## Appendix

### Annex A: Search Strategy

We searched for English language publications with the use of broad search terms: “hepatitis C virus” AND (“child” OR "adolescent") together with (AND) either “epidemiology”, “transmission”, “natural history", “prevention", “diagnosis", or “treatment" from Jan 1st, 2010, to December 31st, 2017. The age limit “birth-18 years” was applied. We included randomised controlled trials, observational studies, retrospective studies, meta-analyses, review articles, editorials, and case reports. Animal studies and in-vitro studies were excluded. We also searched reference lists of articles identified by this strategy and included additional relevant studies. The final list of eligible studies was based on those of direct relevance to the key topics of this review.

**Table A.** Summary of key studies reporting the natural history of hepatitis C in adolescents and children

| Author | n | Duration of follow up, years [mean±SD; median (range)] | Type of study | Region | Route of acquisition | HIV status | Key findings |
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| Garazzino, 2014[1] | 45 | NR | prospective | Italy | vertical 100% | negative | 26·7% presented spontaneous clearance of HCV; all children were asymptomatic; non-organ-specific autoantibodies were detected in 53·3% and 33·3% presented cryoglobulinemia |
| Lai, 2013[2] | 50 | 26 (22-30) | prospective | Italy | parenteral 100% | NR | patients with thalassemia major: 44·2% presented spontaneous clearance of HCV; IL-28B genotypes (SNP rs12980275, rs8099917, rs11881222, rs12979860) were significantly different between subjects who cleared the virus and subjects who did not; liver biopsies were performed in 32 patients (13 HCV RNA negative and 19 HCV RNA positive); cirrhosis was found in one HCV RNA–positive patient (17 years after infection); liver iron was associated with fibrosis development |
| Chen, 2009[3] | 42 | 11·6 +-4·7 | prospective | Taiwan | vertical 18% parenteral 80% unknown 2% | negative | 14·3% presented spontaneous clearance of HCV; patients with spontaneous viral clearance had lower mean RNA levels (cut-off value at enrolment of $4{\cdot}5 \cdot 10^4$ IU/mL achieved 66·7% specificity -, and 80·6%specificity -) |
| Bortolotti, 2008[4] | 504 | 5·9 ± 3·8 | prospective | Italy | vertical 57% parenteral 31% unknown 12% | negative | 7·5% presented spontaneous clearance of HCV (independently predicted by HCV genotype 3); 1·8% of the patients with persistent viraemia progressed to decompensated cirrhosis (mean age, 9·6 years) |
| Mohan, 2007[5] | 60 | 3·3 ± 1·7 | prospective | US | vertical 13% parenteral 68% unknown 19% | 3% | 25% had normal ALT, 62% had ALT values one to three times the ULN and 13% greater than three times the ULN ; 42 patients underwent liver biopsy: 71% had minimal to mild inflammation, 88% absent or minimal fibrosis in and 12% bridging fibrosis; age at infection and serum gamma-glutamyltranspeptidase correlated with fibrosis; serum alanine aminotransferase correlated with inflammation; four patients underwent repeat biopsies within 1 to 4 years with no significant progression in three and cirrhosis in one |
| European Pediatric HCV, 2005[6] | 266 | 4·2 (0·3-15·9) | prospective | Europe | vertical 100% | 26 | hepatomegaly was the only clinical sign reported (10%); ∼50% of the children presented chronic asymptomatic infection (intermittent viremia, normal ALT levels, rare hepatomegaly); ∼30% presented chronic, active infection (persistent viremia, frequent abnormal ALT levels, and hepatomegaly in some cases) |
| Resti, 2003[7] | 62 | 2 (2-11) | prospective | Europe | vertical 100% | negative | 19% presented spontaneous clearance of HCV within 30 months of life; among those presenting spontaneous clearance 66% developed an ALT peak greater than 5 times the ULN at onset (versus 28% of children with persistent viremia; $P < 0{\cdot}05$), 50% had HCV genotype 3 (versus 17% of viremic children); hepatomegaly was the only clinical sign reported in 10% of children; 11 patients underwent liver biopsy and liver disease was mild in all |
| Tovo, 2000[8] | 104 | 4 (0·5-12·7) | prospective | Europe | vertical 100% | negative | chronic infection was asymptomatic in all but 2 children who developed hepatomegaly; mean ALT concentrations decreased |

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| | | | | | | | substantially after the first two years of life; 20 patients underwent liver biopsy that showed signs of minimal to moderate inflammation |
| Stallings-Smiths, 2015[9] | 113 | 30 (28-36) | retrospective/prospective | US | parenteral 100% | 0·8% | paediatric cancer survivors; cumulative incidence of cirrhosis increased at each 10-year interval from 0% after 10 years to 13% after 40 years (p trend<0·001); median age at diagnosis of cirrhosis was 30 years (interquartile range=24-38); a linear trend in incidence was observed for males (P trend<0·001), with a cumulative incidence of 18% after 40 years (versus female 6·5%) |
| Mizuochi, 2017[10] | 348 | NR | retrospective/prospective | Japan | | negative | 9% presented spontaneous clearance of HCV; 147 children underwent liver biopsy that showed no or mild fibrosis in 91% and bridging fibrosis in 9%; none had cirrhosis |
| Modin, 2018[11] | 1049 | NR | retrospective | UK | injecting drug use in adolescents 53% infected blood products 24% vertical 11% unknown 11% | 4% | 32% of developed cirrhosis at a medican of 33 years from exposure irrespective of mode of infection; risk factors for development of cirrhosis were male gender and heavy alcohol use; patients with vertical infection developed cirrhosis earlier at a median age of 36yrs (range 17-53yrs) compared to 48yrs (range 33-68yrs), 46yrs (range 12-61yrs), and 51.5yrs (range 12-65yrs) in the intravenous drug use, blood, and unknown groups, respectively (p<0.001). Hepatocellular carcinoma was in 5%, liver transplant in 4% and death in 3% |
| Abdel-Hady, 2011[12] | 133 | NR | retrospective | UK | vertical 49% parenteral 51% | NR | 17·5% presented spontaneous clearance of HCV; 66 children underwent liver biopsy at diagnosis: 46% showed no evidence of fibrosis (median age at the time of the biopsy 6·3 years), 50% mild fibrosis and 4% moderate to severe fibrosis (median age at the time of the biopsy 10·1 years); none had cirrhosis; fibrosis score was related to older age at the time of biopsy (p = 0·02) and longer duration of infection (p = 0·05) |
| Delgado-Borrego, 2010[13] | 102 | NR | retrospective | US | NR | negative | 102 children underwent liver biopsy; 23·5% showed fibrosis stages 3 and 4 |
| Rumbo, 2006[14] | 91 | NR | retrospective | US | vertical 58% parenteral 22% unknown 20% | negative | 35 patients underwent liver biopsy; 7·7% of the patients had cirrhosis at presentation (mean age, 11·7 years); stage 3 or 4 fibrosis was more common in patients with abnormal ALT (33·3%) compared with those with normal or near normal ALT (0; p 0·05); four patients (4·4%) underwent liver transplantation, all experienced HCV recurrence, 2 died, 1 was re-transplanted, and 1 has compensated cirrhosis |
| Iorio, 2005[15] | 125 | 9 (3·4-20·9) | retrospective | Italy | vertical 43% parenteral 43% unknown 14% | NR | 7·2% presented spontaneous clearance of HCV; 100% of the patients were asymptomatic; 80% of the patients had detectable HCV RNA and abnormal ALT, 12·8% had detectable HCV RNA and normal ALT; 64 patients underwent liver biopsy; histological lesions were mild in all; no linear correlation was found between duration of disease and progression of fibrosis; examination of a follow-up liver biopsy specimen revealed cirrhosis only in 1 (4·7%) of 21 children. |
| Rerksuppahol, 2004[16] | 31 | NR | retrospective | Australia | vertical 100% | negative | 19% presented spontaneous clearance of HCV; 100% of the patients were asymptomatic; 4 patients underwent liver biopsy that revealed mild to moderate fibrosis and/or necroinflammatory activity, but no cirrhosis |
| Casiraghi, 2004[17] | 31 | NR* | retrospective | Italy | parenteral 100% | negative | blood transfusion recipients; 56·2% had normal ALT levels; 31·3% <1·5 the upper normal limit, 12·5% > 1·5 the upper normal limit; 11 patients underwent liver biopsy: 81·8% had no fibrosis or mild portal |

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| | | | | | | | fibrosis and 18·2% had discrete or marked fibrosis; five patients underwent repeat biopsies at a five years interval that revealed no substantial modifications in four cases and progression from absence of fibrosis to mild portal fibrosis in the fifth |
| Jara, 2003[18] | 224 | 6·2 ± 4·7 | retrospective | Europe | vertical 45%<br>parenteral 44%<br>unknown 6%<br>other 5% | negative | 6% presented spontaneous clearance of HCV; 87% were asymptomatic; 48% had ALT levels < or =2 times the upper limit of normal; 92 patients underwent liver biopsy: the mean fibrosis score (+/-SD) was 1·5+/-1·3 for children <15 years of age and 2·3+/-1·2 for children > or =15 years of age (range, 0-6 years; P<·01). |

Legend: SD, standard deviation; HIV, human immunodeficiency virus; NR, not reported; IL, interleukin; SNP, single nucleotide polymorphism; ALT, alanine aminotransferase; ULN, upper limit of normal; * 31 individuals given mini transfusions of HCV-infected blood as newborn infants were enrolled 30 years later

**Table B**. Summary of completed clinical trials of direct-acting antivirals regimens for hepatitis C virus infected, treatment-naïve and –experienced adolescents (aged 12 to 17 years) and children (aged less than 12 years)

| Drugs (ClinicalTrials.gov Identifier) | HCV genotypes | Study design | Ages (years) | n | Countries | Dose and duration | PK Data | SVR12 | Other endpoint results | Published reference |
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| sofosbuvir + ribavirin<br><br>(NC02175758) | 2, 3 | Non-randomized, open label, interventional, phase III trial in treatment-naïve and –experienced (PEG IFN and ribavirin) HCV-infected, with or without compensated cirrhosis | 12-17 | 52<br>GT2: 13 (25%);<br>GT3: 39 (75%) | US, Australia, Germany, Italy, New Zealand, Russia, UK | sofosbuvir 400mg daily;<br>ribavirin 15mg/kg/day up to 1,400mg/day, in 2 divided doses;<br><br>GT2: 12 weeks<br>GT3: 24 weeks | Comparable plasma exposures of sofosbuvir to those observed in adults | 51 (98%)<br>GT2 13 (100%)<br>GT3 12 (97%) 1 LTFU after achieving SVR4 | Drugs well tolerated<br><br>nausea 14 (27%)<br>headache 12 (23%)<br>asthenia 6 (12%) | [19] |
| | | | 3-12 | 50 | US | sofosbuvir 200mg daily<br>ribavirin 15mg/kg/day up to 1,400mg/day, in 2 divided doses;<br><br>GT2: 12 weeks<br>GT3: 24 weeks | Comparable plasma exposures of sofosbuvir to those observed in adults | 6-12 yrs: 39 (100%);<br>3-<6 years: 12 (92%)<br><br>A 4-year old patient discontinued treatment after 3 days due to vomiting and abnormal drug taste | Drugs well tolerated<br><br>vomiting and fatigue reported in ≥10% of patients | [20-22] |
| ledipasvir/sofosbuvir (fixed dose combination)<br><br>(NCT02249182) | 1 | Non-randomized, open label, interventional, phase III trial in treatment-naïve and –experienced (PEG IFN and ribavirin) HCV-infected, with or without compensated cirrhosis | 12-17 | 100 | US, Australia, UK | ledipasvir/sofosbuvir 90mg/400mg daily;<br><br>GT1: 12 weeks | Comparable plasma exposures of sofosbuvir, GS-331007, and ledipasvir to those observed in adults | 98 (98%) 2 LTFU | Drugs well tolerated<br><br>headache 27 (27%)<br>diarrhea 14 (14%)<br>fatigue 13 (13%) | [23] |
| | 1,3,4 | | 6-11 | 90 | | ledipasvir/sofosbuvir 45mg/200mg daily;<br><br>GT1 and 4: 12 weeks<br>GT1 treatment-experienced with | Comparable plasma exposures of sofosbuvir and ledipasvir to those observed in adults | 89 (99%) | headache 27 (27%)<br>fever 15 (17%)<br>abdominal pain 6 (12%) | [22,24] |

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| | | | | | | cirrhosis and GT3: 24 weeks | | | | |
| | 1,4 | | 3-5 | 34 | | ledipasvir/sofosbuvir 45mg/200mg daily if >17 Kg; 33.75 mg/150mg daily if <17 Kg;<br><br>GT1 and 4: 12 weeks | Comparable plasma exposures of sofosbuvir and ledipasvir to those observed in adults | 33 (97%) | Vomiting, pyrexia, cough, rhinorrhea, streptococcal pharyngitis (>10%) | [21,25] |
| ombitasvir-paritaprevir-ritonavir ± dasabuvir ± ribavirin (NCT02486406) | 1,4 | Non-randomized, open label, interventional, phase III trial in treatment-naïve and –experienced (PEG IFN and ribavirin) HCV-infected, with or without compensated cirrhosis | 12-17 | 38 | US, Germany, UK | ombitasvir-paritaprevir-ritonavir 150/100/25 mg<br>dasabuvir 250 mg twice daily<br>ribavirin 15mg/kg/day up to 1,400mg/day, in 2 divided doses | Comparable plasma exposures of sofosbuvir and ledipasvir to those observed in adults | 38 (100%) | Drugs well tolerated<br><br>headache 8 (21%)<br>fatigue 7 (18%)<br>nasopharingitis 5 (13%) | [26] |
| ledipasvir/sofosbuvir (fixed dose combination) | 4 | Non-randomized, open label, interventional, phase III trial in treatment-naïve and –experienced (PEG IFN and ribavirin) HCV-infected, with or without compensated cirrhosis | 12-17 | 144 | Egypt | ledipasvir/sofosbuvir 90mg/400mg daily;<br><br>GT4: 12 weeks | Not available | 142 (99%) | Drugs well tolerated<br><br>headache 29 (20%)<br>diarrhea 17 (12%)<br>pruritus 16 (11%) | [27] |
| ledipasvir/sofosbuvir (fixed dose combination) | 4 | Non-randomized, open label, interventional, phase III trial in treatment-naïve and –experienced (PEG IFN and ribavirin) HCV-infected, with or without compensated cirrhosis | 12-17 | 40 | Egypt | ledipasvir/sofosbuvir 90mg/400mg daily;<br><br>GT4: 12 weeks | Not available | 39 (97·5%) | Drugs well tolerated<br><br>asthenia 21 (52,5%) headache 19 (47·5%)<br>diarrhea 17 (12%)<br>irritability 13 (32·5%) | [28] |
| ledipasvir/sofosbuvir (fixed dose combination) | 4 | Non-randomized, open label, interventional, phase III trial in treatment-naïve and –experienced (PEG IFN and ribavirin) HCV-infected, without cirrhosis | 6-11 | 20 | Egypt | ledipasvir/sofosbuvir 45mg/200mg daily;<br><br>GT4: 12 weeks | Not available | 19 (95%) | Drugs well tolerated, no side effect was reported | [29] |

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| sofosbuvir + daclatasvir | 4 | Non-randomized, open label, interventional, phase III trial in treatment-naïve patients HCV-infected, without cirrhosis | 12-17 | 10 | Egypt | sofosbuvir 400 mg daily<br>daclatasvir 60 mg | Not available | 10 (100%) | Drugs well tolerated<br><br>nausea 3 (30%)<br>abdominal pain 3 (30%)<br>fatigue 2 (20%) | [30] |
| sofosbuvir + daclatasvir | 4 | Non-randomized, open label, interventional, phase III trial in treatment-naïve and –experienced (PEG IFN and ribavirin) HCV-infected, without cirrhosis | 12-17 | 30 | Egypt | sofosbuvir 400 mg daily<br>daclatasvir 60 mg | Not available | 29 (96·7%) | Drugs well tolerated<br><br>fatigue 4 (13·3%)<br>nausea 3 (10%)<br>abdominal pain 3 (10%) | [31] |
| glecaprevir/pibrentasvir (DORA Study) | 1-6 | Non-randomized, open label, phase III trial in treatment-naïve and experienced HCV-infected, without cirrhosis | 12-17 | 47 | US, Canada, Japan, Germany, Spain, Puerto Rico, Russia, UK, Belgium | G/P (300 mg/120 mg) with food once daily for 8 or 16 (GT 3) weeks | Steady-state exposures in adolescents were within range of those observed in adults | 47 (100%) | Drugs well-tolerated<br>No treatment discontinuations or serious AEs<br>Safety profile in adolescents consistent with that in adults | [32] |

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