

The use of botulinum toxin for medical-aesthetic purposes in dentistry: a comparative medico-legal approach in the context of the European Union

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Abstract

In the last few years, the interest of dentists in aesthetic treatments has grown considerably. For this reason, many European Union Country (E.U. Countries) have regulated the competences of dentists in the field of aesthetic medicine. One of the most common therapies in this field is represented by the injection of botulinum toxin type A (BTX-A). This study has analyzed the regulatory measures on the BTX-A administration adopted by all the E.U. member States. The search found the presence of a very varied regulatory framework and the need for convergence measures between legislations. In fact, the harmonization of dental competences is one of the pillars of the freedom to provide services under Directive 2005/36/EC. The prevision of common competences is functional not only to allow the professionals movement among the E.U. Member States, but also to guarantee the health of patients and avoid market distortions.

Keywords: botulinum, toxin; dentistry; litigation

Introduction

In recent years, numerous studies have demonstrated the efficacy of BTX-A in the treatment of dental pathologies such as bruxism, temporomandibular disorders (TMD), hemifacial spasm and gummy smile [1] [2] [3] [4].

BTX-A is also able to reduce facial expression lines. In fact, medicines based on BTX-A have been authorized by the EMA (European Medicines Agency) for canthal and forehead wrinkles treatment [5]. BTX-A is also successfully administered to temporarily smooth perioral wrinkles in off-label mode.

The efficacy of BTX-A in both dental and perioral area aesthetic treatments has raised the question if this drug can be legitimately administered by dentists. This issue is particularly important within the context of E.U. Countries because the dentistry field is subject to common rules. In fact, Directive 2005/36/EC has defined a homogeneous context of professional competences to allow the free movement of dentists and the mutual recognition of qualifications [6].

The aim of this study is to highlight the existence of a diversified framework of competences in the administration of BTX-A among E.U. member Countries. The study also revealed that the anatomical fields of dentistry present significant differences between States and the need to provide for a unification of the rules.

Method

This study has taken into account the BTX-A regulation for aesthetic purposes in the 27 E.U. member States. Only the regulations adopted by Institutional Bodies were considered significant results of the research. The selection of regulatory sources has followed hierarchical criteria. The search has privileged the acts of primary rank (State laws or equivalent acts, judgment of the Ordinary Judicial Authority). Failing that, steps were taken first to seek measures adopted by the competent Ministries and Regulatory Agencies (secondary rank). Only if the search of primary and secondary rank acts failed were considered the acts of Dentists/Medical professional Orders.

The conflicts between the normative sources of the same State have been solved with the application of the following criteria: hierarchical (the higher-level source prevails), chronological (if the sources have the same level, the more recent prevails), specialty (between sources of the same level, the one prevails special over the general one).

The issue of the anatomical boundaries of the dentists' competence in BTX-A administration was also analyzed. In absence of indication in the regulatory sources, the BTX-A administration was considered legitimate at least on the tissues covering the jaws (art. 5 of Council Directive 78/687/EEC of 25 July 1978) [7]. The search for

Table I. Summary table on BTX-A regulation for aesthetic reasons in the dentistry field within the E.U.

E.U. Countries	BTX-A Administration for Aesthetic purpose	Anatomical boundary
Austria	Not allowed	
Belgium	Not allowed	
Bulgaria	Not allowed	
Croatia	Allowed	Mouth and jaw, including associated tissue (Directive 78/687/CEE)
Cyprus	No normative restrictions ---> Allowed	Mouth and jaw, including associated tissue (Directive 78/687/CEE)
Denmark	Allowed (only if delegated by a MD)	No restriction
Estonia	Allowed	Mouth and jaw, including associated tissue (Directive 78/687/CEE)
France	Not Allowed	Lips Red vermillion
Germany	Allowed	
Greece	Allowed	Mouth and jaw, including associated Tissue (Directive 78/687/CEE)
Hungary	Not Allowed	
Ireland	Allowed	Mouth and jaw, including associated tissue (Directive 78/687/CEE)
Italy	Not Allowed	
Latvia	Not Allowed	
Lithuania	Not Allowed	
Luxembourg	Allowed	Mouth and jaw, including associated tissue (Directive 78/687/CEE)
Malta	Allowed	Mouth and jaw, including associated tissue (Directive 78/687/CEE)
Netherland	Allowed	Head and neck dermal cover tissue
Poland	Allowed	Craniofacial district
Pourtugal	Allowed	Dermal tissues covering the face
Republic of Czechoslovakia	Allowed	Head and neck dermal cover tissue
Romania	Allowed	Mouth and jaw, including associated tissue
Spain	Not Allowed	
Slovakia	No normative restrictions (de facto allowed)	
Slovenia	No normative restrictions (de facto allowed)	
Sweden	Allowed (only with oral and maxillo-facial specialization degree)	Mouth and jaw, including associated tissue

regulatory sources was conducted with the Google® search engine. The laws were retrieved from the official databases of the Governments of the E.U. Member States. The administrative authorities measures were retrieved from the institutional internet portals (Ministries, Regulatory Authorities, Professional Associations). The translation of the documents from the official language into Italian was carried out with the aid of the Google® “Translator” function.

Results

Significant results were found in 24 E.U. Member States out of the total of 27 (which corresponds to an average of 89%). Only in 3 cases (Cyprus, Slovenia and Slovakia) it was not possible to find institutional normative sources. In these States there are “de facto” no restrictions on BTX-A administration in dentistry. In 5 cases the BTX-A administration was regulated by law, act equivalent to the law and judgment of the judicial authority (Belgium, France, Germany, Poland and Sweden). However, only in Belgium has been adopted a proper law on aesthetic medicine and BTX-A administration [8]. In Germany and Poland, the BTX-A administration has been regulated by judicial authority with a judgment [9] [10] [11]. In France and Sweden, the legal framework on BTX-A administration has been reconstructed on the basis of health care laws [12] [13]. In 14 cases the issue on the legitimacy of BTX-A administration has been addressed by the Health Authorities (Austria [14], Bulgaria [15], Croatia [16], Denmark [17], Estonia [18], Finland [19], Hungary [20], Italy [21] [22] [23], Latvia [24], Lithuania [25], Luxembourg [26], the Netherlands [27], the Czechoslovak Republic [28] and Spain [29]). In all cases, except Italy and Spain, the field of aesthetic medicine and BTX-A administration was regulated by the Ministries of Health of each State. In 7 cases the legitimacy of BTX-A administration in dentistry has been addressed by the Orders of Dentists. In the Netherlands, Poland and Czech Republic, the Orders of Dentists intervened to supplement the ministerial legislation. In Greece [30], Ireland [31], Portugal [32] and Romania [33] the acts adopted by the Orders of Dentists are the only source of legislation (Table 2).

The study showed that the BTX-A administration for aesthetic purposes is legitimate in 18 E.U. Member States out of a total of 27 (equal to an average of 67%). In 15 States has been provided an express authorization for the aesthetic BTX-A administration in dentistry. In the remaining 3 States (Cyprus, Slovenia and Slovakia) the BTX-A administration is allowed due to lack of explicit prohibitions. In fact, explicit bans are provided only by 9 Countries (Austria, Belgium, Bulgaria, France, Hungary, Italy, Latvia, Lithuania and Spain) (Table 1).

Discussion

The results of the analysis on BTX-A regulation have highlighted numerous differences between the E.U. States. In about 2/3 thirds of the E.U. States, dentists are authorized to BTX-A administration for aesthetic treatments. Only in 9 States have been provided an explicit prohibition. Moreover, in Belgium, Bulgaria, France,

Lithuania, and Hungary the generic title of Medical Doctor is not sufficient to administer BTX-A for aesthetic purpose: in these States specialization in dermatology or plastic surgery is necessary (maxillofacial surgeons and ophthalmologists are also authorized in France). Differences were also found among the States that license dentists to administer BTX-A. In fact, In Czech Republic and Sweden, only dentists specializing in oral and maxillofacial surgery are authorized to administer BTX-A. In Croatia, Ireland, Holland, Poland, the Czech Republic and Romania, dentists can administer BTX-A only if they demonstrate specific training (in the Czech Republic, no further training is required only for dentists specializing in oral and maxillofacial surgery). In conclusion, in 7 States out of a total of 18, the title of dentist alone is not sufficient for the administration of BTX-A as further training/specialization is required (corresponding to an average of 38%). In Denmark, dentists can administer BTX-A only on the recommendation of a Medical Doctor specialized in dermatology/plastic surgery or trained in the use of the drug.

From the analysis of the normative sources, differences also emerged in the dentistry anatomical areas of competence.

In Croatia, Cyprus, Estonia, Finland, Greece, Ireland, Luxembourg, Malta, Romania, Slovenia, Slovakia and Sweden, the administration of BTX-A is authorized at least within the anatomical boundaries established by Directive 78/687/EEC (Mouth and jaw, including associated tissue). In fact, in these States the authorization for BTX-A administration do not indicate the anatomical limits. For this reason, at least the anatomical limits recognized by Directive 78/687/EEC were considered included.

In Germany, on the other hand, the anatomical boundaries have been defined in a very limited way (red vermillion of the lips). In Czech Republic, The Netherlands, Poland and Portugal the dentistry field of operation in BTX-A administration is much wider instead. In fact, in Czech Republic and in The Netherlands Dentists can administer BTX-A to the covering tissues of the head and neck. In Poland, the authorization concerns the entire craniofacial area while in Portugal the administration of BTX-A is authorized on tissues of the whole face.

In conclusion, this analysis shows notable differences in the extent of the anatomical boundaries of dental competences in BTX-A administration. In fact, the dental competence goes from the minimal borders of Germany (tissues associated with labial vermillion) to the very extensive ones of Holland, Czech Republic, Poland and Portugal (the entire head and neck district). However, in the majority of cases (12 out of 18 States, equal to an average of 67%) it was found that the administration of BTX-A is legally performed within the anatomical contexts of dental competence provided by Directive 78/687/EEC (Mouth and jaw, including associated tissue).

Conclusions

This study has highlighted the presence of an inhomogeneous framework of competences with respect to the BTX-A administration for medical-aesthetic reasons within the E.U. On the other hand, the correct functioning of the principle of free movement of professionals requires common competences. An intervention by the

Table2. Summary table on normative source on BTX-A administration in dentistry for aesthetic purpose within the E.U.

	Normative source on BTX-A administration in dentistry for aesthetic purpose					
E.U. Countries	Law on Aesthetic medicine	Systematic interpretation of health laws	Judgments of the judicial authority	Measures of the National Health Authorities	Measures of the Order of dentists	No regulation
Austria				X		
Belgium	X					
Bulgaria				X		
Croatia				X		
Cyprus						X
Denmark				X		
Estonia				X		
Finland				X		
France		X		X (National Medicaments Agency)		
Germany			X			
Greece					X	
Hungary				X		
Ireland					X	
Italy				X (National Medicaments Agency)		
Latvia						
Lithuania						
Luxembourg						X
Malta						
Netherland					X	
Poland					X	
Pourtugal					X	
Republic of Czechoslovakia				X	X	
Romania					X	
Spain				X (National Medicaments Agency)		
Slovakia						X
Slovenia						X
Sweden		X				

proper Institutions would therefore be appropriate not only to avoid market distortions, but also to prevent dangers to the health and safety of patients/consumers. The use of the BTX-A in the dental field is in fact becoming more and more common and accepted by the scientific community. However, BTX-A is a drug that is not without risks and side effects. If the competent Institution wanted to include BTX-A in the field of dentistry, it will be also necessary to provide adequate training for the operators. An acceptable solution might be to expand university dentistry curricula or provide mandatory post-graduate training. This kind of solution would also comply with articles 21, paragraph 6 and 36, paragraph 2 of Directive 2005/36/EC which provide that the dentist's competences and his university training can be expanded and modified to adapt them to scientific and technical progress.

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