POLIVY (polatuzumab vedotin) 140 mg powder for concentrate for solution for injection:
Important information on plastic vial flip-off cap colour

Dear Healthcare Professional,

Roche Registration GmbH in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

Summary

- **To avoid a potential shortage of Polivy in some European markets, one batch manufactured for clinical trial use will be repurposed for commercial supply. The shortage risk is not associated with any manufacturing or quality issue but is due to actual demand being above forecast in Europe.**

- **From <date>, Roche will be distributing Polivy 140mg/vial (<Lot/Lots ABC>) with an aqua-coloured plastic vial flip-off cap, in addition to the approved dark blue plastic vial flip-off cap (photos below). Both are equivalent in terms of composition and safe for use.**

- **For the time being, vials with both plastic vial flip-off cap colours (aqua and dark blue) will be on the market. After depletion or expiration of existing stock of vials with aqua plastic vial flip-off cap, Roche will return to distributing the dark blue plastic vial flip-off cap only.**

- **Prescribers and pharmacists should continue to use the existing stocks of Polivy 140 mg/vial until depleted or expired.**

Product	Current (dark blue plastic vial flip-off cap)	Temporary (aqua plastic vial flip-off cap)	Change
Polivy 140 mg/vial EU/1/19/1388/001			Aqua-coloured plastic vial flip-off cap to be temporarily available in addition to the dark blue plastic vial flip-off cap.

Background information

Polivy (polatuzumab vedotin), a CD79b-directed antibody-drug conjugate, is an orphan medicinal product that received a conditional marketing authorization from the European Commission on 16 January 2020 with the following indication:

Polivy in combination with bendamustine and rituximab is indicated for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) who are not candidates for haematopoietic stem cell transplant.

To prevent a potential shortage of Polivy and in order to ensure continuous supply for some European markets, one batch manufactured for clinical trial use will now be repurposed for commercial supply.

This batch is produced according to the commercially registered and validated manufacturing process in the commercial manufacturing facility at BSP Pharmaceuticals S.p.A. but differs in color of the plastic vial flip-off cap as indicated above.

Call for reporting

Healthcare professionals should report any adverse events suspected to be associated with the use of Polivy 140 mg/vial to Roche at <(e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>.

Company contact point

Should you have any questions about the information in this letter or the safe and effective use of Polivy, please feel free to contact us at:
<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Polivy (polatuzumab vedotin)
Marketing authorisation holder(s)	Roche Registration GmbH
Safety concern and purpose of the communication	Important information on plastic vial flip-off cap colour. There is no safety concern associated with these vials. The purpose of the communication is to inform HCPs that vials with either plastic flip-off cap colour (dark blue or aqua) are equivalent and safe for use.
DHPC recipients	The DHPC recipients must be decided at the national level, which will include HCPs who will be receiving aqua-coloured vial cap.
Member States where the DHPC will be distributed	France,*Germany and the United Kingdom

Timetable**	Date
DHPC and communication plan (in English) agreed by CHMP	22 April 2020
Submission of translated DHPCs to the national competent authorities for review	27 April 2020
Agreement of translations by national competent authorities	1 May 2020
Dissemination of DHPC	2 May 2020

*In France, clinical vials with aqua cap colour are already in distribution under cATU which will continue until 15th July 2020, therefore this DHPC would not serve any purpose at this time. However, after 15th July 2020, if there is a need to distribute the clinical vials with aqua color cap, the DHPC will be distributed at that time.
**The earliest possible event dates in any of the impacted member states are depicted in this table.