



The challenge of integrating ADR reporting into clinical health record systems

30th Anniversary of the National Pharmacovigilance System, INFARMED
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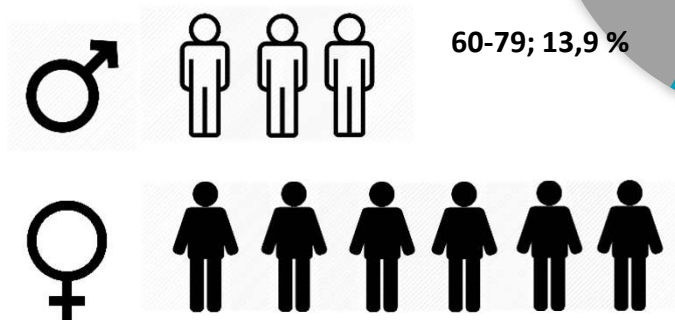
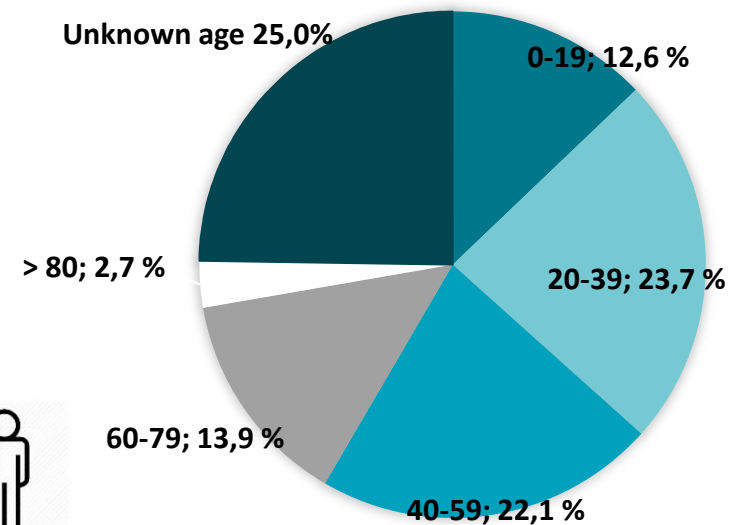
Norwegian Medicines Agency

- National Competent Authority in Norway for
 - Medicinal products
 - Medical devices
 - E-cigarettes
- Approximately 350 employees

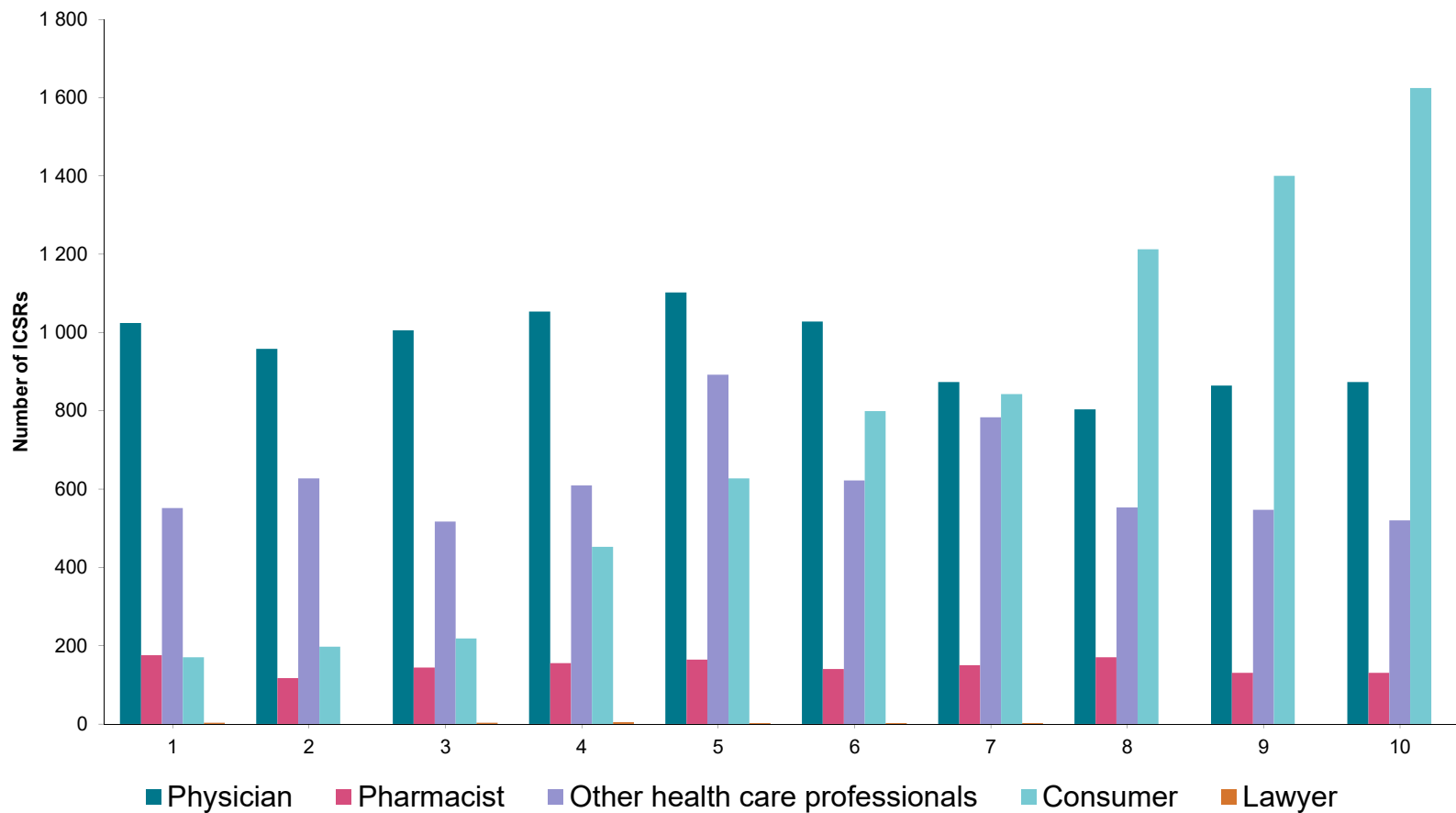


Key numbers 2020 (the last normal year...)

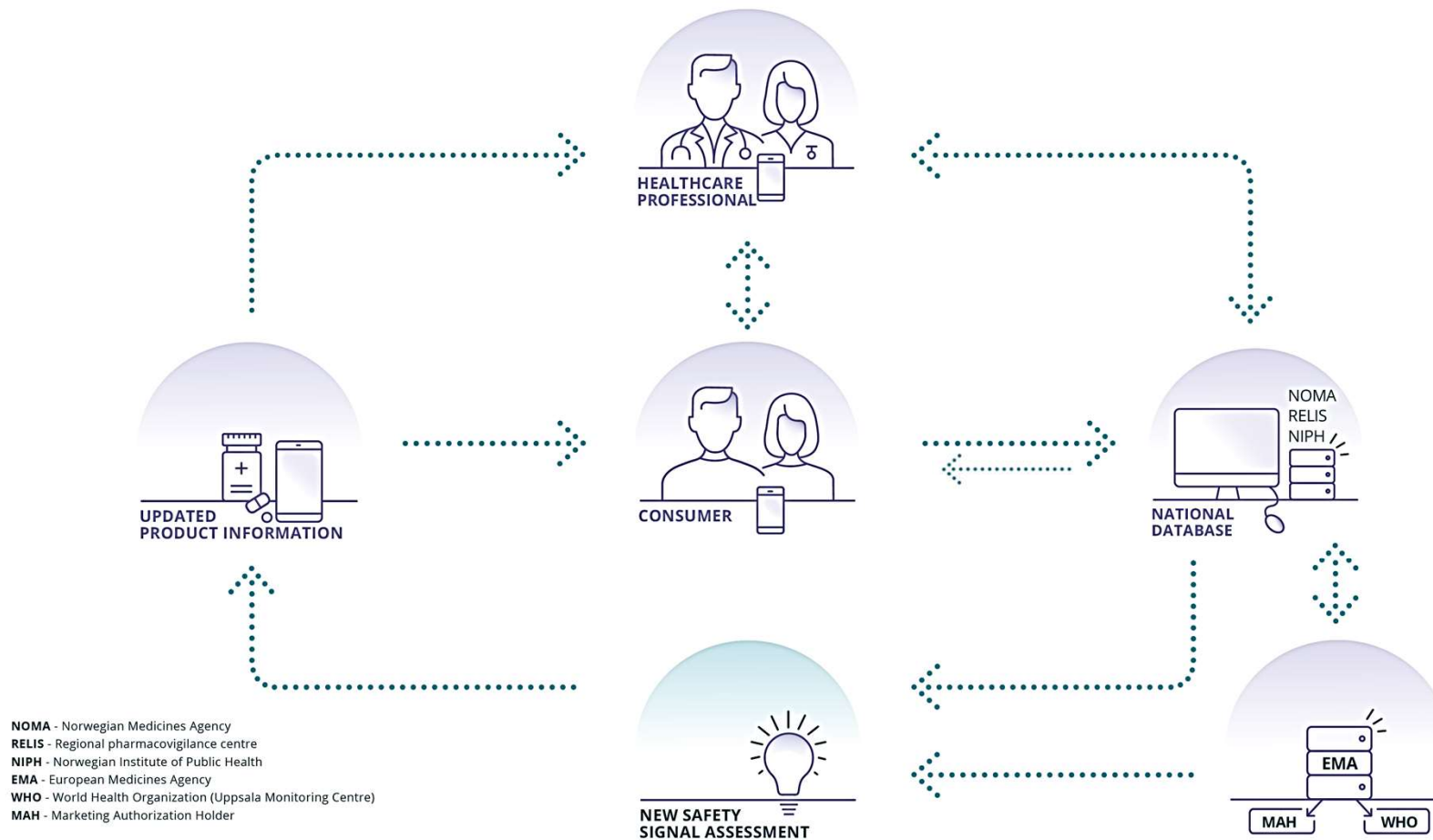
- Population: 5.4 million
- ICSRs: 5097
 - 0.95 cases per 1000 inhabitants
- 62 % if ICSRs reported directly to NOMA
- Serious 32 %



Received ICSRs by reporter type (not reported by MAH)



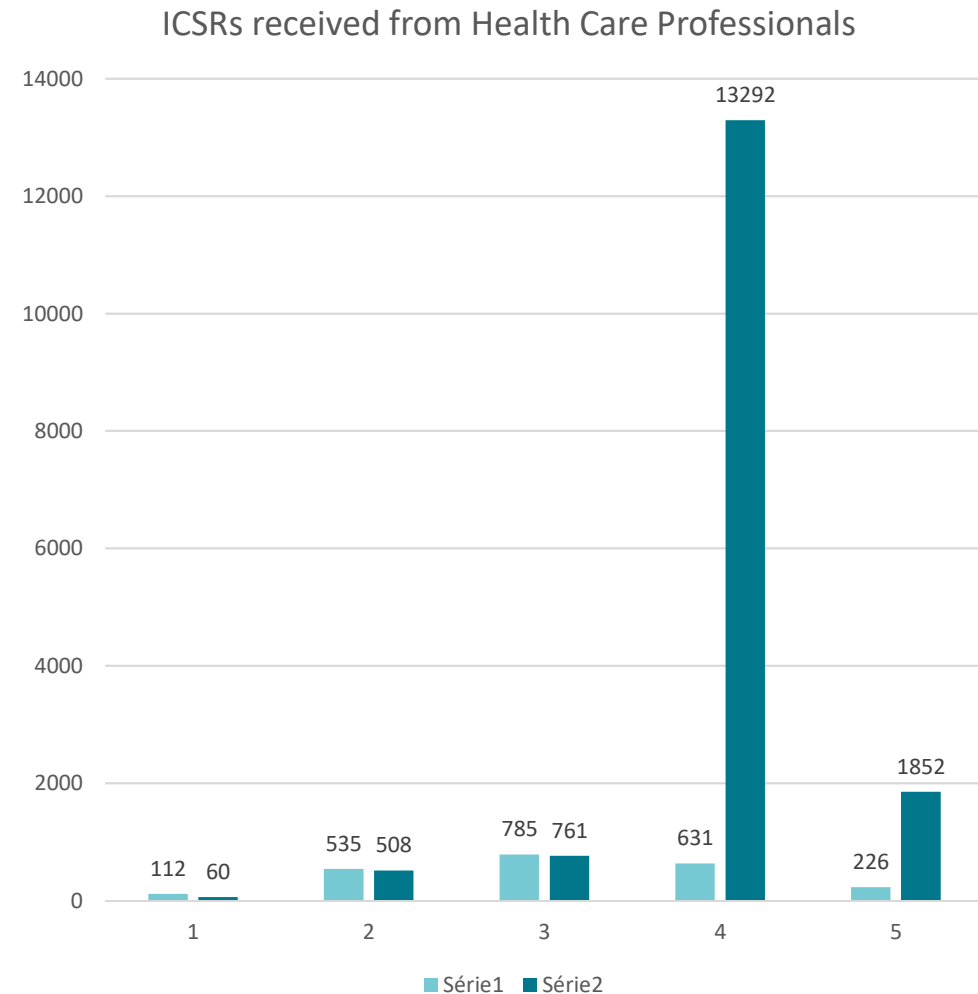
Spontaneous reporting system in Norway



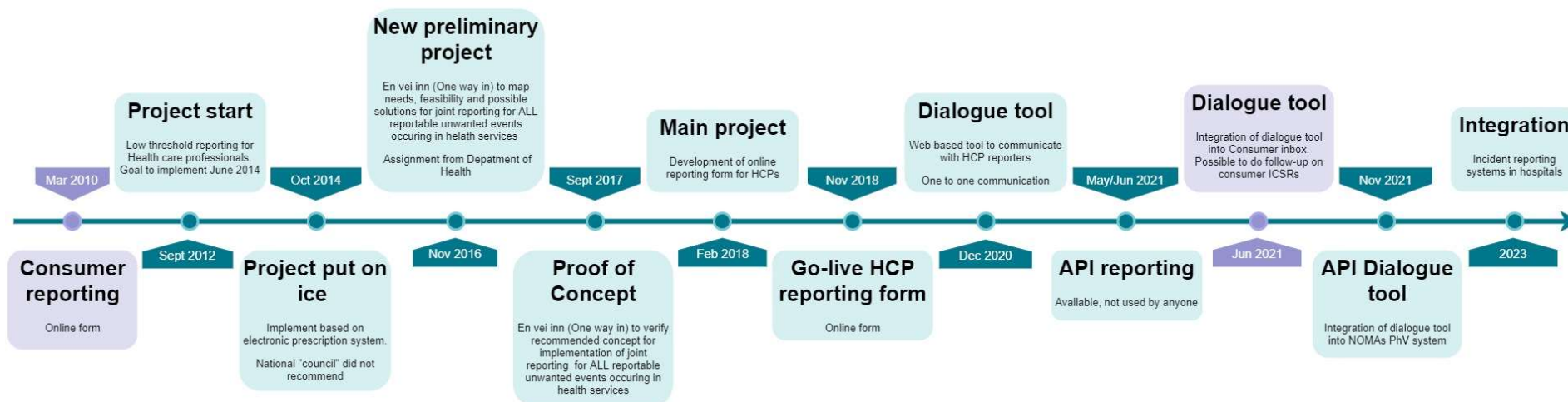
Paper vs electronic

- Consumer reporting is 100% electronic
- HCPs:
 - Paper form still available
 - Online form increasingly used
 - Pandemic has changed habits?

NOMA does not accept reporting by phone, fax or email



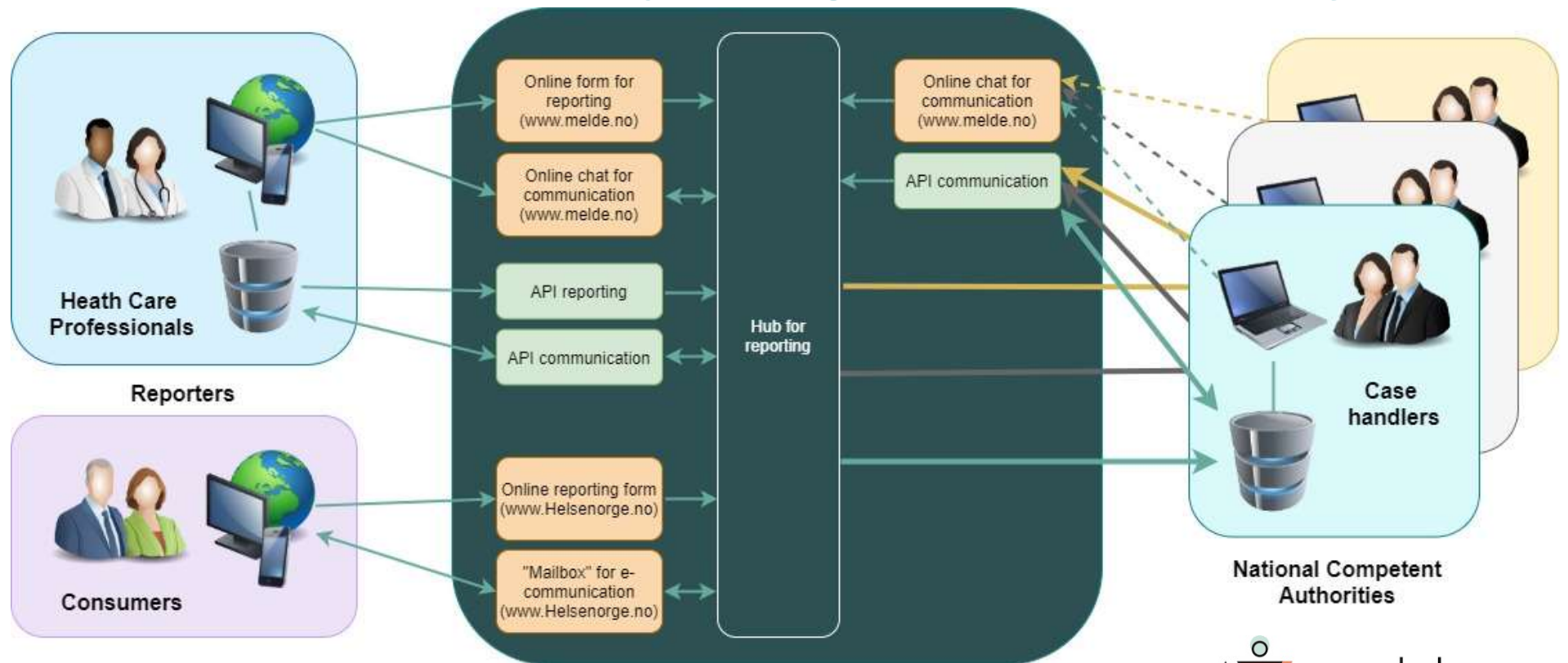
Timeline



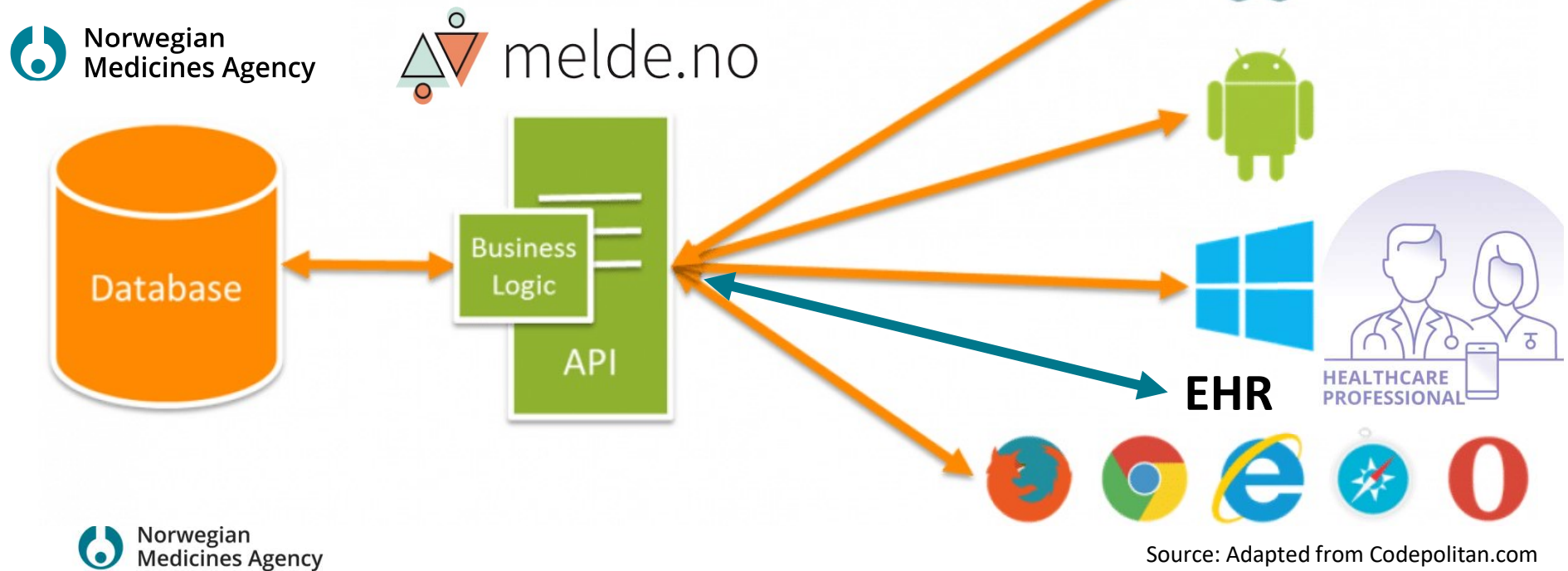
"Your patience will be rewarded sooner or later"

Fortune cookie, opened during implementation of new PhV system

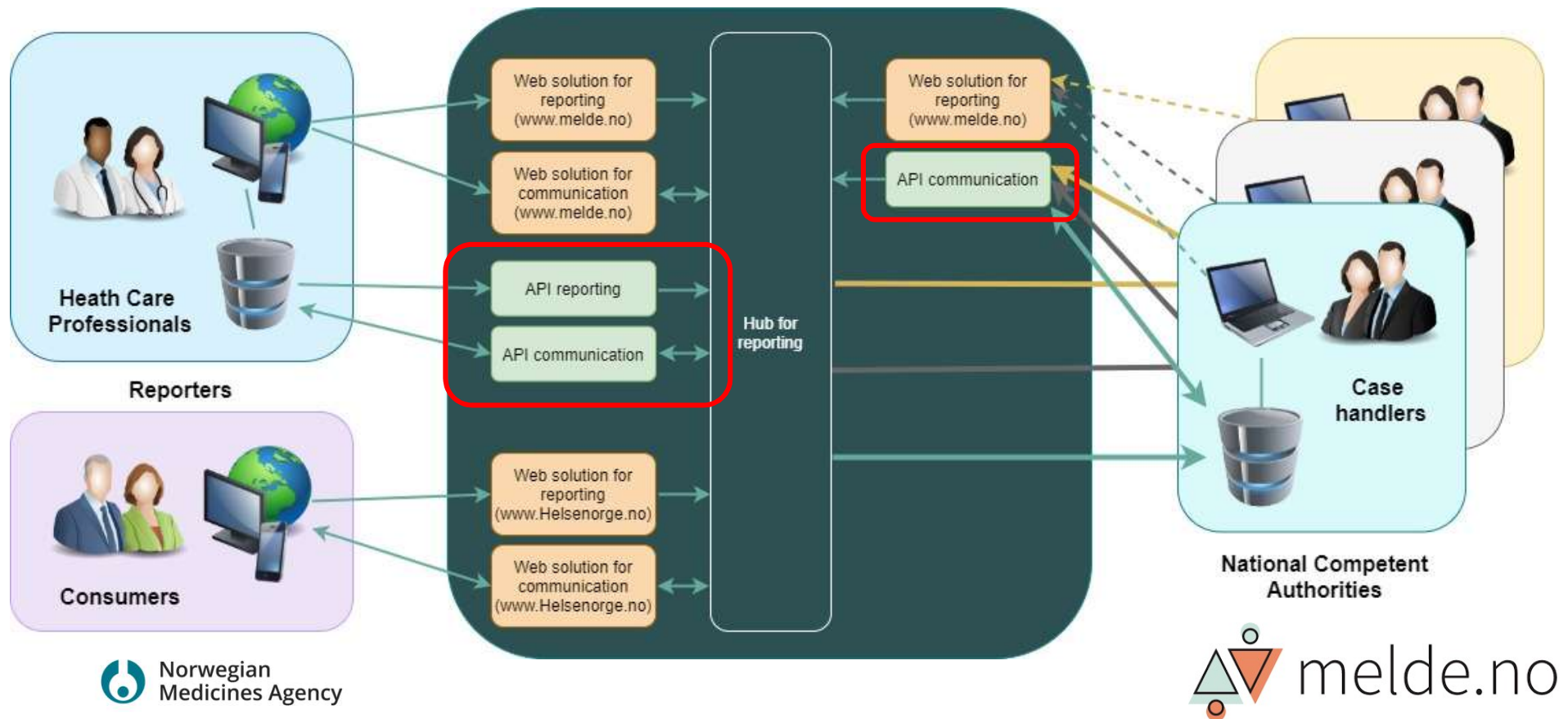
How electronic reporting works in Norway



What is an API (Application Programming Interface)?



How electronic reporting works in Norway



Reporting systems included in the national portal for reporting unwanted effects

- Adverse Drug Reactions
 - NCA: NOMA
- Adverse Drug Reactions for vaccines
 - NCAs: NOMA and the National Institute of Public Health (NIPH)
- Adverse events from Medical Devices
 - NCA: NOMA
- Serious adverse events in the Health care Services
 - NCAs: Norwegian Board of Health Supervision and Norwegian Healthcare Investigation Board (NHIB)
- Adverse events related to blood, cells, tissues and organs
 - NCA: Norwegian Board of Health Supervision
- Unwanted reactions from cosmetic products
 - NCA: Norwegian Food Safety Authority
- Adverse reactions from Dietary supplements
 - NCA: Norwegian Food Safety Authority





- Choose reporting system
- Online form “built” based on choice
- Joint “modules” for information where possible
- If possible: Information automatically fetched from other sources
 - Example: Reporter details, patient details, further details on medicinal products

Hva gjelder den uønskede hendelsen, skaden eller bivirkningen?

Noen uønskede hendelser (avvik) kan være melde- eller varslingspliktig til flere. Basert på valgene du gjør i skjemaet, sender vi hendelsen til den eller de ordningene den skal til.

Velg en eller flere ordninger hendelsen, skaden eller bivirkningen skal til.

<input type="checkbox"/> Bivirkningsregisteret for legemidler og vaksiner Behandles av RELIS og FHI (vaksiner) for Statens Legemiddelverk	?
<input type="checkbox"/> Varselordningen for alvorlige hendelser Behandles av Statens Helseetilsyn og Statens undersøkelseskommisjon i helse- og omsorgstjenesten	?
<input type="checkbox"/> Meldeordningen for uønsket hendelse med blodgivning og blodtransfusjon (hemovigilans), humane organer eller celler og vev Behandles av Helseetilsynet	?
<input type="checkbox"/> Meldeordningen for medisinsk utstyr Behandles av Statens Legemiddelverk	?
<input type="checkbox"/> Meldeordningen for kosttilskudd Behandles av Mattilsynet	?
<input type="checkbox"/> Meldeordningen for kosmetikk Behandles av Mattilsynet	?

Avbryt

Gå videre

It is very time
consuming to fill
out the online
form!



It would be a lot easier to report ADRs if the reporting form was integrated in our Electronic Health Record systems



This functionality is
not prioritised by the
Health Care
Professionals



Thi

As long as it is not
prioritised by users,
we will not develop,
even if you pay us...



Norwegian law says...

- It is mandatory to report suspected ADRs of medicinal products if:
 - It has led to fatal or life-threatening reactions
 - ADRs has caused lasting serious consequences
 - The suspected ADRs are unknown or unexpected
- The business where the health care services are provided are responsible for **ensuring that the reporting obligations can be fulfilled** and **must ensure that there are routines** that ensure this.

Future development – Integration 😊

- Integration into Incident reporting system at hospitals
 - Step 1: Serious adverse events in the Health Care Services. Implementation first half of 2023
 - Step 2: ADRs medicinal products (included vaccines). Planning starts second half of 2023
- Integration into Central Prescribing Module
 - Plug-in for EHR systems in primary care

Challenges

- Technical
- Structured data vs unstructured data
 - Easy for the reporter vs easy for NCA
- Terminology
- «Tribal language»
- Data protection and other legal requirements
- Fitting a square peg into a round hole...
 - Trying to merge several reporting forms for different national competent health authorities
 - It might look like you are collecting the same information, but it is maybe not so
- Financial
- Uptake
 - Multiple EHR systems
 - Important, but rarely needed?

The dream scenario

- A solution for reporting that makes it easy for the reporter
 - Minimal entry of information already available in Electronic Health Records or other systems
 - The reporter only report once, the system makes sure that the report is
 - recorded in local incident reporting system
 - submitted to relevant NCAs

A lot of challenges, but ...

It is possible 😊

*“Your patience will be rewarded
sooner or later”*

Technical specifications for APIs

- Norwegian webpage but technical specifications in English

<https://utviklerportal.nhn.no/informasjontjenester/melde/>

Thank you for listening!

noma.no



Norwegian
Medicines Agency