<Date>

Potential Missing Package Leaflet in Folding Boxes of RoActemra (tocilizumab), Hemlibra (emicizumab), Herceptin (trastuzumab), Kadcyla (trastuzumab emtansine), MabThera (rituximab), Phesgo (pertuzumab / trastuzumab) and Tecentriq (atezolizumab).

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 of the concern

- In April 2023, it was identified during packaging operations that due to an automation issue, a package leaflet was missing from two folding boxes of Tecentriq (atezolizumab).
- RoActemra (tocilizumab), Hemlibra (emicizumab), Herceptin (trastuzumab), Kadcyla (trastuzumab emtansine), MabThera (rituximab) and Phesgo (pertuzumab/trastuzumab) are additional products packed on the same line.
- Roche cannot fully exclude that a folding box/boxes of the above listed products may have been distributed in the EEA market with a missing package leaflet. Any batches manufactured between 15 November 2021 and 24 April 2023 are potentially impacted by this defect. There is no impact on the quality of the medicines.
- Healthcare Professionals should check the folding box prior to dispensing the above medicines. In case of a missing package leaflet, healthcare professionals should refer to the attached package leaflet in the Annexes or consult the link referred to in the Annexes for the package leaflet's online version and provide accordingly to patients.
- Healthcare Professionals should report any missing package leaflet via the Company contact point below.

Background information

In April 2023, it was identified during packaging operations that a package leaflet was missing from two folding boxes of Tecentriq (atezolizumab). The medicines RoActemra (tocilizumab), Hemlibra (emicizumab), Herceptin (trastuzumab), Kadcyla (trastuzumab emtansine), MabThera (rituximab) and Phesgo (pertuzumab/trastuzumab) are packed on the same line and may also be affected.
Roche cannot fully exclude that a folding box/boxes of the above listed products may have been distributed in the EU market with a missing package leaflet.
Any batches manufactured between 15 November 2021 and 24 April 2023 are potentially impacted by this defect. No market complaints for missing package leaflets have been received since the start of commercial packaging on this line on 15 November 2021. There is no impact on the quality of the medicines.

The purpose of this communication is to clarify that the products can still be used and to provide copies of the relevant package leaflets, available via the links below and / or the attached package leaflet in the Annexes.

In terms of preventative action, a balance has been implemented from 24 April 2023 as a mandatory check on all folding boxes on the automated packaging line in question to ensure that the package leaflet is included in every box.

Company contact point

Should you have any questions regarding the use of RoActemra (tocilizumab), Hemlibra (emicizumab), Herceptin (trastuzumab), Kadcyla (trastuzumab emtansine), MabThera (rituximab), Phesgo (pertuzumab/trastuzumab), or Tecentriq (atezolizumab) please contact us at: <Insert local contact information>.

Annexes
Package leaflets (pdf format)
Links to a digital version of package leaflets

Yours sincerely,
<Company Name of Affiliate>

<Signature of authorised contact person>

Communication plan for Direct Healthcare professional communication

DHPC COMMUNICATION PLAN		
Medicinal product(s)/active substance(s)	RoActemra (tocilizumab), Hemlibra (emicizumab), Herceptin (trastuzumab), Kadcyla (trastuzumab emtansine), MabThera (rituximab), Phesgo (pertuzumab / trastuzumab) and Tecentriq (atezolizumab).	
Marketing authorisation holder(s)	Roche Registration GmbH	
Safety concern and purpose of the communication	To inform healthcare professionals about potential missing package leaflet in folding boxes of several Roche products.	
DHPC recipients	RoActemra (tocilizumab), Herceptin (trastuzumab), Kadcyla (trastuzumab emtansine), MabThera (rituximab), Phesgo (pertuzumab / trastuzumab) and Tecentriq (atezolizumab).	Prescribing physicians, nurses/pharmacists as per country specific distribution channels, wholesalers, hospitals, and clinics, according to local regulations.
	Hemlibra (emicizumab)	Prescribing physicians, nurses/pharmacists as per country specific distribution channels, wholesalers, hospitals, and clinics, according to local regulations. Healthcare providers to inform patients and carers of this issue.
Member States where the DHPC will be distributed	RoActemra (tocilizumab)	Norway
	Hemlibra (emicizumab)	Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden

	Herceptin (trastuzumab)	*Estonia, Finland, Latvia,* Slovakia, Sweden
	Kadcyla (trastuzumab emtansine)	Norway
	MabThera (rituximab)	Belgium, Czech Republic
	Phesgo (pertuzumab / trastuzumab)	Austria, Czech Republic, Croatia, Romania, Slovenia, Ireland
	Tecentriq (atezolizumab)	Norway

Timetable	**Date**
DHPC and communication plan (in English) agreed by CHMP	**20 July 2023**
Submission of translated DHPCs to the national competent authorities for review	**Above date +1 week**
Agreement of translations by national competent authorities	**Above date +1 week**
Dissemination of DHPC	**Above date +2 week**