Labco

Consultation on healthcare mobility

2007

Labco SAS, 34 boulevard Haussmann , 75009 Paris, France
Labco Diagnostics, 480 avenue Louise, 1050 Brussels, Belgium
Labco Liguria, Via Roma 166, 18038 San Remo, Italy
Labco Deutschland, Lindenallee 59, 50968 Köln, Germany

http://www.labco.fr/

In order to better illustrate the impact and the legal and economic measures to be taken in the context of cross-border healthcare accessibility, we will address the issues from the specific standpoint of our organization: Labco as a network of private clinical laboratory services.

Labco is the largest network of private clinical laboratories in Europe. Our 100 labs are processing over 20 millions samples per year, providing quality lab-test results to over 4 millions patients a year throughout Europe.

Labco has been set-up in 2003 with the following objectives :

- Develop local networks of private clinical labs in Europe.
- Expand the scope of services to patients and healthcare professionals from proximity [1] and emergency to online access to lab test results and diagnostic support services.
- Improve the quality standards of the profession using well recognized processes.
- Facilitate access of patients and physicians to new diagnostic technologies.
- Enhance the economic efficiency of diagnostics services through the promotion of economies of scale

As a major healthcare provider in Europe, we are at the forefront of critical issues pertaining to the future of European healthcare services such as :

- Freedom of goods, services and capital
- Cross border and free access of patients to services

This perspective is particularly relevant for a number of perspectives

1. This is an area of healthcare in Europe which remains extremely fragmented with a very large number of providers (from 2 to 7 / 100,000 laboratories / inhabitants [2] [3] [4]).
2. Progressive adoption of pan European quality standards and the development of new diagnostics and information technologies require significant investments that can only be supported by large scale organisations such as providers networks.
3. Clinical laboratory services remain at the centrefold of diagnostics services. In turn diagnostics is becoming a key area in the decision making process in healthcare: prediction, prevention, positive diagnostics or long term follow-up are definite sources of efficiencies and quality in healthcare.

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[1] Lucas Gabrielli V et al., Les soins de proximité, une exception française ; bulletin d'information en économie de santé, 39, 2001

[2] Labco Research : www.labco.fr

3 Xerfi : Etude des laboratoires d'analyses médicales en France, 2005

4 IGAS : Rapport de l'inspection générale des affaires sociales (IGAS) sur l'organisation de la biologie médicale en France, 15 mai 2006 ; http://www.social.gouv.fr/htm/minister/igas/igas_rappcom.htm

4. Clinical laboratory services, although a modest share (usually < 3%) of total healthcare expenditures [5], represent a source of significant efficiencies in any healthcare system [6 7 8].
5. Finally, clinical lab testing has been fairly standardized in its delivery process as well as in technology, therefore making trans-national utilization particularly relevant.

In addition, the issue of mobility in healthcare is particularly crucial and relevant to laboratory services for the following reasons :

- Cross-border utilization of lab services (delivery of service from the territory of one member state into the territory of another) is already in place thanks to the development of pan European health care providers expanding standardized services over different borders in Europe.
- Similarly, the use of lab services abroad (i.e. a patient moving to a healthcare provider in another member) has recently been identified and inserted into several regulations under the EU pressure [9 10].
- Finally the private sector of laboratory services represent a significant and growing share of the total laboratory services in Europe (60% in France, 40% in Belgium and in Italy, 30% in Spain, <10% in the UK) [11].

In this context, we will address the following questions from the private clinical laboratory testing angle.

[5] Souêtre et al. : Economic evaluation of lab testing : Methodological recommandation, Biologiste Info 2005
[6] Souêtre-E , Designing and performing health-economic studies in the context of guidelines: The research perspective. In Drug-Information-Journal. 30/2; 513-516, 1996
[7] Hernandez J S, Cost effectiveness of Laboratory testing ; Archives of pathology and laboratory medicine 2003, 127(4) : 440-445
[8] Sevenens J L, van der Wilt G J, Economic evaluation of diagnostic tests, A reiview of published studies ; Int J Technol Assess health Care, summer 1999, 15(3) : 480-496
[9] Affaire C 496/01 Commission des Communautés européennes contre la République française (JO C44 du 16.2.2004 p.9) « Manquement d'État - France - Libre prestation des services - Droit d'établissement - Régime des laboratoires d'analyses de biologie médicale - Conditions de délivrance des autorisations administratives de fonctionnement - Siège d'exploitation sur le territoire français »
[10] Coppet M Masseyeff R La directive européenne« Bolkestein » sur les services n'a pas de conséquences pour la biologie médicale française. Biologiste Info 2005, 09
[11] Masseyeff. Ou l 'Europe conduit-elle la biologie Française ? Spectra biologie 2004

Question 1: what is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

Overall, the current impact of cross-border delivery or utilization of clinical laboratory services seems to remain minimal. Being the leader in lab testing in Europe, our own analysis has shown a very marginal activity pertaining to cross border services (1% in volume [12]).

However, we expect cross border delivery and utilization of lab services to increase significantly in the next few years for the following reasons :

- Trans-national organization like ours are likely to emerge in Europe, using economies of scale across countries to increase investments in quality processes, training of professionals, patients information services and new technologies .
- Standardization of services (identical pre analytical and analytical procedures, lab test results delivery) will facilitate offer (i.e. delivery). In that respect, the development of services facilitating protected access of patients and professionals to health care data will bring efficiency and support improvement of quality in healthcare.

Therefore, we can anticipate the potential impact as follows :

1. Although technically feasible, we do not foresee any significant development of cross border delivery by local providers: i.e. Local or national clinical laboratories are not likely to expend their services abroad as such. Disparity and rigidity of national (France, Germany) or regional (Spain, Italy) regulations remain the main obstacle. In addition local and national competition will deter new entrance.
2. However we foresee the expansion of a limited number of “networks” of private laboratories working with a “franchising” model, protecting local and national specificities. A trend towards uniformisation and exchange of services across countries will develop overtime.
3. Assuming that proper standardized information is provided to patients and that quality standards are applied across countries, patients will gradually seek lab testing across countries. However, the relatively “low cost” of those services will make it irrelevant for most ambulatory care services. Therefore, mainly inpatient labs (private clinics or hospitals and public hospitals) will be affected by patients mobility.

1. Financial : Issues on transfer pricing
2. Financial : Ability of healthcare provider to deliver similar healthcare at a different price (e.g.; labs France vs. Spain), issue of cost of production
3. Issue of “choice” of facility : few providers may be overwhelmed by patients demand

Quality : increased expectations, also need for more information (e.g. France vs. Spain or Germany).

[12] Labco research : www.labco.fr

Question 2: what specific legal clarification and what practical information is required by whom (e.g.; authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

1. From the healthcare authorities standpoint, public-health issues must be addressed with proper legal and information processes.

    a. As far as lab testing services are concerned, the standardization of quality processes represents the main facilitator of cross border utilization. Several factors lead to the progressive harmonization of quality standards :
        i. Internationally recognised processes (e.g. ISO) are readily available in healthcare and are widely used by large providers.
        ii. Laboratory equipment and technology is currently provided by a small number of powerful suppliers, leading to a high level of standardisation of technical laboratory equipment throughout Europe.
        iii. However quality comes at a cost that only large networks of providers can afford. Several studies have demonstrated that too small providers can not secure the financing [13] needed to meet international quality standards[14].

    b. Although the CE marking and process does apply to the delivery and marketing of most new lab tests in Europe, some barriers to technology dissemination do remain in place in some member state under the form of specific regulations (e.g. medical utility studies in France). However, the wide exchange of information and the rapid growth of well organized and well financed networks of providers will facilitate the dissemination of new technologies in Europe.

2. Purchasers have now access to pricing information throughout Europe[15]. Although publication of tariffs may remain somehow obscure in several countries in Europe, the standardization of services and the concentrations or suppliers are leading to easier access to economic in formations. The development of larger providers across Europe is facilitating the dissemination of pricing information to purchasers and insurers.

3. Although the market of private lab testing remains fragmented, the emergence of well financed private organizations will facilitate the access to cross border lab testing services. Assuming that national regulations support the proper and independent financing of pan European providers, those will be able to provide high level quality standards and access to new technologies.

[13] Souêtre E, Chassaing S Financement des laboratoires d'analyses médicales, Biologiste Info 12 2003
[14] IGAS, Rapport sur l'organisation de la biologie en France, Parution 15 mai 2006
[15] Souêtre E : Tarifs de biologie médicale en Europe : mode d'emploi, Biologistes Infos, à paraître

4. At the patients level, standardized and readily accessible information remain the main challenge. However the use of web-based solution by large organization is already facilitating cross national utilization [16].

Question 3: which issues (e.g.: clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for the different kinds of cross-border healthcare described in section 2.2 above?

In relation to the provision of lab testing services, several angles must be considered.

1. The country in which services are provided must be responsible for ensuring proper quality of services and easy access to new technologies. Although this is already the case, greater collaboration across countries must be developed.
2. Similarly, providers must be responsible for proper information and for the protection of healthcare data.
3. Countries of origin must be responsible for ensuring proper information related to reimbursement, coverage, and pricing of services.

Question 4: who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patients be ensured?

Providers remain responsible for safety, under the specificities of national regulations.

The standardisation of services (e.g. lab testing), the use of common quality standards (e.g. ISO across Europe) and the development of trans-national healthcare providers are the basis for cross border healthcare utilisation.

Question 5: what action is needed to ensure that treating patients from other Member States is compatible with the provision of a balanced medical and hospital services accessible to all (for example, by means of financial compensation for their treatment in 'receiving' countries)?

1. Standardized Quality policies: member states should recognize and/or adopt quality standards valid throughout Europe.
2. Pricing transparency: member states should require from purchasers and insurers greater transparency related to the price of services.
3. Free access to new technology across Europe. Although the EC marking greatly facilitates pan European adoption of new technologies, further support must be given in terms of listing and reimbursement of those technologies.
4. Flexible regulations [17] pertaining to the development of well financed trans-national providers: remaining barriers to capital flow, to investment and to

[16] e.g. www.labco.fr

ownership of healthcare providers must be lifted in order to support their development.

5. Harmonisation of production expenditures, especially suppliers expenditures : negotiations must be developed with the suppliers (in vitro diagnostic industry) to practice price convergence and avoid parallel import of products and services.

Question 6: are there further issues to be addressed in the specific context of health services regarding movement of health professionals or establishment of healthcare providers not already addressed by Community legislation?

EU provisions must accelerate the harmonisation of professionals training and trans national diploma recognition.

Similarly, incentives, including at the provider level, must be developed to facilitate the cross-fertilisation of services and organisation through free movement of professionals.

Question 7: are there other issues where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other Member States – such as healthcare providers and social security institutions – suggest in order to facilitate cross-border healthcare?

1. In order to equalize opportunities of economies of scale and of proper investment in quality and technology, national and EU bodies must improve regulations that will facilitate the flexible financing of private (or public) trans national healthcare providers.
2. This flexibility (ownership, access to financing, legal structure) is the basis of rapid growth leading to critical mass and potential economies of scale

Question 8: in what ways should European action help support the health systems of the Member States and the different actors within them? Are there areas not identified above?

The EU action should be concentrated on helping (or pushing) member state to adopt legislation promoting the development and proper financing of networks of providers (private hospitals, diagnostic centres, clinical centres, pharmacies, …). The decisions of the Commission [18] [19] [20] [21] definitely support this approach.

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[17] Souêtre et al. Analyse comparative des réglementations européennes en matière de biologie médicale, Biologistes Info à paraître

[18] EC, Belgium IP/02/1095, 2002

[19] Avis motivé envoyé à la France par la Commission Européenne : IP/06/505 ; Libre prestation de services et liberté d'établissement : procédures d'infraction à l'encontre de la France et des Pays-Bas

[20] Avis motivé envoyé au Portugal par la Commission Européenne, Direction du Marché intérieur : Mise en demeure concernant les laboratoires d'analyses médicales au Portugal Date : 03/7/2002

[21] Avis motivé envoyé à l'Italie par la Commission Européenne, Direction du Marché intérieur : procédures d'infraction concernant les pharmacies en Italie Référence : IP/05/1665 Date : 21/12/2005

Question 9: what tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through Community legislation and what through non-legislative means?

- Broader acceptance of pan European quality standards in healthcare
- More detailed information systems pertaining to pricing of healthcare services
- On line tools pertaining to healthcare information, access to healthcare providers, pricing and access to protected personal healthcare data.
- Strong incentives for prospective evaluation of both quality and economic efficiency of healthcare delivery (particularly crucial in diagnostics) [22]

[22] Hernandez J S, Cost effectiveness of Laboratory testing ; Archives of pathology and laboratory medicine 2003, 127(4) : 440-445