JCP'S ATTRIBUTION METHODOLOGY TO THE PHARMACEUTICAL SECTOR APRIL 2019

EXECUTIVE SUMMARY

The pharmaceutical sector in Jordan is considered one of the main pillars of the Jordanian economy, an advanced sector and one step ahead of regional competitors. This is due to the sector's various strengths which include qualified local human resources and a favorable business environment. Despite the sector's positive performance on the trade balance, JCP believed there is room for expansion in exports and employment opportunities with the given growth in the regional market and with advantageous government support.

In its first year, Jordan Competitiveness Program (JCP) studied Jordan's highest-potential sectors and identified pharmaceuticals as a primary driver of economic growth and job creation. At the time, the industry was constrained by regional conflicts, including in Iraq and Syria—traditional trading partners whose borders were effectively sealed by ongoing violence—and losing main markets like Libya and Yemen due to war.

The pharmaceutical sector was, to borrow a phrase, "too big to fail"—a signature Jordanian industry that contributed tens of millions of dollars to the national economy and could catalyze the country's recovery in the face of shrinking exports and an economy struggling under the weight of an unprecedented refugee crisis. As JCP's remit was to boost the competitiveness of Jordan's economy, the pharmaceutical sector was an obvious choice for the kind of assistance only USAID, with its resources and long history of working with the Jordanian government, could provide.

Hence, with the exports, investment and jobs as main targets; the pharmaceutical sector fell perfectly under JCP's direction and areas of focus. Therefore, JCP started and continues to play a substantial role in the development and upgrading of the pharmaceutical industry into world-class standards by working closely with the Jordan Food & Drug Administration (JFDA) and the industry through the Jordanian Association of Pharmaceutical Manufacturers (JAPM).

With the long pharmaceutical value chain and cycle, in addition to the major qualitative and quantitative contributions to the sector by JCP; an attribution methodology aimed to evaluate and measure the performance of the portfolio of activities supported by JCP for the pharmaceutical sector has been the

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+962 79 6772888
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main purpose and the main objective of this document. Specifically, a focus on the evaluation of those interventions that support streamlining the drug registration process and thus accelerate reviews of new drug submissions especially for locally manufactured generics; which would expedite the registration of pharmaceutical products by JFDA; reduce the time to market for drugs; facilitate access to export markets and increase exports to regional and international markets, and also create new job opportunities.

This document also includes a description of the drug registration process, and the different interventions undertaken by JCP across the pharmaceutical value chain to improve it and to better prepare local manufacturers to meet the stringent registration requirements locally and in the export markets.

This attribution document reveals how JCP has exerted a significant influence on enhancing pharmaceutical exports and employment by streamlining the drug registration process. The formulas for calculating the attribution are presented below, which estimates JCP's attribution for the annual pharmaceutical exports at 12.27 % of the overall exports of 2018 and 2.5% of the over export in 2019 considering a 2.23 years average time needed for locally manufactured medicines to be available to export markets[1]. In addition, to an estimation of 633 direct jobs and 968 indirect jobs increase in sector's employment for 2017 and beyond.

This is measured under JCP's custom indicator 1.3.1 "Estimated percentage increase in two key export sectors as a result of JCP sector level intervention", while Employment figures are measured under the following custom indicator; "1.2 Number of Direct and Indirect Jobs created but not filled as a result of JCP's interventions". The results for both have been accumulated from two main pillars:

1- Impact of JCP on drug registration by clearing the drug backlog between the years (2013- 2015) resulting in:
   a. 12.27 % improvement of annual Pharma exports
   b. 538 Direct Jobs Generated
   c. 823 Indirect Jobs Generated.

2- Impact of JCP on drug registration based on the timelines saved and on the actual number of registered dossiers in 2016 where the actual exports realization will start to occur at least at an average of 2.23 years after registration; this has resulted in:
   a. 2.5% improvement in annual Pharma exports in 2019
   b. 95 Direct Jobs Generated
   c. 145 Indirect Jobs Generated.

The above impact from backlog clearing of dossiers 2013-2015 is separate from the impact of streamlining work dossiers of 2016.

[1] Average process time for Saudi market x % exports to Saudi + Average process time for rest of markets X % of exports to rest of markets
= 3 years x 23% + 2 years x 77%
= 2.23 years

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The employment numbers are based on the study that has been conducted earlier by IQVIA measuring the contribution of the pharmaceutical sector to the Jordanian economy in additional to DoS numbers.

INTRODUCTION

The Jordanian pharmaceutical industry is considered as one of the pioneers and most competitive industries in the Arab countries. Pharmaceutical companies export 80 percent of their production to 87 countries worldwide, in addition to supplying 30 percent of all pharmaceuticals sold in the domestic market. The industry is primarily driven by branded generic exports.[2]

However, the highly regulated industry is facing several challenges that are hindering further growth and negatively impacting its profitability and competitiveness. Stringent regulatory and registration requirements represent significant barrier to entry. The "drug registration" in Jordan is the first step to move to export markets. Any pharmaceutical product must be registered by the regulatory authority to be approved for sale in the market. Jordanian Food and Drug Administration (JFDA) is the official body in charge of approving pharmaceutical products for sale in Jordan.

JCP has intensively studied the pharmaceutical value chain, identified bottlenecks, hurdles and corresponding interventions, where delays of drug registration were identified as the main bottleneck during JCP's accelerator workshops conducted at the start-up of the project in collaboration with public and private sectors. The below figure (*Figure 1*) illustrates the different interventions undertaken by JCP across the pharmaceutical value chain.

[2] JAPM Data

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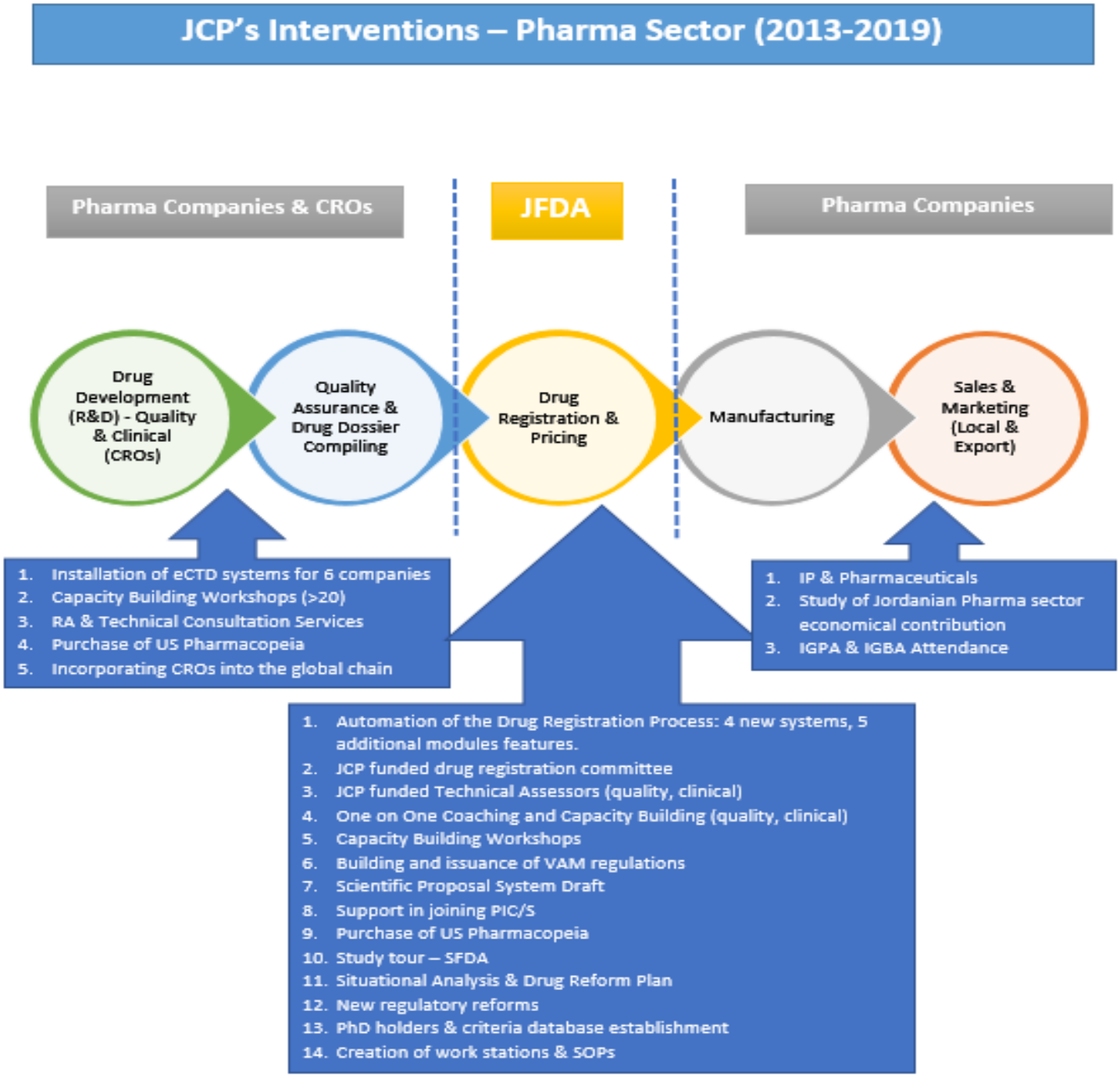

Figure 1 JCP's Interventions in the Jordanian Pharmaceutical Sector (2013-2019)

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As it can be noticed from the figure above, a great number of activities are directed towards working with the regulatory authority for medicine in Jordan which is the JFDA. To explain more, to enable any locally manufactured medicine to either sell locally or in the export markets, it has to be registered in Jordan which is considered "the country of origin".

Focus group meetings, workshops and interviews with local drug manufacturers and stakeholders in the sector conducted by JCP at the start of the project revealed it takes around two years for local and international drug manufacturers to register their drugs in Jordan after conducting a rigorous assessment. Thus, this has been identified as the main bottleneck hindering fast export; the main reasons for the significant delay in registering the pharmaceutical products in Jordan are:

1) Improper or insufficient submission of products' dossiers resulting in several back and forth deficiency letters and,
2) Limited resources and staff of the JFDA to deal with the increasing number of dossier submissions.

The following section illustrates additional explanation of the drug registration process for further understanding of how the attribution methodology is built up.

DRUG REGISTRATION PROCESS

The drug registration process consists of several phases starting at the drug manufacturer's side of dossier development, compilation and submission to JFDA where a series of comprehensive assessments, review and analysis takes place.

For simplicity in description and analysis, we have labelled and described these steps/phases as follows:

- ***Pre-Submission:*** The preparation of drug registration dossier by pharmaceutical companies to be ready for electronic submission to JFDA.

- ***Submission:*** The submission of registration dossiers according to JFDA requirements and the set standards and criteria. After initial assessment the dossier is sent back to the manufacturer for incompletions, if any, before it moves to the next phase.

- ***Review:*** This phase is the longest and most critical stage in the process. It consists of a number of overlapping reviews; specifically, technical evaluation, drug lab validation and clinical assessment.

The registration process sequence and dependencies is illustrated in the below figure (*Figure 2*). During any point of assessment, if any deficiencies are identified, feedback is sent to the manufacturer to be addressed and resubmitted. After passing all assessments, the dossier moves to issuance of the drug dossier approval and registration certificate.

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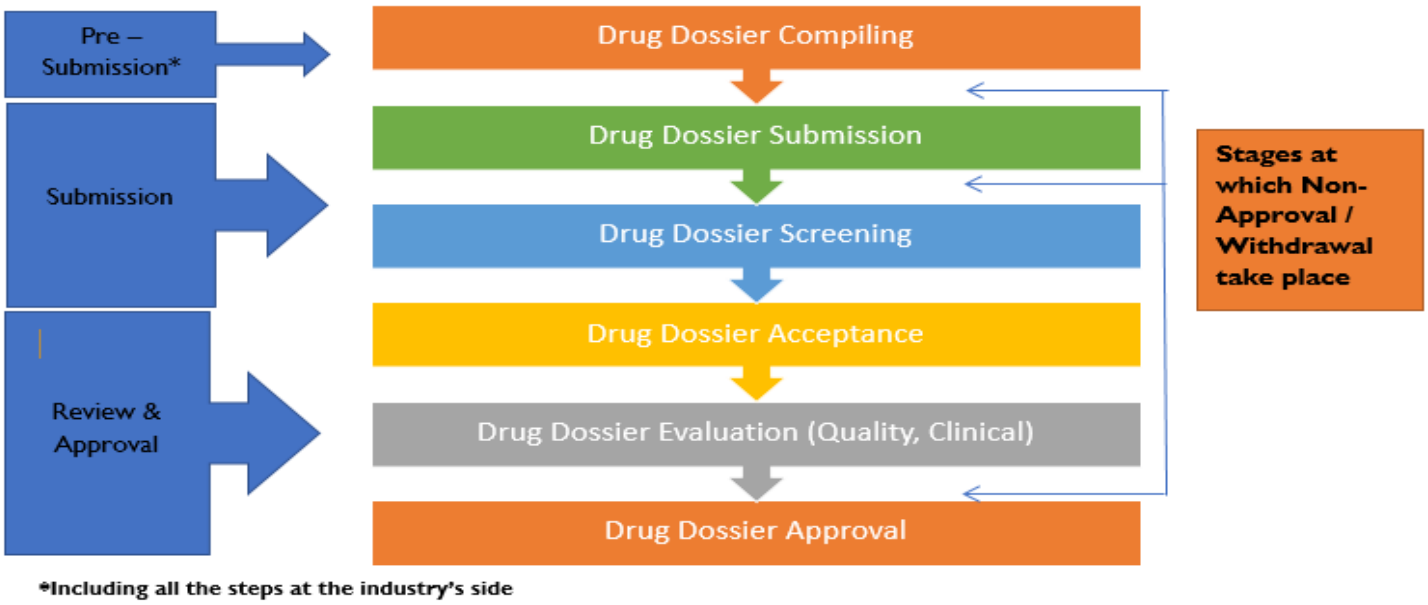

Figure 2 JFDA's Drug Registration Process

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ATTRIBUTION METHODOLOGY

The drug registration process improvement is determined by comparing its efficiency prior and post JCP's interventions. The process efficiency is measured by the increased technical capacity (human and technological resources) at the JFDA for drug back log clearance, in addition to the decreased time frame for the registration of drug dossiers as detailed below:

- At the beginning the average time for studying and registering a file was 2 years. In end of 2016; the mid review indicated reduction in the time to be 1 year and 4 months based on sample of files studied (2014-2016). JCP is working with JFDA on the final review to measure the time saved after the completion of all interventions.
- When JCP started the backlog clearance process, it started with back log from 2012 and today, JFDA actually are clearing backlog of files submitted in 2018/2019 and for the BE 2019. JFDA are on track.
- JCP and JFDA conducted pre and post assessments for the registration team to evaluate the gained knowledge and identify further areas of development that JFDA can build their capacity building plan upon. Refer to Annex 5.

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The attribution calculations followed the following process

1. Setting the Credit Attribution Criteria - Statistical View
2. Categorizing JCP's Interventions per Registration Phase
3. Identifying the Relative Importance (%) of each Registration Phase
4. Identifying Weights per Each Registration Phase
5. Calculating JCP's Credit Attribution per Phase
6. Calculating JCP's Impact on Pharma Exports from:
   - Clearing Drug Backlog (2013-2015)
   - Time Savings on drug registration (2016 onwards)
7. Calculating the Actual Realization of Exports
8. Calculating JCP's Impact on Sector Employment

Hence, in the coming sub-sections, we explain how we set criteria to evaluate the relative input of the main stakeholders (JCP, JAPM and JFDA) in improving the registration process; then we discuss how this input resulted in process improvement, how much of this improvement is attributable to JCP, and how much this translates to improvements in sector exports; mainly speaking, calculating the impact of JCP from:

1- Clearing the drug backlog between the years (2013- 2015).
2- Time savings and the actual number of registered dossiers in 2016 where the actual exports realization will occur at least 2.23 years after registration – refer to section 7 of this document for details on calculating the 2,23 years.

As for employment, the numbers are based on the study that has been conducted earlier by IQVIA measuring the contribution of the pharmaceutical sector to the Jordanian economy. Further details are explained in later sections.

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LIMITATION AND MITIGATION

The drug registration process consists of several phases starting at the drug manufacturer's side of dossier development, compilation and submission to JFDA where a series of comprehensive assessments, review and analysis takes place. The laid out process in this attribution, was labelled as described earlier for simplicity in description and analysis.

The team within JFDA working with JCP for the past 5 years, are the registration team who are engaged in their daily operational activities within JFDA; and the limitation in resources didn't allow JFDA to assign dedicated team to work with JCP on the implementation of activities; which resulted in extended duration of implementation and the response needed from JFDA to finish activities in timely manner and collection of data for verification, monitoring and evaluation purposes.

The data utilized needed for the calculations in this report comes from four sources:

1. JFDA records
2. JCP records and previous studies
3. JAPM records
4. DOS

This has helped in the ability to obtain and verify the data. However, this does not mean that the available data is readily useful and in an easily accessible form, several additional efforts took place in order to clean the data, verify the numbers and propose the attribution above. This is especially true for data at JFDA as it compiles and consolidates data in specific ways to support its day to day work. Data from JFDA was available per product, while data from DOS was available for total annual export value of the Pharmaceutical sector. JCP staff and advisors needed to work very closely with JFDA to assimilate the needed figures in a manner that is useful for our analysis. Even though this was a very time-consuming effort but it proved to be a time that is well invested as both JCP and JFDA now have the understanding of what data is needed (and in what form) for future updates.

Where data was not easily obtained and available in the required forms for the purpose of this document, in certain cases we opted to use a conservative approach of showing less credit to JCP based on the reliable data available or decided not to claim credit to JCP at all in a specific intervention or a specific year.

1. CREDIT ATTRIBUTION CRITERIA

JCP, JAPM and JFDA took part in different ways in the interventions leading to registration process improvement. To reach the specific contribution of JCP in comparison to other players, criteria for determining credit among these three players were developed.

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Division of credit among stakeholders

- 100% credit when sole players during any stage.
- 75% credit for lead role among stakeholders.
- 60% credit for prominent role among stakeholders.
- Equal credit for similar role among stakeholders.

The criteria sets a percentage to the contribution of players depending on how key of a role they played at any given stage and the number of contributors who played a meaningful role at that stage.

- **100% credit** is given to the party that was the sole player in undertaking a certain activity or was clearly the leading party with minimal support from other parties.
- **75% credit** is given to the party that took the lead on an activity, but the cumulative role of other parties as supporting actors was also important.
- **60% credit** is given to a party that contributed more than all the other actors combined but not to the point where it was considered to have been leading the group with the other actors combined considered to have been operating in a supporting role.
- **Equal credit** is given to two or more parties who are estimated to have shared equally in an activity. Therefore, if between two actors the credit is 50% each, among three it becomes 33.33%, and so on.

2. JCP'S INTERVENTIONS PER REGISTRATION PHASE

As the drug registration process is the longest and most time consuming process in the Jordanian pharmaceutical value chain to enable medicines to start generating sales and revenues; JCP's interventions in support of streamlining this process covered all the phases of drug registration.

Since 2014, JCP's support took many forms including: capacity building, technical assistance, introduction of new systems, automation and institutional strengthening, etc. JCP worked collaboratively with local manufacturers through (JAPM) and the regulator (JFDA) to ensure the maximum benefit from its interventions.

First, the methodology aimed at grouping the activities conducted by JCP where they most fit under the three phases of the drug registration process explained earlier and according to the support type whether technical assistance, procurement and/or capacity building.

This has been done to:

1. Illustrate the depth and breadth of JCP's support to the sector.
2. To enable us to quantify the activities and set weights for them in a later stage of the attribution methodology.

The below tables summarize JCP interventions grouped by phase of registration process. Further details are illustrated in Annex 1 including which entity was primarily supported by each activity.

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Pre-Submission Phase:

Support Type	Activities
Technical Assistance Activities[3]	1. Drug registration task force establishment; 2. Preparing a situation analysis matrix for the drug registration process at JFDA; 3. Developing a reform plan with short, medium- and long-term solutions; 4. Providing technical assistance to JFDA to understand JFDA's exact relevant business needs, challenges, technical & capacity readiness in relation to eCTD. 5. Conducting regulatory affairs and technical consultation services to the industry; 6. Scientific advice system drafting and proposal; 7. Study the Jordanian pharmaceutical sector contribution to Jordan's economy, investment climate and health expenditure cost savings.
Procurement Activities	1. Purchasing the United States Pharmacopeia (USP); 2. eCTD systems installation at 6 pharmaceutical manufacturing companies.
Capacity Building Activities	1. Scientific and Regulatory Assessment of Generic Registration Dossiers Workshop (for JFDA); 2. Assessment of Generic Pharmaceutical Applications, from JFDA Assessors' Perspective Workshop (for Industry); 3. USP Development and Validation of Analytical Procedures Workshop: 4. IP & Pharmaceuticals Workshop; 5. Bioequivalence Workshop; 6. PIC/S training and capacity building workshop for JFDA Inspectorate by PIC/S Expert; 7. Post Approval Changes New Guidelines Workshop; 8. Scientific and Regulatory Assessment of Generic Registration Dossiers Workshop; 9. How to Avoid Bioequivalence (BE) Deficiencies Workshop; 10. Validation of Analytical Methods Workshop; 11. Value Added Medicine Workshop; 12. Supported Jordanian delegation participation in the IGPA and IGBA conferences; 13. Sponsored US Pharmacopeia Education Training; 14. Training on requirements for testing drugs and validation of analytical methods.

Submission Phase:

[3] Pre and post tests were performed by JCP trainers to measure the effectiveness of the training sessions and to determine further capacity building needs by the participants. An example of such reviews in provided in annex 5.

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Support Type	Activities
Technical Assistance Activities	1. Create workstations for receiving and reviewing drug registration files at JFDA; 2. Intern to JFDA to prepare administrative arrangements for technical committee; 3. Work instructions for registration file receipt, screening and technical assessment.
Capacity Building Activities	1. Conducted a study tour to Saudi Food and Drug Authority (SFDA)

Review Phase:

Support Type	Activities
Technical Assistance Activities	1. Amended "Incentives & Rewards Regulation No. 72 for year 2003"; 2. Establishment of a comprehensive database of pharmaceutical Ph.D. holders and selection and assessment criteria for evaluating technical experts' competencies; 3. Support JFDA in Joining Pharmaceuticals Inspection Corporation Scheme - PIC/S; 4. Establish Value Added Medicine Task Force creating a draft for VAM regulations; 5. Technical assistance to help draft VAM regulations plus VAM capacity building; 6. Technical assistance to review the quality part of the dossiers, Capacity Building for JFDA's staff & competencies gap analysis; 7. Technical Evaluator for the quality part; 8. Technical Evaluator for the BE part; 9. Review sub-committees fully funded by USAID JCP, clearing the backlog since 2012
Procurement Activities	1. Purchase and Install eCTD EURS System; 2. Import / Export System Integration; 3. E-Payment Solution Purchase and Integration; 4. Invoicing Portal Solution Integration; 5. Integration of 5 additional features to the eJDWS; 6. Purchasing the United States Pharmacopeia (USP) to enable the JFDA to review according to the most recent updates.
Capacity Building Activities	1. Assessment of Analytical Methods and Validation Workshop; 2. Assessment and review of Bioequivalence (BE) dossiers; 3. Training for the current and potential technical committee members' experts. 4. Capacity Building for JFDA's staff with regards to Bioequivalence; 5. Capacity Building for JFDA's staff with regards to Biowaivering;

3. IDENTIFYING THE RELATIVE IMPORTANCE (%) OF EACH REGISTRATION PHASE

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Each of the activities performed by JCP was analyzed from the relative contribution value provided by each of JCP, JAPM and JFDA. This analysis is based on –the Credit Attribution Criteria developed above. JCP's team in collaboration with both JAPM and JFDA have reviewed the Pharma interventions and set credit distribution percentages based on the effort and value performed by each. The interventions and credit distribution are detailed in Annex 1.

Different methods were considered to determine the practicality of evaluating each intervention on its own and tagging a weight to its value in comparison to other activities:

1. First, we considered the value added to be connected to the dollar value of each intervention, but this approach did not produce indicative results. For example, a study tour involved more expenses but is not necessarily more valuable than a locally held training session by an expert on a common area of weakness among all manufactures. Similarly, procurement of an expensive system that is a requirement in the Pharma sector is not necessarily more valuable than a workflow system developed locally to address inefficiency in process flow within JFDA.

2. The same line of thinking applies to value by type of activity: procurement versus capacity building versus technical assistance. This did not result in convincing conclusions because all the different activities overlap, complement and/or feed into each other.

3. Accordingly, this attribution methodology has concluded to group all activities as per the registration phases explained earlier. This has proved to be the most logical and most practical solution, especially that there are no available measurements or benchmarks in the industry to show how each activity alone affects the overall registration process.

The below summary demonstrates the overall credit for each of JCP, JFDA and JAPM per each phase of the drug registration process. The grouping of the activities with weights is found in Annex 1.

Credit Attribution by Phase as per Activities Grouping			
Phase	**JCP**	**JFDA**	**JAPM**
Pre-Submission	67.3%	12.2%	20.5%
Submission	80.0%	5.0%	15.0%
Review	72.5%	23.6%	3.9%

4. IDENTIFYING WEIGHTS PER EACH REGISTRATION PHASE

The next step in the analysis determines the relative importance of each phase in the process. Research on industry standards or literature did not yield any useful information to back this decision. We, therefore, resorted to two ways of analysis:

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1. We evaluated applying the same value to each phase since they sequentially follow each other, and the next phase cannot start until the previous one ends. While this is a valid approach, it does not address the complexity, length or resources needed during each phase. A case in point is the review phase which involves expert technical committees, lab tests and bioequivalence evaluation. The review phase is more complicated and time consuming in comparison with other phases, it also forms the bottleneck of the registration process where a backlog of drug dossiers accumulates to be reviewed. This has required major interventions by JCP to streamline the process.

2. The second method was to attach different weights to each phase depending on its complexity and duration. In consultation with JCP's team, JAPM and JFDA the below weights were assigned to fairly represent the relative importance of each phase.

Relative Importance of Each Phase		
Phase	**Weight**	**Comments**
Pre-Submission	30%	Drug manufacturers need to go through a complicated R&D process and several studies to be able to accumulate a complete dossier for submission purposes, noting that the dossier needs to comply with the regulatory standards (in Jordan, JFDA standards)
Submission	20%	This is a short process that requires less effort than pre-submission but still requires expertise to ensure if the drug dossier is complete according to the countries regulatory standards and requirements to be able to move to the review phase. .
Review	50%	This phase includes three critical technical and sensitive assessments (quality review, clinical evaluation, and laboratory validation testing) that lead to the dossier approval, deficiency (ies) generation or rejection decision. In the latter two, the drug dossier is sent back to manufacturer to address the deficiencies to be re-submitted for another review cycle. This phase is thus the most complicated and most time consuming.

5. CALCULATING JCP'S CREDIT ATTRIBUTION PER PHASE

JCP's overall credit attribution (from all the activities it undertook during all review phases resulting in streamlining the dossier submission and review process) is 72.4%. This percentage is calculated by multiplying JCP's attribution per phase with the relative weight of that phase as shown in the below table:

JCP's Credit Attribution			
Phase	**JCP Attribution**	**Phase Weight**	**Totals**

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Pre-Submission	67.3%	30%	20.2%
Submission	80.0%	20%	16.0%
Review	72.5%	50%	36.3%
JCP's Overall Attribution			72.4%

For comparison purposes, if we use equal weights for each phase then JCP's overall attribution would be almost the same according to the calculations in the below table.

JCP's Credit Attribution by Using Equal Weights			
Phase	**JCP attribution**	**Phase Weight**	**Totals**
Pre-Submission	67.3%	33.33%	22.4%
Submission	80.0%	33.33%	26.7%
Review	72.5%	33.33%	24.2%
JCP's Overall Attribution			73.2%

6. CALCULATING JCP'S IMPACT ON PHARMA EXPORTS

To measure JCP's impact on exports, the below section explains the methodology that resulted in the proposed total percentage of a 12.27% improvement in annual pharmaceutical exports for the year 2018 and 2.5% improvement in 2019. This improvement has been derived from two main pillars:

1. Impact of JCP on drug registration by clearing the drug backlog between the years (2013- 2015) resulting in 12.27% improvement of annual Pharma exports for the year 2018 only,
2. Impact of JCP on streamlining the drug registration process based on the timelines saved and on the actual number of registered dossiers in 2016 where the actual exports realization will start at least 2.23 years after registration; this has resulted in 2.5% improvement in annual Pharma exports for the year 2019.

For the years beyond 2019; the same equations can be reflected once the data is available

Further details are as follows:

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6.1 JCP'S IMPACT ON EXPORT FROM CLEARING DRUG BACKLOG (2013-2015)

In 2014 and 2015, JCP worked with JAPM and JFDA on a number of projects to improve drug registration. Although benefits of these interventions were starting to take shape during those years, still there was no formal assessment of the improvement in process efficiency. This has led us to refrain from claiming credit to JCP in this regard although it is warranted.

However, between the years 2013 and 2015, a large number of dossiers submitted by local manufactures had been waiting in queue at the JFDA to be reviewed. In 2015 JCP, in coordination with JFDA, identified qualified assessors to form an additional review committee at JFDA that was fully funded by JCP for a period of 11 months to clear the backlog of locally submitted drug dossiers

Hence, we limit JCP's credit evaluation to its role in clearing the backlog of drugs dossier submissions (2013 – 2015) that had accumulated at JFDA at the time. This was the base to measure the Impact of JCP on drug registration in earlier years (2013-2015) according to the following steps of analysis:

1. According to JCP's required reporting from the funded committee, **221 applications were reviewed** (few more than one time) and cleared during the period from May 2015 till March of 2016.

2. During years 2013 -2015 (Annex 2); an average of **12.65%** of dossiers were reviewed and rejected according to JFDA records. Applying this average to dossiers reviewed by JCP committee as well, results in:

   221 x (1-12.65%) = 193 drugs cleared and not rejected by JCP funded committee

3. JFDA records also show that all drug dossiers that were submitted (excluding the rejected ones) made it through the review process and became registered. **This leads to the conclusion that the 193 drugs referred to above became registered drugs and eligible for export.**

4. As explained earlier in the report, before JCP's interventions, drug dossiers took 2 years to go through the registration process. Now, with JCP's interventions that started in 2014, processing time was decreased to 16.5 months by 2016[4]. **This means that 7.5 months are saved in making the drugs available in the market.**

5. We used this improvement in time to calculate JCP's impact on the exports of drugs that were cleared by its funded committee. The time improvement due to JCP is probably more because the backlog could have stayed unaddressed for some time if the JCP funded committee was not established. Lack of data, however, does not allow delving fruitfully into this analysis. **JCP's**

[4] JCP was the primary consultant working with JFDA and local producers on the improvements necessary to streamline the process of submission (and review) of dossiers. JFDA and JAPM also played roles in these efforts and their contributions were acknowledged when determining the credit attributable to JCP.

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efforts led to the availability of 193 drugs in the market and ready to export 7.5 months earlier than it would have normally taken them without the support of the JCP funded committee.

6. In other words, sales in the local market and eventually to export markets became available 7.5 months (0.625 years) earlier due to JCP's effort. **This translates to impact on exports as follows:**

   a. **Drugs cleared and registered due to JCP funded committee efforts**
   = 193

   b. **Production available for exports account for 80% of total production; this implies that drugs available to exports are:**
   = 193 x 0.8
   = 154.4

   c. **Export value attributable to JCP**
   = (Drugs ready for export attributed to JCP x average annual value of exports per drug (JFDA's Exports Data 2016-2018*) X decrease in number of years drug became available for exports due to JCP effort
   = 154.4 x 577,120x 0.625
   = 55,692,112JD

   **The last three years of available export data.*

   d. **Reflecting this value in terms of percentage improvement in exports over one year's worth of Pharma exports**
   = Export value attributable to JCP / average annual Pharma exports (DoS Export Data 2016-2018) x100%
   = (55,692,112/453,741,533) x 100%
   = 12.27% improvement in one year's worth of annual sector exports due to JCP

   e. **The above improvement in exports is a onetime improvement over the life of JCP. Due to the fact that JCP's activity in clearing the drug registration back-log dossiers was initiated and concluded between May 2015 and March 2016 and considering the 2.23 average time to start export beyond the year 2015 and an additional year to record one full year of exports, then this percentage improvement is reflected in 2018's annual pharma exports**
   = 12.27 % improvement in 2018 annual sector exports due to JCP

6.2 JCP'S IMPACT ON EXPORT FROM TIME SAVINGS ON THE DRUG REGISTRATION PROCESS (2016 ONWARDS)

Since JCP's early start, JCP's staff conducted a number of interviews with local drug manufacturers and stakeholders in the sector. These interviews revealed that the drug registration process took around two years.

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Then in early 2017, JCP conducted another investigation where they studied over 100 dossiers reviewed and registered by JFDA. **The result was that the process time had dropped by 2016 from two years[5] to 1 year and 4.5 months - a total reduction of 7.5 months.** This improvement is used to measure JCP's attributable impact on drug registration for dossiers submitted to JFDA in 2016.

JFDA follows a method of recording all the data related to the dossiers submitted for registration from the submission point till the registration/rejection point per year. For dossiers submitted in 2016, the recorded data is summarized in Annex 2. It shows that the number of drugs registered from those submitted in that year is 107.

In order to measure JCP's attribution out of the registered products, the calculation is as follows:

a. **Number of drugs that would have been registered if the streamlining effort had not taken place**
   = Actual Drugs registered in 2016 X new duration / old duration
   = 107 drugs X 16.5 months / 24 months
   = 73.56 drugs

b. **Improvement due to process streamlining is then**
   = 107 – 73.56
   = 33.44 drugs

c. **We had established earlier that improvement in process streamlining attributable to JCP is 72.4%, hence Improvement attributable to JCP in terms of drugs registered is**
   = JCP's attributable share from all process improvement at JFDA x number of additional drugs registered due to JCP interventions
   = 72.4% X 33.44
   = 24.21 drugs

d. **Drug exports from total production by local companies is 80% as mentioned in the Introduction of this report and as was confirmed by JAPM. This implies that drugs available for export**
   = 24.21 x 80%
   = 19.37 drugs

e. The export value of these drugs is extracted by compiling company export figures from official JFDA records for all the products exported from the local manufacturers and their export value over three years. The analyzed data (available in Annex 3) shows that the average value per drug exported per year during the three years is JD 577,120– see Annex 3 for details.

[5] The two year timeframe was determined through stakeholder interviews and group discussions including private sector players and public sector representatives.

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f. This is used as the indicative figure of annual exports per drug in our below calculations to determine JCP's attributable impact on exports.
= (Drugs registered attributed to JCP x Annual value of exports per drug / total annual Pharma exports for 2018latest year of reference for exports) x 100%
= (19.37 x 577,120) / 446,626,400) x 100%
= 2.5% improvement in annual sector exports in 2019*

** Considering 2.23 years to export registered drugs and one additional year to record one full year of exports then exports of drugs registered in 2016 will be mostly recorded in 2019 - refer to section 7 of this document for full details on this calculation.*

We also note that in the above calculations, figures of export values per product for all local pharmaceutical companies are all obtained from JFDA, while the national exports for the Pharma sector were obtained from DOS (being the official source of this data).

g. Improvement in Annual Exports after 2019 can be calculated based on the Actual Drugs Registered in 2017, 2018 and 2019 and on the Annual Value of Exports per Product for 2020 and beyond. However, the data is not available yet.

7. CALCULATING THE DATES OF ACTUAL REALIZATION OF IMPACT ON EXPORTS

JCP's efforts in support of drug registration resulted, per our analysis, to improvement in export of

- 12.27% for cleared dossier backlog from 2013-2015, for the year 2018 only
- 2.5% for drug dossiers submitted in 2016, hence estimate exports for the year 2019 only,

This improvement is not however realized in exports of same years that the drugs were registered. This is because there is normally a registration process of at least 2 years in the export markets after drugs are registered at JFDA. Moreover, specifically for Saudi Arabia (which forms 23% of Jordan's Pharma exports) there is also an additional marketing year that the manufacturer has to wait after JFDA's approval before it can submit for registration in the Saudi Market.

The average time then for a drug to be available to export market is as follows:
Average process time for Saudi market x % exports to Saudi + Average process time for rest of markets X % of exports to rest of markets
= 3 years x 23% + 2 years x 77%
= 2.23 years

Therefore, i.e. for a drug registered in the end of June 2016 (average of all drugs registered between Jan-Dec 2016), it will take till the fourth quarter of 2018 for it to start exporting. Furthermore, to capture a full year of exports figures for the same drug would need to be collected until the fourth quarter of 2019.

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In reality then, the full impact of realized exports from JCP's interventions in the sector will actually start to show after the JCP's lifetime ends.

8. CALCULATING JCP'S IMPACT ON SECTOR'S EMPLOYMENT

During 2017; JCP has granted the Jordanian Association of Local Manufacturers (JAPM) a grant to conduct a study to measure the impact of the local pharmaceutical sector on the Jordanian economy. The study was led and managed by IQVIA which is a renowned company in healthcare statistics and data; it is considered the best worldwide with regards to health and pharmaceutical related data.

Considering the aforementioned study, in addition to official sources (DoS); the local employment generated as a result of JCP's Impact has been calculated according to the following procedure:

1. Total employment of the pharmaceutical sector extracted from IQVIA Study where they have extracted the numbers from DoS.

Employment in Pharma Industry	Number Of Employees		
	2013	2014	2015
Male	4,403	5,470	6,998
Female	3,492	3,325	3,252
Total	**7,895**	**8,795**	**10,250**

2. A CAGR (compound annual growth rate) has been calculated to extract the employment numbers for 2016, 2017, and 2018

Employment in Pharma Industry	Extrapolated Numbers			
	*CAGR**	2016	2017	2018
Male	*17%*	8167	9531	11122
Female	-2%	3176	3101	3028
Total	**Total**	**11342**	**12632**	**14151**

**CAGR (Compound Annual Growth Rate) (t1,t2)=((V(t2)/V(t1))^(1/t2-t1))-1 where V(t1) is the starting value and V(t2) is the finishing value*

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3. Total number of locally manufactured products has been extracted from JFDA's website (Annex 4) = 3221 product.

4. Now, The Employment per product is calculated by dividing the (total employment per year/ total number of locally manufactured products); results are:

Employment in Pharma Industry	Number Of Employees / Product*					
	2013	2014	2015	2016	2017	2018
Male	1.4	1.7	2.2	2.5	3.0	3.5
Female	1.1	1.0	1.0	1.0	1.0	0.9
Total	**2.5**	**2.7**	**3.2**	**3.5**	**3.9**	**4.4**

** This is even a more conservative approach as we are taking the total number of local products now; even though they are less in the past years.*

To measure JCP's impact on jobs, the below section explains the methodology that resulted in the proposed 633 Direct Jobs and 969 Indirect Jobs increased in sector's employment for the years 2016-2017 and beyond. This number has been accumulated from two main pillars based on JCP's attribution methodology:

1. Impact of JCP on drug registration by clearing the drug backlog between the years (2013- 2015) resulting in 193 locally manufactured drugs registered.
2. Impact of JCP on streamlining the drug registration process based on the timelines saved and on the actual number of registered dossiers in 2016 resulting in 24.21 drugs registered attributable to JCP (see section 6.2 c, page 16).

Further details are as follows:

1. JCP's Impact on Sector's Employment as a result of Backlog Clearance (Annex 4):
    a. Average Employment per Product (2017, the year that follows drug registration) = 2.8
    b. Direct Jobs Generated after Drug Registration = (Average Employment * No. of Drugs Registered Attributed to JCP) = (2.8*193) = 538 direct job attributable to JCP
    c. Adopting a 1:1.53 direct to indirect jobs ratio per IQVIA study; then indirect jobs = 823 indirect job attributable to JCP

2. JCP's Impact on Sector's Employment Based on Time Savings of drugs registered in 2016 (Annex 4):
    a. Employment/Product (2017, year that follows drug registration) = 3.9
    b. Direct Jobs Generated after Drug Registration = (Employment 2017 * No. of Drugs Registered Attributed to JCP) = (3.9*24.21) = 95 direct job attributable to JCP
    c. Adopting a 1:1.53 direct to indirect jobs ratio per IQVIA study; then indirect jobs = 145 indirect job attributable to JCP

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Total Impact of JCP on Sector's Employment for year 2017 is:

1. **Direct Jobs: 538+95 = 633 direct job.**
2. **Indirect Jobs = 823 + 145 = 968 indirect job**

FUTURE STEPS FOR CALCULATING JCP'S IMPACT

The JCP team will utilize the formula developed in this report and will rely on the identified resources to continue to measure the project's impact due to its drug registration streamlining interventions. For consistent measurement of impact and the portion attributable to JCP, the assumption is that the following factors will remain relatively stable:

- Improvement in workflow and process efficiency will be maintained at JFDA
- Capacity within JFDA and its access to experts for efficient drug registration reviews remain
- A conducive business environment in Jordan, in general, remains.

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Annex 1: JCP Interventions per Phase and Relative Contribution by Stakeholders

Timeline	Phase	Primary Recipient	Activity	Entities' Ro	
				JCP	JFDA
September 2013 - March 2017	Pre-submission	JFDA, JAPM & Industry	Drug Registration Task Force Establishment	33.3%	33.3%
September 2013 - March 2017	Pre-submission	JFDA	Preparing a situation analysis matrix for the drug registration process at JFDA	33.3%	33.3%
September 2013 - March 2017	Pre-submission	JFDA, JAPM & Industry	Developing a reform plan with short, medium and long term solution	33.3%	33.3%
September 2013 - March 2017	Pre-Submission	JFDA	Providing technical assistance to JFDA to conduct full business and technical assessments in relation to eCTD, to understand JFDA's exact relevant business needs, challenges, technical & capacity readiness.	100%	0%
September 2013 - March 2017	Pre-Submission	JAPM & Industry	Conduct Regulatory Affairs and Technical Consultation Services	100%	0%
September 2013 - March 2017	Pre-Submission	JFDA, JAPM & Industry	Purchasing the United States Pharmacopeia (USP) to enable the industry to adhere to the international health regulatory and technical requirements; which is key factor in saving time in the development phase, faster registration time for new drugs and opening new markets	100%	0%
September 2013 - March 2017	Pre-Submission	JAPM & Industry	6 eCTD systems installation at 6 pharmaceutical manufacturing companies	100%	0%
March 2017 - August 2018	Pre-Submission	JAPM & Industry	Full-fledged economic study aiming towards illustrating the Jordanian Pharmaceutical Sector Contribution to Jordan's Economy, Investment Climate and Health Expenditure Cost Savings	100%	0%
September 2013 - March 2017	Pre-Submission	JFDA, JAPM & Industry	Conducted training workshop on the requirements for testing drugs and validation of analytical methods for Pharmaceutical companies in collaboration with JFDA	60%	10%
September 2013 - March 2017	Pre-Submission	JFDA, JAPM & Industry	Sponsored US Pharmacopeia Education Training Course for pharmaceutical companies on the analysis of elemental impurities and the validation and verification of analytical procedures.	60%	10%
March 2017 - August 2018	Pre-Submission	JAPM & Industry	Supported Jordanian delegation of 8 participants from Pharmaceutical companies and CROs to participate in the 18th annual International Generic Pharmaceutical Alliance (IGPA) to present Jordan to the international arena; benefit from the network opportunities and get updated on the global and regional market trends; global scientific and regulatory developments and the developments in the global intellectual properties.	100%	0%
September 2013 - March 2017	Pre-Submission	JAPM & Industry	Assessment of Generic Pharmaceutical Applications, from JFDA Assessors' Perspective workshop	60%	10%
September 2013 - March 2017	Pre-Submission	JAPM & Industry	USP Development and Validation of Dissolution Procedures	60%	10%

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September 2013 - March 2017	Pre-Submission	JAPM & Industry	IP & Pharmaceuticals Workshop	60%	10%
September 2013 - March 2017	Pre-Submission	JFDA, JAPM & Industry	Bioequivalence Workshop	60%	10%
March 2017 - August 2018	Pre-Submission	JFDA	PIC/S training and capacity building workshop for JFDA Inspectorate by PIC/S Expert; the 5-days workshop	60%	40%
March 2017 - August 2018	Pre-Submission	JFDA, JAPM & Industry	Post Approval Changes New Guidelines Workshop	60%	10%
March 2017 - August 2018	Pre-Submission	JFDA, JAPM & Industry	Scientific and Regulatory Assessment of Generic Registration Dossiers: The Most Recent Updates Workshop.	60%	10%
March 2017 - August 2018	Pre-Submission	JFDA, JAPM & Industry	How to Avoid Bioequivalence (BE) Deficiencies Workshop	60%	10%
March 2017 - August 2018	Pre-Submission	JFDA, JAPM & Industry	Validation of Analytical methods workshop	60%	10%
March 2017 - August 2018	Pre-Submission	JFDA, JAPM & Industry	Value Added Medicine Workshop	60%	10%
March 2017 - August 2018	Pre-Submission	JFDA	Scientific Advice System Drafting and proposal	60%	20%
September 2013 - March 2017	Submission	JFDA	Create separate workstations for receiving and reviewing the drug registration files at JFDA	100%	0%
September 2013 - March 2017	Submission	JFDA & JAPM	Conducted a study tour to Saudi Food and Drug Authority (SFDA) for purpose of benchmarking drug registration process, to learn from their experience in the implementation of eCTD system in all its stages, and to help Jordanian pharmaceutical companies to comply with the requirements of SFDA.	60%	10%
September 2013 - March 2017	Submission	JFDA	Provided JFDA with intern to prepare the administrative arrangements for the technical committee meetings.	60%	10%
September 2013 - March 2017	Submission	JFDA	Prepared work instructions for file receipt, screening and technical assessment of the registration file	100%	0%
September 2013 - March 2017	Review	JFDA	Review sub-committees fully funded by USAID JCP; clearing the backlog since 2012*	0%	0%
September 2013 - March 2017	Review	JFDA	Conducted training for the current and potential technical committee members' experts on technical assessment of drug registration file' by JFDA staff to harmonize the assessment process of generic dossiers	60%	10%
September 2013 - March 2017	Review	JFDA	Amended "Incentives & Rewards Regulation No. 72 for year 2003" to increase the limit of the technical committee rewards more than JD 100 per month (to become JD 200 per month)	75%	25%

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September 2013 - March 2017	Review	JFDA	USAID JCP has created a comprehensive database of pharmaceutical Ph.D. holders willing and able to participate in JFDA's drug registration review committees and developed selection and assessment criteria for evaluating technical experts' competencies	100%	0%
March 2017 - August 2018	Review	JFDA	Purchase and Install eCTD EURS System	75%	25%
March 2017 - August 2018	Review	JFDA	Import / Export System Integration	60%	40%
March 2017 - August 2018	Review	JFDA	E-Payment & Invoicing Portal Solution Integration	60%	40%
March 2017 - August 2018	Review	JFDA	Integration of additional features to the eJDWS	60%	40%
March 2017 - August 2018	Review	JFDA	Support JFDA in supporting JFDA in Joining Pharmaceuticals Inspection Corporation Scheme - PIC/S	100%	0%
March 2017 - August 2018	Review	JFDA	Establish Value Added Medicine Task Force creating a draft for VAM Regulations	60%	20%
March 2017 - August 2018	Review	JFDA	Technical assistance to help draft VAM regulations, VAM capacity building for the industry and the JFDA, develop FAQ document & work to develop the scientific advice system	60%	20%
March 2017 - August 2018	Review	JFDA	Technical Evaluator for the Quality Part	75%	25%
March 2017 - August 2018	Review	JFDA	Technical Evaluator for the Quality Part + Capacity Building for JFDA's internal staff & competencies gap analysis	75%	25%
March 2017 - August 2018	Review	JFDA	Technical Evaluator for the BE Part	75%	25%
March 2017 - August 2018	Review	JFDA	Capacity Building for JFDA's internal staff & competencies gap analysis with regards to Bioequivalence	75%	25%
March 2017 - August 2018	Review	JFDA	Capacity Building for JFDA's internal staff & competencies gap analysis with regards to Biowaivering	75%	25%
March 2017 - August 2018	Review	JFDA, JAPM & Industry	Assessment of Analytical Methods and Validation Workshop	60%	40%
March 2017 - August 2018	Review	JFDA	The assessment and review of Bioequivalence (BE) dossiers	60%	40%
September 2013 - March 2017	Review	JFDA	Purchasing the United States Pharmacopeia (USP) to enable the JFDA to review according to the most recent updates	100%	0%

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Annex 2: JFDA Dossiers Status for Dossiers Submitted between (2013 – 2017)

Local Manufacturer's Registration Status (2013-2017)																												
No	Rank	Local Manufacturer's Name	2013				Total	2014				Total	2015				Total	2016				Total	2017				Total
			Registered	Rejected	Deficiency	Not Reviewed		Registered	Rejected	Deficiency	Not Reviewed		Registered	Rejected	Deficiency	Not Reviewed		Registered	Rejected	Deficiency	Not Reviewed		Registered	Rejected	Deficiency	Not Reviewed	
1	2	Al Taqaddom Pharma	23	2	-	-	25	23	7	-	-	30	25	3	-	-	28	15	1	3	-	19			6	1	7
2	2	Amman Pharmaceutical Industries	2	-	-	-	2	2	-	-	-	2	6	2	-	-	8	1	1	1	-	3			7	-	5
3	1	Dar Al Dawa Pharma	29	1			30	20	1			21	15	-	-	-	15	8	2	-	-	10		-	7	-	7
4	2	Hayat Pharma	9	-	-	-	9	1	-	-	-	1	3	-	-	-	3	-	-	-	-	-					
5	1	Hikma Pharma	20	3	-	-	23	15	4	2	2	23	25	1	-	-	26	18	1	1	-	20	7		2	3	12
6	3	Al-Gadeed Pharma	-	-	-	-	-	-	-	-	-	-	3	2	-	-	5	2	-	-		2			5	-	5
7	3	Jerash Pharma	5	1		-	6	4	-	-	-	4	2	-	-	-	2	-	-	-	-	-	1	-	2	3	6
8	2	JPM	15	4	-	-	19	2	1	-	-	3	3	-	-	-	3	-	-	-	-			2	2	-	4
9	3	Joriver Pharma	1	1	-	-	2	3	4	-	-	7	-	1	-	-	1	6	-	2	-	8			10	-	10
10	1	JOSWE	17	-	-	-	17	13	2	-	-	15	11	1	-	-	12	8	2	-	-	10			4	-	4
11	3	MidPharma	-	6	-	-	6	-	6	-	-	6	-	2	-	-	2	-	-	-	-	-					
12	3	MS Pharma	-	-	-	-	-	35	2	-	-	37	31	-	-	-	31	13	5	12	-	30	1	2	11	9	23
13	2	Pella Pharma	1	-	-	-	1	1	-	-	-	1	-	-	-	-	-	-	1	-	-	1					
14	1	Pharma International	2	-	-	-	2	3	-	-	-	3	10	-	-	-	10	14	3	-	-	17		1	9	2	12
15	2	Philadelphia Pharma	1	-	-	-	1	-	-	-	-	-	-	-	-	-	-	2	2	1	-	5	1	1	-	-	2
16	3	Retaj Pharma	2	-	-	-	2	-	-	-	-	2	1	1	-	-	2	-	-	-	-	-	1				1
17	3	Savvy Pharma	-	-	-	-	-	8	-	-	-	8	11	-	-	-	11	7	-	2	-	8	4	-	5	-	9
18	1	APM	3	1	-	-	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-					
19	2	United Pharma	21	1	-	-	22	28	-	-	-	28	30	1	-	-	31	13	-	4	1	18	11		17	-	28
20	2	Ram Pharma	1	5			6		1			1	1	4	-	-	5		4	-	-	4	1		13	-	13
21	3	Motaqademeh Pharma																								1	1
22	3	Sana Pharma																					1		1		2
Totals			152	25	0	0	177	158	28	2	2	192	177	18	0	0	195	107	22	26	1	155	28	6	101	19	151
				14%					15%					9%													
Average of Rejected Dossiers (3 years)			12.65%																								

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Annex 3: JFDA Data on Products and Exports per Company and Per Quarter

Data is in attached excel book.

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+962 79 6772888
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Annex 4: Employment and Locally Manufactured Products

Data is in attached excel book.

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Annex 5: Example of Post Training Evaluation Results

Data is in attached document

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