

Champagne, anyone? EC adoption of the Communication moves one step closer to bringing rare diseases out of the shadows



The news was reported as far away as [China](#). The European Commission on 11 November adopted a Communication and a proposal for a Council Recommendation on rare diseases that delineate a strategy supporting Member States in diagnosing, treating and caring for citizens with rare diseases. Rare diseases are perhaps the textbook example of the necessity to collaborate at the European level in order to maximise resources and expertise to address a common cause. In an official press release, European Commissioner for Health Androulla Vassiliou remarked that working together at the European level will "...bring patients with rare diseases out of the shadows. Expertise on rare diseases is fragmented across the Union. Even the very existence of some of these diseases is not fully recognised. That means that too many patients spend years of uncertainty before their conditions are correctly diagnosed and treated". The Communication lays out a Community strategy for action in three key areas: improving recognition and visibility; supporting Member State national plans for rare diseases; and strengthening EU-level cooperation and coordination in the field.

The long and winding road

The adoption of the Communication and a proposal for a Council Recommendation on rare diseases is being celebrated as one of many hurdles successfully cleared on the path leading to a cohesive harmonised approach to rare diseases across Europe. It has been a long journey, beginning with the original penning of the future Communication on European Action in the Field of Rare Diseases, entitled *Rare Diseases: Europe's Challenges*, drafted by the European Commission in close collaboration with the Rare Disease Task Force between June and October 2007. The document opened for public consultation in mid-November. Readers may recall that the public consultation to the Communication garnered an unprecedented number of responses: Almost 600 contributions were received from 15 MS during the three-month consultation period, outdistancing the previous contender for most responses by over 400 comments. (The average number of responses to a consultation is 60). This overwhelming reaction was taken as a sign of proof of the pertinence of the Consultation on Rare Diseases and the desire across Europe to see its provisions implemented in the near future. The comments received were consulted and the document was adapted accordingly. Next, the Communication was subject to an impact assessment that studied the political and financial consequences, amongst other considerations, between March and June 2008. It then went for an inter-service consultation from July 2008 through October 2008 involving DG Enterprise, DG Research, DG Information and Society, DG Budget, DG Employment, DG Relex, DG Market and the legal service of the European Commission. Finally, on 11 November 2008, the Communication on rare diseases was adopted via oral procedure, by the college of Commissioners, along with a proposal for a European Council Recommendation on a European action in the field of rare diseases.

But it ain't over 'til it's over

The two documents are now available on the Commission [website](#) in the 23 EU languages. They have already been officially transmitted to the Parliament, the Council, the European Economic and Social Committee and the Committee of Regions. The first discussions will take place on 27 November at a Council working party. The upcoming meeting of the Employment, Social Policy, Health and Consumer Affairs Council under the French EU Presidency (15 and 16 December) has given the rare disease texts priority status on the agenda, demonstrative of the commitment of the French presidency to keep the process moving forward. The meeting of the Council of Ministers for adoption of the documents is scheduled for 9 June 2009, under the Czech Presidency, providing that the Parliament has already expressed its opinion (which is not mandatory but is desirable). The possibility exists that the Parliament will not deliver on time. With the upcoming elections taking place in June, most parliament members will be busy campaigning. If the documents are not adopted in June 2009 they will have to be submitted to the Council under the Swedish Presidency, most likely in November 2009.

The RDTF weighs in

At the annual European Commission's [Rare Disease Task Force](#) meeting earlier in the month, the significance of the proposal adoption was reviewed. Despite overall satisfaction that the process is moving forward, discussions arose over certain key elements of the initial text that were removed from the final version. RDTF members expressed their disappointment and concern that the proposal for a public-private partnership in the field of R&D for rare diseases was removed. They also deeply regret that the proposal for a scientific assessment, at EMEA level, of the medical added-value of each orphan drug was deleted. The explanation given revealed that the decision was based on a misunderstanding. Despite the overall joy that adoption of the Communication elicits, it is difficult to understand and accept the absence of this crucial proposal that would do so much to ensure timely access to orphan medicines across Europe.

RDTF members will be lobbying their national MEPs sitting on the Committee in charge in order to press forward action. RDTF members will also establish contact with the two key persons responsible for the Communication adoption at the Council level: the national representative at the European Commission and the individual in charge of commenting on the document at the national ministry of health level.