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THE COMPANY TARGETING
UNMET NEEDS IN ONCOLOGY

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THE LATEST IN DRUG DELIVERY

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BRINGING BIOSCIENCE TO THE
UK'S NORTH EAST

PHARMACEUTICAL

European
manufacturer

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THE *RIGHT ROUTE* TO TAKE

Nemera explores how to manage drug overdosing
through the use of a smart nasal spray device

CONVERGING TRENDS IN NASAL DELIVERY

The intranasal route of administration is commonly used to treat various therapeutic areas. As a matter of fact, nasal delivery is an attractive option for locally acting medications as well as for systemic therapies which may vary from benign to serious health conditions. The nose anatomy allows us to administer the medications systemically or locally by targeting the right area for drug deposition in the nose to eventually treat certain conditions.

For instance, a nasal spray could be used to manage several chronic or acute pathologies topically such as allergic rhinitis, sinusitis, and nasal congestion. Indeed, the dynamic number of pipelines via the nasal route for systemic or nose-to-brain applications has grown over the years, as the nasal route is not invasive, and does not require healthcare professionals' intervention. With the advantage of nose physiology, even emergency and crisis could be addressed with nasal delivery.

Considering this, for instance, patients who experience breakthrough pain due to their chronic conditions such as cancer could opt for a nasal route treatment delivery. In such a case, systemic acting drugs are administered through the nostrils to relieve the pain, as a complementary option to pills.

NASAL FOR PAIN MANAGEMENT

There is a wide range of drugs that are used for painkillers. As an example, opioid treatment is used to relieve pain with its rapid onset of action through unit-dose or multidose nasal drug delivery: opioids are

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a class of drugs including prescription painkillers such as fentanyl. Due to their pharmacological effects, they can cause difficulties with breathing, and opioid overdose can lead to death¹. Worldwide, about 0.5 million deaths are attributable to drug use. More than 70% of these deaths are related to opioids, with more than 30% of those deaths caused by overdose. In the USA, the number of people dying from opioid overdose increased by 120% between 2010 and 2018, and two-thirds of opioid-related overdose

deaths in 2018 in the USA involved synthetic opioids, including fentanyl and its analogues².

Indeed, fentanyl is a potent drug, used to treat severe pain that has become the main driver of recent increases in synthetic opioid deaths. The fentanyl painkiller is used on a regular basis by patients with cancer. For multidose nasal spray presentations, this may lead to opioid overdose when it is not used according to the treatment posology. Given this, it is crucial to consider the mode and way

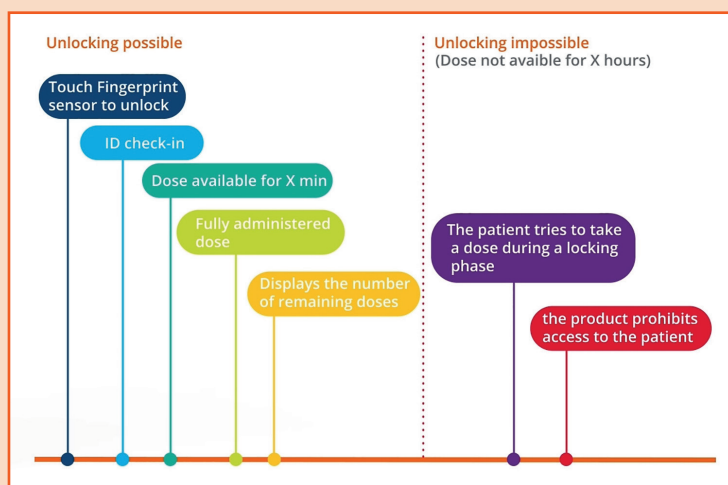
of administration to ensure the patients' safety.

OUR SOLUTION: SAFE'N'SPRAY

On that account, Nemera developed a smart electronic concept device with child-resistant, dose counting and locking features, Safe'n'Spray, which offers solutions to prevent overdosing on potent drugs. It is an integrated device with a reusable electronic locking unit and fingerprint identification, to monitor drug dose delivery in a defined period of time to ultimately ensure patient's safety. The device is intuitive, thanks to its interactive and animated user-interface which helps patients use the device correctly through audio and visual feedback. It has a simple display indicating the number of doses left and the remaining time for the next dose. Moreover, with reusable and disposable parts, Safe'n'Spray offers a unique possibility to reuse the "SAFE" electronics for sustainability once the "SPRAY" part with the drug content is empty; of course, this is both economic and eco-friendly.

The fingerprint sensor feature for patient unique identification prevents any abuse of use by other people than the one(s) pre-determined, as the device is personalised for specific individuals (e.g. patient, relative, healthcare professional, etc.). Besides, this acts as an easy and intuitive child-resistant feature, without the need for adding any secondary packaging with a smart child-resistant function.

Opposite to fully integrated devices, Safe'n'Spray does not change the manufacturing process of primary packaging on existing filling lines, as another module will deal with assembling Safe'n'Spray around primary packaging.



Safe'n'Spray™ usage sequence customized to each drug posology



With a growing tendency of self-administration as well as digitalisation, Safe'n'Spray is designed as a connected device, linked to e-Nemera Cloud Solution, Nemera's cloud platform. With a customised development fitting each customer need, it can offer access to patients, healthcare professionals, and pharmaceutical companies for data exploitation. Patients could be able to manage and track their treatment history, whilst healthcare professionals could also follow patients' treatment management closely and evaluate their conditions with unbiased information. On the other hand, the pharmaceutical companies may for instance use the statistical analysis generated from the available data. Ultimately, thanks to its innovative concept, key features, and benefits for better chronic treatment management, Safe'n'Spray bagged two awards in PharmaPack 2020 as the "Best Innovation in Drug Delivery Device" and CPHI Festival of Pharma 2020 under the category "Excellence in Pharma Drug Delivery Devices".

OUR WAY OF WORKING: DEVELOPING PRODUCTS WITH PATIENTS IN MIND

As mentioned earlier, in order to treat a specific condition, it is important to reach the right targeted areas using the right device for drug deposition, which is adapted for a certain patient population. This with both performance and usability perspectives in mind.

Therefore, it is important to understand the patient journey from the beginning of the device concept to correctly address their pain-points to answer their needs. As a world-leading drug device combination solutions specialist, Nemera's purpose of putting patients first enables the company to design and manufacture devices that maximise treatment efficacy. Through human factor studies, we ensure that the device features and parameters are set to ease patients' life therefore improve their quality of life.

Nemera's expertise within the device development ecosystem for nasal route delivery allows a thorough end-to-end understanding of the

combination-product solutions. Patients are on-board with us since the beginning of the device conception.

Nemera is the utmost holistic partner and helps its customers succeed in the sprint to market. From early device strategy to state-of-the-art manufacturing, Nemera is committed to the highest quality standards. Agile and open-minded, Nemera works with its customers as partners. Together, they go the extra mile to fulfill their mission.

* Safe'n'Spray is a registered trademark by Nemera

REFERENCES

- 1) "Opioid overdose. Who.int. 2021"
- 2) CDC WONDER (2020). National Center on Health Statistics



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