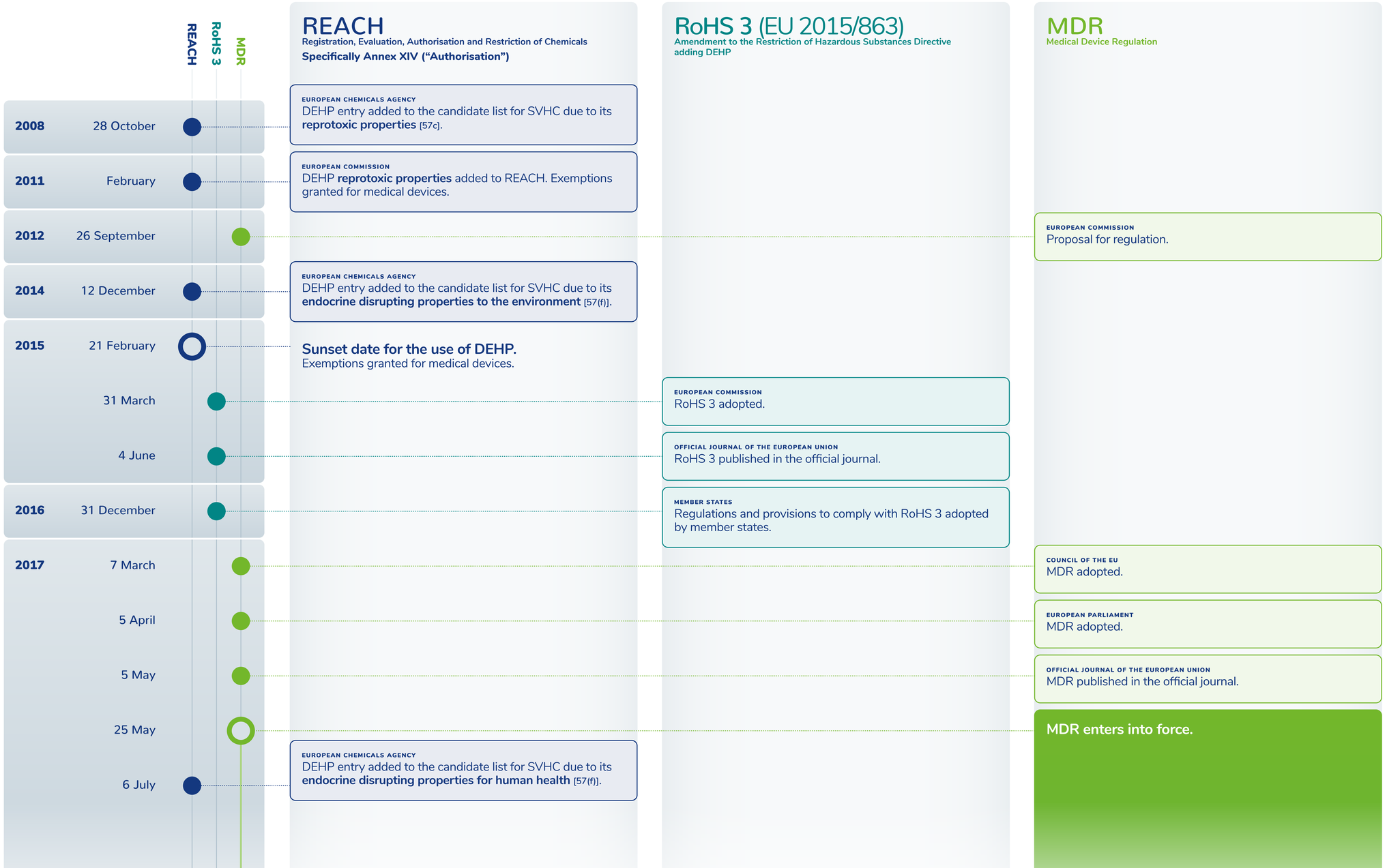
Timeline of European regulations on DEHP 1/2

PVC Med ALLIANCE



Timeline of European regulations on DEHP 2/2

PVC Med ALLIANCE

REACH RoHS 3 MDR

REACH
Registration, Evaluation, Authorisation and Restriction of Chemicals
Specifically Annex XIV (“Authorisation”)

RoHS 3 (EU 2015/863)
Amendment to the Restriction of Hazardous Substances Directive adding DEHP

MDR
Medical Device Regulation

2018

5 June – 6 August

EUROPEAN CHEMICALS AGENCY
Eight-week public consultation on draft recommendation.

12 December

EUROPEAN CHEMICALS AGENCY
Draft recommendation published, considering whether exemptions are still justified.

12 December – 12 March

EUROPEAN CHEMICALS AGENCY
90-day public consultation on draft recommendation.

2019

26 June

MEMBER STATE COMMITTEE
Opinion on draft recommendation adopted.

10 July

EUROPEAN CHEMICALS AGENCY
Recommendation published.

22 July

RoHS 3 enters into force.

2021

26 May

Provisions applied.
Including the justification for the presence of CMR and ED substances, such as DEHP.

22 July

RoHS 3 goes into effect for medical devices containing DEHP.

21 December

EUROPEAN COMMISSION
DEHP **endocrine disrupting properties to human health and the environment** added to REACH.

2027

31 December

Deadline for CE marking of all legacy high-risk medical devices.
Presence of DEHP must be duly justified according to the latest relevant SCHEER guidelines.

2028

31 December

Deadline for CE marking of all legacy low-risk medical devices.
Presence of DEHP must be duly justified according to the latest relevant SCHEER guidelines.

2029

1 January

EUROPEAN COMMISSION
Latest application date for authorisation.

2030

1 July

Sunset date after which use of DEHP is banned.