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Reflection paper on forecasting demand for medicinal products in the EU/EEA

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[1] Adopted by the EU Executive Steering Group on Shortages of Medicines Caused by Major Events on 21 May 2021

1. Introduction

As stated in Article 81 of Directive 2001/83/EC "The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered. The arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition…" Therefore, marketing authorisation holders are responsible for the continued supply of medicinal products.

Shortages of medicinal products are an important public health issue. They are particular concerns in the context of exceptional (e.g. pandemic) situations that lead to a considerable increase in the demand for certain medicines. This reflection paper has been developed in the context of such an event – the COVID-19 pandemic – and builds on the experience accumulated by the regulatory authorities during the initial months of this pandemic with respect to ICU medicines used in the treatment of COVID-19 patients. It aims at setting recommendations for medicines' demand forecasting, which is essential for correct adjustments in the manufacturing and distribution of medicinal products to avoid or at least mitigate the impact of shortages. Although the focus of the reflection paper is on demand forecasting at national level by EU/EEA Member State authorities during the COVID-19 pandemic, its principles can be also applied for forecasting demand in other situations and/or by other stakeholders.

2. Aim of the reflection paper

The aim of this reflection paper is to facilitate forecasting demand for medicinal products for human use in the EU/EEA. This reflection paper, therefore, provides a set of recommendations that can support demand forecasting at national level. It is based on learnings accumulated by EU National Competent authorities during the first wave of the COVID-19 pandemic and aims at summarising best practices and facilitating a harmonised EU approach to forecasting demand for medicines, whenever such activity is undertaken. It includes considerations on the general principles of demand forecasting, as well as practical suggestions for the creation of comparable national demand forecasts.

The reflection paper includes practical recommendations and examples specific to help with the preparations for a further progression of the COVID-19 pandemic. However, many of the general principles set out in this reflection paper could be used in the context of other pandemics where there is a need to forecast demand for medicines.

While the reflection paper is intended to support such demand forecasting by the national competent authorities for medicines, such additional forecasting activity is in no way intended to substitute for the responsibilities set in the legislation for marketing authorisation holders.

The reflection paper reflects the knowledge and experience accumulated at the time of its adoption. The reflection paper will be updated in light of new information.

3. Main principles of demand forecasting

While major uncertainties with regards to the actual future demand for the medicines exist, the imperative public health need to prepare for potential major increase in demand dictates the need to make pragmatic predictions of demand for certain medicines through the use of best available information. While more precise estimates may be available for a short-term outlook (for around a

month), considering that the ultimate goal of demand forecasting is to inform the planning of the manufacturing of medicines, it is recommended that the demand forecast covers at least a period of 6 months.

It must also be taken into account that there may be important differences between the Member States, e.g. with regards to clinical practices or the extent of data available. Therefore, whenever possible, alternative approaches are being proposed which are considered to be compatible and allow for comparable demand forecasting in the EU/EEA.

In the context of COVID-19 pandemic, it is proposed that the demand forecasts are calculated based on the number of mechanically ventilated and not mechanically ventilated COVID-19 patients expected to be treated in ICU, the average consumption of the medicines for each category and the expected demand for non COVID-19 patients, considering also the impact of stock levels on the future demand (in case of a surplus stock or planned replenishment of stocks).

4. Estimation of future epidemiological progression

An **epidemiological model** is the foundation for determining the forecast of the quantity of medicines needed in the context of an epidemic or pandemic, quantifying the number of patients who may need to be treated over time, while accounting for uncertainty.

Many factors can influence the course of this pandemic, which may or may not differ for each Member State, including:

- MS's response strategy to the coronavirus disease: pharmaceutical interventions (PIs, i.e. treatment, vaccination), non-pharmaceutical interventions (NPIs, e.g. stay-at-home recommendations, physical distancing measures, hand and respiratory hygiene, use of facemasks), exit strategy, testing policies, contact tracing, strategies adopted regarding specific medically vulnerable populations (long-term care facilities, high-risk groups, socially vulnerable groups, etc.), healthcare strategies and surge of capacity both for outpatient and inpatient care;

- Adherence of the population to the measures;

- Re-importation of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the population;

- Seasonality in transmission;

- Protective immunity in the population (including its persistence);

- Availability of vaccines or effective treatments; and,

- Other actions based on new scientific evidence.

The **policy choices** made by various governments are possibly the most challenging factor to anticipate and include in predictions. These choices of NPIs, healthcare, strategy in long-term care facilities, etc. have a significant impact on the course of the pandemic, which makes it difficult to accurately predict the evolution of the implications of disease in the **longer term**.

4.1. Methods

Different Member States have so far used **different models or methods** for forecasting the possible future epidemiological progression for which the preparations must be made:

- Long-term predictions can be made by **exploring different epidemic pathways and scenarios**; mathematical modelling allows the robust quantification of uncertainty alongside such predictions.

As it is impossible to predict the exact course of the pandemic, this approach would require a **policy choice** to determine the outcome for which one wishes to prepare, e.g. realistic case, worst case, average (i.e. choice of the most adequate scenario).

The forecast should be considered as a snapshot based on which the future needs are determined. Given the fact that the situation can change or evolve very quickly, it must be recalled that this snapshot can quickly become obsolete because it would no longer be based on the most recent information and insights. Accordingly, the demand forecasts will have to be updated on a regular (monthly) basis.

- Given the uncertainty in available epidemiological models, a pragmatic approach could be envisaged by modelling the demand forecast based on the **maximum capacity of Intensive Care Unit (ICU) beds** in each Member State. This is based on the assumption that the full ICU capacity will be reached and maintained for a period of time, which possibly means an overestimation.

  In this approach, the requirements for stocks and supply are based on the maximum number of beds available and not the demand itself. However, it has the advantage that the number of ICU beds per Member State is a known and comparable parameter that can be applied in a short period and will be standard for next pandemics. It is also recommended to consider any potential increase of ICU beds capacity, in order to use the maximum capacity which is not necessarily the actual capacity. It is also necessary to compensate for the fact that not all ICU beds will be occupied by COVID-19 patients, also because the medicine requirements are different for a COVID-19 versus a non-COVID-19 patient.

- A third approach consists of using **historic data from previous wave(s)** of the pandemic and to forecast the needs based on a wave similar to the first one, taking into account also new information on the disease treatment, progression to ICU, stay in ICU etc. This approach has its limitations as some Member States will not necessarily be affected to the same extent during a future progression of the pandemic. This is reinforced by the fact that the policy and the measures taken may not be identical to that in the first wave, and testing, tracing and treatments may have in the meantime evolved.

The heterogeneity of the different models used means that the resulting current demand forecast data are not fully comparable. For a coordinated European forecasting, therefore, it is necessary to use **common principles in modelling** to achieve an approach that can be applied for each Member State, taking into account local specificities of each Member State.

4.2. Indicators

Different indicators can be relevant for the demand forecasting, giving a progression over time of the daily number of:

- New confirmed cases;
- New hospital admissions of COVID-19 patients;
- Total hospitalised COVID-19 patients (or occupancy);
- New ICU admissions of COVID-19 patients;
- Total ICU COVID-19 patients (or occupancy);
- Newly mechanically ventilated patients;
- Total mechanically ventilated patients (or occupancy);
- New deaths.

For most ICU medicines, the number of **ICU patients to treat** is considered the most relevant indicator, to be expressed in patient-days for each month. This information can either be obtained by multiplying the number of ICU admissions with the average duration of stay at ICU[2] or by drawing the cumulative total number of ICU patient-days per Member State (i.e. the sum of the number of ICU patients for each day of the month or average number of ICU patients per day multiplied by number of days in the month).

It is acknowledged that it can be very difficult to differentiate the number of **mechanically ventilated patients** directly in the model. In the absence of this information, it is recommended to use presumptions on the proportion of mechanically ventilated patients (e.g. based on historic data from previous wave(s)).

It is recommended to consider whether a **margin** should be built in the forecasting or not, to compensate for a potential underestimation of the progression of the pandemic. The need for building in a margin will depend on the policy choice made on the scenario used for demand forecasting.

Additional parameters can be important for demand forecasting, which can also vary from country to another, e.g. average length of stay in ICU and hospitals, the proportion of COVID-19 patients in ICU and hospital. Some of these parameters can be available through ECDC TESSY (The European Surveillance System).

4.3. Identification of best available data source in the context of COVID-19 pandemic

To calculate medicines' demand, the estimation of future pandemic progression must result in the expected total number of ICU COVID-19 patient-days per month (or a comparable parameter, see section 5), for a 6-month period. It is also necessary to indicate separately this parameter for the subgroup of mechanically ventilated patients. Various sources and approaches to estimating these parameters exist, with differences in their reliability and the time period covered. Therefore, the most reliable and suitable source should be selected for each month of the forecast period.

Single-scenario epidemiological models can only produce short-term reliable forecasts – currently in the EU such forecasts for all MSs are available for a 1-month period and are provided by ECDC. Epidemiological modelling work based on the same methodology for all EU MSs is also conducted by the Joint Research Centre (JRC) of the European Commission, with longer term forecasts being limited by the uncertainties in application of further response measures.

As longer-term demand forecasts are needed for making changes to production planning, it is necessary to also explore different scenarios for a long-term progression of the pandemic. To ensure homogeneity, a harmonised set of prospective scenarios for a future progression of the pandemic would preferably be developed at EU/EEA level. In this regard the JRC have developed an online tool for generation of several possible scenarios (possible for all MSs) with a harmonised methodology, to which the access can be granted for MS representatives. It will be necessary to identify at the national level the most suitable scenario for estimating expected progression of the pandemic, based on the particular situation in the respective country. Future learnings, e.g. with regards to identification of circumstances when response measures are being introduced or lifted could be incorporated in updated scenarios, when more information on latest Member States' practices becomes available. In the meantime, in case a more detailed information on expected response measures is available nationally, the scenarios may be developed nationally. When several possible scenarios for pandemic progression are identified, considering that it is not possible to calculate an exact probability of each scenario, a

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[2] Multiplying number of ICU admissions with average ICU stay duration will not take into account that the ICU stay of patients admitted by the end of a given month can span into the following month. This approach can therefore lead to an overestimation of the ICU activity for the respective month and an underestimation for the following month.

policy choice on which scenario to use as a basis for forecasting demand and preparing for the progression of the pandemic is needed. Such policy decision should identify the most plausible worst-case scenario.

Other possible sources include estimates based on total ICU capacity and extrapolation of data from previous wave(s) of the pandemic.

The recommended sources, in decreasing sequence of preference, are the following:

1. Data from a common, harmonised EU epidemiological model with separate outputs for each MS (i.e. a model that considers also the factors at national level that impact the progression of the pandemic);

2. Data from a national epidemiological model;

3. Data from one of several identified possible scenarios for progression of the pandemic (identified through a policy choice as the most plausible worst-case scenario) – harmonised EU/EEA level scenarios (or nationally developed scenarios) can be used and choice of a particular scenario preferably is to be made for the entire EU/EEA;

4. Data based on ICU capacity (with addition of estimates for the maximum ICU bed occupancy rate by COVID-19 patients);

5. Extrapolation of data from previous wave(s) of the pandemic (with adjustments to account for changes in various factors affecting the progression of the pandemic, where possible).

If a national model and/or scenario is being used, it is still necessary to ensure that the data are comparable, therefore experience from other Member States should be considered when developing national models. In addition, caution should be exercised when combining data from different models for different months of the forecast, to avoid over- or under-estimation due to differences between models in the expected time of peak patient numbers (e.g. not to select the months with highest level of ICU activity from each model).

In certain cases, it may be necessary to combine several sources to obtain the necessary estimates (e.g. number of infected patients obtained from epidemiological model, and proportion of ICU patients and mechanically ventilated ICU patients extrapolated from experience in previous wave(s) of the pandemic).

5. Data elements for demand forecasting

Forecasting demand for medicines is essential for an effective medicines supply chain, in particular in an epidemic context, to avoid shortages. An integrated approach is proposed which takes into account:

- *what will be needed for treatment of patients,*

- *what will be needed to restore planned minimum stock levels,*

- *what is currently available in the stocks held by e.g. hospitals, wholesalers and manufacturers.*

One of the important steps of the *demand forecasting process* is the selection of the appropriate data elements (variables) that would enable predicting the expected level of need.

During the 1st wave of the COVID-19 pandemic, several countries developed their own approaches to forecasting demand with models differing in many respects, including data sources, level of granularity of outputs and time period covered. Based on existing modelling practices in some Member States and the need to ensure comparability of demand forecasts, it is necessary to define a set of data elements to be used in demand forecasting.

As countries have different information systems and different levels of data granularity, it is considered important to identify variables that are essential for forecasting demand in a harmonised manner in the EEA/EU (hereafter referred to as *minimum data needs*). In addition, variables that may increase forecast accuracy, but may not be available in all countries and/or were not considered essential for obtaining comparable demand forecasts, are presented as *optional data elements*.

5.1. Data elements for forecasting demand

To forecast demand of ICU medicines, it is important to take into account:

- Need for these medicines - both for COVID-19 and non COVID-19 patients;
- Planned minimum stock – *the minimum amount of a medicinal product that should be present in the country's supply chain to assure continuity of supply to patients at any moment in time;*
- Available Stock - currently available stocks within the supply chain.

Forecasting COVID-19 patients' needs should in principle be based on estimated ICU occupancy and the average daily use of medicines, while non COVID-19 patients' needs can be estimated by historical use, adjusted by variations in non COVID-19 activity (e.g. decrease of non-urgent medical care). Additional sources of demand may need to be estimated at national level in some cases, where relevant in the context of the respective healthcare system (e.g. use of some of the ICU medicines for COVID-19 patients outside ICU setting).

The impact of stocks is to be accounted for by taking into account the current available stocks and planned minimum stocks. If the current available stocks exceed the planned minimum stocks, it implies that there is surplus stocks that can be used without a need to replenish them, while in case the planned minimum stocks exceed current available stocks it implies that the country will increase the stock levels during the forecast period.

5.1.1. COVID-19 patients' needs

The estimation of COVID-19 patients' needs should preferably be based on estimated number of patient-days and average medication use per medicine per patient per day. However, in absence of forecast for the total number of COVID-19 patients requiring ICU care, it is acceptable to base the demand forecasting on the total ICU capacity.

5.1.1.1. ICU Occupancy

The recommended variable to express ICU occupancy is the **number of ICU patient-days** in a **month**.

Number of ICU patient-days	
Definition	Expected number of COVID-19 patient-days in ICU
Period	Calendar month
Source	Identified epidemiological scenario/prediction model in section 4

Calculation of ICU activity in patient-days

		Month x
Epidemiological model/scenario outputs	Average number of patients in ICU	α
	Average number of mechanically ventilated patients in ICU	β
	Number of new ICU admissions	γ
	Number of new patients with mechanical ventilation initiated	δ
	Number of patients in ICU for each day of the month	ε
	Number of mechanically ventilated patients in ICU for each day of the month	ζ
Data on ICU care	Average duration of stay in the ICU	η
	Average duration of mechanical ventilation	θ
	Proportion of ICU patients that are mechanically ventilated	ι
Month	Number of days in the month	κ
ICU activity	Number of COVID-19 ICU patient-days (d)	$(α-β)*κ$ or $γ*η-δ*θ$ or $α*κ*(1-ι)$ or $γ*η*(1-ι)$ or $Σ(ε)-Σ(ζ)$
	Number of COVID-19 ICU mechanically ventilated ICU patient-days (e)	$β*κ$ or $δ*θ$ or $α*κ*ι$ or $γ*η*ι$ or $Σ(ζ)$

When data on predicted ICU patient-days are not available in a MS, an estimate can be based on a combination of the number of hospitalisations, the percentage of these transferred to ICU and average duration of stay.

In case this information is also not available, total (planned) **ICU capacity** could be used, which in fact reflects the worst-case scenario – *all ICU beds are occupied*. This should include the currently existing capacity as well as any additional capacity that is planned (or can be deployed) during future progression of the pandemic. Despite being more easily available, the use of this variable can lead to an overestimation of the needs, therefore it is recommended to establish what proportion of beds would be used by COVID-19 patients in case of a full ICU occupancy. With this approach it is also important to consider whether the full ICU occupancy would last for the entire forecast period (normally 6 months), or whether it is expected that additional measures to limit SARS-CoV2 transmission would be put in place in a situation of full ICU occupancy, leading to a lower occupancy in subsequent months (in demand forecast calculations such lower expected occupancy would have to be reflected by lover estimated proportion of beds used by COVID-19 patients).

Number of ICU bed-days	
Definition	Number of (planned) ICU beds available in the country, multiplied by the number of days in the month, multiplied by the estimated proportion of ICU beds occupied by COVID-19 patients[3] In case information on the proportion of ICU beds occupied by COVID-19 patients is not possible to estimate, the total number of ICU beds can be used.[4]
Period	Calendar month
Source	Hospital data and other national sources

Calculation of ICU activity in bed-days

		Month x
ICU capacity	Number of ICU beds	λ
	Number of mechanically ventilated ICU beds	μ
Month	Number of days in the month	κ
COVID-19 patients' needs	Number of ICU bed-days (d)	$(\lambda-\mu)*\kappa$
	ICU mechanically ventilated bed-days (e)	$\mu*\kappa$

If both the patient-day and bed-day forecasts are provided, the data on patient-days should be used for the calculation.

The number of mechanically **ventilated ICU patient-days** is important for certain medicines where use differs between mechanically ventilated and not mechanically ventilated patients and therefore should be considered separately. Preferably, this information should be available from the epidemiological model. In the absence of an estimate for number of mechanically ventilated ICU patients, an average proportion of mechanically ventilated patients must be assumed for the calculations (e.g. based on experience from previous wave(s)). In case the approach based on total ICU capacity is used (see above), the total number of mechanically ventilated ICU beds should be used accordingly for this purpose.

Separate calculations based on number of ICU patients with or without mechanical ventilation is only useful if average use of medicines differs between these two groups of patients. In case there are no substantial differences between the groups (or if separate average use of medicines values cannot be obtained) the same value for average use of medicines can be used for both groups.

5.1.1.2. Medicine Use

To express the expected use of medicines, the recommended variable is the **average daily use** per medicine per ICU COVID-19 patient-day.

Two approaches to defining the average daily use are possible – it can either be based on consumption data, adjusted based on clinical input, or it can be based on input from clinical experts only.

Historical data on medicines use can be used to estimate average use per medicine per patient-day after consultation with clinical experts and where applicable, making adjustments according to new scientific knowledge and the possible impact of new products.

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[3] In this case the occupancy should be estimated as proportion of beds available (and not as proportion of total COVID-19 and non-COVID-19 ICU patient numbers) in order to account also for any unoccupied beds, if applicable
[4] In case of a calculation based on full ICU occupancy for COVID-19 patients, it is particularly important to consider the impact on use of medicines for non COVID-19 patients.

For example, for dexamethasone, the use pattern changed after the RECOVERY study. Therefore, if historic consumption is used for dexamethasone to estimate average daily use, it is necessary to identify when medication use started to reflect current use pattern and only historical data from this time point onwards should be used.

The estimates of medicines use should preferably be made at national level, as clinical practices often vary between the countries. However, in case it is not possible to obtain this information, the estimates developed for other MSs with similar clinical practices or estimates provided by experts could be used.

Average use per medicinal product for COVID-19 patients	
Definition	Expected average daily use per medicine per ICU patient-day: *Based on input from clinical experts*: Average daily dose x (duration of treatment/ duration of ICU stay) x proportion of patients needing the medicine *Or* *Based on recent consumption data*: Cumulative daily use over all ICU patient-days divided by total number of ICU patient-days, adjusted based on clinical input (where necessary)
Source	Based on input from clinical experts or historical consumption data adjusted based on clinical input

Parameters for all medicines	
Average duration of the ICU stay without mechanical ventilation (days)	q
Average duration of mechanical ventilation (days)	r
Parameters for an individual medicine	
Duration of treatment for ICU patient without mechanical ventilation	s
Duration of treatment for mechanically ventilated patient	t
Average daily dose for ICU patient without mechanical ventilation	u
Average daily dose for mechanically ventilated ICU patient	v
Proportion of ICU patients without mechanical ventilation requiring the medicine at some point during the mechanical ventilation	w
Proportion of mechanically ventilated ICU patients requiring the medicine during the ICU stay (excluding mechanical ventilation, if applicable)	x
Average use per medicinal product for COVID-19 ICU patients without mechanical ventilation	$u*w*s/q$
Average use per medicinal product for COVID-19 mechanically ventilated ICU patients	$v*x*t/r$

Since medicines use might differ between mechanically ventilated and not mechanically ventilated patients, the above calculations are recommended to be done separately for mechanically ventilated and not mechanically ventilated patients (or beds).

In cases where values of average use of medicines per patient per day are not available for the specific member state the use of average values obtained from the available EU/EEA data can be considered instead, but the impact of differences in national practices must be considered and adjustments made, where possible.

COVID-19 patients' needs calculation

Medicine A		Month x
ICU Activity	Number of ICU patient-days	a
	ICU mechanically ventilated patient-days	b
	Number of ICU bed-days	d
	ICU mechanically ventilated bed-days	e
	Estimated occupancy by COVID-19 patients	f
COVID-19 patients' medicines use	ICU mechanically ventilated patient average use	h
	ICU not mechanically ventilated patient average use	i
COVID-19 patients' needs	Total ICU mechanically ventilated patients' needs	(b OR e*f) *h
	Total ICU not mechanically ventilated patients' needs	[(a-b) OR (d-e)*f)] *i

5.1.1.3. Use outside the ICU setting

In case healthcare arrangements in a MS lead to the use of the concerned medicines in COVID-19 patients outside the ICU setting, e.g. in regular wards or care homes, this use should also be accounted for. Unless already included in the above calculations (e.g. as part of estimated 'ICU' patient-days), it is recommended to estimate and report separately the expected extent of such use.

The expected use outside the ICU settings can be calculated similarly to that of the ICU setting, i.e. by multiplying the expected number of COVID-19 patient-days with use outside ICU setting with the expected average daily use per medicine per patient-day outside ICU.

Number of patient-days with use outside ICU setting	
Definition	Expected number of COVID-19 patient-days with use of ICU medicines outside ICU setting
Period	Calendar month
Source	Identified epidemiological scenario/prediction model or another source as discussed in section 4

Average daily use of medicinal product for COVID-19 patients outside ICU setting	
Definition	Expected average daily use per medicine per patient-day (for patients using the medicines outside ICU setting):
	Based on input from clinical experts: Average daily dose x (duration of treatment / duration of stay in the facility or setting where patients are taken into account for the number of patient-days with ICU medicines use outside ICU setting) *Or* *Based on recent consumption data*: Cumulative daily use over all patient-days divided by total number of patient-days, adjusted based on clinical input (where necessary)
Source	Based on input from clinical experts or historical consumption data adjusted based on clinical input

COVID-19 patients' needs calculation

	Medicine A	Month x
Activity outside ICU setting	Number of patient-days with use outside ICU setting	c
COVID-19 patients' medicines use outside ICU setting	Patient average daily use outside ICU setting	g
COVID-19 patients' needs outside ICU setting	Total COIVD-19 patients' needs outside ICU setting	c * g

5.1.2. Non COVID-19 patients' needs

For the non COVID-19 patients, medicine use forecasts can be based on historical use or supply, preferably matched for the same month of the year, to account for seasonal patterns of demand (particularly important for antibiotics) and adjusted for any (expected) changes to the regular non COVID-19 hospital and/or ICU activity.

Medicinal product use for non-COVID-19 patients	
Definition	ICU medicine use in historical month (or, if not available, annual monthly average)
Period	Month
Source	Historical medicinal products use/supply pre-COVID-19. If historical use is based on supply, it is recommended to adjust it for recurrent shortages.

Non COVID-19 patients' needs calculation

	Medicine A	Month x
Non COVID-19 medicines' use	Historical use by month	j
Hospital Activity	Parameter for reduction in non COVID-19 activity (0 = no reduction, 1 = no non-COVID-19 use)	k
	Total non COVID-19 patients' needs	j*(1-k)

5.1.3. Data elements concerning stocks

Although elements reflecting stocks may not be available in all countries and for all segments of the distribution chain, this information is essential to accurately forecast demand. For those countries where data on stocks is not available, developing a reporting system that can provide such data should be considered.

In this section, it is important to distinguish the two types of stocks that are needed to forecast demand:

- **Available stocks** – Current stock levels in the distribution chain available at wholesaler, hospital and manufacturers level[5.] If a strategic reserve of medicines is in place, this should also be considered as available stock.

- **Planned minimum stocks** – the minimum amount of a medicinal product that should be present in the country's supply chain to assure continuity of supply to patients at any moment in time.

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[5] Products at manufacturer level that are not intended for that market should be excluded from the calculation

5.1.3.1. Available stocks

In some MSs, information from a stakeholder might not be available or might be too difficult to obtain, in which case any missing data need to be clearly identified. If data is not available for a specific stakeholder, it is recommended to assume no stock is available, as worst-case scenario.

Available stocks	
Definition	medicines available at a defined moment in the supply chain (at strategic reserve, wholesaler, hospital and manufacturers level, excluding products not intended for that market)
Period	One specific date at the beginning of the demand forecast period
Source	National reporting system

Available stocks calculation

Medicine A	Stakeholder	On date mm/dd/yyyy
Available stock in distribution chain	Pharmaceutical companies	l
	Wholesalers	m
	Hospitals	n
	Member State (strategic reserve)	o
	Total Stock	**l + m + n + o**

5.1.3.2. Planned minimum stock levels

A minimum stock level, intended to be maintained at all times, can be established at MS level (depending on local requirements and situation it could be e.g. decided that a 1-month consumption will be used as the safety stock value or it could be calculated based on the consumption during a previous wave of a pandemic or base it on an estimate of total stock level that will always be attempted to maintained by respective stakeholders). Based on this information, when calculating the amount of medicines needed any surplus stock (i.e. the amount by which available stocks exceed planned minimum stocks) can be taken into account as available stock that does not require replenishment. Any deficit in the stocks (i.e. the amount by which planned minimum stocks exceed current stocks) can be taken into account when calculating the demand expected for replenishing the stocks (i.e. in addition to demand for treatment of new patients).

In cases when available stock information is known but planned minimum stocks have not been identified, the stock effect should not be taken into account in the calculation of the total demand, in order to avoid underestimation of the expected demand.

5.2. Examples of demand forecast calculations

Example 1 – Forecast demand for a medicine based on ICU patient-days, including expected use for COVID-19 patients outside ICU setting

	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Number of COVID-19 ICU patient-days (a)	1000	1100	1200	1500	1300	1200
Number COVID-19 ICU mechanically ventilated patient-days (b)	400	500	700	900	800	750
Average use per not mechanically ventilated patient-day (h)	0.4	0.4	0.4	0.4	0.4	0.4
Average use per mechanically ventilated patient-day (i)	0.8	0.8	0.8	0.8	0.8	0.8
Total ICU mechanically ventilated patients' needs	320	400	560	720	640	600
Total ICU not mechanically ventilated patients' needs	240	240	200	240	200	180
Use for COVID-19 patients outside ICU setting	0	50	100	100	50	50
Total COVID-19 patients' needs, grams	**560**	**690**	**860**	**1060**	**890**	**830**
Historical use of the medicine per month, grams (j)	800	840	860	850	840	830
Parameter for Non COVID-19 activity reduction (k)	0	0.1	0.2	0.3	0.2	0.2
Total Non COVID-19 patients' needs (j*(1-k))	**800**	**756**	**688**	**595**	**672**	**664**
Available Stock at Month 1:						
Stock at pharmaceutical compnies (l)	600					
Stock at wholesalers (m)	1100					
Stock at hospitals (n)	300					
Member State's Strategic Reserve (o)	300					
Total Available Stock at the start of the month (l+m+n+o)	**2300**	**2,333**	**2,367**	**2,400**	**2,433**	**2,467**
Planned Minimum Stock (p)						**2500**
Demand forecast per month, grams of active substance	**1,393**	**1,479**	**1,581**	**1,688**	**1,595**	**1,527**

Example 2 – Forecast demand for a medicine based on ICU bed-days, with no expected use for COVID-19 patients outside ICU setting

	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Number of ICU bed-days (d)	1800	1800	1800	1800	1800	1800
Number of mechanically ventilated ICU bed-days (e)	1200	1200	1200	1200	1200	1200
Estimated occupancy by COVID-19 patients	0.6	0.7	0.8	0.9	0.8	0.7
Average use per not mechanically ventilated patient-day (h)	0.4	0.4	0.4	0.4	0.4	0.4
Average use per mechanically ventilated patient-day (i)	0.8	0.8	0.8	0.8	0.8	0.8
Total ICU mechanically ventilated patients' needs	576	672	768	864	768	672
Total ICU not mechanically ventilated patients' needs	144	168	192	216	192	168
Use for COVID-19 patients outside ICU setting	0	0	0	0	0	0
Total COVID-19 patients' needs, grams	**720**	**840**	**960**	**1080**	**960**	**840**
Historical use of the medicine per month, grams (j)	800	840	860	850	840	830
Parameter for Non COVID-19 activity reduction (k)	0	0.1	0.2	0.3	0.2	0.2
Total Non COVID-19 patients' needs (j*(1-k))	**800**	**756**	**688**	**595**	**672**	**664**
Available Stock at Month 1:						
Stock at pharmaceutical compnies (l)	600					
Stock at wholesalers (m)	1100					
Stock at hospitals (n)	300					
Member State's Strategic Reserve (o)	300					
Total Available Stock at the start of the month (l+m+n+o)	**2300**	**2,333**	**2,367**	**2,400**	**2,433**	**2,467**
Planned Minimum Stock (p)						**2500**
Demand forecast per month, grams of active substance	**1,553**	**1,629**	**1,681**	**1,708**	**1,665**	**1,537**

5.3. Measurement units for reporting demand forecasts

Besides identifying the variables needed to forecast demand, measurement units for reporting the calculated demand for a particular medicine, also need to be defined. It is recommended to use the following units:

Medicinal product identification	Measurement units
Active substance and route of administration (or pharmaceutical form)	*Total mass of active substance* (in grams or other units of mass, to be determined for each product based on suitability in light of the posology) *Notes: For fixed dose combination products the mass of the active substance that is listed first should be used.* *An exception is to be applied for products where mass is not used for expressing product strength, e.g. use IU for heparin.*
Example: midazolam solution for injection	*x milligrams*