### Evidence Table D-4. Harms for pharmacological treatment (KQ1a)

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Arm</th>
<th>Harm</th>
<th>N for analysis</th>
<th>Time point (s)</th>
<th>N of patients with outcomes</th>
<th>% of patients with outcomes</th>
</tr>
</thead>
</table>
| Abraira, 1997<sup>a</sup>  
VACSDM | Group A: intensive | Hypoglycemia | 75 | 7.8 years | 5 | 6% |
| Abraira, 1997<sup>a</sup>  
VACSDM | Group B: standard | Hypoglycemia | 78 | 7.8 years | 2 | 2.5% |
| UKPDS<sup>1</sup>  
Arm 1: intensive glycemic control | Severe hypoglycemia | 2729 | 10.7 years | NR | 1.2% - Chlorpropamide arm; 1.0%- Glibenclamide arm; 2.0% insulin arm |
| UKPDS<sup>1</sup>  
Arm 2: conventional treatment | Severe hypoglycemia | 1138 | 10.7 years | NR | 0.7% conventional 0.6% metformin arms |
| Gaede, 2003<sup>3</sup>  
Steno-2 | Arm 1: intensive glycemic control | Severe hypoglycemia | 80 | 7.8 years | 12 | 15% |
| Gaede, 2003<sup>3</sup>  
Steno-2 | Arm 2: conventional treatment | Severe hypoglycemia | 80 | 7.8 years | 5 | 6% |
| Dormandy, 2005<sup>5</sup>  
PROactive | Arm 1: Pioglitazone | Hypoglycemia | 2605 | 34.5 months | 728 | 28% |
| Dormandy, 2005<sup>5</sup>  
PROactive | Arm 2: placebo | Hypoglycemia | 2633 | 34.5 months | 528 | 20% |
| Duckworth, 2009<sup>11</sup>  
VADT | Arm 1: intensive glycemic control | Hypoglycemia | 892 | 6 years | 76 | 9% |
| Duckworth, 2009<sup>11</sup>  
VADT | Arm 2: standard | Hypoglycemia | 760 | 6 years | 28 | 5% |
| Jaiswal, 2015<sup>11</sup>  
Arm 1: Exenatide | Severe hypoglycemia | 22 | 18 months | 0 | 1% |
| Jaiswal, 2015<sup>11</sup>  
Arm 2: insulin Glargine | Severe hypoglycemia | 24 | 18 months | 1 | 4% |
| Jaiswal, 2015<sup>11</sup>  
Arm 1: Exenatide | GI problems | 22 | 18 months | 6 | 27% |
| Jaiswal, 2015<sup>11</sup>  
Arm 2: insulin Glargine, | GI problems | 24 | 18 months | 4 | 17% |

GI = Gastrointestinal; PROactive = Prospective Pioglitazone Clinical Trial in Macrovascular Events; Steno-2 = Randomized open parallel trial for patients with type 2 diabetes Mellitus at the Steno Diabetes Center in Denmark; UKPDS = United Kingdom Prospective Diabetes Study; VACSDM = Veterans Affairs Cooperative Study on glycemic control and complications in type 2 Diabetes Mellitus; VADT = Veterans Affairs Diabetes Trial;