RESTRICTED

S/WPDR/W/48/Add.1

30 April 2013

(13-2288) Page: 1/4

Working Party on Domestic Regulation

REGULATORY ISSUES IN SECTORS AND MODES OF SUPPLY

NOTE BY THE SECRETARIAT

Addendum

1 INTRODUCTION

1.1. At its meeting of 21 March 2013, the Working Party on Domestic Regulation requested that the Secretariat prepare a Note on regulatory issues in the health services sector, which would complement the Note on "Regulatory Issues in Sectors and Modes of Supply" circulated by the Secretariat in June 2012 (S/WPDR/W/48, 13 June 2012).

1.2. This Note provides background information on regulatory practices in the health services sector. It should be noted that, contrary to other sectors addressed in the June 2012 Note, health services were not the subject of a Background Note in the Council for Trade in Services. Hence, this Note stands on its own.

1.3. For the purpose of this Note, "health services" are understood to include the services listed under Section 8 of the W/120 ("Health related and social services"), namely hospital services, other human health services and social services. It also covers professional health services listed in section I.A of W/120, namely medical and dental services and services provided by midwives, nurses, physiotherapists and para-medical personnel.

1.4. As with the June 2012 Note, Members are invited to use this Note to bring their own specific experiences or contribute additional regulatory issues to the discussions, as appropriate.

2 HEALTH SERVICES

2.1 General observations

2.1. Each society organizes the provision of health services according to prevailing social preferences, cultural values, institutional characteristics and economic constraints. Some societies attribute a predominant, if not exclusive, role to the public sector, while, other systems rely almost exclusively on private supply. Most systems, however, are somewhere in-between and provide for a combination of both public and private supply. The vast majority of health systems share similar objectives, namely universal access, equitable provision, quality services and efficient use of resources.

2.2. The primary objective of regulation in the health sector is the protection of the patients. The need for governmental intervention is particularly strong given the peculiar professional responsibilities of medical practitioners – arising, e.g., from the right to prescribe treatment and drugs, risks for patients' physical integrity linked to malpractice, confidentiality imperatives, etc. – and the existence of important information asymmetries. The latter refers to the fact that the supplier tends to have better information because it is generally difficult for a patient to assess critical elements such as doctors' competences and the adequacy or quality of treatment provided in a medical facility. Hence, regulation is necessary to ensure that health personnel and facilities comply with certain quality, safety and ethical standards, to name a few.

2.3. Also, an increased offer in health services tends to generate increased demand and costs. What appears to be a market failure arises as a result of a combination of factors, including:

(i) prices are regulated[1], (ii) treatment costs are borne by a third party (e.g., a health insurer), and (iii) capital investment in increasingly sophisticated medical equipment is significant. In this context, suppliers may be tempted to induce oversupply of healthcare, for instance by prescribing treatment which is not strictly necessary. This means that governments may feel compelled to intervene in order to regulate the overall level of supply.

2.4. Furthermore, medical systems are coming under stress in many countries. Ageing populations, a higher incidence of non-communicable diseases[2] requiring long and expensive treatments, as well as patients' increasing expectations are contributing to surging medical costs. The problem is acute in developed countries and has begun to affect low and middle-income countries as well. Against this background, the sustainability of health systems has become an important concern and various measures are put in place to control and contain treatment costs.

2.2 The regulation of health professionals

2.5. The regulation of health professionals aims at ensuring that only properly qualified health professionals can provide their services to the public. Regulatory control takes place mainly before health care providers enter the market. There is, however, an increasing emphasis on continuous medical training and various systems, more or less binding, are being put in place in order to ensure that doctors keep abreast of new developments in medical practice.

2.6. Virtually all countries in the world have a licensing system for medical doctors. Licensing is generally granted after obtaining a medical diploma in a recognized institution (university or medical school). The average length of time for medical studies varies between 5 to 7 years and normally includes compulsory 1 or 2 years practical training in a health facility. Specialist doctors need to undertake additional training requirements (postgraduate studies).

2.7. The responsibility for licensing medical doctors normally lies with institutions reporting to the Ministry of Health or, sometimes, the Ministry of Education. In a number of countries, registration with a professional body is an additional legal requirement before the right to practice is granted. In addition to adequate formal education and professional training, doctors may be asked to bring evidence of being a national of the country, being of good moral standing (e.g. absence of criminal record), and benefitting from satisfactory physical and mental health.

2.8. Professional bodies may play an important role in relation to licensing and registration of medical doctors. They may exercise delegated responsibilities, including the right to suspend or withdraw a licence to practice, for instance in case of serious professional misconduct. Professional bodies may also issue and mandate compliance with codes of conduct, ethical standards, or rules regarding continuous training.

2.9. Licences are normally issued for an indefinite period, but there is a tendency to put in place "re-licensing" systems in order to ensure that practitioners undertake continuous medical training. Under these systems, individual practitioners must justify a certain number of certified activities, such as attending educational programmes or international conferences, lecturing or publishing. Failure to do so may lead to sanctions, including suspension or withdrawal of the licence to practice.

2.10. Virtually all countries have in place legislation addressing the licensing of non-nationals holding foreign qualifications. Applicants are often required to take a special examination and may also be required to carry out a compulsory period of work under supervision in a local health facility. Similar requirements may apply to nationals holding foreign qualifications. Moreover, foreign doctors may need to demonstrate that they are licenced, have a right to practice in their

[1] "The common rationale for government regulation of prices is either equity-based – to ensure affordable services and access to all income groups – or efficiency-based – to control the cost of care and overall health system expenditure." Busse R., N. Hafez-Alfifi and A. Harding, Regulation of Health Services, in Harding A. and A. Preker (eds), "Private Participation in Health Services", World Bank, 2003, p. 256.

[2] Non-communicable (also referred to as "chronic") diseases are not passed from person to person. They are of long duration and generally slow progression. The four main types of non-communicable diseases are cardiovascular diseases (like heart attacks and stroke), cancers, chronic respiratory diseases (such as chronic obstructed pulmonary disease and asthma) and diabetes. They are the leading cause of mortality in the world, representing over 60 % of all deaths. Contrary to common perception, 80 % of chronic diseases deaths occur in low and middle income countries. See http://www.who.int/mediacentre/factsheets/fs355/en/.

country of origin, and have a working permit or provide evidence of residence. Some countries do not have a centralized licensing body, and recognition requirements may thus vary from one regional authority to another. The granting of licences to foreign doctors may be subject to further conditions, such as issuance for a limited period or non-availability of local resident of national with similar qualifications. Additional restrictions often apply to foreign doctors wishing to establish an independent practice.

2.11. Language requirements are common in the health sector as the ability of health practitioners to communicate with patients, professional bodies and public authorities is seen as an essential prerequisite for providing reliable services. Special language examinations are not uncommon.

2.12. The regulation of nursing appears to vary considerably in terms of prescriptiveness and coverage: while some countries have developed detailed standards for obtaining the title of, and the right to practice as a nurse, in other countries regulation of nursing practice is very limited, if not inexistent. Hence, there seem to be important disparities among nurses across the world in terms of education and professional qualifications. In countries where the title of nurse is protected, practitioners need a licence in order to practice as such. Midwifery is often considered a specialty of nursing and, therefore, few countries have specific legislation for midwives.

2.13. Boundaries between nursing and social care are not clear. Social care workers carry out a number of different tasks (e.g. provision of care to older people or to young children), sometimes informal, in different contexts. This is an area which appears to be not well defined and poorly regulated.

2.3 The regulation of health facilities

2.14. Health facilities are generally subject to a mandatory licensing process whose main purpose is to ensure that they deliver quality healthcare and meet certain basic safety requirements. This process entails, inter alia, the screening of inputs (physical infrastructure, personnel, equipment, hygiene, sanitary facilities, food, etc.) in order to ensure that they comply with certain pre-determined standards. The complexity and stringency of licensing standards for health care facilities vary from country to country.

2.15. Health facilities may also seek to obtain accreditation. These standards tend to be voluntary and, contrary to licensing standards, are developed and implemented by non-governmental bodies. They are also based on process-oriented criteria (namely, how is healthcare delivered), rather than structures and inputs. Accreditation aims at informing the public that a given facility meets certain quality standards.

2.16. In addition to quality and safety, licensing may also be used to regulate the capacity of the health system in order to prevent waste of resources or concentration of healthcare in certain areas. In other words, licensing is used to ensure that additional capacity respond to a social need.[3] Hence, many jurisdictions use various measures to control additional capacity, through e.g., limitations on the number of medical establishments or beds, or restrictions on the purchase of heavy medical equipment (e.g. CAT Scan equipment), the type of medical procedures which can be performed in a given facility or the number of staff which may be employed. Criteria for licencing a new facility may take into account indicators such as existing capacity, distance between health facilities and types of medical procedure provided, population size and age structure, as well as transport infrastructure, to name a few.

2.17. Some regulatory measures may also focus on the minimum size of individual hospitals, e.g. by stipulating a minimum number of beds. The operation of health facilities benefits from economies of scale associated with, inter alia, specialized personnel and use of heavy equipment; hence, for a given treatment, the average cost per patient may be lower in a bigger hospital. Minimum size regulation may thus contribute to controlling health costs.

2.18. Capital investment in health facilities is very high and returns on investment tend to be low. Various types of financial incentives exist in the health sector, with the purpose of ensuring

[3] The rationale behind this type of regulation is that, in systems where risks are pooled, society at large ends up paying for additional beds.

universal access health care, in particular to remote or poor areas. Financial incentives include a wide array of instruments, such as government loans at low interest, government guarantees for borrowing on private markets, tax waivers and exemptions, direct government subsidies or bonuses to operate in underserved areas.

2.19. Establishment of health facilities can also be hampered by poor and inadequate regulatory frameworks. Inadequate needs assessments – which may lead to excess supply – and deficient enforcement of quality standards, as well as an overall lack of transparency and predictability in healthcare policy may adversely affect the establishment and viability of new health facilities.

2.20. Regulation may affect patients' choice, e.g. by limiting their options in selecting practitioners or medical establishment, but also by restricting or ruling out reimbursement of treatment undertaken abroad (so-called medical tourism).

2.4 Telemedecine

2.21. Telemedicine transactions can take place between two health practitioners or between a health practitioner and a patient. When these transactions take place cross-border, with suppliers and consumers in different jurisdictions, complex regulatory issues arise.

2.22. First, it is necessary to have guarantees regarding the quality of the service provided and to ensure that safety is maintained. This also raises the issues of verification of licensing and qualifications of practitioners, and liability in case of malpractice. Patient's data and privacy needs to be preserved. Finally, there are questions linked to the reimbursement of costs (will local insurance reimburse health practitioners abroad?) and tax issues. Some governments have started to regulate telemedicine delivered within national borders. However, information regarding regulation of cross-border telemedicine is scarce. Absence of, or uncertainties surrounding, reimbursement is reported to be a barrier to the wider adoption of telemedicine.

2.5 Possible questions for further discussion

2.23. Members may want to consider the following questions:

a. With respect to the regulation of the health services sector, where are the most significant problems from a trade perspective and how might disciplines under VI:4 help to address them?

b. Could it be useful to exchange information on Members' national regulatory practices in the health services sector, or specific segments, and review possible GATS implications?

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MAIN SOURCES USED IN THE PREPARATION OF THIS NOTE

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