(iii) The first MA for the ATOZET, the combination of ezetimibe and atorvastatin, in the Community was that issued by France on 12 September 2015, two days after the end of procedure communication had been issued by the RMS, and one day before the patent expired in the UK. Thus the duration of any SPC in the UK (which is calculated using Article 13 of the SPC Regulation) will be calculated using this MA which was granted before expiry of the SPC. It is sufficient to know that an MA will be granted in the UK, it is not so important to know when it will be granted in the UK because it is not relevant for the purpose of working out the duration of the SPC.

(iv) The procedure for approval of this application was conducted in English and thus all the documents which the RMS approved and recommended to the CMS in the *End of Procedure Communication of Approval* were all in English. Thus there is no need for a translation of documents to be submitted in the national step, as recommended by the flowchart and related guidance, thus there is noting that can happen, in UK (at least), to prevent the mutually agreed SmPC, PIL and package label sent by the RMS with the '*End of Procedure Communication of Approval*', dated 10 September 2014, from being used directly in the granted UK MA. These mutually agreed documents were sent to MHRA (the NCA representing UK as CMS) before expiry of the patent and before the application for the SPC was made. The applicant suggested that all the MHRA had to do was basically make a copy of these documents and include them with the UK grant certificate.

82 It is the case that there will always be differences between when MAs are granted in each MS which reflects the different ways that the government of each MS chooses to deliver this function in their national administration. The SPC regulation recognises this and provides, for example, under Article 13 that account is taken of when the first MA in the European community was granted to work out the duration of the SPC. The SPC regulation also recognises that MS may chose to implement it only in relation to Article 3(a) and 3(b) – see Article 10(5) of the SPC Regulation. However, it appears to me the impact of the approach being proposed by the applicant is that all the MAs would be deemed to take effect from the end of procedure approval step – this would be the same date in all MS. However, this fails to take account of the fact that each country has to grant the MA in a manner that takes legal effect in their country and has a date of legal effect that can be determined.

83 If the applicant can supplement the application in the way they propose what they are saying is that *de facto* the MA application is effective from the date of the end of procedure approval email from the RMS but that until the MA is actually granted in the Member State concerned by its NCA then it does not actually have legal effect. I find this comparison between when something is approved and when something can have legal effect to be an interesting one. The CJEU has recently ruled in *Seattle Genetics, C-471/14,* that the date when a Marketing Authorisation issued by the EMA takes effect is not when the decision is approved but rather when the holder of the marketing authorisation can actually put the product on the market based on the centralised MA issued by the European Commission, i.e. the date the holder