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Investigating the EU Legal Context for Teleradiology

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During a presentation at the Portoroz eHealth Meeting, Jean Bergevin (Head of DG Internal Market and Services) addressed a number of important questions regarding the legal context for the provisions laid out by the European Community eCommerce Directive which governs teleradiology. In an interview with IMAGING Management, Mr. Bergevin made a compelling argument for the merit of the Directive. Here, we provide an overview of the pertinent issues.

There is growing concern that the EU cannot regulate teleradiology services provided to clients from service providers operating from outside the EU. This impacts greatly on legalities involved in utilising services offered by the fast-developing global teleradiology market.

According to Mr. Bergevin and other legal experts involved in the creation of the Directive, teleradiology transactions between parties within the EU are explicitly governed by Directive 2000/31/EC on electronic commerce, which stipulates that any conflicts that may arise in unsatisfactory service provision are subject to the law that governs the source country.

Mr. Bergevin acknowledges that EU legislation does not apply to situations in which the teleradiology provider is located outside of the EU's legal jurisdiction. In that case, only bilateral agreements between the EU and said country apply; which raises significant questions about how the EU can possibly cover all eventualities that may arise in the provision of teleradiology services. Where does this leave the patients whose radiologists are sending images for reporting to India, if a breach of confidentiality occurs or a case is misreported?

Key Points from the Directive

The Directive sheds light on how cross-border e-commerce transactions should be carried out. According to the Directive, it is necessary that both sides be clear on the technical steps to achieve a contract. The service provider should also register the contract and make explicit how it will be accessible to the other party, as well as how to correct input errors in the contract. Finally, it is imperative that the language of the contract be completely clear. In other words, confirmation of the contract is an obligatory step, making the contract safe.

Another issue addressed by Mr. Bergevin is the ethical integrity of radiology advertising. Given a lack of harmonisation within the EU, ethical requirements remain primarily at the hands of individual societies. Therefore regulations of what professionals can communicate about their services are very old and limited, which harms competition.

It is suggested therefore that radiologists develop a European code of practice for advertising. This code should delineate how advertising of radiology services is regulated and by whom, alleviating this dilemma.

Remaining Complications

A question remains: What if the provider is outside the EU but has offices within the EU that handles administrative matters but not the reading of reports? Will EU Directive 2000/31/EC apply in this case? Or, are there other provisions thinkable about how this teleradiology provider would be seen as a party residing within the EU?

Says Mr Bergevin: "Community law here specifically governs an "establishment", a particular legal term that governs where the centre of economic activity is. A subsidiary company can be considered as an establishment, though this cannot be a mere postal address. Legally and logically, once there is an economic activity in the EU promoting the service – then it falls under that directive for the specific services which it offers."

The point being, the service must be offered within the EU in order to qualify. He continues, "If the radiologist sends his reports to the subsidiary office in the EU, which then subcontracts to the outside EU country, and the

EU centre has trained radiologists, then this would fall under the scope of the Directive. The EU office would then be responsible for enforcement of the Directive, which means that they could go to court if necessary.

"Finally, in the case where the EU-based subsidiary company advertises teleradiology services online from an operation that resides legally outside of the EU, this is an 'information society service' called online advertising. That is subject to the Directive. However, only the advertising is subject to Directive in this case."

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