

DRAFT

Government Affairs Project
May 2016

Foreword

The client expressed its interest in engaging in a Government Affairs (GA) activity at the regional level, in support of its business expansion plans throughout Italy.

In a preliminary meeting with Telos A&S, 3 Regions were identified as priority targets:

- Toscana
- Lazio
- Puglia.

This paper contains Telos A&S proposal for a Government Affairs activity to be undertaken *vis-à-vis* the identified Regions.

Background

As a general principle, dental care is **not** included in the range of “*Basic Levels of Assistance*” (*Livelli Essenziali di Assistenza*), i.e. services that are offered to patients by the National Healthcare Service (NHS). Therefore, private clinics do not enter any agreement with the NHS in order for the treatments they provide to be reimbursed by the latter (what in the Italian system is called “*accreditamento*”).

However, like the establishment of any private clinic providing healthcare services to patients, the establishment of dental clinics is subject to an **authorisation process**, which is foreseen by the national legislation (Law n. 502/1992, as amended by the Law n. 229/1999) but is regulated and managed at the regional and local level.

The basic principle inspiring the authorisation regime is that **the establishment of a private clinic/ambulatory shall be subject to an assessment by the relevant Region of whether or not the new clinic/ambulatory fits the “healthcare needs” of the relevant area**. The issuance of an authorisation by the relevant Municipality is conditional upon the positive outcome of such an assessment by the competent regional department. This principle is applied across the country.

Although each of the 21 Italian Regions/Autonomous Provinces has a rather wide margin of discretion, the distribution of powers within each Region in **regulating the authorisation regime** typically works as follows:

- A Regional Law (*Legge regionale*) sets the terms of the authorisation procedure, applying to all new clinics
- A Regional implementing act (typically a *Delibera della Giunta Regionale*) lays down the specific structural, operational and technological standards applying to dental clinics.

The actual **authorisation process** can be summarised as follows:

- The request for authorisation of any new dental clinic shall be submitted to the relevant **Municipality** (*Comune*)
- The Municipality submits every authorisation request to the **Regional Government**, which is in charge of assessing whether or not the establishment of a new dental clinic in the regional territory fits with the “healthcare needs” of the relevant area/areas (according to the general principle laid down by the national law). A bureaucratic unit

within the Regional healthcare Directorate General is typically in charge of the assessment and the consequent adoption of the opinion

- The Municipality is also in charge of assessing whether or not the new clinic complies with the regional structural, operational and technological requirements. In the performance of this task, the Municipality may cooperate with the Local Healthcare Unit (*Azienda Unità Sanitaria Locale – AUSL*)

The process we have briefly summarised is in place in all the three Regions of priority interest for the client.

Two reasons that may help explain the unusual length and complexity of the authorisation process in Lazio are the following:

1. The regional law provides for **no compelling deadlines**, both for the Region to issue its opinion and for the Municipality to either grant or reject the authorisation
2. Until a recent reform of authorisation requirements (September 2015), the Lazio Region had a complex authorisation process in force not only for dental clinics/ambulatories, but also for private practices (*studi dentistici*).

Government Affairs activity

Rationale and objectives

Against this backdrop, Telos A&S deems that a Government Affairs activity at the regional level would allow the client to:

- a) **Engage with Regional Governments** in order to make them aware of the client's plans to expand its business in the relevant areas and of the potential benefits in terms of quality, accessibility and affordability of dental care as well as in terms of employment of healthcare professionals.
- b) **Open an early dialogue with the relevant Region prior to submitting authorisation requests for individual clinics:** this would considerably help make the authorisation process smoother and mitigate the risk of authorisation requests rejection, because:
 - Regional officials would be aware of the client's plans before they are asked by relevant Municipalities to assess whether or not those plans fit with healthcare needs
 - the Region would be engaged by the client at a higher level than the competent bureaucratic unit
- c) *Possibly* ask the Regional interlocutors to **facilitate a preliminary dialogue with the Authorities in charge of assessing compliance with the structural, operational and technological requirements** (typically the Local Healthcare Unit, AUSL). In this case as well, opening an early dialogue would then make any *ex post* control smoother and less risky
- d) *Possibly* engage with the Region on the need for **changes in the regional regulation** which disciplines the authorisation process or for a **revision of requirements**.

Proposed strategic approach

Telos A&S agrees that the best approach is that of prioritising a relatively small number of Regions (2-3) in a single year, and gradually widen the scope of the GA activity to further Regions as the client's business expands throughout the country.

Telos A&S would also suggest that every Region should be engaged at the highest possible technical level – i.e. not the competent officer in charge of clinics authorisation, but the Head of the competent Unit if not the Director General.

Other possible activities

Improving the client's positioning towards influential stakeholders is another major goal to be pursued as the company expands its business throughout the country.

Relations with the professional Association of dentists are of course of primary interest and may involve engaging on sensitive topics such as **advertising**, on which the stance taken by ANDI and reflected in the Association's code of conduct has been challenged by the Italian Competition Authority in recent years.

Telos A&S agrees that the best way for the client to proceed to improve relations with the professional Association is to engage with individual high-profile members of the Association, having either a national or a regional standing. While this activity is, strictly speaking, out of the scope of the GA plan, Telos A&S can provide the client with its strategic advice on how to manage its relations with relevant stakeholders, including the professional Association.

Outline of the activities

GA - Preliminary phase

This phase includes:

- Telos A&S and the client to **exchange any relevant information/documentation** that may be of interest with a view to planning and implementing the Regional GA activity
- Telos A&S to carry out an **analysis of the regulatory framework** concerning authorisation of dental clinics in the three Regions concerned (Toscana, Lazio, Puglia)
- Telos A&S to draft a **GA Plan**, describing the suggested PA strategy for each of the three Regions concerned, with regard to:
 - Decision-makers whom the client should engage with
 - Main topics to be covered in the meetings
 - Team for the meeting
 - Expected timeframe of the activity.
- Telos A&S and the client to align on the GA Plan and refine it.

GA - Implementation phase

Upon alignment on the PA plan, Telos A&S will:

- Send the letters of request for a meeting with the relevant decision-makers in each of the three Regions concerned
- Prepare any briefing documentation for engagement with the decision-makers, basing on the data and analysis provided by/agreed with the client

- Organise the contact programme: this includes arranging meeting schedule, supporting at the meetings, drafting minutes and advising on next steps
- Carry out any follow-up activity that may be appropriate
- Whenever appropriate, refocus the strategy according to the outcomes of the meetings.

Strategic Advice

Beyond the GA activity at the regional level, Telos A&S will also provide the client with strategic advice on:

- The management of the company's relations with the professional Association of dentists and/or any other major stakeholder
- Any external communication activity that may be appropriate, in order to ensure that the messages conveyed are in line with the purpose and the state of play of the GA strategy.

DRAFT