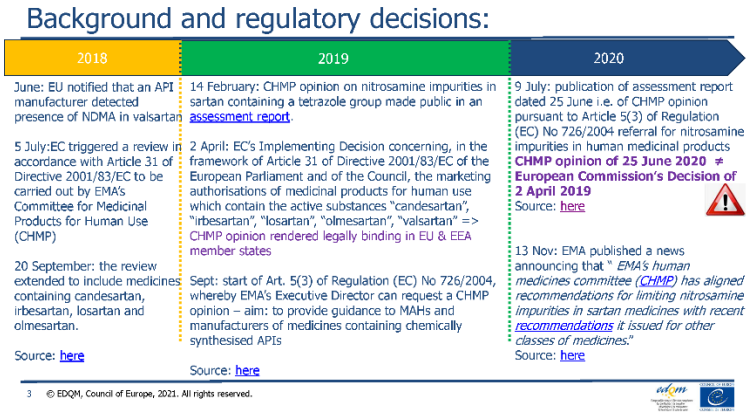
EDQM Webinar on N-Nitrosamines Impurities (21/01/2021)

N-nitrosamine impurities in medicinal products, Presentation by Cathie Vielle

Background & Regulatory Decisions - Useful information & urls links:



2018 Source:https://www.ema.europa.eu/en/documents/variation-report/sartans-article-31-referral-chmp-assessment-report_en.pdf

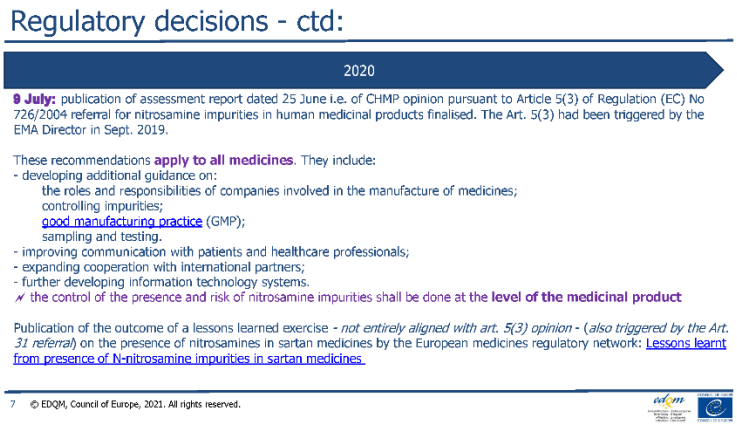
Assessment Report: https://www.ema.europa.eu/en/documents/variation-report/sartans-article-31-referral-chmp-assessment-report_en.pdf

2019 Source: https://ec.europa.eu/health/documents/community-register/2019/20190402144194/dec_144194_en.pdf

2020 Source: https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report_en.pdf

Recommendations: https://www.ema.europa.eu/en/documents/referral/nitrosamine-impurities-final-outcome-art-53_en.pdf

2020 Source: https://www.ema.europa.eu/en/news/nitrosamines-ema-aligns-recommendations-sartans-those-other-medicines



Lessons Learnt Publication: https://www.ema.europa.eu/documents/report/lessons-learnt-presence-n-nitrosamine-impurities-sartan-medicines_en.pdf

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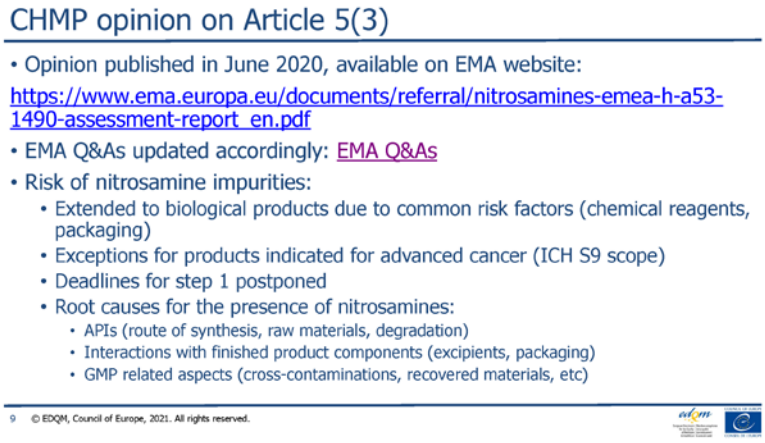
N-nitrosamine impurities: CEP applications, Presentation by Ekaterina Nagdiyev



EMA Q&As: https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-questions-answers-marketing-authorisation-holders/applicants-chmp-opinion-article-53-regulation-ec-no-726/2004-referral-nitrosamine-impurities-human-medicinal-products_en.pdf