order to establish health care structures (i.e., build new facilities or to modify old ones), it was then necessary to obtain one authorization granted by municipalities after agreement with the regional health planning unit, taking into account the demand. This procedure applied also to facilities of private providers not operating on behalf of the NHS (i.e., not financed by the State).

16. The 1999 reform introduced **two additional criteria for regional authorities to grant accreditation**. The first requires regular assessment of the quality of the organizational, managerial and technological infrastructure of health care providers and of the skills and practices of health professionals. The second requires the evaluation of the contribution by each newly accredited provider, taking into consideration existing regional

³ For inpatient care (ordinary and day-hospital treatments), patients are classified according to the diagnosis-related group scheme, whereas for outpatient care, diagnostic services and specialist treatments, reimbursement should be based on fees for services.

health services and the benefit package to be delivered in order to control the entry of new providers into the public health market on the basis of planned need. The 1999 reform, backed by a constitutional reform in 2001, gave Regions the freedom to set their own accreditation criteria and procedures, as long as the basic package benefit was attained.

17. The reform also introduced **more stringent requirements for the contractual arrangements** between ASLs and accredited providers, in terms of volume, quality and remuneration. The 1999 reform, therefore, allowed ASLs to choose their “preferred” accredited providers on a value-for-money basis (that is, through a comparative evaluation of quality and cost). In other words, the legislator abandoned its bottom-up, quasi-market approach, to restore a top-down model, relying on regional planning and public providers while leaving a more marginal role to private providers. As a result of this shift, regional health systems have gradually planned and controlled the services to be offered by each accredited provider by predefining volumes, mix, prices and possibly other features, such as waiting times and quality. At present, contractual arrangements between the ASLs and accredited private providers, vary across Regions and in some Regions are barely present⁴.

18. In terms of **payment systems**, the 1999 reform strengthened the principle of a prospective payment system although there are considerable interregional variations, such as how fees are set and which services are excluded.

2.4. The NHS today: financial control and regional fragmentation

19. Since 2001, a series of measures were introduced to ensure the financial recovery of Regions with large health-care expenditure deficits. They include compulsory **financial recovery plans**, whereby Regions with deficits are forced to comply with specific terms to improve their financial balances within given deadlines. Such Regions are regularly monitored by national government agencies and can be sanctioned if they fail to comply with their recovery plan’s terms⁵.

20. Since the international financial crisis of 2009, government interventions in the NHS have mostly consisted of **cuts to public expenditure**. An example is the significant reduction in the expenditure caps on purchasing medical equipment and services by the NHS. Such measures were strengthened in 2012, with an emphasis on the **identification of standard costs** for all NHS contracts for goods and services purchased by the ASLs. Another revision of the health-care system was made in 2012, with Law No. 189/2012. The reform revised the basic benefit package for the first time since 2001 and introduced, *inter alia*, measures to contain pharmaceutical costs.

⁴ According to a 2010 report of the Ministry of Health, among the 21 regional health systems, only Lazio, Campania, Molise and Lombardy present a rather high level of private providers, with 30% of total hospitalization supplied by private operators. See: Ministero della Salute (2010a). Schede di Dimissione Ospedaliera – SDO Report 2010. [Hospital Discharge Forms – SDO Report 2010]. Roma, Direzione Generale della Comunicazione e delle relazioni istituzionali.

⁵ Sanctions include the possible appointment of a national government-appointed commissioner to temporarily oversee the management of the Region’s health-care system, temporary suspension of the Region’s workforce turnover, as well as mandated (by the central government) tax increases. The details of these conditions have been continually redefined over the years, towards increasing controls and sanctions.

21. Today, the NHS is largely funded through national and regional taxes, supplemented by co-payments for pharmaceuticals and outpatient care. Although most funding is pooled at national level and redistributed to Regions, there is significant regional variation in tax rates as poorer Regions need to increase tax rates more than high-income Regions. In addition, some Regions adopt the **criterion of historical expenditure**, for which the funds are distributed to the structures already accredited by virtue of the volume of services registered in the previous year, without any consideration concerning productivity or efficiency.

22. The role of **voluntary health insurance** (VHI) is marginal as it accounted for 0.9 % of total health expenditure in 2012, with no significant change since 2000⁶. It plays a double role: a complementary role, covering user charges and co-payments required within the NHS, services excluded from the public system or partially covered; a supplementary role, to ensure faster access and/or enhance consumer choice of providers (i.e. intra-moenia services⁷).

23. Over the last decade, it appears that most regional policies have returned to **integration**, namely through the re-attribution of some hospitals to Local Health Agencies, the concentration of purchasing activities in regional or supra-organizational entities and the enlargement of the size of ASLs. In addition, most Regions have strengthened control over their (public) providers. Therefore, after being partly de-integrated, mainly by making hospitals independent of ASLs from the mid-1990s, the Italian NHS might return to its original design, to be again an integrated system.

24. With respect to **quality and performance**, the Italian National Agency for Regional Healthcare Services (AGENAS), set up in 1993 and reorganized in 2018, has the responsibility to monitor quality of care, carry out comparative effectiveness analyses, and give scientific support to regional health departments. In recent years, Italy increased its focus on performance measurement: accredited providers are obliged by law to report different performance indicators, such as waiting times and quality measures, as part of a ‘health services chart’ published nationally. In 2012, the first results of a permanent programme for the evaluation of health-care outcomes were released to the public.

25. The main outstanding issues of the NHS remain regional fragmentation and the need to maintain financial control within regional health systems. While the central government has acted to control total health expenditures (in December 2015, eight regions were placed under financial recovery plans), performance in terms of health protection is

⁶ See: Ferré F, de Belvis AG, Valerio L, Longhi S, Lazzari A, Fattore G, Ricciardi W, Maresso A. *Italy: Health System Review. Health Systems in Transition*, 2014, 16(4):1–168, pag. 61, available at: http://www.euro.who.int/_data/assets/pdf_file/0003/263253/HiT-Italy.pdf

⁷ Since 1999, doctors working in the public sector have been required to choose between public and private practice but with the possibility of working privately within a public hospital (‘intra-moenia’) both in the area of inpatient and outpatient specialist care. Most physicians have chosen to remain in the public sector and opted for intra-moenia practice, i.e., they can offer their services to privately paying patients within NHS facilities as part of their (part-time) private practice. For patients willing to skip waiting lists or choose an individual specialist, care is also available outside statutory coverage through private providers or NHS specialists operating intra-moenia at patient expenses. In such cases (private visits), patients have direct access to the facility without a referral from a GP and pay the total cost without any reimbursement from the NHS.

increasingly governed at regional level, with large variations, mainly but not exclusively, between the northern and southern parts of the country

26. The Italian NHS has also been assessed by the European Commission (EC) under the EU State Aid rules. In a recent case⁸, in addressing the preliminary question as to whether the public hospitals exercise an economic activity when they provide hospital services on behalf of the national health system and can thus be considered as undertakings, the EC has concluded that the Italian NHS is still not economic in nature, confirming the view adopted in a previous case⁹. According to the EC, the 1992 and 1999 reforms, which introduced corporatization, accreditation and freedom of choice of patients, did not change the NHS's guiding principles laid down by the 1978 law, that is universality and solidarity.

3. The advocacy activity of the AGCM

27. The AGCM's advocacy activity in the health sector has focused on different aspects aimed both at fostering competition, facilitating entry wherever possible, and empowering demand, allowing patients the possibility to make efficient choices.

28. More specifically, the Authority's advocacy interventions concerned the following aspects of the Italian NHS: (i) the institutional design of the health organizations; (ii) access for private operators to the market for the provision of health services within and outside the NHS; (iii) the criteria for allocating the NHS's budget to accredited and selected private operators; and (iv) transparency in relation to performance statistics of health structures.

29. In this context, the Authority has used all the toolbox of advocacy instruments, including the provision that empowers it to challenge before Courts administrative acts which restrict competition¹⁰.

⁸ See the EC case: State Aid SA.39913 (2017/NN) – Italy Alleged compensation of public hospitals in Lazio, Letter to the Member State - Published on 14.02.2018, and available at the following link: http://ec.europa.eu/competition/state_aid/cases/271629/271629_1963634_74_4.pdf

⁹ See: Commission Decision 2013/284/EU of 19 December 2012 on State aid SA.20829 (C 26/2010, ex NN 43/2010 (ex CP 71/2006)) Scheme concerning the municipal real estate tax exemption granted to real estate used by non-commercial entities for specific purposes implemented by Italy (OJ 2013 L 166, p. 24), paragraphs 169-170. The decision stated that health care services in Italy are provided on a non-commercial basis if (i) the activities are accredited by the State and performed under a contract or an agreement with the State, the Regions or local authorities; (ii) the activities are part of or complementary to the public national health system, and (iii) the services are provided to users free of charge or for a low fee which covers only a small fraction of the actual cost of the service. In that case, the Commission concluded that the Italian national health system provides universal cover and is based on the principle of solidarity. The Commission also concluded that nonpublic hospitals which fulfill the conditions above did not did not qualify as undertakings.

¹⁰ On the basis of article 21-bis of Law n. 287/90, the AGCM has the power to challenge before Courts any administrative act - by central or local administrations - which restricts competition. It is a two steps process where the Authority, firstly, delivers a reasoned opinion to the concerned administration and, then, should the administration fail to comply within sixty days, AGCM may lodge an appeal before the competent administrative Court within the following thirty days.

3.1. Institutional design of health sector: integration versus separation

30. In its first intervention in 1998, the AGCM addressed the core issue of the institutional design of the health system¹¹. Assessing the effects of the 1992 reform, the Authority noted that the achievement of the objectives of free user choice and price containment was being hindered by Local Health Agencies (ASLs) performing the **dual function of purchaser and provider**. The effect of mixing these two roles was to distort competition and the efficient allocation of public resources. Indeed, in planning their health expenditure, ASLs were induced to use most of their yearly fixed budget to make contracts with their “preferred” (public) providers, through an improper use of the authorization and accreditation process (see next section). As a result, only residual funds were left for other potential providers, typically newly accredited private operators. Therefore, patients choice of the providers, a pillar of the 1992 reform, was unduly restricted.

31. As a **potential remedy**, the AGCM suggested that the service-provider function should be performed by the public or private health structures accredited by the Regions, while the purchasing function, and the power to check and monitor the quality of the services provided by the accredited structures, should fall to ASLs. Lastly, but not least, in the AGCM’s opinion, the planning function should be attributed to the Regions.

3.2. Access and competition for the provision of health services

32. In several advocacy opinions¹², the Authority has dealt with the challenges posed by the revised framework in terms of regulatory barriers to entry into the market for the provision of health services. The AGCM observed that the 1992 reform objectives of creating a level playing field for health-care providers and guaranteeing patients freedom of choice still appeared far from being achieved in a satisfactory manner. This was largely the result of choices made by the Regions, which had made improper use of the authorization-accreditation procedures by applying discretionary criteria in the selection of health-care providers eligible to work for the NHS, with the result of blocking or delaying the entry of newly accredited private hospitals.

33. As for **authorization to build health-care structures** by NHS-funded providers or private providers introduced by the 1999 reform, the Authority outlined the possible anticompetitive effects of authorizations conditional on discretionary evaluations by the health unit/region of the geographic location of the structures and the overall regional health care requirements. It pointed out that this could create a situation where operators

¹¹ See AGCM opinion n. *AS145 - Prestazioni Sanitarie Ospedaliere*, 1998, available at (goo.gl/P5LBCM).

¹² See AGCM opinions n.: *AS175 - Norme per la razionalizzazione del servizio sanitario nazionale* (goo.gl/GDQKhQ); *AS852 - Norme in materia di autorizzazione alla realizzazione di strutture e all’esercizio di attività sanitarie e socio-sanitarie, di accreditamento istituzionale e di accordi contrattuali e riordino della disciplina in materia sanitaria, a norma dell’articolo 1 della legge 23 ottobre 1992, n. 412* (goo.gl/L14P2f); *AS988 - Proposte di riforma concorrenziale ai fini della legge annuale per il mercato e la concorrenza anno 2013* (goo.gl/tE8CB6); *AS1037 - Regione Lazio/Rilascio autorizzazioni all’esercizio e alla realizzazione di strutture sanitarie private* (goo.gl/an2rGx); *AS1368 - Regione Puglia/Parametro di compatibilità per il calcolo del fabbisogno di diagnostica per immagini con grandi macchine* (goo.gl/yqxRJ6).

already holding authorizations were induced to increase the level of service they provided in order to reduce the potential demand, on which the number of authorizations depended, and consequently reduce the opportunities for more efficient operators to enter the sector.

34. This provision appeared to be even less justified when the new entrants provide a service that is not funded by the NHS. As these private operators do not constitute a burden for public finances and can play an important role in the realization of facilities and the operation of health services, such limits to their access are considered harmful of consumer welfare. In the AGCM view, private operators outside the NHS can, indeed, contribute to increase efficiency and the quality of the services provided, with an overall positive effect on the productivity of supply.

35. Similarly, as described in the box 1 below, the Authority has also advised a Region that any denial to authorize private operators, which are active outside to the NHS, to install specific medical equipment, can be considered competition restrictive unless it is justified by imperative reasons of general interest. In the Authority's view, the advocacy value of such intervention goes beyond the particular issue at stake as it is intended to draw the attention of Regions towards any anti-competitive use of the authorization procedure.

Box 1. AGCM Opinion AS1368 – Denied authorization for installation of medical equipment by Puglia Region

In January 2017, the AGCM sent a reasoned opinion pursuant to Article 21-bis of Law n. 287/1990 to the Puglia Region, regarding the latter's refusal to authorize the installation of a diagnostic imaging equipment by a private operator providing services outside the NHS.

This refusal was issued in implementation of the Regional Regulation n. 3/2006, that includes criteria and parameters necessary for the authorization and accreditation of health facilities: it establishes the need for diagnostic devices in relation to the number of inhabitants, but without making distinction whether machines are provided by structures accredited, contracted or merely authorized, as well as charged or not to the NHS.

The Authority stated that the refusal was restrictive of competition, as it introduced a limitation to the supply of health services provided by private operators outside the NHS, that was not justified by any imperative reason of general interest and not proportionate to the objectives pursued, harming the principle of the free choice of the patients.

After having received AGCM's reasoned opinion, the Puglia Region provided a late reply, which was nevertheless considered to be non-resolutive of the competitive problems encountered. Thus, the Authority appealed to the Court of First Instance (TAR) of Bari. In February 2018 the Court of First Instance of Bari decided to uphold the action brought by the ACGM, asserting that the authorization (i) requires only the compliance of the structure with specific sanitary requirements, and (ii) is aimed at ensuring that the health activities are carried out under conditions of full security. Consequently, authorizations should not be subject to quantitative limitations or any other condition that constitute a barrier to entry, in breach of competition principles.

Therefore, the decision of the Puglia Region and a part of the Regional Regulation n. 3/2006 have been annulled.

36. In relation to the **authorization for the provision of services**, the Authority affirmed that it should be based exclusively on objective, non-discriminatory criteria

hinging on the verification of the necessary professional qualifications and the quality standards of the structures and equipment involved.

37. Competition restrictions were also identified in relation to the second step for access to the NHS: the **accreditation process**. Without being accredited, operators cannot enter in contractual arrangements with the local health authorities and cannot, consequently, access public funds. The AGCM pointed out that the accreditation process should rely on objective criteria rather than being conditional on discretionary evaluations which also include the verification of the overall regional health care requirements¹³. In the Authority's view, since accreditation was simply a precondition and not a guarantee of access to the sector, it should be based on evaluations of the efficiency of would-be operators rather than financial compatibility, and should be subject to regular checks that the requirements were still being met. For this purpose, it was vitally important that a National Commission for Accreditation and Quality in the Health Services be created, as envisaged in the 1999 reform. Furthermore, the Authority highlighted that Regions can restrict competition also, and foremost, with their inertia to verify their needs, *de facto* blocking the accreditation process. In this regard, the Authority also advised the government to introduce the obligation for Regions to carry out periodic selections of the NHS providers based on fair, objective and transparent criteria, with a view of rationalizing the network of the accredited operators for health care services.

3.3. Allocation of the NHS budget

38. The AGCM has intervened in several occasions¹⁴ to challenge the sole use of the historical expenditure method by some regions (see box 2 below for an example), which would eliminate any incentive to compete on quality and innovation between the structures already accredited and affiliated with the NHS, thus giving the incumbents an undue competitive advantage. The Authority called for an allocation of the NHS's budget based not only on historical expenditure, which may freeze market positions, but also on criteria inspired to the principles of non-discrimination, maximization of efficiency of the individual health-care structure, as well as on the actual satisfaction of the needs of the demand.

39. Furthermore, the use of historical expenditure was no longer appropriate with the *introduction of standard costs in healthcare (Legislative Decree No. 68/2011), to be implemented starting from the year 2013 through the use of a set of indicators*

¹³ See AGCM opinions n. *ASI45 - Prestazioni Sanitarie Ospedaliere* (goo.gl/P5LBCM); *ASI137 - Proposte di riforma concorrenziale ai fini della legge annuale per il mercato e la concorrenza anno 2014* (goo.gl/1ihN86); *ASI234 - Regione Puglia/Interventi in materia sanitaria* (goo.gl/WnyfZ5); *ASI522 - Regione Basilicata/Accreditamento delle strutture sanitarie* (goo.gl/sG8ymg).

¹⁴ See AGCM opinions n. *ASI137 - Proposte di riforma concorrenziale ai fini della legge annuale per il mercato e la concorrenza anno 2014* (goo.gl/1ihN86); *ASI142 - Distribuzione del tetto di spesa per il triennio 2013/2015 tra le diverse strutture sanitarie private* (goo.gl/CNzgK8); *ASI181 - Regione Calabria/Determinazione dei tetti di spesa per le prestazioni di assistenza specialistica da privato anno 2014* (goo.gl/VjT1Qq); *ASI387 - Regione Sicilia/Determinazione degli aggregati di spesa per l'assistenza specialistica da privato anno 2016* (goo.gl/i5KyeV); *ASI524 - Regione Sicilia/Definizione dei criteri per la determinazione degli aggregati di spesa per l'assistenza specialistica da privato* (goo.gl/rMFN5o); *ASI539 - Regione Basilicata/Definizione dei criteri per la determinazione degli aggregati di spesa per l'assistenza specialistica da privato* (<https://goo.gl/i98xc3>).

that enable the assessment of the levels of efficiency and appropriateness for each Region.

Box 2. AGCM Opinion AS1181 – Budget allocation based on historical expenditure by Calabria Region

In December 2014, the AGCM sent a reasoned opinion pursuant to Article 21-bis of Law n. 287/1990 to the Calabria Region, regarding the content of Decree n. 68/2014 of the Commissioner ad acta, about the "Determination of spending ceilings for private specialist assistance services".

More specifically, the Decree specified that (i) the determination of the spending ceiling and the division of the budget among the assistance structures fall within the regional health planning, which is characterized by a wide discretion and (ii) the setting of limits on spending ceilings is exclusively within the competence of the Regions, in relation to the needs of financial balance and rationalization of public spending. Furthermore, the Decree states that spending ceilings are identified according to the previous year results, assessing whether or not the given budget was achieved.

The Authority has highlighted that the use of the criteria of historical expenditure constitutes a violation of competition principles as it eliminates any incentive to compete between the accredited structures and assigns to companies already affiliated with the NHS an undue competitive advantage.

In fact, most efficient structures cannot be rewarded for the results achieved both in terms of cost containment and demand satisfaction. Moreover, the allocation of the budget on the basis of historical expenditure obstructs access to the market of new facilities, crystallizing market positions.

After having received AGCM's reasoned opinion, the Calabria Region informed the Authority that it considered its intervention legitimate, due to its exclusive competence in planning and defining the spending ceilings. Moreover, according to the Region, the possible crystallization of the market derives from the constraints on public spending and not from the distribution criteria used. Thus, AGCM appealed to the Court of First Instance (TAR) of Catanzaro.

In May 2016, the Court of First Instance of Catanzaro decided to uphold the action brought by the ACGM confirming that (i) the criteria of historical expenditure assigns to companies already contractualized with the NHS an undue competitive advantage, (ii) while planning and defining the spending ceilings, Commissioner ad acta must respect the principles to protect the competition and (iii) constraints on public spending are legitimate, but the criteria of historical expenditure crystalize market players' positions.

Therefore, the Decree n. 68/2014 of the Commissioner ad acta has been annulled.

3.4. Remuneration of health-care services and public procurement by ASLs

40. In its first advocacy intervention¹⁵, the Authority outlined that the prospective payment system introduced by the 1992 reform could potentially generate distortions due to the dual role of the ASLs: as a provider, ASLs had incentives to ask for the maximum rates by qualifying their services as of “exceptional nature” while as a purchaser ASLs were induced to select the most remunerative health services for a given quality.

41. Moreover, the Authority welcomed the introduction, by some Regions, of mechanisms designed to reduce the NHS expenditure and provide incentives for service providers to reduce their costs. These mechanisms included limits on the supply: where the number of services exceeded a pre-set limit, NHS refunds to the providers would only cover a part of the actual price, based on a predefined coefficient. According to the Authority, this type of **mechanisms for cutting fees** are pro-competitive for two reasons: on the one hand, it induces individual providers to reveal the actual price of the services offered; on the other, it implies that health-care structures bearing high costs are induced to limit, or even cancel, their offer, thus diverting the demand towards more efficient health facilities and also allowing the achievement of objectives to contain expenditure.

42. More recently, with a view to containing the expenditure in relation to the **procurement of goods and services** from suppliers, a provision was introduced in 2011 to oblige ASLs to renegotiate prices that are at least above 20% the reference level. However, the Authority advised the government to extend the possibility of price renegotiation also to cases in which prices are below the 20% threshold¹⁶. Furthermore, the Authority has also suggested the introduction of **competitive tender procedures** for the procurement of goods and services purchased by the ASLs. In particular, in relation to the purchasing of medical equipment by the ASLs, the AGCM recommended not only the adoption of competitive tendering procedures but also the set-up of a commission of experts whose task is to define categories grouping similar products so to allow for a broader market participation in the procurement process.

3.5. Patient choice, transparency and performance

43. Since its earliest interventions, the AGCM has called for the need to provide more information to consumers in order to allow them to compare and choose properly among different service providers. Cross region mobility of patients became a feature of the Italian decentralized health system in which performance, quality of care and accreditation policy have varied greatly between Italian Regions, causing a considerable financial impact on regional budgets.

44. In this context, the Authority has advocated for more transparency and access to information and data concerning the performance of health-care providers¹⁷, in order to

¹⁵ See AGCM opinion n. *AS145 - Prestazioni Sanitarie Ospedaliere*, 1998, available at (goo.gl/P5LBCM).

¹⁶ See AGCM opinion n. *AS1137 - Proposte di riforma concorrenziale ai fini della legge annuale per il mercato e la concorrenza anno 2014* (goo.gl/1ihN86)

¹⁷ See AGCM opinions n. *AS988 - Proposte di riforma concorrenziale ai fini della legge annuale per il mercato e la concorrenza anno 2013* (goo.gl/tE8CB6); and *AS1137 - Proposte di riforma*

drive the demand towards the more efficient and innovative operators, fostering quality competition among them. More specifically, the Authority highlighted that, in order to facilitate patient choice (both in terms of structures and doctors), it is necessary to strengthen the yearly programme for the evaluation of health-care outcomes by:

- increasing the information available about the performance of public and private operators, particularly in terms of management's efficiency and quality of the service;
- establishing online databases that ensure the public availability of data on the activity medical and the quality of the service provided (as the number of interventions performed divided by type of intervention, success rate of the interventions, medical and nursing curricula, waiting times for the provision of a service); and,
- defining a common standard for the release of information in order to allow for meaningful use and comparison of such data.

4. *Final remarks*

45. *The Authority's advocacy activity in the health-care sector has accompanied the key stages of the evolution of the NHS in the past two decades.*

46. *The aim of the Authority's interventions has been to ensure that the benefits, in terms of improved efficiency, better quality and increased innovation, of the two elements introduced by the 1992 reform - free choice for patients and competition on the provision of health-care services – could be realized to the greatest extent possible allowed by the institutional setting of the Italian NHS, without undermining its guiding principles of universal service and solidarity. In this context, the Authority, in its advocacy activity, has invited policymakers to promote market transparency on quality and performance and ensure careful monitoring of access conditions.*

concorrenziale ai fini della legge annuale per il mercato e la concorrenza anno 2014 (goo.gl/1ihN86).