

Below please find the information currently available at Bayer AG, Leverkusen (Germany).

There are three confirmed counterfeit cases affecting Bayer's original batches BXHUBD2, BXHXL41 and BXHVHC3. All genuine batches were produced in 2017 at the Supply Center Leverkusen with the country make-up in Polish/Slovakian. The batches were not serialized. The batches were sold from the Bayer warehouse in Poland between:

BXHUBD2 (Dec 2017 – April 2018)

BXHXL41 (Jan 2018 – July 2018)

BXHVHC3 (Jan 2018 – June 2018)

The samples of three batches (BXHUBD2, BXHXL41, BXHVHC3) from the UK parallel importer Shakespeare Pharma have been identified as counterfeited. Batch BXHVHC3 and BXHXL41 can be identified by the weak/missing perforation of the blisters. However, the perforation of the sample blister of batch BXHUBD2 is visible. The instruction for identification of falsification provided for batch BXHVHC3 might not work properly for other batches. Bayer will update its instruction for the identification of falsified Xarelto 20 mg product (Polish/Slovakian make-up 1x28 tabl.).

Bayer received a sample of batch BXHVHC3 from the German parallel importer ACA Mueller and determined the product to be genuine.

Bayer received very recently photos from samples of batch BXHVHC3 from the Dutch parallel importer Medcor. Based on their investigation Medcor concluded that the product is falsified. Actual product samples have been requested by Bayer. The investigation into the origin of the product is on-going.

Complaint case No.	Reported by	Batch No	Packaging size	Shelf life	Original batch serialized	NIR of tablet sample	Primary Packaging Material	Secondary packaging material	Conclusion
2018-062904	Foil manufacturer in Poland	BXHUBD2	XARELTO 20 MG 28 TABL	SEP 2020	N	Does not comply	Does not comply	Does not comply	Counterfeited
2018-062904	Foil manufacturer in Poland	BXHXL41	XARELTO 20 MG 28 TABL	SEP 2020	N	Complies	Complies	Complies	Original
2019-037911	Shakespeare Pharma Lyons	BXHVHC3	XARELTO 20 MG 28 TABL	SEP 2020	N	Does not comply	Does not comply	Does not comply	Counterfeited

Complaint case No.	Reported by	Batch No	Packaging size	Shelf life	Original batch serialized	NIR of tablet sample	Primary Packaging Material	Secondary packaging material	Conclusion
2019-044074	ACA Müller ADAG Pharma AG, Germany (non-serious Adverse Event)	BXHVHC3	XARELTO 20 MG 98 TABL	SEP 2020	N	Complies	Complies	Packaged at ACA Müller	Original
2019-044409	Shakespeare Pharma Lyons	BXHUBD2	XARELTO 20 MG 28 TABL	SEP 2020	N	Does not comply	Does not comply	Under investigation	Counterfeited
2019-044409	Shakespeare Pharma Lyons	BXHXL41	XARELTO 20 MG 28 TABL	SEP 2020	N	Does not comply	Does not comply	Under investigation	Counterfeited
2019-047434	Medcor, NL	BXHVHC3	Unknown	SEP 2020	N	Sample has been requested by Bayer	Sample has been requested by Bayer	Sample has been requested by Bayer	Unknown
Not applicable	Recall Oropharm, Germany	BXHVHC3	XARELTO 20 MG 98 TABL	SEP 2020	N	No sample available			Unknown