

References to drug agency materials that appear only in Table 1 (see *** under Table 1)

[a] EMA.pr.2018.08.10: EMA. Update on review of valsartan medicines due to detection of NDMA: EMA reviewing valsartan produced by another company Zhejiang Tianyu. Press release, document EMA/543774/2018, 10 August 2018. URL: https://www.ema.europa.eu/en/documents/press-release/update-review-valsartan-medicines-due-detection-ndma_en.pdf (dostęp 2019.07.30).

[b] EDQM.pr.2018.08.28: EDQM: update on EDQM's actions following detection of impurity in valsartan. Press release. 28 August 2018, Strasbourg, France. URL: <https://www.edqm.eu/sites/default/files/pressrelease-update-on-edqm-actions-following-detection-of-impurity-in-valsartan-august2018.pdf> (dostęp 2019.07.30).

[c] FDA.up.2018.12.20: 12/20/2019: UPDATE – FDA alerts patients and health care professionals to Torrent's recall of losartan medication due to NDEA. URL: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan> (dostęp 2019.07.30); error in the original title: should read "12/20/2018: UPDATE...".

[d] EMA.pr.2018.09.13: EMA. Update on review of valsartan medicines: risk from NDMA remains low, a related substance NDEA also being investigated. Press release 13/09/2018, document EMA/585263/2018. URL: https://www.ema.europa.eu/en/documents/press-release/update-review-valsartan-medicines_en.pdf (dostęp 2019.07.30).

[e] FDA.fnr.2018.09.13: FDA provides update on its ongoing investigation into valsartan products; and reports on the finding of an additional impurity identified in one firm's already recalled products. FDA news release. URL: <https://www.fda.gov/news-events/press-announcements/fda-provides-update-its-ongoing-investigation-valsartan-products-and-reports-finding-additional> (dostęp 2019.07.30).

[f] EMA.pr.2018.11.19: EMA. Valsartan from Mylan laboratories in India can no longer be used in EU medicines due to NDEA impurity. Press release 19/11/2018, document EMA/809509/2018. URL: https://www.ema.europa.eu/en/documents/press-release/valsartan-mylan-laboratories-india-can-no-longer-be-used-eu-medicines-due-ndea-impurity_en.pdf (dostęp 2019.07.30).

[g] EDQM.up.CEP2018.11.19: EDQM: Update on the review of CEP applications for sartans, 2018.11.19. Strasbourg, France. URL: <https://www.edqm.eu/en/news/update-review-cep-applications-sartans> (dostęp 2019.07.13).

[h] FDA.up.2018.11.21: 11/21/2018: UPDATE – FDA alerts patients and health care professionals to Mylan's recall of valsartan products due to NDEA. URL: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan> (dostęp 2019.07.30).

[i] RIS.up.2018.12.24: Europe Update on the review of CEP applications for sartans. Par RIS.WORLD - 24/12/2018. URL: <http://www.ris.world/europe-update-on-the-review-of-cep-applications-for-sartans-2/> (dostęp 2019.07.16).

[j] FDA.up.2019.01.02: 1/2/2019: UPDATE – FDA alerts patients and health care professionals to Aurobindo's recall of valsartan medication due to NDEA. URL: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan> (dostęp 2019.07.30).

[k] TGA.rec.2018.12.18: The Therapeutic Goods Administration. APO-Valsartan (valsartan) tablets. Recall – potential contamination.

18 December 2018. URL: <https://www.tga.gov.au/alert/apo-valsartan-valsartan-tablets> (dostęp 2019.07.13).

[l] EDQM.pr.CEP2018.10.17: EDQM: Update on the review of CEP applications for sartans and the availability of test methods for nitrosamines. Press release, 17 October 2018, Strasbourg, France. URL: https://www.edqm.eu/sites/default/files/press_release_-_update_review_cep_applications_for_sartans_and_availability_test_methods_-_october_-_2018.pdf (dostęp 2019.07.30).

[m] EMA.pr.2018.10.15: EMA. EU authorities take further action in ongoing review of sartans: Zhejiang Huahai placed under increased supervision; Aurobindo Pharma stopped from supplying irbesartan to the EU. Press release 15/10/2018, dokument EMA/703416/2018. URL: https://www.ema.europa.eu/en/documents/press-release/eu-authorities-take-further-action-ongoing-review-sartans_en.pdf (dostęp 2019.07.30).

[n] FDA.up.2018.10.30: 10/30/2018: UPDATE – FDA alerts patients and health care professionals to ScieGen's irbesartan recall due to NDEA. URL: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan> (dostęp 2019.07.30).

[o] EDQM.up.CEP2019.01.18: EDQM: Update on the review of CEP applications for sartans (18 January 2019). Strasbourg, France. <https://www.edqm.eu/en/news/update-review-cep-applications-sartans-18-january-2019> (dostęp 2019.07.13).

[p] FDA.up.2019.01.18: 1/18/2019: UPDATE – Irbesartan distributed by Solco Healthcare voluntarily recalled. URL: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan> (dostęp 2019.07.30).

[r] FDA.up.2018.11.09: 11/9/2018: UPDATE – FDA alerts patients and health care professionals to Sandoz's losartan potassium and hydrochlorothiazide recall of one lot due to NDEA. URL: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan> (dostęp 2019.07.30).

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[t] FDA.up.2019.02.25: 2/25/2019: UPDATE – Losartan distributed by Macleods Pharmaceuticals voluntarily recalled. URL: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan> (dostęp 2019.07.30).

[u] EDQM.up.CEP2019.02.04: EDQM: Update on the EDQM review of CEP applications for sartan substances (4 February 2019). Strasbourg, France. URL: <https://www.edqm.eu/en/news/update-edqm-review-cep-applications-sartan-substances-4-february-2019> (dostęp 2019.07.30).

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