EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 October 2016
EMA/PRAC/196120/2016 Rev.3

Timetable for the procedure

Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data

Daklinza (daclatasvir)	EMEA/H/A-20/1438/C/3768/0016
Exviera (dasabuvir)	EMEA/H/A-20/1438/C/3837/0017
Harvoni (sofosbuvir/ledipasvir)	EMEA/H/A-20/1438/C/3850/0027
Olysio (simeprevir)	EMEA/H/A-20/1438/C/2777/0019
Sovaldi (sofosbuvir)	EMEA/H/A-20/1438/C/2798/0029
Viekirax (ombitasvir/paritaprevir/ritonavir)	EMEA/H/A-20/1438/C/3839/0018

Procedural step:	Date
Notification:	9 March 2016
Start of the procedure (PRAC):	March 2016 PRAC
List of questions (LoQ):	17 March 2016
Addendum to LoQ:	14 April 2016
Submission of responses to LoQ as adopted on 17 March 2016 :	28 April 2016
Submission of responses to Addendum to LoQ as adopted on 14 April 2016:	17 May 2016
Re-start of the procedure:	09 June 2016
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]	20 June 2016

[1] Committee for Medicinal Products for Human Use

Procedural step:	Date
Comments:	27 June 2016
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	30 June 2016
PRAC list of outstanding issues (LoOIs):	7 July 2016
Submission of responses to the LoOIs:	02 September 2016
Re-start of the procedure:	29 September 2016
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP:	10 October 2016
Scientific Advisory Group (SAG) meeting:	10 October 2016
Comments:	17 October 2016
Updated rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP:	20 October 2016
PRAC second LoOIs:	November 2016 PRAC (24-27 October 2016)
Submission of responses to the second LoOIs:	09 November 2016
Re-start of the procedure:	14 November 2016
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP:	21 November 2016
Comments:	23 November 2016
Updated rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP:	25 November 2016
PRAC recommendation:	December 2016 PRAC (28 November – 1 December 2016)